Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



[DAAP19]

Product type(s) [2,3,4,5]

[Sodium Hypochlorite as included in the Union list of approved active substances]

Case Number in R4BP: [BC-MT048077-13]

Evaluating Competent Authority: [FR]

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# CONCLUSION

**General**

France, as e-CA, received an application for the first authorization of the Biocidal product family DAAP19 based on 1.6% to 14.2% w/w of active chlorine released from sodium hypochlorite (pure content).

Products are intended to be used for disinfection of swimming pools and footbaths, surfaces, toilet bowls, laundry, animal housing and livestock transportation, disinfection of water and for algaecide and fungicide effect on outdoor surfaces, in PT2, 3, 4 and 5 uses.

The biocidal product family (BPF) is composed of 22 meta SPCs. The products are to be used by professionnal and non professionnal users.

The structure of the BPF is based on the the intended uses, the formulation and the mode of application of the products. Its composition as claimed by the applicant is summarized in the table below:

|  |  |  |  |
| --- | --- | --- | --- |
|  | % available chlorine | Users | Description |
| meta SPC 1.1 | 9,6% | Non pro | Disinfection of swimming pools and footbath |
| meta SPC 1.2 | 12,5% | Pro | Disinfection of swimming pools and footbath |
| meta SPC 2.1 | 2,6% | Non pro | Bleach for for wide-use domestic disinfection (PT2, 3, 4) |
| meta SPC 2.21 | 4,8% | Non pro | Bleach for for wide-use domestic disinfection (PT2, 3, 4) |
| meta SPC 2.22 | 3,6% | Non pro | Bleach for for wide-use domestic disinfection (PT2, 3, 4)s |
| meta SPC 3 | 2,6% | Pro Non pro | Ready to use Gel for PT2 surface disinfection |
| meta SPC 4 | 1,5% | Pro Non pro | Ready to use Gel for PT2 surface disinfection |
| meta SPC 5 | 1,5% | Pro Non pro | Ready to use Trigger spray for PT2 surface disinfection |
| meta SPC 6.1 | 9,6% | Non pro | Bleach for for wide-use domestic disinfection (PT2, 3, 4) |
| meta SPC 6.21 | 9,6% | Pro | Bleach for professional uses for wide use disinfection (PT2, 3, 4, 5) |
| meta SPC 6.22 | 12,5-13,5% | Pro | Bleach (PT2, 3, 4, 5) |
| meta SPC 7.11 | 3,6% | Pro | Bleach (PT2, 3, 4, 5) |
| meta SPC 7.12 | 4,8% | Pro | Bleach (PT2, 3, 4, 5) |
| meta SPC 7.2 | 2,6% | Pro | Bleach (PT2, 3, 4, 5) |
| meta SPC 8 | 1,6% | Non pro | Bleach for wide-use domestic disinfection (PT2, 3, 4) |
| meta SPC 9 | 9,6% | Non pro | Algicide and fungicide for outdoors |
| meta SPC 10.1 | 2,6% | Pro | Detergent (PT2, 3, 4) |
| meta SPC 10.2 | 4,8% | Pro | Detergent (PT2, 3, 4) |
| meta SPC 11 | 6,0% | Pro | Detergent (PT2, 3, 4) |
| meta SPC 12 | 4,8% | Pro | Ready to use Trigger spray (PT2) |
| meta SPC 13 | 4,5% | Pro | Ready to use Gel for toilet bowls |
| meta SPC 14 | 9,6% | Pro Non pro | Algicide and fungicide Gel for outdoors |

The biocidal product family DAAP19 is claimed to be used for:

|  |  |  |
| --- | --- | --- |
| **PTs** | **Claimed uses** | **META SPC concerned** |
| 2 | Disinfection of public and private swimming pools | 1.1, 1.2 |
| Shock disinfection of public and private swimming pools |
| Disinfection of footbaths in public and private swimming pools |
| Disinfection of surfaces (floors and other than floors) | 2.1, 2.21, 2.22, 3, 4, 6.1, 8 |
| Disinfection of surfaces in medical area, insitutions and industries | 6.21, 6.22, 7.11, 7.12, 7.2, 10.1, 10.2, 11 |
| Disinfection of surfaces by spraying | 5, 12 |
| Disinfection of toilet bowls | 2.1, 2.21, 2.22, 3, 4, 8, 13 |
| Laundry disinfection | 2.1, 2.21, 2.22, 6.1, 6.21, 6.22, 7.11, 7.12, 7.2, 8, 10.1, 10.2 |
| Algaecide and fungicide for outdoor surfaces | 9, 14 |
| 2 and 4 | Disinfection of hard surfaces by CIP | 6.21, 6.22, 7.11, 7.12, 7.2, 10.1, 10.2, 11 |
| 4 | Disinfection of surfaces in contact with food | 2.1, 2.21, 2.22, 6.1, 6.21, 6.22, 7.11, 7.12, 7.2, 8, 10.1, 10.2, 11 |
| Disinfection of inner surfaces in human drinking water systems | 6.21, 6.22, 7.11, 7.12, 7.2 |
| Disinfection of inner surfaces in veterinary water systems |
| 3 | Disinfection of companion animal housing and associated equipment | 2.1, 2.21, 2.22, 6.1, 8 |
| Disinfection of hard surfaces in veterinary area | 6.21, 6.22, 7.11, 7.12, 10.1, 10.2, 11 |
| Disinfection of non-porous hard surfaces in livestock transportation vehicles | 6.21, 6.22, 7.11, 7.12, 7.2, 10.1, 10.2, 11 |
| 5 | Disinfection of water intended for human consumption | 6.21, 6.22, 7.11, 7.12, 7.2 |

Conclusions of the assessments of each section are given here below:

**Conclusion regarding physico chemical properties and analytical methods**

Products of the family are ready to use formulations (meta SPC 3, 4, 5, 12, 13) and soluble concentrates to be diluted (other meta SPCs). Meta SPC 5 and 12 are ready to use trigger sprays.

Physico chemical properties have been provided for several formulations identified as worst cases by the applicant and read across have been found acceptable. Compatibility with HDPE packaging, PVC berlingot and trigger spray has been demonstrated. However compatibility of products from Meta SPC 6.21 with PVC berlingot is missing.

All products should be stored below 30°C, protected from direct sunlight and from frost. Some products have been reported as foaming formulations when diluted.

Spray characteristics (size distribution, MMAD, spray pattern, clogging and discharge rate) are missing for products of Meta SPC 5 after storage and they should be provided as post authorisation data.

Products of this family should not be used in conjunction with acids or ammonia.

Due to the nature of the active substance:

* EUH206 (“Warning! Do not use together with other products. May release dangerous gases (chlorine)”) is necessary for products for non professional users and when active chlorine content in biocidal products is > 1% w/w.
* EU031 (“Contact with acids liberates toxic gas”) is necessary when pure sodium hypochlorite content in biocidal products is ≥ 5% w/w.

Shelf lives can be set for all meta SPCs. When degradation of active substance is higher than 10% of initial content, shelf life is supported with efficacy justification, except for meta SPC, 9 and 14. For these meta SPCs, shelf life is set at the time point where active substance loss is below 10% of initial content. For meta SPC 6.22, efficacy justification can only support shelf life for products at 12.5% and not up to 13.5%.

Products of the family DAAP19 are not explosive, flammable or auto-flammable. They have no oxidizing properties. All products are classified H290 Met Corr. I according to the tests provided. A DSC test on representative products of the BPF should be provided in post registration in order to confirm that products are not self reactive.

Methods for the determination of active chlorine and sodium chlorate in products of the biocidal family DAAP19 are sufficiently validated according to the BPR. For soil, air, surface water, body fluids and tissues, the applicant has access to the CAR of the active substance.

**Conclusion of Efficacy**

The DAAP19 BPF has been shown to be efficacious for the following uses:

- Disinfection of private swimming pools againt bacteria, virus and algae, by continuous and shock treatment;

- Disinfection of PT2 hard surfaces (household, institutions, industries, medical and agricultural areas, cosmetic industries

- Disinfection of PT3 hard surfaces (veterinary areas)

- Disinfection of hard surfaces in PT4 (household areas, institutions, industries and medical areas, milk industries, non-alcoholic beverages industries, alcoholic beverages industries)

Nevertheless, for some uses, specific target organisms and validated application rates cannot be authorised. More information are detailed in the efficacy section and in the SPC.

Efficacy has not been demonstrated for the following uses:

* Disinfection of footbaths in public and private swimming pools since no appropriate efficacy data against virus has been submitted
* Disinfection of laundry since no appropriate phase 2 step 2 tests have been submitted;
* Disinfection of water intended for human consumption since no appropriate simulated-use test has been submitted

**Conclusion for human Health**

The details on the risk assessment and conclusions for the human health are presented in the table below. The assessment has been conducted for the active substance and the identified substance of concern when necessary.

|  |  |
| --- | --- |
| **Summary table on the human health risk assessment conclusions** | |
| META-SPC 1.1  No SoC | Significant exposure of non professional users to corrosive (H314) products - Unacceptable risks for all the PT02 uses. |
| META-SPC 1.2  No SoC | Acceptable risks for all PT02 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall, goggles and a respiratory protection during the application of the product and the maintenance of the system. |
| META-SPC 2.1  No SoC | Significant exposure of non professional users to corrosive (H314) products - Unacceptable risks for all the PT02, PT03 and PT04 uses. |
| META-SPC 2.21  SoC: NaOH | Significant exposure of non professional users to corrosive (H314) products - Unacceptable risks for all the PT02, PT03 and PT04 uses. |
| META-SPC 2.22  SoC: NaOH | Significant exposure of non professional users to corrosive (H314) products - Unacceptable risks for all the PT02, PT03 and PT04 uses. |
| META-SPC 3  SoC: NaOH | Significant exposure of non professional users to corrosive (H314) products - Unacceptable risks for all the PT02 non professional uses except toilet bowl disinfection considering a specific packaging (bottle with gooseneck).  Acceptable for PT02 professional use for “toilet bowl disinfection” considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product. |
| META-SPC 4  SoC: NaOH | Significant exposure of non professional users to corrosive (H314) products - Unacceptable risks for all the PT02 non professional uses except toilet bowl disinfection considering a specific packaging (bottle with gooseneck).  Acceptable for PT02 professional uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product. * Do not enter the room before the treated surfaces are completely dried; * Pour the product directly on surfaces and wipe with a cloth. |
| META-SPC 5  SoC: NaOH | Significant exposure of non professional users to corrosive (H314) products - Unacceptable risks for all the PT02 non professional uses.  Acceptable for PT02 professional uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall, goggles and respiratory equipment during the application of the product. * The spray application must be performed downward in order to avoid exposure. * Do not be present in the treatment area during the disinfection process. If necessary to be present, wear the same PPE/RPE than the applicator of the products. * Do not enter the treated area before the treated surfaces are completely dried. |
| META-SPC 6.1  No SoC | Significant exposure of non professional users to corrosive (H314) products - Unacceptable risks for all the PT02, PT03 and PT04 uses. |
| META-SPC 6.21  No SoC | Acceptable for all the TP02 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and/or application). * Do not enter the treated area before the treated surfaces are completely dried.   For CIP disinfection:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system).   Acceptable for all the PT03 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. * Do not let animals enter the treated area (animal housing or transport vehicles) during the disinfection process; * Do not let animals enter the treated area before the surfaces are completely dried.   Acceptable for all the PT04 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |
| META-SPC 6.22  No SoC | Acceptable for all the PT02 and PT04 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the treated area before the treated surfaces are completely dried.   FOR CIP disinfection and inner surface disinfection:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system).   Acceptable for all the PT03 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the treated area before the treated surfaces are completely dried. * Do not let animals enter the treated area (animal housing or transport vehicles) during the disinfection process; * Do not let animals enter the treated area before the surfaces are completely dried. |
| META-SPC 7.11  No SoC | Acceptable for all the PT02 and PT04 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the treated area before the treated surfaces are completely dried.   FOR CIP disinfection and inner surface disinfection:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system).   Acceptable for all the PT03 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the treated rea before the treated surfaces are completely dried. * Do not let animals enter the treated area (animal housing or transport vehicles) during the disinfection process; * Do not let animals enter the treated area before the surfaces are completely dried. |
| META-SPC 7.12  No SoC | Acceptable for all the PT02 and PT04 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the treated area before the treated surfaces are completely dried.   FOR CIP disinfection and inner surface disinfection:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system).   Acceptable for all the PT03 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the treated area before the treated surfaces are completely dried. * Do not let animals enter the treated area (animal housing or transport vehicles) during the disinfection process; * Do not let animals enter the treated area before the surfaces are completely dried. |
| META-SPC 7.2  No SoC | Acceptable for all the PT02 and PT04 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the treated area before the treated surfaces are completely dried.   FOR CIP disinfection and inner surface disinfection:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system).   Acceptable for all the PT03 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the treated area before the treated surfaces are completely dried. * Do not let animals enter the treated area (animal housing or transport vehicles) during the disinfection process; * Do not let animals enter the treated area before the surfaces are completely dried. |
| META-SPC 8  No SoC | Significant exposure of non professional users to corrosive (H314) products - Unacceptable risks for all the PT02, PT03 and PT04 uses. |
| META-SPC 9  No SoC | Significant exposure of non professional users to corrosive (H314) products - Unacceptable risks for all the PT02 uses. |
| META-SPC 10.1  No SoC | Acceptable for all the PT02 and PT04 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the treated area before the treated surfaces are completely dried.   FOR CIP disinfection and inner surface disinfection:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system).   Acceptable for all the PT03 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the treated area before the treated surfaces are completely dried. * Do not let animals enter the treated area (animal housing or transport vehicles) during the disinfection process; * Do not let animals enter the treated area before the surfaces are completely dried. |
| META-SPC 10.2  SoC: NaOH | Acceptable for all the PT02 and PT04 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the treated area before the treated surfaces are completely dried.   FOR CIP disinfection and inner surface disinfection:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system).   Acceptable for all the PT03 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the treated area before the treated surfaces are completely dried. * Do not let animals enter the treated area (animal housing or transport vehicles) during the disinfection process; * Do not let animals enter the treated area before the surfaces are completely dried. |
| META-SPC 11  SoC: NaOH | Significant exposure of professional users to corrosive (H314) products even with PPE - Unacceptable for PT02, PT03 and PT04 spray application uses.  Acceptable for all the other PT02 and PT04 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the treated area before the treated surfaces are completely dried. * For wiping, pour the product directly on the surfaces and wipe with a cloth. * For mopping, pour the product directly on surfaces and mop with a cloth and a handle.   FOR CIP disinfection and inner surface disinfection:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). * Wear a respiratory protection during the post-application tasks (maintenance of the system).   Acceptable for all the other PT03 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the treated area before the treated surfaces are completely dried. * Do not let animals enter the treated area (animal housing or transport vehicles) during the disinfection process; * Do not let animals enter the treated area before the surfaces are completely dried. * For wiping, pour the product directly on the surfaces and wipe with a cloth. * For mopping, pour the product directly on surfaces and mop with a cloth and a handle. |
| META-SPC 12  SoC: NaOH | Acceptable for all the PT02 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall, goggles and RPE with APF at minima 4 during the application of the product. * The spray application must be performed downward in order to avoid exposure. * Do not be present in the treatement area during the disinfection process. If necessary to be present, wear the same PPE/RPE than the applicator of the product. * Do not enter the treated area before the treated surfaces are completely dried. |
| META-SPC 13  SoC: NaOH | Acceptable for all the PT02 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product. |
| META-SPC 14  No SoC | Significant exposure of non professional users to corrosive (H314) products - Unacceptable for all the PT02 non professional uses.  Acceptable for all the professional PT02 uses considering:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information during), a protective coverall and goggles during the mixing and loading phase (corresponding to the dilution phase) and the application of the product. * The spray application must be performed downward in order to avoid exposure. * Do not touch the treated surfaces before they are completely dried. * Do not be present in the treatment area during the disinfection process. If necessary to be present, wear the same PPE/RPE than the applicator of the product. |

For PT 5 intended use, no application rate is detailed. Therefore, no exposure assessment can be performed for this use.

**Conclusion for indirect exposure via food:**

By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore, residues in food or feed are not expected.

For PT3 and PT 4 uses, residues in food, feed or drink must be further investigated. Due to the high reactivity of chlorine species, residues on surfaces degrade very rapidly. Hence, residue formation (other than chlorate) is assumed to be negligible for aqueous solutions of chlorine. Conversely, chlorate residues, a stable metabolite that can be formed from hypochlorite sodium in aqueous chlorine solutions, are considered relevant for dietary exposure from the uses of active substance as food area disinfectant.

Regarding PT 4 professional use, considering the current knowledge about chlorate and the EU official chlorate limits in food[[1]](#footnote-2), there is no concern for the general public from indirect exposure to either available chlorine or chlorate in food, feed and drinking water.

Considering PT 4 non-professional uses, a food contamination with chlorate via treated surface was estimated using maximalist scenario. No concern for general public from indirect exposure to either available chlorine or chlorate in food is observed when a rinsing of treated surfaces occurs.

Considering PT 3 professional and non-professional uses, livestock exposure and associated consumer exposure via food of animal origin to chlorate remaining on treated surfaces were estimated using scenarios and default values defined in European guidance document[[2]](#footnote-3). No concern for general public from indirect exposure to either available chlorine or chlorate in food of animal origin is observed when a rinsing of treated surfaces occurs.

Moreover, for PT 3 professional use, it can also be concluded that, after disinfection of transport vehicle by DAAP19, residue in animal tissues are below existing MRLs for chlorate established in Regulation (EU) 2020/749.

For PT 5 intended use, no application rate is detailed. Therefore, no exposure assessment can be performed for this use.

**Conclusion on Environment:**

The details on the risk assessment and conclusions for the environment are presented in the table below. The assessment has been conducted for the active substance only. No substance of concern has been identified for the environment.

|  |  |
| --- | --- |
| **Summary table on the environmental risk assessment conclusions** | |
| META-SPC 1.1  No SoC | Acceptable risks for all the PT02 uses.  Nevertheless, the following RMM must be applied for uses:  - disinfection of private swimming pools  - shock disinfection of private swimming pools  ***Application of this product is exclusively allowed in swimming pools with connection to a STP. It is not allowed to directly discharge swimming pool water to the surface water*** |
| META-SPC 1.2  No SoC | Acceptable risks for all the PT02 uses.  Nevertheless, the following RMM must be applied for uses:  - disinfection of public and private swimming pools  - shock disinfection of public and private swimming ***Application of this product is exclusively allowed in swimming pools with connection to a STP. It is not allowed to directly discharge swimming pool water to the surface water*** |
| META-SPC 2.1  No SoC | Acceptable risks for all the PT02/03/04 uses. No specific RMM required. |
| META-SPC 2.21  No SoC | Acceptable risks for all the PT02/03/04 uses. No specific RMM required. |
| META-SPC 2.22  No SoC | Acceptable risks for all the PT02/03/04 uses. No specific RMM required. |
| META-SPC 3  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required. |
| META-SPC 4  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required. |
| META-SPC 5  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required. |
| META-SPC 6.1  No SoC | Acceptable risks for all the PT02/03/04 uses. No specific RMM required. |
| META-SPC 6.21  No SoC | Acceptable risks for all the PT02/03/04 uses. No specific RMM required. |
| META-SPC 6.22  No SoC | Acceptable risks for all the PT02/03/04 uses. No specific RMM required. |
| META-SPC 7.11  No SoC | Acceptable risks for all the PT02/03/04 uses. No specific RMM required. |
| META-SPC 7.12  No SoC | Acceptable risks for all the PT02/03/04 uses. No specific RMM required. |
| META-SPC 7.2  No SoC | Acceptable risks for all the PT02/03/04 uses. No specific RMM required. |
| META-SPC 8  No SoC | Acceptable risks for all the PT02/03/04 uses. No specific RMM required. |
| META-SPC 9  No SoC | Acceptable risks for all the PT02 uses.  Nevertheless, the following RMM must be applied for the use “Algaecide and fungicide for outdoor surfaces”:  ***Do not apply where the product can directly reach surface water.*** |
| META-SPC 10.1  No SoC | Acceptable risks for all the PT02/03/04 uses. No specific RMM required. |
| META-SPC 10.2  No SoC | Acceptable risks for all the PT02/03/04 uses. No specific RMM required. |
| META-SPC 11  No SoC: | Acceptable risks for all the PT02 uses. No specific RMM required.  Acceptable risks for all the PT03 uses. No specific RMM required.  Acceptable risks for all the PT04 uses. No specific RMM required. |
| META-SPC 12  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required. |
| META-SPC 13  No SoC: | Acceptable risks for all the PT02 uses. No specific RMM required. |
| META-SPC 14  No SoC | Acceptable risks for all the PT02 uses.  Nevertheless, the following RMM must be applied for the use “Algaecide and fungicide for outdoor surfaces**”:**  ***Do not apply where the product can directly reach surface water.*** |

For PT 5 intended use, no application rate is detailed. Therefore, no exposure assessment can be performed for this use.

**Substances of concern (SoCs)**

Sodium hydroxide has been identified as a substance of concern in the biocidal product family for human health.

Please refer to the confidential annex for further details.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product family.

Please refer to the confidential annex for further details.

**Post-authorisation conditions:**

The authorisation holder shall complete, within one year:

* A DSC test on representative products of the in order to confirm that products are not self reactive
* The following spray characteristics for products of Meta SPC 5 after storage: size distribution, MMAD, spray pattern, clogging and discharge rate.
* ***Overall conclusion***

According to the assessment performed for the biocidal product family DAAP19, the following uses are proposed for authorization, considering the appropriate risk mitigation measures indicated in the SPC below (§ 2):

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **PTs** | **Uses** | **Meta SPC** | **Target organisms** | **Users** | **Conclusions** |
| 2 | Disinfection of public and private swimming pools  Shock disinfection of public and private swimming pools | 1.1 | Bacteria, viruses, (algae claimed for shock dsinfection) | Non pro | **Not acceptable**  Unacceptable risk for Human health |
| 1.2 | Pro | **Acceptable** |
| 2 | Disinfection of footbaths in public and private swimming pools | 1.1, 1.2 | Bacteria, viruses, algae | Pro  Non pro | **Not acceptable**  Efficacy not demonstrated |
| 2 | Disinfection of surfaces (floors and other than floors) | 2.1, 2.21, 2.22, 3, 6.1, 8 | Bacteria, fungi and yeasts, viruses | Non pro | **Not acceptable**  Unaccepatble risk for Human health |
| 4 | Pro | **Acceptable** |
| 2 | Disinfection of surfaces in medical area, insitutions and industries | 6.21, 6.22, 7.11, 7.12, 7.2, 10.1, 10.2, 11 | Bacteria, fungi and yeasts, viruses | Pro | **Acceptable** |
| 2 | Disinfection of surfaces by spraying | 5 | Bacteria, fungi and yeasts, viruses | Non pro | **Not acceptable**  Unacceptable risk for Human health |
| 5, 12 | Pro | **Acceptable** |
| 2 | Disinfection of toilet bowls | 2.1, 2.21, 2.22, 3, 4, 8 | Bacteria, fungi and yeasts, viruses | Non pro | **Not acceptable**  Unaccepatble risk for Human health for meta SPC 2.1, 2.21, 2.22 and 8 |
| 3, 4, 13 | Pro  Non pro | **Acceptable** |
| 2 | Laundry disinfection | 2.1, 2.21, 2.22, 6.1, 6.21, 6.22, 7.11, 7.12, 7.2, 8, 10.1, 10.2 | Bacteria, fungi and yeasts, viruses | Pro  Non pro | **Not acceptable**  Efficacy not demonstrated |
| 2 | Algaecide and fungicide for outdoor surfaces | 9, 14 | Algae, fungi | Pro  Non pro | **Not acceptable**  Efficacy not demonstrated |
| 2, 4 | Disinfection of hard surfaces by Cleaning in place (CIP) | 6.21, 6.22, 7.11, 7.12, 7.2, 10.1, 10.2, 11 | Bacteria, fungi and yeasts, viruses | Pro | **Acceptable** |
| 4 | Disinfection of surfaces in contact with food | 2.1, 2.21, 2.22, 6.1, 8 | Bacteria, fungi and yeasts, viruses | Non pro | **Not acceptable**  Unacceptable risk for Human health |
| 6.21, 6.22, 7.11, 7.12, 7.2, 10.1, 10.2, 11 | Pro | **Acceptable** |
| 4 | Disinfection of inner surfaces in water systems | 6.21, 6.22, 7.11, 7.12, 7.2 | Bacteria (and legionella), fungi and yeasts, viruses | Pro | **Not acceptable**  Target organism Legionella not validated |
| Bacteria, fungi and yeasts, viruses | **Acceptable** |
| 3 | Disinfection of companion animal housing and associated equipment | 2.1, 2.21, 2.22, 6.1, 8 | Bacteria, fungi and yeasts, viruses | Non pro | **Not acceptable**  Unacceptable risk for Human health |
| 3 | Disinfection of hard surfaces in veterinary area and in livestock transportation vehicles | 6.21, 6.22, 7.11, 7.12, 7.2, 10.1, 10.2, 11 | Bacteria, fungi and yeasts, viruses | Pro | **Acceptable** |
| 5 | Disinfection of water intended for human consumption | 6.21, 6.22, 7.11, 7.12, 7.2 | Bacteria (and legionella), fungi and yeasts, viruses | Pro | **Not acceptable**  No claimed doses and lack of efficacy data |

# ASSESSMENT REPORT

**Part I - First information level**

## Summary of the product assessment

### Administrative information

#### Identifier of the product family

| **Identifier[[3]](#footnote-4)** | **Country (if relevant)** |
| --- | --- |
| DAAP19 | FRANCE |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Ets. PINTAUD |
| **Address** | Rue Maurice Pintaud  16230 Mansle  France |
| **Authorisation number** | FR-2022-0034 | |
| **Date of the authorisation** | 05/04/2022 | |
| **Expiry date of the authorisation** | 04/04/2032 | |

#### Manufacturer(s) of the products of the family

|  |  |
| --- | --- |
| **Name of manufacturer** | Ets. PINTAUD |
| **Address of manufacturer** | Rue Maurice Pintaud  16230 Mansle  France |
| **Location of manufacturing sites** | Rue Maurice Pintaud  16230 Mansle  France |
|  |  |

#### Manufacturer(s) of the active substance(s)

|  |  |
| --- | --- |
| **Active substance** | Sodium Hypochlorite |
| **Name of manufacturer** | Arkema France |
| **Address of manufacturer** | 420, rue d’Estienne d’Orves  92705 Colombes Cedex  France |
| **Location of manufacturing sites** | Route nationale 85  BP 1  38560 Jarrie  France |

|  |  |
| --- | --- |
| **Active substance** | Sodium Hypochlorite |
| **Name of manufacturer** | Electroquímica de Hernani, S.A. |
| **Address of manufacturer** | Entidad Epele 29  20120 Hernani  Santiago Odriozola  SPAIN |
| **Location of manufacturing sites** | Entidad Epele 29  20120 Hernani  SPAIN |

|  |  |
| --- | --- |
| **Active substance** | Sodium Hypochlorite |
| **Name of manufacturer** | KEM ONE |
| **Address of manufacturer** | KEM ONE  Immeuble Le Quadrille  19, Rue Jacqueline Auriol   69008 Lyon, FRANCE |
| **Location of manufacturing sites** | KEM ONE  Etablissement de Saint Fons  Quai Aulagne CS 70035 69191 Saint-Fons Cedex, FRANCE  KEM ONE  Etablissement de Lavera  Ecopolis Lavera Sud  BP3  13117 Lavera Cedex, FRANCE |
|  |  |

### Product family composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Active chlorine released from sodium hypochlorite |
| **IUPAC or EC name** | Sodium hypochlorite |
| **EC number** | 231-668-3 |
| **CAS number** | 7681-52-9 |
| **Index number in Annex VI of CLP** | 017-011-00-1 |
| **Minimum purity / content** | Minimum purity of the releaser sodium hypochlorite: aqueous solution with an active chlorine concentration ≤ 180 g/kg (i.e. ≤ 18 % w/w).  One relevant impurity is present: sodium chlorate (≤5.4% w/w of the active chlorine, meaning 0.08 - 0.7% w/w in the biocidal product family containing 1.5-13.5% w/w av chlorine) |
| **Structural formula** | Na+ Cl-O- |

#### Candidate(s) for substitution

None.

#### Qualitative and quantitative information on the composition of the biocidal product family2

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 1.50 | 13.50 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 10.71 | 96.42 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.00 | 8.55 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical active substance is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the typical content claimed is 140g/kg.

#### Information on technical equivalence

Origins are recognized at EU leve in the CAR. For some origins, technical equivalence have been performed by Echa.

Technical equivalence assessment by ECHA is still ongoing for manufacturer Arkema in the case of one of their products (hypochlorite with 24%a.c). At this stage, this origin cannot be used for the manufacture of biocidal products. Please note that a maximum content of 18% w/w for active chlorine in aqueous solution has been set according to the reference specifications and Assessment Report.

See the active substance evaluation dossier submitted by Eurochlor for further details.

#### Information on the substance(s) of concern

Sodium hydroxide has been identified as a substance of concern in the biocidal product family for human health.

Please refer to the confidential annex for further details.

#### Assessment of endocrine disruption (ED) properties of the biocidal product family

None of the co-formulants contained in the DAAP 19 family are regulatory identified as endocrine disruptors or have significant ED properties.

However, that are indications that some co-formulants have ED properties and they should be further assessed in the frame of REACH Regulation.

Hence, it is not possible to conclude whether these co-formulants should be considered to have ED properties or not before the end of the assessment. In case any co-formulants are finally identified as ED, the biocidal product will be considered as ED and authorisation will have to be revised accordingly.

PLease refer tot he confidential Annex.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) No 2017/2100 were identified for the non-active substances contained in the BPF.

#### Type of formulation

|  |
| --- |
| soluble concentrate / ready to use gel / ready to use liquid (spray) |

**Part II - Second information level - meta SPC 1.2**

### Meta SPC 1.2 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 1.2 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | TP 2 |
| --- | --- |

### Meta SPC 1.2 composition

#### Qualitative and quantitative information on the composition of the meta SPC 1.2

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 12.50 | 12.50 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 89.29 | 89.29 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical active substance is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the typical purity claimed is 140g/kg.

#### Type(s) of formulation of the meta SPC 1.2

|  |
| --- |
| Soluble concentrate |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1.2

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Corr.1  Eye Dam.1  Aquatic acute 1  Aquatic chronic 2 |
| Hazard statement | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H411: Toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
|  | |
| **Labelling** | |
| GHS pictogram | GHS05 |
| Signal words | Danger (Dgr) |
| Hazard statements | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage  H410: Very toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
| Precautionary statements | P234: keep only in original packaging  P273: Avoid released to the environment  P260: Do not breathe dust/fume/ gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P280: Wear protective gloves/ protective clothing/eye protection/face protection.  P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P310: Immediately call a POISON CENTER/doctor/…  P321: Specific treatment (see … on this label).  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P405: Store locked up.  P390: absorb spillage to prevent material damage  P391: Collect spillage  P501: Dispose of contents/container in accordance with the national regulation |
|  | |
| Note | EUH031: Contact with acids liberates toxic gas  EUH071 : Corrosive to the respiratory tract |

### Authorised use(s) of the META SPC 1.2

#### Use description

Table 1. Use # 1.2.1 – disinfection of public and private swimming pools

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Virus |
| **Field of use** | Indoor  Outdoor |
| **Application method(s)** | Automated dosing continuous flow or pouring of the concentrated product into the swimming pool |
| **Application rate(s) and frequency** | Continuous disinfection for pools:  3 mg/L available chlorine in water |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE can in 10L, 20L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
|  |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

#### Use description

Table 2. Use # 1.2.2 – shock disinfection of public and private swimming pools

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Virus  Green Algae |
| **Field of use** | Indoor  Outdoor |
| **Application method(s)** | Automated dosing or pouring of the concentrated product into the swimming pool |
| **Application rate(s) and frequency** | 50 mg/L of available chlorine in water  Contact times:   * bacteria and virus: 10 minutes * algae: 48 hours |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE can in 10L, 20L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
|  |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

### General directions for use of the meta SPC 1.2

#### Instructions for use

|  |
| --- |
| * Comply with the instructions for use. * Inform the registration holder if the treatment is ineffective. * Products should not be used in conjunction with acids or ammonia. |

#### Risk mitigation measures

|  |
| --- |
| * Application of this product is exclusively allowed in swimming pools with connection to a STP. It is not allowed to directly discharge swimming pool water to the surface water. * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall, goggles and a respiratory protection during the application of the product and the maintenance of the system. |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| **IF ON SKIN:** Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes.  Call a POISON CENTRE or a doctor.  **IF IN EYES:** Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.  Call 112/ambulance for medical assistance.  Information to Healthcare personnel/doctor:  The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid  **IF SWALLOWED:** Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.  **IF INHALED:** Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Do not store above 30°C  Protect from frost  Protect from direct sunlight  Shelf life: 4 months |

### Other information

|  |
| --- |
|  |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1.2**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 10L STROMB Anticalcaire  20L STROMB Anticalcaire | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | active substance | / | / | 12.50 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 89.29 |

**Part II - Second information level - meta SPC 3**

### Meta SPC 3 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 3 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | PT 2 |
| --- | --- |

### Meta SPC 3 composition

#### Qualitative and quantitative information on the composition of the meta SPC 3

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.60 | 2.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 18.57 | 18.57 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.65 | 0.65 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical active substance is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the typical purity claimed is 140g/kg.

#### Type(s) of formulation of the meta SPC 3

|  |
| --- |
| Ready to use gel |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 3

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Corr.1  Eye Dam.1  Aquatic acute 1  Aquatic chronic 2 |
| Hazard statement | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H411: Toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
|  | |
| **Labelling** | |
| GHS pictogram | GHS05 |
| Signal words | Danger (Dgr) |
| Hazard statements | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage  H410: Very toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand.  P102: Keep out of reach of children and pets.  P234: keep only in original packaging  P273: Avoid released to the environment  P260: Do not breathe dust/fume/ gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P280: Wear protective gloves/ protective clothing/eye protection/face protection.  P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P310: Immediately call a POISON CENTER/doctor/…  P321: Specific treatment (see … on this label).  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P405: Store locked up.  P390: absorb spillage to prevent material damage  P391: Collect spillage  P501: Dispose of contents/container in accordance with the national regulation |
|  | |
| Note | EUH206: Warning! Do not use together with other products. May release dangerous gases (chlorine). |

### Authorised use(s) of the META SPC 3

#### Use description

Table 2. Use # 3.2 – Disinfection of toilet bowls

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Household  Professional only: institutions, industries (general case), healthcare  Indoor |
| **Application method(s)** | Direct application of the product (by pressing on the packaging) and rinse with flush |
| **Application rate(s) and frequency** | Ready to use product.  Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Non-professional, professional |
| **Pack sizes and packaging material** | For professional users:  HDPE bottle with gooseneck 0.75L  HDPE bottle 0.75L  For non professional users:  HDPE bottle with gooseneck 0.75L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
|  |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

### General directions for use of the meta SPC 3

#### Instructions for use

|  |
| --- |
| * Products should not be used in conjunction with acids or ammonia. * Comply with the instructions for use. * Inform the registration holder if the treatment is ineffective. * Make sure to wet surfaces completely. Allow to take effect for the contact time needed. |

#### Risk mitigation measures

|  |
| --- |
| * For professionnals, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product. * Wash hands after use. * Avoid contact with eyes. |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| * If medical advice is needed, have product container or label at hand   **IF ON SKIN:** Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes.  Call a POISON CENTRE or a doctor.  **IF IN EYES:** Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.  Call 112/ambulance for medical assistance.  Information to Healthcare personnel/doctor:  The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid  **IF SWALLOWED:** Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.  **IF INHALED:** Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Do not store above 30°C  Protect from frost  Protect from direct sunlight  Shelf life: 11 months  Keep out of reach of children and pets |

### Other information

|  |
| --- |
|  |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 750mL Gel WC avec Javel à 2,6%c.a. BEC | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | active substance | / | / | 2.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 18.57 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.65 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 750mL Gel WC avec Javel à 2,6%c.a. BEC Citron  750mL Gel WC Javellisant Citron First Clean  750mL Nettoyant Javellisant Citron Homsens  750mL Gel désinfectant Citron Prochlor  750mL Ultra Système Gel WC avec Javel Citron GEH  750mL Gel Javel WC Purochlor + Citron | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | active substance | / | / | 2.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 18.57 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.65 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 750mL Gel WC avec Javel à 2,6%c.a. BEC Eucalyptus  750mL Gel WC Javellisant Eucalyptus First Clean  750mL Nettoyant Javellisant Eucalyptus Homsens  750mL Gel désinfectant Eucalyptus Prochlor  750mL Ultra Système Gel WC avec Javel Eucalyptus GEH  750mL Gel Javel désinfectant Assainythol Sanitaire  750mL Gel Javel WC Purochlor + Eucalyptus | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | active substance | / | / | 2.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 18.57 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.65 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 750mL Gel Javel 2,6%c.a. APTA Cible Eucalyptus  750mL Gel Javel 2,6%c.a. BEC Touch' Fraîcheur Boisée  750mL Gel Parf. LE LYNX  Gel Javel précise W5 750ml parfum Eucalyptus | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | active substance | / | / | 2.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 18.57 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.65 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 750mL Gel Javel 2,6%c.a. APTA Cible  750mL Gel Javel 2,6%c.a. BEC Touch'  5L GEL JAVEL BEC 2,6%c.a.  2L GEL JAVEL BEC 2,6%c.a.  750mL Gel LE LYNX | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | active substance | / | / | 2.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 18.57 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.65 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 750mL Gel Javel 2,6%c.a. BEC Touch' Citron  Gel Javel précise W5 750ml parfum Citron | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | active substance | / | / | 2.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 18.57 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.65 |

**Part II - Second information level - meta SPC 4**

### Meta SPC 4 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 4 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | PT 2 |
| --- | --- |

### Meta SPC 4 composition

#### Qualitative and quantitative information on the composition of the meta SPC 4

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 1.50 | 1.50 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 10.71 | 10.71 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.66 | 0.66 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical active substance is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the typical purity claimed is 140g/kg.

#### Type(s) of formulation of the meta SPC 4

|  |
| --- |
| Ready to use gel |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 4

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Aquatic chronic 3  Skin Corr.1  Eye Dam.1 |
| Hazard statement | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage  H318: Causes serious eye damage  H412: Harmful to aquatic life with long lasting effects |
| Suppl. hazard statement |  |
|  | |
| **Labelling** | |
| GHS pictogram | GHS05 |
| Signal words | Danger |
| Hazard statements | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage  H412: Harmful to aquatic life with long lasting effects |
| Suppl. hazard statement |  |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand.  P102: Keep out of reach of children and pets.  P234: keep only in original packaging  P273: Avoid released to the environment  P260: Do not breathe dust/fume/ gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P280: Wear protective gloves/ protective clothing/eye protection/face protection.  P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P310: Immediately call a POISON CENTER/doctor/…  P321: Specific treatment (see … on this label).  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P390: absorb spillage to prevent material damage  P405: Store locked up.  P501: Dispose of contents/container in accordance with the national regulation |
|  | |
| Note | EUH206: Warning! Do not use together with other products. May release dangerous gases (chlorine). |

### Authorised use(s) of the META SPC 4

#### Use description

Table 1. Use # 4.1 – Disinfection of surfaces (other than floors) by wiping with cloth and bucket

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Household  Professionnal users only: institutions, healthcare, industries (general case)  Indoor |
| **Application method(s)** | Wiping |
| **Application rate(s) and frequency** | Ready to use product.  Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Profesionnal |
| **Pack sizes and packaging material** | HDPE bottle with gooseneck 0.75L  HDPE bottle 1L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product. * Do not enter the room before the treated surfaces are completely dried. * Pour directly the product on surfaces and wipe. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

Table 2. Use # 4.2 – Disinfection of toilet bowls

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Household |
| **Application method(s)** | Direct application of the product (by pressing on the packaging) and rinse with flush |
| **Application rate(s) and frequency** | Ready to use product.  Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Non professional |
| **Pack sizes and packaging material** | HDPE bottle with gooseneck 0.75L |

##### Use-specific instructions for use

|  |
| --- |
| * Comply with the instructions for use. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Wash hands after use. * Avoid contact with eyes. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

### General directions for use of the meta SPC 4

#### Instructions for use

|  |
| --- |
| * Products should not be used in conjunction with acids or ammonia. * Comply with the instructions for use. * Inform the registration holder if the treatment is ineffective. * Make sure to wet surfaces completely. Allow to take effect for the contact time needed. |

#### Risk mitigation measures

|  |
| --- |
| * - Avoid any direct or indirect contact with food |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| * If medical advice is needed, have product container or label at hand   **IF ON SKIN:** Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes.  Call a POISON CENTRE or a doctor.  **IF IN EYES:** Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.  Call 112/ambulance for medical assistance.  Information to Healthcare personnel/doctor:  The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid  **IF SWALLOWED:** Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.  **IF INHALED:** Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Do not store above 30°C  Protect from frost  Protect from direct sunlight  Shelf life:11 months  Keep out of reach of children and pets |

### Other information

|  |
| --- |
| ~~-~~ |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 1L Gel avec Javel BEC Multi-Usages  1L GEL MULTI-USAGES LE LYNX  1L Ultra Cuisine Gel Javellisant GEH  1L Gel Javel First Clean | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | active substance | / | / | 1.50 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 10.71 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.66 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 750mL Gel WC avec Javel 1,5%c.a. BEC SOFT POWER  Gel WC Javel W5 750ml parfum pin | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | active substance | / | / | 1.50 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 10.71 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.66 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 750mL Gel WC avec Javel 1,5%c.a. BEC | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | active substance | / | / | 1.50 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 10.71 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0,66 |

**Part II - Second information level - meta SPC 5**

### Meta SPC 5 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 5 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | PT 2 |
| --- | --- |

### Meta SPC 5 composition

#### Qualitative and quantitative information on the composition of the meta SPC 5

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 1.50 | 1.50 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 10.71 | 10.71 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.62 | 0.62 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical active substance is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the typical purity claimed is 140g/kg.

#### Type(s) of formulation of the meta SPC 5

|  |
| --- |
| Ready to use liquid (spray) |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 5

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Corr.1  Eye Dam.1  Aquatic chronic 3 |
| Hazard statement | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage  H318: Causes serious eye damage  H412: Harmful to aquatic life with long lasting effects |
| Suppl. hazard statement |  |
|  | |
| **Labelling** | |
| GHS pictogram | GHS05 |
| Signal words | Danger |
| Hazard statements | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage  H412: Harmful to aquatic life with long lasting effects |
| Suppl. hazard statement |  |
| Precautionary statements | P234: keep only in original packaging  P273: Avoid released to the environment  P260: Do not breathe dust/fume/ gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P280: Wear protective gloves/ protective clothing/eye protection/face protection.  P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P310: Immediately call a POISON CENTER/doctor/…  P321: Specific treatment (see … on this label).  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P390: absorb spillage to prevent material damage  P405: Store locked up.  P501: Dispose of contents/container in accordance with the national regulation |
|  | |
| Note | EUH206: Warning! Do not use together with other products. May release dangerous gases (chlorine).  EUH071: Corrosive to the respiratory tract |

### Authorised use(s) of the META SPC 5

#### Use description

Table 1. Use # 5.1 – Disinfection of surfaces by spraying with trigger spray

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Household  Professionnal users only: institutions, healthcare, industries (general case)  Indoor |
| **Application method(s)** | Spraying |
| **Application rate(s) and frequency** | Ready to use product.  Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professionnal |
| **Pack sizes and packaging material** | HDPE bottle with PP/PE trigger spray TS 5S 0.5L, 0.75L |

##### Use-specific instructions for use

|  |
| --- |
| * Allow to take effect at least 5 minutes and then rinsing is required. |

##### Use-specific risk mitigation measures

|  |
| --- |
|  |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

### General directions for use of the meta SPC 5

#### Instructions for use

|  |
| --- |
| * Products should not be used in conjunction with acids or ammonia. * Inform the registration holder if the treatment is ineffective. * Make sure to wet surfaces completely. Allow to take effect for the contact time needed. |

#### Risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall, goggles and respiratory equipment during the application of the product. * The spray application must be performed downward in order to avoid exposure. * Do not enter the room during the disinfection process. * Do not enter the room before the treated surfaces are completely dried |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| **IF ON SKIN:** Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes.  Call a POISON CENTRE or a doctor.  **IF IN EYES:** Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.  Call 112/ambulance for medical assistance.  Information to Healthcare personnel/doctor:  The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid  **IF SWALLOWED:** Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.  **IF INHALED:** Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Do not store above 30°C  Protect from frost  Protect from direct sunlight  Shelf life: 11 months |

### Other information

|  |
| --- |
|  |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 500mL Spray Javel à 1,5%c.a. BEC X-SPRAY  750mL Spray Javel à 1,5%c.a. BEC X-SPRAY  500mL SPRAY LE LYNX  Spray nettoyant Javel 1,5% W5 cuisine et salle de bain 750ml | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 1.50 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 10.71 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.62 |

**Part II - Second information level - meta SPC 6.21**

### Meta SPC 6.21 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 6.21 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | PT 2, 3, 4 |
| --- | --- |

### Meta SPC 6.21 composition

#### Qualitative and quantitative information on the composition of the meta SPC 6.21

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 9.60 | 9.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 68.57 | 68.57 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical active substance is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the typical purity claimed is 140g/kg.

#### Type(s) of formulation of the meta SPC 6.21

|  |
| --- |
| SL soluble concentrate |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 6.21

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Corr.1  Eye Dam.1  Aquatic acute 1  Aquatic chronic 2 |
| Hazard statement | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H411: Toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
|  | |
| **Labelling** | |
| GHS pictogram | GHS05 |
| Signal words | Danger (Dgr) |
| Hazard statements | H290: may be corrosive to metals.  H314: Causes severe skin burns and eye damage  H410: Very toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
| Precautionary statements | P273: Avoid released to the environment  P234: keep only in original packaging  P260: Do not breathe dust/fume/ gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P280: Wear protective gloves/ protective clothing/eye protection/face protection.  P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P310: Immediately call a POISON CENTER/doctor/…  P321: Specific treatment (see … on this label).  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P405: Store locked up.  P390: absorb spillage to prevent material damage  P391: Collect spillage  P501: Dispose of contents/container in accordance with the national regulation |
|  | |
| Note | EUH031: Contact with acids liberates toxic gas  EUH071 : Corrosive to the respiratory tract |

#### Authorised use(s) of the META SPC 6.21

#### Use description

Table 1. Use # 6.21.1 – Disinfection of surfaces in medical area

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | healthcare  Indoor |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria and yeasts: 8.9% v/v   Other target organisms:   * Fungi and virus: 8.9% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 0.25L  HDPE container 5L, 10L, 20L  HDPE drum 200L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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| --- |
|  |

#### Use description

Table 2. Use # 6.21.2 – Disinfection of surfaces in contact with food

|  |  |
| --- | --- |
| **Product Type** | PT 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural), institutions  Indoor |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries and alcoholic beverages industries) by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 8.9% v/v   Other target organisms:   * Fungi and virus: 8.9% v/v   Contact time: 5 min  Room temperature  Disinfection of non-alcoholic beverages industries by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 13.5% v/v   Other target organisms:   * Fungi and virus: 13.5% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural industries by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 13.5% v/v   Other target organisms:   * Fungi: 13.5% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 0.25L  HDPE container 5L, 10L, 20L  HDPE drum 200L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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|  |

#### Use description

Table 3. Use # 6.21.3 – Disinfection of surfaces in institutions/industry

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (cosmetics, agricultural, general case, institutions) |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case)) by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeast: 8.9% v/v   Other target organisms:   * Fungi and virus: 8.9% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural industries by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeast: 13.5% v/v   Other target organisms:   * Fungi: 13.5% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 0.25L  HDPE container 5L, 10L, 20L  HDPE drum 200L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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|  |

#### Use description

Table 4. Use # 6.21.4 – Disinfection of surfaces by CIP

|  |  |
| --- | --- |
| **Product Type** | PT 2, 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (cosmetics, agricultural, general case, meat, milk, non-alcoholic, alcoholic beverages), institutions, |
| **Application method(s)** | CIP |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by CIP:  Mandatory target organisms:   * Bacteria and yeasts: 8.9% v/v   Other target organisms:   * Fungi and virus (exceot for agricultural areas): 8.9% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in non-alcoholic beverages industries by CIP:  Mandatory target organisms:   * Bacteria and yeasts: 13.5% v/v   Other target organisms:   * Fungi and virus: 13.5% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural industries by CIP:  Mandatory target organisms:   * Bacteria and yeasts: 13.5% v/v   Other target organisms:   * Fungi: 13.5% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 0.25L  HDPE container 5L, 10L, 20L  HDPE drum 200L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * For PT2 uses, avoid any direct or indirect contact with food * For PT 4 uses, rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 6. Use # 6.21.6 – Disinfection of non-porous hard surfaces in veterinary area

|  |  |
| --- | --- |
| **Product Type** | PT 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings  Indoor |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria and yeasts: 8.1% v/v   Other target organisms:   * Fungi: 9.2% v/v * Virus: 10.5% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 0.25L  HDPE container 5L, 10L, 20L  HDPE drum 200L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Only use in empty animal housing. * Remove all feed and drinks prior to treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. * Do not let animals enter the treated area before the surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 7. Use # 6.21.7 – Disinfection of non-porous hard surfaces in livestock transport vehicles

|  |  |
| --- | --- |
| **Product Type** | PT 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings  Indoor |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria, yeasts and virus: 10.5% v/v   Other target organisms:   * Fungi: 10.5% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 0.25L  HDPE container 5L, 10L, 20L  HDPE drum 200L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Only use in empty livestock transport vehicles. * Remove all feed and drinks prior to treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. * Do not let animals enter the treated area before the surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

#### Use description

Table 8. Use # 6.21.8 – Disinfection of inner surfaces in human drinking water distribution systems

|  |  |
| --- | --- |
| **Product Type** | PT 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Industry institutional area (homes, hotels, etc.) and medical area  Indoor |
| **Application method(s)** | CIP, stand disinfection |
| **Application rate(s) and frequency** | Human drinking water systems in medical area, industries (general case), institutions:  Mandatory target organisms:   * Bacteria: 1.4% v/v   Other target organisms:   * Yeasts: 4.1% v/v * Fungi: 4.1% v/v * Virus: 3.4% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 0.25L  HDPE container 5L, 10L, 20L  HDPE drum 200L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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|  |

#### Use description

Table 9. Use # 6.21.9 – Disinfection of inner surfaces in veterinary water systems

|  |  |
| --- | --- |
| **Product Type** | PT 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Veterinary industry, animal farms, dairy farms, animal houses  Indoor |
| **Application method(s)** | CIP, stand disinfection |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria: 8.9% v/v   Other target organisms:   * Yeasts: 8.9% v/v * Fungi: 8.9% v/v * Virus: 10.5% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 0.25L  HDPE container 5L, 10L, 20L  HDPE drum 200L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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|  |

### General directions for use of the meta SPC 6.21

#### Instructions for use

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| --- |
| * Products should not be used in conjunction with acids or ammonia. * Inform the registration holder if the treatment is ineffective. * Make sure to wet surfaces completely. Allow to take effect for the contact time needed. |

#### Risk mitigation measures

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| --- |
|  |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| **IF ON SKIN:** Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes.  Call a POISON CENTRE or a doctor.  **IF IN EYES:** Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.  Call 112/ambulance for medical assistance.  Information to Healthcare personnel/doctor:  The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid  **IF SWALLOWED:** Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.  **IF INHALED:** Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Do not store above 30°C  Protect from frost  Protect from direct sunlight  Shelf life: 6 months |

### Other information

|  |
| --- |
| * For PT3 and PT4 professional uses, the applicant should inform users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs. * For professional PT4 use Disinfection of inner surfaces in water systems: The user should control the concentration of chlorate present in the drinking water to ensure that this concentration does not exceed the parametric values set in Directive 2020/2184. |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6.21**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Dose 250mL Eau de Javel à 9,6%c.a. BEC Professionnels  10L Eau de Javel à 9,6%c.a. BEC Professionnels  20L Eau de Javel à 9,6%c.a. BEC Professionnels  1000L Eau de Javel à 9,6%c.a. BEC Professionnels  FV 250mL Eau de Javel 9,6%c.a. Lajot  5L Eau de Javel à 9,6%c.a. PROMOCASH  200L Eau de Javel à 9,6%c.a. BEC Professionnels  5L REIJAVEL L  20L REIJAVEL L | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 9.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 68.57 |

**Part II - Second information level - meta SPC 6.22**

### Meta SPC 6.22 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 6.22 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | PT 2, 3, 4 |
| --- | --- |

### Meta SPC 6.22 composition

#### Qualitative and quantitative information on the composition of the meta SPC 6.22

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 12.50 | 12.50 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 89.29 | 89.29 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical active substance is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the typical purity claimed is 140g/kg.

#### Type(s) of formulation of the meta SPC 6.22

|  |
| --- |
| SL soluble concentrate |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 6.22

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Corr.1  Eye Dam.1  Aquatic acute 1  Aquatic chronic 2 |
| Hazard statement | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H411: Toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
|  | |
| **Labelling** | |
| GHS pictogram | GHS05 |
| Signal words | Danger (Dgr) |
| Hazard statements | H290: may be corrosive to metals.  H314: Causes severe skin burns and eye damage  H410: Very toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
| Precautionary statements | P273: Avoid released to the environment  P234: keep only in original packaging  P260: Do not breathe dust/fume/ gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P280: Wear protective gloves/ protective clothing/eye protection/face protection.  P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P310: Immediately call a POISON CENTER/doctor/…  P321: Specific treatment (see … on this label).  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P405: Store locked up.  P390: absorb spillage to prevent material damage  P391: Collect spillage  P501: Dispose of contents/container in accordance with the national regulation |
|  | |
| Note | EUH031: Contact with acids liberates toxic gas  EUH071 : Corrosive to the respiratory tract |

### Authorised use(s) of the META SPC 6.22

#### Use description

Table 1. Use # 6.22.1 – Disinfection of surfaces in medical area

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | healthcare  Indoor |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria and yeasts: 7.9% v/v   Other target organisms:   * Fungi and virus: 7.9% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container: 10L, 20L  HDPE tank: 1000L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 2. Use # 6.22.2 – Disinfection of surfaces in contact with food

|  |  |
| --- | --- |
| **Product Type** | PT 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural), institutions  Indoor |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries and alcoholic beverages industries) by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 7.9% v/v   Other target organisms:   * Fungi and virus: 7.9% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in non-alcoholic beverages industries by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 11.2% v/v   Other target organisms:   * Fungi and virus: 11.2% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 11.2% v/v   Other target organisms:   * Fungi: 11.2% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 10L, 20L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 3. Use # 6.22.3 – Disinfection of hard surfaces in institutions/industry

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (cosmetics, agricultural, general case), institutions  Indoor |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case) and cosmetic industries) by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 7.9% v/v   Other target organisms:   * Fungi and virus: 7.9% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural industries by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 11.2% v/v   Other target organisms:   * Fungi: 11.2% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 10L, 20L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
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##### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 4. Use # 4 Use # 6.22.4 – Disinfection of hard surfaces by CIP

|  |  |
| --- | --- |
| **Product Type** | PT 2 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (cosmetics, agricultural, general case, meat, milk, non-alcoholic, alcoholic beverages), institutions |
| **Application method(s)** | CIP |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by CIP:  Mandatory target organisms:   * Bacteria and yeasts: 7.9% v/v   Other target organisms:   * Fungi and virus: 7.9% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in non-alcoholic beverages industries by CIP:  Mandatory target organisms:   * Bacteria and yeasts: 11.2% v/v   Other target organisms:   * Fungi and virus (except for agricultural areas): 11.2% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural industries by CIP:  Mandatory target organisms:   * Bacteria and yeasts: 11.2% v/v   Other target organisms:   * Fungi: 11.2% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 10L, 20L  HDPE tank 1000L |

##### Use-specific instructions for use

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##### Use-specific risk mitigation measures

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| --- |
| * For PT 2 uses, avoid any direct or indirect contact with food * For PT 4 uses, rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 6. Use # 6.22.6 – Disinfection of non-porous hard surfaces in veterinary area

|  |  |
| --- | --- |
| **Product Type** | PT 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria and yeasts: 7.1% v/v   Other target organisms:   * Fungi: 8.1% v/v * Virus: 9.3% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 10L, 20L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Only use in empty animal housing. * Remove all feed and drinks prior to treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. * Do not let animals enter the treated area before the surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 7. Use # 6.22.7 – Disinfection of non-porous hard surfaces in livestock transport vehicles

|  |  |
| --- | --- |
| **Product Type** | PT 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria, yeasts and virus: 9.3% v/v   Other target organisms:   * Fungi: 9.3% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 10L, 20L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Only use in empty livestock transport vehicles. * Remove all feed and drinks prior to treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried.; * Do not let animals enter the treated area before the surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 8. Use # 6.22.8 – Disinfection of inner surfaces in human drinking water systems

|  |  |
| --- | --- |
| **Product Type** | PT 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria Fungi  Yeast Virus |
| **Field of use** | Industry, institutional area (homes, hotels, etc.) and medical area |
| **Application method(s)** | CIP, stand disinfection |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria: 1.2% v/v   Other target organisms:   * Yeasts: 3.6% v/v * Fungi: 3.6% v/v * Virus: 3% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 10L, 20L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 9. Use # 6.22.9 – Disinfection of inner surfaces in veterinary water systems

|  |  |
| --- | --- |
| **Product Type** | PT 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast Virus |
| **Field of use** | Veterinary industry, animal farms, dairy farms, animal houses |
| **Application method(s)** | CIP, stand disinfection |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria: 7.9% v/v   Other target organisms:  - Yeasts: 7.9% v/v  - Fungi: 7.9% v/v  - Virus: 9.3% v/v  Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 10L, 20L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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### General directions for use of the meta SPC 6.22

#### Instructions for use

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| * Products should not be used in conjunction with acids or ammonia. * Inform the registration holder if the treatment is ineffective. * Make sure to wet surfaces completely. Allow to take effect for the contact time needed. |

#### Risk mitigation measures

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|  |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| **IF ON SKIN:** Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes.  Call a POISON CENTRE or a doctor.  **IF IN EYES:** Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.  Call 112/ambulance for medical assistance.  Information to Healthcare personnel/doctor:  The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid  **IF SWALLOWED:** Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.  **IF INHALED:** Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

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| --- |
| Do not store above 30°C  Protect from frost  Protect from direct sunlight  Shelf life: 3 months |

### Other information

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| --- |
| * For PT3 and PT4 professional uses, the applicant should inform users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs. * For professional PT4 use Disinfection of inner surfaces in water systems: The user should control the concentration of chlorate present in the drinking water to ensure that this concentration does not exceed the parametric values set in Directive 2020/2184. |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6.22**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 20L Eau de Javel 12,5%c.a. STROMB  1000L Eau de Javel 12,5%c.a. STROMB  10L Eau de Javel 12,5%c.a. STROMB  20L Eau de Javel 12,5%c.a. First Clean | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 12.50 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 89.29 |

**Part II - Second information level - meta SPC 7.11**

### Meta SPC 7.11 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 7.11 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | PT 2, 3, 4 |
| --- | --- |

### Meta SPC 7.11 composition

#### Qualitative and quantitative information on the composition of the meta SPC 7.11

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 3.60 | 3.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 25.71 | 25.71 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical active substance is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the typical purity claimed is 140g/kg.

#### Type(s) of formulation of the meta SPC 7.11

|  |
| --- |
| SL soluble concentrate |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 7.11

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Corr.1  Eye Dam.1  Aquatic acute 1  Aquatic chronic 2 |
| Hazard statement | H290: May be corrosive to metals  H314: Causes severe skin burns and eye damage  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H411: Toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
|  | |
| **Labelling** | |
| GHS pictogram | GHS05 |
| Signal words | Danger (Dgr) |
| Hazard statements | H290: May be corrosive to metals  H314: Causes severe skin burns and eye damage  H410: Very toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
| Precautionary statements | P234: keep only in original packaging  P273: Avoid released to the environment  P260: Do not breathe dust/fume/ gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P280: Wear protective gloves/ protective clothing/eye protection/face protection.  P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P310: Immediately call a POISON CENTER/doctor/…  P321: Specific treatment (see … on this label).  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.P405: Store locked up.  P390: absorb spillage to prevent material damage  P391: Collect spillage  P501: Dispose of contents/container in accordance with the national regulation |
|  | |
| Note | EUH071 : Corrosive to the respiratory tract |

### Authorised use(s) of the META SPC 7.11

#### Use description

Table 1. Use # 7.11.1 – Disinfection of surfaces in medical area

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | healthcare  Indoor |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria and yeast: 23% v/v   Other target organisms:   * Fungi and virus: 23% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 0.12L, 0.25L  HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 2. Use # 7.11.2 – Disinfection of surfaces in contact with food

|  |  |
| --- | --- |
| **Product Type** | PT 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural), institutions |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries and alcoholic beverages industries) by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeast: 23% v/v   Other target organisms:   * Fungi and virus: 23% v/v   Contact time: 5 min  Room temperature    Disinfection of hard surfaces in non-alcoholic beverages industries by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeast: 34% v/v   Other target organisms:   * Fungi and virus: 34% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeast: 34% v/v   Other target organisms:   * Fungi: 34% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 0.12L, 0.25L  HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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|  |

#### Use description

Table 3. Use # 7.11.3 – Disinfection of surfaces in institutions/industry

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (cosmetics, agricultural, general case), institutions |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case) and cosmetic industries) by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeast: 23% v/v   Other target organisms:   * Fungi and virus: 23% v/v   Contact time: 5 min  Room temperature    Disinfection of hard surfaces in agricultural industries by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeast: 34% v/v   Other target organisms:   * Fungi: 34% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 0.12L, 0.25L  HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

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| --- |
| * Avoid any direct or indirect contact with food * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 4. Use # 7.11.4 – Disinfection of surfaces by CIP

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| **Product Type** | PT 2, 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (cosmetics, agricultural, general case, meat, milk, non-alcoholic, alcoholic beverages), institutions, veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| **Application method(s)** | CIP |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by CIP:  Mandatory target organisms:   * Bacteria and yeast: 23% v/v   Other target organisms:   * Fungi and virus: 23% v/v   Contact time: 5 min  Room temperature    Disinfection of hard surfaces in non-alcoholic beverages industries by CIP:  Mandatory target organisms:   * Bacteria and yeast: 34% v/v   Other target organisms:   * Fungi and virus: 34% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural industries by CIP:  Mandatory target organisms:   * Bacteria and yeast: 34% v/v   Other target organisms:   * Fungi: 34% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 0.12L, 0.25L  HDPE container 5L |

##### Use-specific instructions for use

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##### Use-specific risk mitigation measures

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| --- |
| * For PT2 uses, avoid any direct or indirect contact with food * For PT 4 uses, rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 6. Use # 7.11.6 – Disinfection of non-porous hard surfaces in veterinary area

|  |  |
| --- | --- |
| **Product Type** | PT3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria and yeast: 21% v/v   Other target organisms:   * Fungi: 23% v/v * Virus: 27% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 0.12L, 0.25L  HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

##### Use-specific risk mitigation measures

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| * Rinse surfaces after treatment * Only use in empty animal housing. * Remove all feed and drinks prior to treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. * Do not let animals enter the treated area before the surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 7. Use # 7 Use # 7.11.7 – Disinfection of non-porous hard surfaces in livestock transportation vehicles

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| --- | --- |
| **Product Type** | PT3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | livestock transportation vehicles |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria, yeast and virus: 27% v/v   Other target organisms:   * Fungi: 27% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 0.12L, 0.25L  HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Only use in empty livestock transport vehicles. * Remove all feed and drinks prior to treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. * Do not let animals enter the treated area before the surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 8. Use # 7.11.8 – Disinfection of inner surfaces in human drinking water systems

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Industry (meat, non alcoholic beverages, alcoholic beverages, dairy, agricultural), institutional area (homes, hotels, etc.) and medical area |
| **Application method(s)** | CIP, stand disinfection |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria: 3.4% v/v   Other target organisms:  - Yeast: 10.1% v/v  - Fungi: 10.1% v/v  - Virus: 8.4% v/v  Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 0.12L, 0.25L  HDPE container 5L |

##### Use-specific instructions for use

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##### Use-specific risk mitigation measures

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| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 9. Use # 7.11.9 – Disinfection of inner surfaces in veterinary water systems

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Veterinary industry, animal farms, dairy farms, animal houses |
| **Application method(s)** | CIP, stand disinfection |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria: 22.3% v/v   Other target organisms:  - Yeast: 22.3% v/v  - Fungi: 22.3% v/v  - Virus: 26.3% v/v  Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 0.12L, 0.25L  HDPE container 5L |

##### Use-specific instructions for use

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##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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### General directions for use of the meta SPC 7.11

#### Instructions for use

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| * The products should not be used in conjunction with acids or ammonia. * Inform the registration holder if the treatment is ineffective. * Make sure to wet surfaces completely. Allow to take effect for the contact time needed. |

#### Risk mitigation measures

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#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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| **IF ON SKIN:** Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes.  Call a POISON CENTRE or a doctor.  **IF IN EYES:** Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.  Call 112/ambulance for medical assistance.  Information to Healthcare personnel/doctor:  The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid  **IF SWALLOWED:** Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.  **IF INHALED:** Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. |

#### Instructions for safe disposal of the product and its packaging

|  |
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| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Do not store above 30°C  Protect from frost  Protect from direct sunlight  Shelf life: 11 months |

### Other information

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| * For PT3 and PT4 professional uses, the applicant should inform users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs. * For professional PT4 use Disinfection of inner surfaces in water systems: The user should control the concentration of chlorate present in the drinking water to ensure that this concentration does not exceed the parametric values set in Directive 2020/2184. |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 7.11**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 120mL Eau de Javel 3,6%c.a. Oxolis  250mL Eau de Javel 3,6%c.a. Oxolis  5L JAVEL BEC BLANC 3,6%c.a. | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 3.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 25.71 |

**Part II - Second information level - meta SPC 7.12**

### Meta SPC 7.12 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 7.12 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | PT 2,3,4 |
| --- | --- |

### Meta SPC 7.12 composition

#### Qualitative and quantitative information on the composition of the meta SPC 7.12

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 4.80 | 4.80 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 34.29 | 34.29 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical active substance is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the typical purity claimed is 140g/kg.

#### Type(s) of formulation of the meta SPC 7.12

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| SL soluble concentrate |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 7.12

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Corr.1  Eye Dam.1  Aquatic acute 1  Aquatic chronic 2 |
| Hazard statement | H290: May be corrosive to metals  H314: Causes severe skin burns and eye damage  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H411: Toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
|  | |
| **Labelling** | |
| GHS pictogram | GHS05 |
| Signal words | Danger (Dgr) |
| Hazard statements | H290: May be corrosive to metals  H314: Causes severe skin burns and eye damage  H410: Very toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
| Precautionary statements | P234: keep only in original packaging  P273: Avoid released to the environment  P260: Do not breathe dust/fume/ gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P280: Wear protective gloves/ protective clothing/eye protection/face protection.  P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P310: Immediately call a POISON CENTER/doctor/…  P321: Specific treatment (see … on this label).  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P405: Store locked up.  P390: absorb spillage to prevent material damage  P391: Collect spillage  P501: Dispose of contents/container in accordance with the national regulation |
|  | |
| Note | EUH031: Contact with acids liberates toxic gas  EUH071 : Corrosive to the respiratory tract |

### Authorised use(s) of the META SPC 7.12

#### Use description

Table 1. Use # 7.12.1 – Disinfection of surfaces in medical area

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | healthcare  Indoor |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria and yeasts: 15% v/v   Other target organisms:   * Fungi and virus: 15% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 2L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 2. Use # 7.12.2 – Disinfection of surfaces in contact with food

|  |  |
| --- | --- |
| **Product Type** | PT 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural), institutions |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries and alcoholic beverages industries) by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 15% v/v   Other target organisms:   * Fungi and virus: 15% v/v   Contact time: 5 min  Room temperature    Disinfection of hard surfaces in non-alcoholic beverages industries by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 23% v/v   Other target organisms:   * Fungi: 23% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural industries by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 23% v/v   Other target organisms:   * Fungi: 23% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 2L |

##### Use-specific instructions for use

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| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 3. Use # 7.12.3 – Disinfection of surfaces in institutions/industry

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agriculutural areas) |
| **Field of use** | Industry (cosmetics, agricultural, general case), institutions |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case) andcosmetic industries) by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 15% v/v   Other target organisms:   * Fungi and virus: 15% v/v   Contact time: 5 min  Room temperature    Disinfection of hard surfaces in agricultural industries by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 23% v/v   Other target organisms:   * Fungi: 23% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 2L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 4. Use # 7.12.4 – Disinfection of surfaces by CIP

|  |  |
| --- | --- |
| **Product Type** | PT 2, 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agriculutural areas) |
| **Field of use** | Industry (cosmetics, agricultural, general case, meat, milk, non-alcoholic, alcoholic beverages), institutions |
| **Application method(s)** | CIP |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by CIP:  Mandatory target organisms:   * Bacteria and yeasts: 15% v/v   Other target organisms:   * Fungi and virus: 15% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in and non-alcoholic beverages industries by CIP:  Mandatory target organisms:   * Bacteria and yeasts: 23% v/v   Other target organisms:   * Fungi and virus: 23% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural industries by CIP:  Mandatory target organisms:   * Bacteria and yeasts: 23% v/v   Other target organisms:   * Fungi: 23% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 2L |

##### Use-specific instructions for use

|  |
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|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * For PT 2 uses, avoid any direct or indirect contact with food * For PT 4 uses, rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 6. Use # 7.12.6 – Disinfection of non-porous hard surfaces in veterinary area

|  |  |
| --- | --- |
| **Product Type** | PT3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria and yeasts: 14% v/v   Other target organisms:   * Fungi: 16% v/v * Virus: 18% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 2L |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Only use in empty animal housing. * Remove all feed and drinks prior to treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. * Do not let animals enter the treated area before the surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 7. Use # 7.12.7 –Disinfection of non-porous hard surfaces in livestock transportation vehicles

|  |  |
| --- | --- |
| **Product Type** | PT3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Livestock transportation |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria, yeasts and virus: 18% v/v   Other target organisms:   * Fungi: 18% v/v   Contact time: 5 minutes  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 2L |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Only use in empty livestock transport vehicles. * Remove all feed and drinks prior to treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. * Do not let animals enter the treated area before the surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 8. Use # 7.12.8 – Disinfection of inner surfaces in human drinking water systems

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Industry (meat, non alcoholic beverages, alcoholic beverages, dairy, agricultural), institutional area (homes, hotels, etc.) and medical area |
| **Application method(s)** | CIP, stand disinfection |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria: 2.2% v/v   Other target organisms:   * Yeasts: 6.7% v/v * Fungi: 6.7% v/v * Virus: 5.6% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 2L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

#### Use description

Table 9. Use # 7.12.9 – Disinfection of inner surfaces in veterinary water systems

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Viruses |
| **Field of use** | Veterinary industry, animal farms, dairy farms, animal houses |
| **Application method(s)** | CIP, stand disinfection |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria: 14.7% v/v   Other target organisms:   * Yeasts: 14.7% v/v * Fungi: 14.7% v/v * Virus: 17.4% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 2L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

### General directions for use of the meta SPC 7.12

#### Instructions for use

|  |
| --- |
| * The products should not be used in conjunction with acids or ammonia. * Inform the registration holder if the treatment is ineffective. * Make sure to wet surfaces completely. Allow to take effect for the contact time needed. |

#### Risk mitigation measures

|  |
| --- |
|  |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| **IF ON SKIN:** Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes.  Call a POISON CENTRE or a doctor.  **IF IN EYES:** Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.  Call 112/ambulance for medical assistance.  Information to Healthcare personnel/doctor:  The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid  **IF SWALLOWED:** Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.  **IF INHALED:** Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Do not store above 30°C  Protect from frost  Protect from direct sunlight  Shelf life: 8 months |

### Other information

|  |
| --- |
| * For PT3 and PT4 professional uses, the applicant should inform users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs. * For professional PT4 use Disinfection of inner surfaces in water systems: The user should control the concentration of chlorate present in the drinking water to ensure that this concentration does not exceed the parametric values set in Directive 2020/2184. |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 7.12**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 2L Eau de Javel à 4,8%c.a. BEC Professionnels | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 4.80 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 34.29 |

**Part II - Second information level - meta SPC 7.2**

### Meta SPC 7.2 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 7.2 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | PT 2, 3, 4 |
| --- | --- |

### Meta SPC 7.2 composition

#### Qualitative and quantitative information on the composition of the meta SPC 7.2

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.60 | 2.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 18.57 | 18.57 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical active substance is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the typical purity claimed is 140g/kg.

#### Type(s) of formulation of the meta SPC 7.2

|  |
| --- |
| SL soluble concentrate |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 7.2

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Corr.1  Eye Dam.1  Aquatic acute 1  Aquatic chronic 1 |
| Hazard statement | H290: May be corrosive to metals  H314: Causes severe skin burns and eye damage  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
|  | |
| **Labelling** | |
| GHS pictogram | GHS05 |
| Signal words | Danger (Dgr) |
| Hazard statements | H290: May be corrosive to metals  H314: Causes severe skin burns and eye damage  H410: Very toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
| Precautionary statements | P234: keep only in original packaging  P273: Avoid released to the environment  P260: Do not breathe dust/fume/ gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P280: Wear protective gloves/ protective clothing/eye protection/face protection.  P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P310: Immediately call a POISON CENTER/doctor/…  P321: Specific treatment (see … on this label).  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P405: Store locked up.  P390: absorb spillage to prevent material damage  P391: Collect spillage  P501: Dispose of contents/container in accordance with the national regulation |
|  | |
| Note | EUH071 : Corrosive to the respiratory tract |

### Authorised use(s) of the META SPC 7.2

#### Use description

Table 1. Use # 7.2.1 – Disinfection of surfaces in medical area

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | healthcare |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Disinfection of surfaces in medical area:  Mandatory target organisms:   * Bacteria and yeasts: 30% v/v   Other target organisms:   * Fungi and virus: 30% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 1L, 2L  HDPE container 5L, 10L,20L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 2. Use # 7.2.2 – Disinfection of surfaces in contact with food

|  |  |
| --- | --- |
| **Product Type** | PT 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural), institutions |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries and alcoholic beverages industries) by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 30% v/v   Other target organisms:   * Fungi and virus: 30% v/v   Contact time: 5 min  Room temperature    Disinfection of hard surfaces in non-alcoholic beverages industries by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 45% v/v   Other target organisms:   * Fungi and virus: 45% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural industries by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 45% v/v   Other target organisms:   * Fungi: 45% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 1L, 2L  HDPE container 5L, 10L,20L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 3. Use # 7.2.3 – Disinfection of surfaces in institutions/industry

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (cosmetics, agricultural, general case), institutions |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case) and cosmetic industries) by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 30% v/v   Other target organisms:   * Fungi and virus: 30% v/v   Contact time: 5 min  Room temperature    Disinfection of hard surfaces in agricultural industries by wiping, mopping:  Mandatory target organisms:   * Bacteria and yeasts: 45% v/v   Other target organisms:   * Fungi: 45% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 1L, 2L  HDPE container 5L, 10L,20L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 4. Use # 7.2.4 – Disinfection of surfaces by CIP

|  |  |
| --- | --- |
| **Product Type** | PT 2, 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agriculutural areas) |
| **Field of use** | Industry (cosmetics, agricultural, general case, meat, milk, non-alcoholic, alcoholic beverages), institutions |
| **Application method(s)** | CIP |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by CIP:  Mandatory target organisms:   * Bacteria and yeasts: 30% v/v   Other target organisms:   * Fungi and virus: 30% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in non-alcoholic beverages industries by CIP:  Mandatory target organisms:   * Bacteria and yeasts: 45% v/v   Other target organisms:   * Fungi and virus: 45% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural industries by CIP:  Mandatory target organisms:   * Bacteria and yeasts: 45% v/v   Other target organisms:   * Fungi: 45% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 1L, 2L  HDPE container 5L, 10L,20L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * For PT 2 uses, avoid any direct or indirect contact with food * For PT 4 uses, rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 6. Use # 7.2.6 – Disinfection of non-porous hard surfaces in veterinary area

|  |  |
| --- | --- |
| **Product Type** | PT3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Viruses |
| **Field of use** | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria and yeasts: 27% v/v   Other target organisms:   * Fungi: 31% v/v * Virus: 35% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 1L, 2L  HDPE container 5L, 10L,20L |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Only use in empty animal housing. * Remove all feed and drinks prior to treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. * Do not let animals enter the treated area before the surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 7. Use # 7.2.7 – Disinfection of non-porous hard surfaces in livestock transportation vehicles

|  |  |
| --- | --- |
| **Product Type** | PT3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Livestock transportation vehicles |
| **Application method(s)** | Wiping, mopping |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria, yeasts and virus: 35% v/v   Other target organisms:   * Fungi: 35% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 1L, 2L  HDPE container 5L, 10L,20L |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Only use in empty livestock transport vehicles. * Remove all feed and drinks prior to treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. * Do not let animals enter the treated area before the surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 8. Use # 7.2.8 – Disinfection of inner surfaces in human drinking water systems

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Industry (meat, non alcoholic beverages, alcoholic beverages, dairy, agricultural), institutional area (homes, hotels, etc.) and medical area |
| **Application method(s)** | CIP, stand disinfection |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria: 4.4% v/v   Other target organisms:   * Yeast: 13.3% v/v * Fungi: 13.3% v/v * Virus: 11.1% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 1L, 2L  HDPE container 5L, 10L,20L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
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|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

#### Use description

Table 9. Use # 7.2.9 – Disinfection of inner surfaces in veterinary water systems

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Veterinary industry, animal farms, dairy farms, animal houses |
| **Application method(s)** | CIP, stand disinfection |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria: 22.1% v/v   Other target organisms:   * Yeast: 29.3% v/v * Fungi: 29.3% v/v * Virus: 34.6% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 1L, 2L  HDPE container 5L, 10L,20L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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| --- |
|  |

### General directions for use of the meta SPC 7.2

#### Instructions for use

|  |
| --- |
| * The products should not be used in conjunction with acids or ammonia. * Inform the registration holder if the treatment is ineffective. * Make sure to wet surfaces completely. Allow to take effect for the contact time needed. |

#### Risk mitigation measures

|  |
| --- |
|  |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| **IF ON SKIN:** Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes.  Call a POISON CENTRE or a doctor.  **IF IN EYES:** Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.  Call 112/ambulance for medical assistance.  Information to Healthcare personnel/doctor:  The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid  **IF SWALLOWED:** Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.  **IF INHALED:** Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Do not store above 30°C  Protect from frost  Protect from direct sunlight  Shelf life: 11 months |

### Other information

|  |
| --- |
| * For PT3 and PT4 professional uses, the applicant should inform users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs. * For professional PT4 use Disinfection of inner surfaces in water systems: The user should control the concentration of chlorate present in the drinking water to ensure that this concentration does not exceed the parametric values set in Directive 2020/2184. |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 7.2**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 250mL Eau de Javel à 2,6%c.a. LAJOT BEC  1L Eau de Javel à 2,6%c.a. BEC Professionnels  2L Eau de Javel à 2,6%c.a. BEC Professionnels  5L Eau de Javel à 2,6%c.a. BEC Professionnels  10L Eau de Javel à 2,6%c.a. BEC Professionnels  20L Eau de Javel à 2,6%c.a. BEC Professionnels | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 18.57 |

**Part II - Second information level - meta SPC 10.1**

### Meta SPC 10.1 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 10.1 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | PT 2,3,4 |
| --- | --- |

### Meta SPC 10.1 composition

#### Qualitative and quantitative information on the composition of the meta SPC 10.1

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.60 | 2.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 18.57 | 18.57 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical active substance is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the typical purity claimed is 140g/kg.

#### Type(s) of formulation of the meta SPC 10.1

|  |
| --- |
| SL soluble concentrate |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 10.1

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Corr.1  Eye Dam.1  Aquatic acute 1  Aquatic chronic 2 |
| Hazard statement | H290: May be corrosive to metals  H314: Causes severe skin burns and eye damage  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H411: Toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
|  | |
| **Labelling** | |
| GHS pictogram | GHS05 |
| Signal words | Danger (Dgr) |
| Hazard statements | H290: May be corrosive to metals  H314: Causes severe skin burns and eye damage  H410: Very toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
| Precautionary statements | P234: keep only in original packaging  P273: Avoid released to the environment  P260: Do not breathe dust/fume/ gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P280: Wear protective gloves/ protective clothing/eye protection/face protection.  P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P310: Immediately call a POISON CENTER/doctor/…  P321: Specific treatment (see … on this label).  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P405: Store locked up.  P390: absorb spillage to prevent material damage  P391: Collect spillage  P501: Dispose of contents/container in accordance with the national regulation |
|  | |
| Note | EUH071 : Corrosive to the respiratory tract |

### Authorised use(s) of the META SPC 10.1

#### Use description

Table 1. Use # 10.1.1 – Disinfection of hard surfaces in medical area

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | healthcare |
| **Application method(s)** | Wiping, mopping, flooding |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria and yeast: 30% v/v   Other target organisms:   * Fungi and virus: 30% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
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|  |

#### Use description

Table 2. Use # 10.1.2 – Disinfection of hard surfaces in contact with food

|  |  |
| --- | --- |
| **Product Type** | PT 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural), institutions |
| **Application method(s)** | Wiping, mopping, flooding |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries and alcoholic beverages industries):  Mandatory target organisms:   * Bacteria and yeast: 30% v/v   Other target organisms:   * Fungi and virus: 30% v/v   Contact time: 5 min  Room temperature    Disinfection of hard surfaces in non-alcoholic beverages industries:  Mandatory target organisms:   * Bacteria and yeast: 45% v/v   Other target organisms:   * Fungi and virus: 45% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural industries:  Mandatory target organisms:   * Bacteria and yeast: 45% v/v   Other target organisms:   * Fungi: 45% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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|  |

#### Use description

Table 3. Use # 10.1.3 – Disinfection of hard surfaces in industries/institutions

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agriculutural areas) |
| **Field of use** | Industry (general case, agricultural, cosmetics), institutions |
| **Application method(s)** | Wiping, mopping, flooding |
| **Application rate(s) and frequency** | Disinfection of surfaces institutions, industries (general case) and cosmetic industries):  Mandatory target organisms:   * Bacteria and yeast: 30% v/v   Other target organisms:   * Fungi and virus: 30% v/v   Contact time: 5 min  Room temperature    Disinfection of hard surfaces in agricultural industries:  Mandatory target organisms:   * Bacteria and yeast: 45% v/v   Other target organisms:   * Fungi: 45% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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|  |

#### Use description

Table 4. Use # 10.1.4 – Disinfection of hard surfaces by CIP

|  |  |
| --- | --- |
| **Product Type** | PT 2, 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural, cosmetics), institutions |
| **Application method(s)** | CIP |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries):  Mandatory target organisms:   * Bacteria and yeast: 30% v/v   Other target organisms:   * Fungi and virus: 30% v/v   Contact time: 5 min  Room temperature    Disinfection of hard surfaces in non-alcoholic beverages industries:  Mandatory target organisms:   * Bacteria and yeast: 45% v/v   Other target organisms:   * Fungi and virus: 45% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural industries:  Mandatory target organisms:   * Bacteria and yeast: 45% v/v   Other target organisms:   * Fungi: 45% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * For PT2 uses, avoid any direct or indirect contact with food * For PT 4 uses, rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
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|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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|  |

#### Use description

Table 6. Use # 10.1.6 – Disinfection of non-porous hard surfaces in veterinary area

|  |  |
| --- | --- |
| **Product Type** | PT 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| **Application method(s)** | Wiping, mopping, flooding |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria and yeast: 27% v/v   Other target organisms:   * Fungi: 31% v/v * Virus: 35% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Only use in empty animal housing. * Remove all feed and drinks prior to treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried.; * Do not let animals enter the treated area before the surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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|  |

#### Use description

Table 7. Use # 10.1.7 – Disinfection of non-porous hard surfaces in livestock transportation vehicles

|  |  |
| --- | --- |
| **Product Type** | PT 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Livestock transportation vehicles |
| **Application method(s)** | Wiping, mopping, flooding |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria, yeasts and virus: 35% v/v   Other target organisms:   * Fungi: 35% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Only use in empty livestock transport vehicles. * Remove all feed and drinks prior to treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. * Do not let animals enter the treated area before the surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
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|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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| --- |
|  |

### General directions for use of the meta SPC 10.1

#### Instructions for use

|  |
| --- |
| * Products should not be used in conjunction with acids or ammonia. * Inform the registration holder if the treatment is ineffective. * Make sure to wet surfaces completely. Allow to take effect for the contact time needed. |

#### Risk mitigation measures

|  |
| --- |
|  |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| **IF ON SKIN:** Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes.  Call a POISON CENTRE or a doctor.  **IF IN EYES:** Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.  Call 112/ambulance for medical assistance.  Information to Healthcare personnel/doctor:  The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid  **IF SWALLOWED:** Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.  **IF INHALED:** Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Do not store above 30°C  Protect from frost  Protect from direct sunlight  Shelf life: 11 months |

### Other information

|  |
| --- |
| * Foaming products * For PT3 and PT4 professional uses, the applicant should inform users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs. |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 10.1**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 5L Détergent BEC avec Javel Eucalyptus | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 18.57 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 5L Détergent BEC avec Javel Classique  5L SOLI-JAVEL + 4 EN 1 | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 18.57 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 5L Détergent BEC avec Javel Citron  5L SOLI-JAVEL + 4 EN 1 CITRON | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.60 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 18.57 |

**Part II - Second information level - meta SPC 10.2**

### Meta SPC 10.2 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 10.2 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | PT 2,3,4 |
| --- | --- |

### Meta SPC 10.2 composition

#### Qualitative and quantitative information on the composition of the meta SPC 10.2

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 4.80 | 4.80 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 34.29 | 34.29 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.16 | 0.16 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical active substance is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the typical purity claimed is 140g/kg.

Type(s) of formulation of the meta SPC 10.2

|  |
| --- |
| SL soluble concentrate |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 10.2

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Corr.1  Eye Dam.1  Aquatic acute 1  Aquatic chronic 2 |
| Hazard statement | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H411: Toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
|  | |
| **Labelling** | |
| GHS pictogram | GHS05 |
| Signal words | Danger (Dgr) |
| Hazard statements | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage  H410: Very toxic to aquatic life with long-lasting effects |
| Suppl. hazard statement |  |
| Precautionary statements | P234: keep only in original packaging  P273: Avoid released to the environment  P260: Do not breathe dust/fume/ gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P280: Wear protective gloves/ protective clothing/eye protection/face protection.  P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P310: Immediately call a POISON CENTER/doctor/…  P321: Specific treatment (see … on this label).  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P405: Store locked up.  P390: absorb spillage to prevent material damage  P391: Collect spillage  P501: Dispose of contents/container in accordance with the national regulation |
|  | |
| Note | EUH031: Contact with acids liberates toxic gas  EUH071 : Corrosive to the respiratory tract |

### Authorised use(s) of the META SPC 10.2

#### Use description

Table 1. Use # 10.2.1 – Disinfection of hard surfaces in medical area

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | healthcare  Indoor |
| **Application method(s)** | Wiping, mopping, flooding |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria and yeast: 15% v/v   Other target organisms:   * Fungi and virus: 15% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

#### Use description

Table 2. Use # 10.2.2 – Disinfection of hard surfaces in contact with food

|  |  |
| --- | --- |
| **Product Type** | PT 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural), institutions |
| **Application method(s)** | Wiping, mopping, flooding |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries and alcoholic beverages industries):  Mandatory target organisms:   * Bacteria and yeast: 15% v/v   Other target organisms:   * Fungi and virus: 15% v/v   Contact time: 5 min  Room temperature    Disinfection of hard surfaces in non-alcoholic beverages industries:  Mandatory target organisms:   * Bacteria and yeast: 23% v/v   Other target organisms:   * Fungi and virus: 23% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural industries:  Mandatory target organisms:   * Bacteria and yeast: 23% v/v   Other target organisms:   * Fungi: 23% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
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|  |

#### Use description

Table 3. Use # 10.2.3 – Disinfection of hard surfaces in industries/institutions

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (general case, agricultural, cosmetics), institutions |
| **Application method(s)** | Wiping, mopping, flooding |
| **Application rate(s) and frequency** | Disinfection of surfaces institutions, industries (general case) and cosmetic industries):  Mandatory target organisms:   * Bacteria and yeast: 15% v/v   Other target organisms:   * Fungi and virus: 15% v/v   Contact time: 5 min  Room temperature    Disinfection of hard surfaces in agricultural industries:  Mandatory target organisms:   * Bacteria and yeast: 23% v/v   Other target organisms:   * Fungi: 23% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 4. Use # 10.2.4 – Disinfection of hard surfaces by CIP

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| --- | --- |
| **Product Type** | PT 2, 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agriculutural areas) |
| **Field of use** | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural, cosmetics), institutions, veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| **Application method(s)** | CIP |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by CIP:  Mandatory target organisms:   * Bacteria and yeast: 15% v/v   Other target organisms:   * Fungi and virus: 15% v/v   Contact time: 5 min  Room temperature    Disinfection of hard surfaces in non-alcoholic beverages industries by CIP:  Mandatory target organisms:   * Bacteria and yeast: 23% v/v   Other target organisms:   * Fungi and virus: 23% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural industries industries by CIP:  Mandatory target organisms:   * Bacteria and yeast: 23% v/v   Other target organisms:   * Fungi: 23% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * For PT2 uses, avoid any direct or indirect contact with food * For PT4 uses, rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 6. Use # 10.2.6 – Disinfection of non-porous hard surfaces in veterinary area

|  |  |
| --- | --- |
| **Product Type** | PT 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| **Application method(s)** | Wiping, mopping, flooding |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria and yeast: 14% v/v   Other target organisms:   * Fungi: 16% v/v * Virus: 18% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Only use in empty animal housing. * Remove all feed and drinks prior to treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. * Do not let animals enter the treated area before the surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 7. Use # 10.2.7 – Disinfection of non-porous hard surfaces in livestock transportation vehicles

|  |  |
| --- | --- |
| **Product Type** | PT 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Livestock transportation vehicles |
| **Application method(s)** | Wiping, mopping, flooding |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria, yeast and virus: 18% v/v   Other target organisms:   * Fungi: 18% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 5L |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Only use in empty livestock transport vehicles. * Remove all feed and drinks prior to treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. * Do not let animals enter the treated area before the surfaces are completely dried. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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### General directions for use of the meta SPC 10.2

#### Instructions for use

|  |
| --- |
| * Products should not be used in conjunction with acids or ammonia. * Inform the registration holder if the treatment is ineffective. * Make sure to wet surfaces completely. Allow to take effect for the contact time needed. |

#### Risk mitigation measures

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#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| **IF ON SKIN:** Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes.  Call a POISON CENTRE or a doctor.  **IF IN EYES:** Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.  Call 112/ambulance for medical assistance.  Information to Healthcare personnel/doctor:  The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid  **IF SWALLOWED:** Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.  **IF INHALED:** Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

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| --- |
| Do not store above 30°C  Protect from frost  Protect from direct sunlight  Shelf life: 8 months |

### Other information

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| --- |
| * Foaming products * For PT3 and PT4 professional uses, the applicant should inform users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs. |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 10.2**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 5L Détergent Concentré BEC avec Javel Eucalyptus | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 4.80 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 34.29 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.16 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 5L Détergent Concentré BEC avec Javel Classique | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 4.80 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 34.29 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.16 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 5L Détergent Concentré BEC avec Javel Citron | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 4.80 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 34.29 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.16 |

**Part II - Second information level - meta SPC 11**

### Meta SPC 11 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 11 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2,3,4 |
| --- | --- |

### Meta SPC 11 composition

#### Qualitative and quantitative information on the composition of the meta SPC 11

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 6.00 | 6.00 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 42.86 | 42.86 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 8.53 | 8.55 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical active substance is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the typical purity claimed is 140g/kg.

#### Type(s) of formulation of the meta SPC 11

|  |
| --- |
| SL soluble concentrate |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 11

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

*[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]*

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Corr.1  Eye Dam.1  Aquatic acute 1  Aquatic chronic 2 |
| Hazard statement | H290: May be corrosive to metals  H314: Causes severe skin burns and eye damage  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H411: Toxic to aquatic life with long-lasting effects |
| Suppl. Hazard statement |  |
|  | |
| **Labelling** | |
| GHS pictogram | GHS05 |
| Signal words | Danger (Dgr) |
| Hazard statement | H290: May be corrosive to metals  H314: Causes severe skin burns and eye damage  H410: Very toxic to aquatic life with long-lasting effects |
| Suppl. Hazard statement |  |
| Precautionary statements | P234: keep only in original packaging  P273: Avoid released to the environment  P260: Do not breathe dust/fume/ gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P280: Wear protective gloves/ protective clothing/eye protection/face protection.  P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P310: Immediately call a POISON CENTER/doctor/…  P321: Specific treatment (see … on this label).  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P405: Store locked up.  P390: absorb spillage to prevent material damage  P391: Collect spillage  P501: Dispose of contents/container in accordance with the national regulation |
|  | |
| Note | EUH031: Contact with acids liberates toxic gas  EUH071 : corrosive to the respiratory tract |

### Authorised use(s) of the META SPC 11

#### Use description

Table 1. Use # 11.1 – Disinfection of hard surfaces in medical area

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | healthcare  Indoor |
| **Application method(s)** | Wiping, mopping, flooding |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria and yeast: 16% v/v   Other target organisms:   * Fungi and virus: 16% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 20L  HDPE drum 200L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * For application by wiping, flooding and mopping, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. * For wiping, pour the product directly on surfaces and wipe with a cloth. * For mopping, pour the product directly on surfaces and mop using a cloth and a handle. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 2. Use # 11.2 – Disinfection of hard surfaces in contact with food

|  |  |
| --- | --- |
| **Product Type** | 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural), institutions |
| **Application method(s)** | Wiping, mopping, flooding, |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries and alcoholic beverages industries) by spraying, wiping, mopping, flooding:  Mandatory target organisms:   * Bacteria and yeast: 16% v/v   Other target organisms:   * Fungi and virus: 16% v/v   Contact time: 5 min  Room temperature    Disinfection of hard surfaces in non-alcoholic beverages industries by spraying, wiping, mopping, flooding:  Mandatory target organisms:   * Bacteria and yeast: 24% v/v   Other target organisms:   * Fungi and virus: 24% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural industries by spraying, wiping, mopping, flooding:  Mandatory target organisms:   * Bacteria and yeast: 24% v/v   Other target organisms:   * Fungi: 24% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 20L  HDPE drum 200L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * For application by wiping, flooding and mopping, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. * For wiping, pour the product directly on surfaces and wipe with a cloth. * For mopping, pour the product directly on surfaces and mop using a cloth and a handle. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 3. Use # 11.3 – Disinfection of hard surfaces in institutions/industries

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Institutions, industries (general case, agricultural, cosmetics) |
| **Application method(s)** | Wiping, mopping, flooding |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case) and cosmetics industries) by spraying, wiping, mopping, flooding:  Mandatory target organisms:   * Bacteria and yeast: 16% v/v   Other target organisms:   * Fungi and virus: 16% v/v   Contact time: 5 min  Room temperature    Disinfection of hard surfaces in agricultural industries by spraying, wiping, mopping, flooding:  Mandatory target organisms:   * Bacteria and yeast: 24% v/v   Other target organisms:   * Fungi: 24% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 20L  HDPE drum 200L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * For application by wiping, flooding and mopping, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried. * For wiping, pour the product directly on the surfaces and wipe with a cloth. * For mopping, pour the product directly on surfaces and mop with a cloth and a handle. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 4. Use # 11.4 – Disinfection of surfaces by CIP

|  |  |
| --- | --- |
| **Product Type** | 2, 4 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus (except for agricultural areas) |
| **Field of use** | Institutions, industries (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural, cosmetics) |
| **Application method(s)** | CIP |
| **Application rate(s) and frequency** | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by CIP:  Mandatory target organisms:   * Bacteria and yeast: 16% v/v   Other target organisms:   * Fungi and virus: 16% v/v   Contact time: 5 min  Room temperature    Disinfection of hard surfaces in non-alcoholic beverages industries by CIP:  Mandatory target organisms:   * Bacteria and yeast: 24% v/v   Other target organisms:   * Fungi and virus: 24% v/v   Contact time: 5 min  Room temperature  Disinfection of hard surfaces in agricultural industries by CIP:  Mandatory target organisms:   * Bacteria and yeast: 24% v/v   Other target organisms:   * Fungi: 24% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 20L  HDPE drum 200L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * For PT 2 uses, avoid any direct or indirect contact with food * For PT 4 uses, rinse surfaces after treatment * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) * Wear a respiratory protection during the post-application tasks (maintenance of the system). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 5. Use # 11.5 – Disinfection of non-porous hard surfaces in veterinary area

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| **Application method(s)** | Wiping, mopping, flooding |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria and yeasts: 15% v/v   Other target organisms:   * Fungi: 17% v/v * Virus: 19% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 20L  HDPE drum 200L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Only use in empty animal housing. * Remove all feed and drinks prior to treatment * For application by wiping, flooding and mopping, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried * Do not let animals enter the treated area before the surfaces are completely dried. * For wiping, pour the product directly on the surfaces and wipe with a cloth. * For mopping, pour the product directly on surfaces and mop with a cloth and a handle. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 6. Use # 11.6 – Disinfection of non-porous hard surfaces in livestock transportation vehicles

|  |  |
| --- | --- |
| **Product Type** | 3 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Livestock transportation vehicles |
| **Application method(s)** | Wiping, mopping, flooding |
| **Application rate(s) and frequency** | Mandatory target organisms:   * Bacteria, yeast and virus: 19% v/v   Other target organisms:   * Fungi: 19% v/v   Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE container 20L  HDPE drum 200L  HDPE tank 1000L |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Only use in empty livestock transport vehicles. * Remove all feed and drinks prior to treatment * For application by wiping, flooding and mopping, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application). * Do not enter the room before the treated surfaces are completely dried * Do not let animals enter the treated area before the surfaces are completely dried. * For wiping, pour the product directly on the surfaces and wipe with a cloth. * For mopping, pour the product directly on surfaces and mop with a cloth and a handle. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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|  |

### General directions for use of the meta SPC 11

#### Instructions for use

|  |
| --- |
| * Products should not be used in conjunction with acids or ammonia.Inform the registration holder if the treatment is ineffective. * Make sure to wet surfaces completely. Allow to take effect for the contact time needed. |

#### Risk mitigation measures

|  |
| --- |
|  |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| **IF ON SKIN:** Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes.  Call a POISON CENTRE or a doctor.  **IF IN EYES:** Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.  Call 112/ambulance for medical assistance.  Information to Healthcare personnel/doctor:  The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid  **IF SWALLOWED:** Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.  **IF INHALED:** Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Do not store above 30°C  Protect from frost  Protect from direct sunlight  Shelf life: 6 months |

### Other information

|  |
| --- |
| * Foaming products * For PT3 and PT4 professional uses, the applicant should inform users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs. |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 11**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 20L Détergent Alcalin Chloré Non-moussant BEC Professionnels  200L Détergent Alcalin Chloré Non-moussant BEC Professionnels  1000L Détergent Alcalin Chloré Non-moussant BEC Professionnels | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 6.00 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 42.86 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 8.55 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 20L Détergent Alcalin Chloré Moussant BEC Professionnels  200L Détergent Alcalin Chloré Moussant BEC Professionnels  1000L Détergent Alcalin Chloré Moussant BEC Professionnels | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 6.00 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 42.86 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 8.55 |

**Part II - Second information level - meta SPC 12**

### Meta SPC 12 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 12 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2 |
| --- | --- |

### Meta SPC 12 composition

#### Qualitative and quantitative information on the composition of the meta SPC 12

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 4.80 | 4.80 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 34.29 | 34.29 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.16 | 0.16 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical active substance is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the typical purity claimed is 140g/kg.

#### Type(s) of formulation of the meta SPC 12

|  |
| --- |
| ready to use liquid (spray) |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 12

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

*[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]*

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Corr.1  Eye Dam.1  Aquatic acute 1  Aquatic chronic 2 |
| Hazard statement | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H411: Toxic to aquatic life with long-lasting effects |
|  | |
| **Labelling** | |
| GHS pictogram | GHS05 |
| Signal words | Danger (Dgr) |
| Hazard statements | H290: May be corrosive to metals  H314: Causes severe skin burns and eye damage  H410: Very toxic to aquatic life with long-lasting effects |
| Precautionary statements | P234: keep only in original packaging  P273: Avoid released to the environment  P260: Do not breathe dust/fume/ gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P280: Wear protective gloves/ protective clothing/eye protection/face protection.  P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P310: Immediately call a POISON CENTER/doctor/…  P321: Specific treatment (see … on this label).  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P405: Store locked up.  P390: absorb spillage to prevent material damage  P391: Collect spillage  P501: Dispose of contents/container in accordance with the national regulation |
|  | |
| Note | EUH031: Contact with acids liberates toxic gas  EUH071 : corrosive to the respiratory tract |

### Authorised use(s) of the META SPC 12

#### Use description

Table 1. Use # 12.1 – Disinfection of hard surfaces by spraying

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Healthcare, institutions, industries (general case) |
| **Application method(s)** | Spraying |
| **Application rate(s) and frequency** | Ready to use product.  Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle with PP/PE trigger spray TS5 S 0.5, 0.75L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
|  |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

### General directions for use of the meta SPC 12

#### Instructions for use

|  |
| --- |
| * Products should not be used in conjunction with acids or ammonia. * Inform the registration holder if the treatment is ineffective. * Make sure to wet surfaces completely. Allow to take effect for the contact time needed. |

#### Risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall, goggles and RPE with APF at minima 4 during the application of the product. * The spray application must be performed downward in order to avoid exposure. * Do not enter the room during the disinfection process. If necessary to be present, wear the same PPE/RPE than the applicator of the product. * Do not enter the room before the treated surfaces are completely dried |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| **IF ON SKIN:** Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes.  Call a POISON CENTRE or a doctor.  **IF IN EYES:** Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.  Call 112/ambulance for medical assistance.  Information to Healthcare personnel/doctor:  The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid  **IF SWALLOWED:** Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.  **IF INHALED:** Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Do not store above 30°C  Protect from frost  Protect from direct sunlight  Shelf life: 8 months |

### Other information

|  |
| --- |
|  |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 12**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 500mL Spray avec Javel à 4,8%c.a. BEC Professionnels  750mL Spray avec Javel à 4,8%c.a. BEC Professionnels | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 4.80 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 34.29 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.16 |

**Part II - Second information level - meta SPC 13**

### Meta SPC 13 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 13 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2 |
| --- | --- |

### Meta SPC 13 composition

#### Qualitative and quantitative information on the composition of the meta SPC 13

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 4.50 | 4.50 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 32.14 | 32.14 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.64 | 0.64 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical active substance is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the typical purity claimed is 140g/kg.

#### Type(s) of formulation of the meta SPC 13

|  |
| --- |
| Ready to use gel |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 13

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

*[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]*

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Corr.1  Eye Dam.1  Aquatic acute 1  Aquatic chronic 2 |
| Hazard statement | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H411: Toxic to aquatic life with long-lasting effects |
|  | |
| **Labelling** | |
| GHS pictogram | GHS05 |
| Signal words | Danger (Dgr) |
| Hazard statements | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage  H410: Very toxic to aquatic life with long-lasting effects |
| Precautionary statements | P234: keep only in original packaging  P273: Avoid released to the environment  P260: Do not breathe dust/fume/ gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P280: Wear protective gloves/ protective clothing/eye protection/face protection.  P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P310: Immediately call a POISON CENTER/doctor/…  P321: Specific treatment (see … on this label).  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P405: Store locked up.  P390: absorb spillage to prevent material damage  P391: Collect spillage  P501: Dispose of contents/container in accordance with the national regulation |
|  | |
| Note |  |

### Authorised use(s) of the META SPC 13

#### Use description

Table 1. Use # 13.1 – Disinfection of toilet bowls in medical area

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Healthcare |
| **Application method(s)** | Direct application of the product (by pressing on the packaging) and rinse with flush |
| **Application rate(s) and frequency** | Ready to use product.  Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle with gooseneck 0.75L  HDPE bottle 0.75L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
|  |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

#### Use description

Table 2. Use # 13.2 – Disinfection of toilet bowls in institutions/industry

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeast  Virus |
| **Field of use** | Industry (general case), institutions |
| **Application method(s)** | Direct application of the product (by pressing on the packaging) and rinse with flush |
| **Application rate(s) and frequency** | Ready to use product.  Contact time: 5 min  Room temperature |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle with gooseneck 0.75L  HDPE bottle 0.75L |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
|  |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

### General directions for use of the meta SPC 13

#### Instructions for use

|  |
| --- |
| * Products should not be used in conjunction with acids or ammonia. * Inform the registration holder if the treatment is ineffective. * Make sure to wet surfaces completely. Allow to take effect for the contact time needed. |

#### Risk mitigation measures

|  |
| --- |
| * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product. |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| **IF ON SKIN:** Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes.  Call a POISON CENTRE or a doctor.  **IF IN EYES:** Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.  Call 112/ambulance for medical assistance.  Information to Healthcare personnel/doctor:  The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid  **IF SWALLOWED:** Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.  **IF INHALED:** Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Do not store above 30°C  Protect from frost  Protect from direct sunlight  Shelf life: 11 months |

### Other information

|  |
| --- |
|  |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 13**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 750mL Gel Javel WC à 4,5%c.a. BEC | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 4.50 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 32.14 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.64 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | 750mL Gel Javel WC à 4,5%c.a. BEC Eucalyptus | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 4.50 |
| Sodium hypochlorite (technical solution with minimum purity of  14.7% w/w NaOCl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 32.14 |
| Sodium hydroxide | Sodium hydroxide | Stabiliser | 1310-73-2 | 215-185-5 | 0.64 |

### Packaging of the biocidal product family

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Meta SPC 1.1 | | | | | |
| Can/tin | 5L | PEHD | Caps | Non-professional | Yes |
| Can/tin | 10L | PEHD | Caps | Non-professional and professional | Yes |
| Can/tin | 20L | PEHD | Caps | Non-professional and professional | Yes |
| Meta SPC 1.2 | | | | | |
| Can/tin | 10L | PEHD | Caps | Non-professional and professional | Yes |
| Can/tin | 20L | PEHD | Caps | Non-professional and professional | Yes |
| Meta SPC 2.1 | | | | | |
| bottle | 1L, 2L | PEHD | Caps | Non-professional | Yes |
| Containers | 5L, 10L | PEHD | Caps | Non-professional | Yes |
| Meta SPC 2.21 | | | | | |
| Flexible pack with spout | 250ML Sachet | PVC | Welding | Non-professional | Yes |
| Meta SPC 2.22 | | | | | |
| bottles with handle | 0.12L, 0.25L, 2L | PEHD | Caps | Non-professional | Yes |
| containers with handle | 5L | PEHD | Caps | Non-professional | Yes |
| Meta SPC 3 | | | | | |
| Bottle with gooseneck | 750ML | HDPE | Caps | Non-professional, professional | Yes |
| bottle (round) | 750ML | HDPE | Caps | Non-professional | Yes |
| Meta SPC 4 | | | | | |
| Bottle with gooseneck | 750ML | HDPE | Caps | Non-professional | Yes |
| bottle | 1L | HDPE | Caps | Non-professional, professional | Yes |
| Meta SPC 5 | | | | | |
| bottle | 750ML | HDPE | Cap with PP/PE trigger TS 5S and switch ON/OFF | Non-professional, professional | Yes |
| bottle | 500ML | HDPE | Cap with PP/PE trigger TS5 S and switch ON/OFF | Non-professional, professional | Yes |
| Meta SPC 6.1 | | | | | |
| containers | 5L, 10L, 20L | HDPE | Cap | Non-professional | Yes |
| Meta SPC 6.21 | | | | | |
| bottles | 250ML | HDPE | Cap | Professional | Yes |
| containers | 5L, 10L, 20L | HDPE | Cap | Professional | Yes |
| Drums | 200L | HDPE | Cap | Professional | Yes |
| tanks | 1000L | HDPE | Cap | Professional | Yes |
| Flexible PVC | 250ML | PVC | Cap | Professional | No |
| Meta SPC 6.22 | | | | | |
| containers | 10L, 20L | HDPE | Cap | Professional | Yes |
| tanks | 1000L | HDPE | Cap | Professional | Yes |
| Meta SPC 7.11 | | | | | |
| bottle | 0.12L, 0.25L, | HDPE | Cap | Professional | Yes |
| containers | 5L | HDPE | Cap | Professional | Yes |
| Meta SPC 7.12 | | | | | |
| bottle | 2L | HDPE | Cap | Professional | Yes |
| Meta SPC 7.2 | | | | | |
| bottle | 1L, 2L | HDPE | Cap | Professional | Yes |
| containers | 5L, 10L, 20L | HDPE | Cap | Professional | Yes |
| Meta SPC 8 | | | | | |
| containers | 2L, 5L | HDPE | Cap | Non-professional | Yes |
| Meta SPC 9 | | | | | |
| containers | 5L, 10L, 20L | HDPE | Cap | Non-professional | Yes |
| Meta SPC 10.1 | | | | | |
| containers | 5L | HDPE | Cap | Professional | Yes |
| Meta SPC 10.2 | | | | | |
| containers | 5L | HDPE | Cap | Professional | Yes |
| Meta SPC 11 | | | | | |
| containers | 20L | HDPE | Cap | Professional | Yes |
| drums | 200L | HDPE | Cap | Professional | Yes |
| tanks | 1000L | HDPE | Cap | Professional | Yes |
| Meta SPC 12 | | | | | |
| bottle | 750ML, 500ML | HDPE | Cap with PP/PE trigger spray TS5 Sand ON/OFF lock | Professional | Yes |
| Meta SPC 13 | | | | | |
| Bottle with gooseneck | 750ML | HDPE | Caps | Non-professional | Yes |
| bottle (round) | 750ML | HDPE | Caps | Non-professional | Yes |
| Meta SPC 14 | | | | | |
| Jerrycan (gel solution) + bottle (bleach) | 5L (with 4L gel) +1L (bleach) to be mixed before application | HDPE | Cap | Non-professional | Yes |

### Documentation

#### Data submitted in relation to product application

New physico chemical studies and analytical methods have been provided.

#### Access to documentation

A LoA has been submitted giving access to the approbation dossier submitted by Eurochlor (representative products).

## Assessment of the biocidal product family

### Intended use(s) as applied for by the applicant for meta SPC 1.1

Table 1. Use #1.1.1 – disinfection of private swimming pools

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** | disinfection of private swimming pools |
| **Target organism (including development stage)** | *Bacteria (tests conducted on P. aeruginosa, S. aureus, E. coli, E. hirae)*  *Viruses (tests conducted on Adenovirus, Norovirus)* |
| **Field of use** | Private swimming pools |
| **Application method(s)** | Automated dosing, continuous flow |
| **Application rate(s) and frequency** | 3mg a.c./L  continuous flow |
| **Category(ies) of users** | Non professional |
| **Pack sizes and packaging material** | PEHD, childproof closure  5L, 10L, 20L |

Table 2. Use # 1.1.2 – shock disinfection of private swimming pools

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** | Shock disinfection of private swimming pools |
| **Target organism (including development stage)** | *Bacteria (tests conducted on P. aeruginosa, S. aureus, E. coli, E. hirae)*  *Viruses (tests conducted on Adenovirus, Norovirus)*  *Algae (Pseudokirchneriella subcapitata)* |
| **Field of use** | Private swimming pools |
| **Application method(s)** | Automated dosing |
| **Application rate(s) and frequency** | 50mg a.c./L  Rarely, when necessary |
| **Category(ies) of users** | Non professional |
| **Pack sizes and packaging material** | PEHD, childproof closure  5L, 10L, 20L |

Table 3. Use # 1.1.3 – disinfection of footbaths in private swimming pools

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** | Disinfection of footbaths in private swimming pools |
| **Target organism (including development stage)** | *Bacteria (tests conducted on P. aeruginosa, S. aureus, E. coli, E. hirae, C. Albicans)*  *Viruses (tests conducted on Adenovirus, Norovirus)* |
| **Field of use** | Private swimming pools |
| **Application method(s)** | Automated dosing |
| **Application rate(s) and frequency** | 5mg a.c./L  Renew water 1-2 times per day |
| **Category(ies) of users** | Non professional |
| **Pack sizes and packaging material** | PEHD, childproof closure  5L, 10L, 20L |

Use-specific instructions for use

|  |
| --- |
|  |

Use-specific risk mitigation measures

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Meta SPC | Product description | |  | RMM |
| meta SPC 1.1 | Swimming pool products - general public | Min (%) | 9.6 | Automated dosing system: no direct contact with skin, or eyes before dilution |
| Max (%) | 9.6 |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 1.1

Instructions for use

|  |
| --- |
| Only use this product with an automated dosing system with pump. Remove cap and dip a hose into the bottle/jerrycan to collect the product.  For an efficient action in swimming-pool, maintain pH between 7.2 and 7.6. If pH is too low, add 5 gramms per m3 of "Cristaux de Soude PHENIX". Controle pH after 4 hours. If the pH is too high, add 15mL per m3 of chlorhydric acid (never mix chlorhydric acid and bleach directly). In case of skin or eyes irritation, or disagreable odor, adjust pH between 7.2 and 7.6.  Time period needed for biocidal effect: 10 minutes. Avoid bathing immediately after treatment (wait 1 to 2 hours of stirring). |

Risk mitigation measures

|  |
| --- |
| None |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Can/tin | 5L | PEHD | Caps with childproof closure | Non-professional | Yes |
| Can/tin | 10L | PEHD | Caps with childproof closure | Non-professional and professional | Yes |
| Can/tin | 20L | PEHD | Caps with childproof closure | Non-professional and professional | Yes |

Authorised use(s) for meta-SPC 1.2

Use description

Table 4. Use # 1.2.1 – disinfection of public and private swimming pools

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** | disinfection of public and private swimming pools |
| **Target organism (including development stage)** | *Bacteria (tests conducted on P. aeruginosa, S. aureus, E. coli, E. hirae)*  *Viruses (tests conducted on Adenovirus, Norovirus)* |
| **Field of use** | Public/private swimming pools |
| **Application method(s)** | Automated dosing continuous flow or pouring of the concentrated product into the swimming pool |
| **Application rate(s) and frequency** | Continuous disinfection for pools:  Target concentration of 3mg a.c./L, corresponding to 35mL of product per m3. |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | PEHD  10L, 20L |

Table 5. Use # 1.2.2 – shock disinfection of public and private swimming pools

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** | Shock disinfection of public and private swimming pools |
| **Target organism (including development stage)** | *Bacteria (tests conducted on P. aeruginosa, S. aureus, E. coli, E. hirae)*  *Viruses (tests conducted on Adenovirus, Norovirus)*  *Algaes (Pseudokirchneriella subcapitata)* |
| **Field of use** | Public/private swimming pools |
| **Application method(s)** | Automated dosing or pouring of the concentrated product into the swimming pool |
| **Application rate(s) and frequency** | 50mg a.c./L, corresponding to 570mL of product per m3  Rarely, when necessary |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | PEHD  10L, 20L |

Table 6. Use # 1.2.3 – disinfection of footbaths in public and private swimming pools

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** | Disinfection of footbaths in public and private swimming pools |
| **Target organism (including development stage)** | *Bacteria (tests conducted on P. aeruginosa, S. aureus, E. coli, E. hirae)*  *Viruses (tests conducted on Adenovirus, Norovirus)*  *Fungi (C. Albicans)* |
| **Field of use** | Public/private swimming pools |
| **Application method(s)** | Automated dosing or pouring of the concentrated product into the footbath |
| **Application rate(s) and frequency** | 5mg a.c./L, corresponding to 60mL of product per m3.  Renew water 1 to 2 times per hour depending on attendance. |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | PEHD  10L, 20L |

Use-specific instructions for use

|  |
| --- |
|  |

Use-specific risk mitigation measures

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Meta SPC | Product description | |  | RMM |
| meta SPC 1.2 | Swimming pool products - pro | Min (%) | 12.5 | Automated dosing system: no direct contact with skin, or eyes before dilution / PPE (gloves - clothes - glasses - mask) |
| Max (%) | 12.5 |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 1.2

Instructions for use

|  |
| --- |
| Only use this product with an automated dosing system with pump. Remove cap and dip a hose into the bottle/jerrycan to collect the product.  For an efficient action in swimming-pool, maintain pH between 7.2 and 7.6. If pH is too low, add 5 gramms per m3 of "Cristaux de Soude PHENIX". Controle pH after 4 hours. If the pH is too high, add 15mL per m3 of chlorhydric acid (never mix chlorhydric acid and bleach directly). In case of skin or eyes irritation, or disagreable odor, adjust pH between 7.2 and 7.6.  Time period needed for biocidal effect: 10 minutes. Avoid bathing immediately after treatment (wait 1 to 2 hours of stirring). |

Risk mitigation measures

|  |
| --- |
| Please wear PPE (in case of manual dilution and pouring into swimming pool) |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Can/tin | 10L | PEHD | Caps | Professional | Yes |
| Can/tin | 20L | PEHD | Caps | Professional | Yes |

Documentation

Data submitted in relation to product application

None.

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 2.1

Uses description

Table 7. Use # 2.1.1 – Disinfection of surfaces (floors) by wiping with mop and bucket

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (floors) by wiping with mop and bucket (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | mopping |
| Application rate(s) and frequency | Dinsinfection of hard surfaces:  For bactericidal activity: Add 3 volumes of bleach into 7 volumes of water.  For a fungicidal/yeasticidal activity: Add 1 volume of bleach into 3 volumes of water.  For virucidal activity: Add 1 volume of bleach into 8 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per week |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | 1L, 2L, 5L, 10L |

Table 8. Use # 2.1.2 – Disinfection of surfaces (other than floors) by wiping with cloth and bucket

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (other than floors) by wiping with cloth and bucket (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Wiping |
| Application rate(s) and frequency | Dinsinfection of hard surfaces:  For bactericidal activity: Add 3 volumes of bleach into 7 volumes of water.  For a fungicidal/yeasticidal activity: Add 1 volume of bleach into 3 volumes of water.  For virucidal activity: Add 1 volume of bleach into 8 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per week |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | 1L, 2L, 5L, 10L |

 Table 9. Use # 2.1.3 – Disinfection of toilet bowls

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of toilet bowls by wiping (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Wiping |
| Application rate(s) and frequency | For bactericidal activity: Add 3 volumes of bleach into 7 volumes of water.  For a fungicidal/yeasticidal activity: Add 1 volume of bleach into 3 volumes of water.  For virucidal activity: Add 1 volume of bleach into 8 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : up to 2 times per week |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | 1L, 2L, 5L, 10L |

Table 10. Use # 2.1.4 – Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Wiping |
| Application rate(s) and frequency | For bactericidal activity: Add 3 volumes of bleach into 7 volumes of water.  For a fungicidal/yeasticidal activity: Add 1 volume of bleach into 3 volumes of water.  For virucidal activity: Add 1 volume of bleach into 8 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency: once per week |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | 1L, 2L, 5L, 10L |

Table 11. Use # 2.1.5 – Disinfection of companion animal housing and associated equipment

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of companion animal housing (such as kennels, hutches, cages) and associated equipment |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Household, companion animals |
| Application method(s) | Wiping |
| Application rate(s) and frequency | For bactericidal activity: Add 1 volume of bleach into 3 volumes of water.  For a fungicidal activity: Add 1 volume of bleach into 2 volumes of water.  For yeast activity: Add 2 volumes of bleach into 5 volumes of water.  For virucidal activity: Add 3 volumes of bleach into 5 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : up to 2 times per year |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | 1L, 2L, 5L, 10L |

Table 12. Use # 2.1.6 – Laundry disinfection with hand soaking

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Laundry disinfection with hand soaking |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Hand soaking |
| Application rate(s) and frequency | For bactericidal activity: Add 1 volume of bleach into 19 volumes of water.  For fungicidal/yeasticidal activity: Add 1 volume of bleach into 5 volumes of water.  For virucidal activity: Add 1 volume of bleach into 8 volumes of water.  Frequency : once per day |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | 1L, 2L, 5L, 10L |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |
| --- |
| Rinse treated surfaces (TP4) |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 2.1

Instructions for use

|  |
| --- |
| Cleaning before disinfection is preferred. Do not transfer product into any other packaging not destined to receive bleach water. |

Risk mitigation measures

|  |
| --- |
| Not required |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic bottle | 1L, 2L, 5L, 10L | PEHD | Caps | Non-professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 2.21

Use description

Table 12. Use # 2.21.1 – Disinfection of surfaces (floors) by wiping with mop and bucket

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (floors) by wiping with mop and bucket (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | mopping |
| Application rate(s) and frequency | 50/50 dilution then follow instructions of products from meta-SPC 2.1 |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | PVC : 3x250ML |

Table 13. Use # 2.21.2 – Disinfection of surfaces (other than floors) by wiping with cloth and bucket

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (other than floors) by wiping with cloth and bucket (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Wiping |
| Application rate(s) and frequency | 50/50 dilution then follow instructions of products from meta-SPC 2.1 |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | PVC : 3x250ML |

 Table 14. Use # 2.21.3 – Disinfection of toilet bowls

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of toilet bowls by wiping (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Wiping |
| Application rate(s) and frequency | 50/50 dilution then follow instructions of products from meta-SPC 2.1 |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | PVC : 3x250ML |

Table 15. Use # 2.21.4 – Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Wiping |
| Application rate(s) and frequency | 50/50 dilution then follow instructions of products from meta-SPC 2.1 |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | PVC : 3x250ML |

Table 16. Use # 2.21.5 – Disinfection of companion animal housing and associated equipment

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of companion animal housing (such as kennels, hutches, cages) and associated equipment (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Household, companion animals |
| Application method(s) | Wiping |
| Application rate(s) and frequency | 50/50 dilution then follow instructions of products from meta-SPC 2.1 |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | PVC : 3x250ML |

Table 17. Use # 2.21.6 – Laundry disinfection with hand soaking

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Laundry disinfection with hand soaking (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Hand soaking |
| Application rate(s) and frequency | 50/50 dilution then follow instructions of products from meta-SPC 2.1 |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | PVC : 3x250ML |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Meta SPC | Product description | |  | RMM |
| meta SPC 2.21 | Javel MDD à 4,8%c.a. | Max (%) | 4,8 | Packaging : no direct contact with skin, or eyes before dilution (spout) |
| Max (%) | 4,8 |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 2.21

Instructions for use

|  |
| --- |
| Cleaning before disinfection is preferred. Do not transfer product into any other packaging not destined to receive bleach water. Products with 4,8%a.c. (flexible PVC pack with spout): pinch the spout and cut it, then pour the liquid into a bottle. For an easier dilution, use “BEC Perce-dose”: Place the “BEC Perce-dose” system on the bottle and squeeze the sachet/berlingot in the spike until the liquid has drained. |

Risk mitigation measures

|  |
| --- |
| Packaging: no direct contact with skin, or eyes before dilution (spout) |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Flexible pack with spout | 250ML Sachet | PVC | Welding | Non-professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 2.22

Use description

Table 18. Use # 2.22.1 – Disinfection of surfaces (floors) by wiping with mop and bucket

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (floors) by wiping with mop and bucket (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | mopping |
| Application rate(s) and frequency | For bactericidal activity: Add 2 volumes of bleach into 7 volumes of water.  For a fungicidal/yeasticidal activity: Add 2 volumes of bleach into 9 volumes of water.  For virucidal activity: Add 1 volume of bleach into 11 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per week |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | HDPE: 1L, 2L, 5L |

Table 19. Use # 2.22.2 – Disinfection of surfaces (other than floors) by wiping with cloth and bucket

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (other than floors) by wiping with cloth and bucket (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Wiping |
| Application rate(s) and frequency | For bactericidal activity: Add 2 volumes of bleach into 7 volumes of water.  For a fungicidal/yeasticidal activity: Add 2 volumes of bleach into 9 volumes of water.  For virucidal activity: Add 1 volume of bleach into 11 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per week |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | HDPE: 1L, 2L, 5L |

 Table 20. Use # 2.22.3 – Disinfection of toilet bowls

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of toilet bowls by wiping (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Wiping |
| Application rate(s) and frequency | For bactericidal activity: Add 2 volumes of bleach into 7 volumes of water.  For a fungicidal/yeasticidal activity: Add 2 volumes of bleach into 9 volumes of water.  For virucidal activity: Add 1 volume of bleach into 11 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : up to 2 times per week |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | HDPE 1L, 2L, 5L |

Table 21. Use # 2.22.4 – Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Wiping |
| Application rate(s) and frequency | For bactericidal activity: Add 2 volumes of bleach into 7 volumes of water.  For a fungicidal/yeasticidal activity: Add 2 volumes of bleach into 9 volumes of water.  For virucidal activity: Add 1 volume of bleach into 11 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per week |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | HDPE: 2L, 5L |

Table 22. Use # 2.22.5 – Disinfection of companion animal housing and associated equipment

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of companion animal housing (such as kennels, hutches, cages) and associated equipment (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Household, companion animals |
| Application method(s) | Wiping |
| Application rate(s) and frequency | For bactericidal activity: Add 2 volumes of bleach into 9 volumes of water.  For fungicidal activity: Add 1 volume of bleach into 3 volumes of water.  For yeasticidal activity: Add 2 volume of bleach into 11 volumes of water.  For virucidal activity: Add 2 volumes of bleach into 5 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : up to 2 times per year |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | HDPE: 2L, 5L |

Table 23. Use # 2.22.6 – Laundry disinfection with hand soaking

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Laundry disinfection with hand soaking (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Hand soaking |
| Application rate(s) and frequency | For bactericidal activity: Add 1 volume of bleach into 27 volumes of water.  For fungicidal/yeasticidal activity: Add 1 volume of bleach into 8 volumes of water.  For virucidal activity: Add 1 volume of bleach into 11 volumes of water.  Frequency : once per day |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | HDPE:1L, 12L, 5L |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Meta SPC | Product description | |  | RMM |
| meta SPC 2.22 | Javel MDD à 3,6%c.a. | Max (%) | 3,6 | Packaging : no direct contact with skin, or eyes before dilution. |
| Max (%) | 3,6 |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 2.22

Instructions for use

|  |
| --- |
| Cleaning before disinfection is preferred. Do not transfer product into any other packaging not destined to receive bleach water. |

Risk mitigation measures

|  |
| --- |
| Gel formulation and diameter reducer on caps to easily apply the product with accuracy  HDPE bottle with handle: remove the cap and pour slowly the product. |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic bottle with handle | 2L, 5L | PEHD | Caps | Non-professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 3

Use description

Table 24. Use # 3.1 – Disinfection of surfaces (other than floors) by wiping with cloth and bucket

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (other than floors) by wiping with cloth and bucket (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | wiping |
| Application rate(s) and frequency | RTU product. Pour the product on a sponge or directly on the surface to be disinfected. Leave on for 5 minutes then wipe and rinse. Repeat the operation 1 to 2 times a day.  Application rate : 100 mL of product per m², equal to a film thickness of 0,1mm.  Frequency : once per week |
| Category(ies) of user(s) | Non-professional |
| Pack sizes and packaging material | HDPE, 750ML |

Table 25. Use # 3.2 – Disinfection of toilet bowls

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of toilet bowls (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household  PRO only: institutions, industries (general case), healthcare |
| Application method(s) | Direct application of the product (by pressing on the packaging) and rinse with flush |
| Application rate(s) and frequency | RTU product  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : up to 2 times per week |
| Category(ies) of user(s) | Non-professional, professional |
| Pack sizes and packaging material | HDPE, 750ML |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Meta SPC | Product description | |  | RMM |
| meta SPC 3 | Produits Gel à 2,6%c.a. | Min (%) | 2.6 | Not required |
| Max (%) | 2.6 |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 3

Instructions for use

|  |
| --- |
| Cleaning before disinfection is preferred. Remove cap and press bottle to direct the product into the surface to be disinfected. |

Risk mitigation measures

|  |
| --- |
| No particular Risk mitigation measure  Gel formulation and diameter reducer on caps to easily apply the product with accuracy. |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle with gooseneck | 750ML | HDPE | Caps | Non-professional, professional | Yes |
| Plastic bottle (round) | 750ML | HDPE | Caps | Non-professional | Yes |

Documentation

Data submitted in relation to product application

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 4

Uses descriptions

Table 26. Use # 4.1 – Disinfection of surfaces (other than floors) by wiping with cloth and bucket

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (other than floors) by wiping with cloth and bucket (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household  Professionnal users only: institutions, healthcare, in-dustries (general case) |
| Application method(s) | wiping |
| Application rate(s) and frequency | RTU product  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day |
| Category(ies) of user(s) | Non-professional  Professional |
| Pack sizes and packaging material | HDPE, 1L |

Table 27. Use # 4.2 – Disinfection of toilet bowls

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of toilet bowls (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Direct application of the product (by pressing on the packaging) and rinse with flush  Application rate : 100 mL of product per m², equal to a film thickness of 0,1mm.  Frequency : 2 times per week |
| Application rate(s) and frequency | RTU product |
| Category(ies) of user(s) | Non-professional |
| Pack sizes and packaging material | HDPE, 750ML, 1L |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |
| --- |
| None |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 4

Instructions for use

|  |
| --- |
| Remove cap and press bottle to direct the product into the surface to be disinfected. |

Risk mitigation measures

|  |
| --- |
| Gel formulation and diameter reducer on caps to easily apply the product with accuracy. |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle with gooseneck | 750ML | HDPE | Caps | Non-professional | Yes |
| Plastic bottle | 1L | HDPE | Caps | Non-professional, professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 5

Uses descriptions

Table 28. Use # 5.1 – Disinfection of surfaces by spraying with trigger spray

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces by spraying with trigger spray. After spraying, rinsing is required. |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household  Professionnal users only: institutions, healthcare, industries (general case) |
| Application method(s) | For more efficient disinfection, clean the surfaces first. Before application, put the gun tip in the "ON" position. After use, return the gun tip to the "OFF" position.  For disinfection  of hard surfaces in a medical, community or industrial environment and surfaces in contact with food intended for human consumption (general case):  Spray the product evenly on the surface to be cleaned. Leave on for 5 minutes then rinse. Renew the operation 1 time per day maximum. Spray every 10 cm of surface to treat. |
| Application rate(s) and frequency | RTU product,  Application rate : 1 squeeze every 10 centimeters.  Frequency : up to 1 times per day. |
| Category(ies) of user(s) | Non-professional  Profesionnal |
| Pack sizes and packaging material | HDPE, 500ML, 750ML |

Use-specific instructions for use

|  |
| --- |
| Trigger the spray 30cm away from the surface to be treated. |

Use-specific risk mitigation measures

|  |
| --- |
| None |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 5

Instructions for use

|  |
| --- |
| Switch mobile cap to “ON” before using the product and switch back to “OFF” after use. Push the trigger when at 20 to 30 cm from the surface to be disinfected. |

Risk mitigation measures

|  |
| --- |
| Not required. |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic bottle | 750ML | HDPE | Cap with trigger and switch ON/OFF | Non-professional, professional | Yes |
| Plastic bottle | 500ML | HDPE | Cap with trigger and switch ON/OFF | Non-professional, professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 6.1

Uses descriptions

Table 29. Use #6.1.1 – Disinfection of surfaces (floors) by wiping with mop and bucket

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (floors) by wiping with mop and bucket (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Mopping |
| Application rate(s) and frequency | For bactericidal activity: Add 1 volume of bleach into 10 volumes of water.  For a fungicidal/yeasticidal activity: Add 1 volume of bleach into 13 volumes of water.  For virucidal activity: Add 1 volume of bleach into 27 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per week. |
| Category(ies) of user(s) | Non-professional |
| Pack sizes and packaging material | HDPE: 5L, 10L, 20L |

Table 30. Use #6.1.2 – Disinfection of surfaces (other than floors) by wiping with cloth and bucket

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (other than floors) by wiping with cloth and bucket |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Wiping |
| Application rate(s) and frequency | For bactericidal activity: Add 1 volume of bleach into 10 volumes of water.  For a fungicidal/yeasticidal activity: Add 1 volume of bleach into 13 volumes of water.  For virucidal activity: Add 1 volume of bleach into 27 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per week. |
| Category(ies) of user(s) | Non professional |
| Pack sizes and packaging material | HDPE: 5L, 10L, 20L |

 Table 31. Use # 6.1.3 – Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Wiping |
| Application rate(s) and frequency | For bactericidal activity: Add 1 volume of bleach into 10 volumes of water.  For a fungicidal/yeasticidal activity: Add 1 volume of bleach into 13 volumes of water.  For virucidal activity: Add 1 volume of bleach into 27 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per week. |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | HDPE: 5L, 10L, 20L |

 Table 32. Use # 6.1.4 – Disinfection of companion animal housing and associated equipment

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of companion animal housing (such as kennels, hutches, cages) and associated equipment (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Household, companion animals |
| Application method(s) | Wiping |
| Application rate(s) and frequency | For bactericidal activity: Add 1 volume of bleach into 13 volumes of water.  For a fungicidal activity: Add 2 volumes of bleach into 19 volumes of water.  For a yeast activity: Add 1 volume of bleach into 11 volumes of water.  For virucidal activity: Add 1 volume of bleach into 8 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : up to 2 times per year. |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | HDPE: 5L, 10L, 20L |

 Table 33. Use # 6.1.5 – Laundry disinfection with hand soaking

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Laundry disinfection with hand soaking |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on Norovirus murin, Poliovirus, Adénovirus) |
| Field of use | Household |
| Application method(s) | Hand soaking |
| Application rate(s) and frequency | For bactericidal activity: Add 1 volume of bleach into 71 volumes of water.  For a fungicidal/yeasticidal activity: Add 1 volume of bleach into 23 volumes of water.  For virucidal activity: Add 1 volume of bleach into 27 volumes of water.  Frequency: up to 1 time per day. |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | HDPE: 5L, 10L, 20L |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |
| --- |
| Packaging: no direct contact with skin, or eyes before dilution with packaging with handle and small bottle neck diameter to avoid splashes. |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 6.1

Instructions for use

|  |
| --- |
| Packaging : pour the product with one hand on the handle and the other on back of the bottle. Close the bottle right after use. |

Risk mitigation measures

|  |
| --- |
| Packaging : no direct contact with skin, or eyes before dilution with packaging with handle and small bottle neck diameter to avoid splashes |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic bottle | 5L, 10L, 20L | HDPE | Caps with childproof | Non-professional | Yes |
| Flexible PVC | 250ML | PVC | Caps with childproof | Non-professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 6.21

Uses descriptions

Table 34. Use # 6.21.1 – Disinfection of surfaces in medical area

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces in medical area (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | healthcare |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Disinfection of surfaces in medical area:  Bactericidal : Add 890mL of product for 10L of diluted solution.  Fongicidal/Yeasticidal : Add 810mL of product for 10L of diluted solution.  Virucidal : Add 340mL of product for 10L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 250mL, 5L, 10L, 20L, 200L, 1000L  PVC : 250ML (sachet), 3x250ML (3x sachets) |

Table 35. Use # 6.21.2 – Disinfection of surfaces in contact with food

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces in contact with food in institutions/industry (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural), institutions |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries and alcoholic beverages industries) by wiping, mopping:  Bactericidal : Add 890mL of product for 10L of diluted solution.  Fongicidal/Yeasticidal : Add 810mL of product for 10L of diluted solution.  Virucidal : Add 340mL of product for 10L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries by wiping, mopping:  Bactericidal : Add 1350mL of product for 10L of diluted solution.  Fongicidal/Yeasticidal : Add 1080mL of product for 10L of diluted solution.  Virucidal : Add 1050mL of product for 10L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 250mL, 5L, 10L, 20L, 200L, 1000L, 250ML  PVC : 250ML (sachet), 3x250ML (3x sachets) |

Table 36. Use # 6.21.3 – Disinfection of surfaces in institutions/industry

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces in institutions/industry (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (cosmetics, agricultural, general case, meat, milk, non-alcoholic, alcoholic beverages), institutions |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by wiping, mopping:  Bactericidal : Add 890mL of product for 10L of diluted solution.  Fongicidal/Yeasticidal : Add 810mL of product for 10L of diluted solution.  Virucidal : Add 340mL of product for 10L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries by wiping, mopping:  Bactericidal : Add 1350mL of product for 10L of diluted solution.  Fongicidal/Yeasticidal : Add 1080mL of product for 10L of diluted solution.  Virucidal : Add 1050mL of product for 10L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L, 10L, 20L, 200L, 1000L, 250ML  PVC : 250ML (sachet), 3x250ML (3x sachets) |

Table 37. Use # 6.21.4 – Disinfection of surfaces by CIP

|  |  |
| --- | --- |
| Product Type(s) | 2, 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces by CIP |
| Target organism (including development stage) | Bactericidal (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (cosmetics, agricultural, general case, meat, milk, non-alcoholic, alcoholic beverages), institutions, |
| Application method(s) | CIP |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by CIP:  Bactericidal : Add 890mL of product for 10L of diluted solution.  Fongicidal/Yeasticidal : Add 810mL of product for 10L of diluted solution.  Virucidal : Add 340mL of product for 10L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries by CIP:  Bactericidal : Add 1350mL of product for 10L of diluted solution.  Fongicidal/Yeasticidal : Add 1080mL of product for 10L of diluted solution.  Virucidal : Add 1050mL of product for 10L of diluted solution.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L, 10L, 20L, 200L, 1000L, 250ML  PVC : 250ML (sachet), 3x250ML (3x sachets) |

 Table 38. Use # 6.21.5 – Laundry disinfection with hand soaking

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Laundry disinfection with hand soaking |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Healthcare, industry |
| Application method(s) | Hand soaking |
| Application rate(s) and frequency | Bactericidal : Add 140mL of product for 10L of diluted solution.  Fongicidal/Yeasticidal : Add 400mL of product for 10L of diluted solution.  Virucidal : Add 340mL of product for 10L of diluted solution.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L, 10L, 20L, 200L, 1000L, 250ML  PVC : 250ML (sachet), 3x250ML (3x sachets) |

 Table 39. Use # 6.21.6 – Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings disinfection (non porous surfaces and in transportation vehicles) by wiping, mopping:  Bactericidal : Add 700mL of product for 10L of diluted solution.  Fongicidal : Add 920mL of product for 10L of diluted solution.  Yeasticidal : Add 810mL of product for 10L of diluted solution.  Virucidal : Add 1050mL of product for 10L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L, 10L, 20L, 200L, 1000L, 250ML  PVC : 250ML (sachet), 3x250ML (3x sachets) |

 Table 40. Use # 6.21.7 – Disinfection of non-porous hard surfaces in livestock transportation vehicles

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings disinfection (non porous surfaces and in transportation vehicles) by wiping, mopping:  Bactericidal : Add 700mL of product for 10L of diluted solution.  Fongicidal : Add 920mL of product for 10L of diluted solution.  Yeasticidal : Add 810mL of product for 10L of diluted solution.  Virucidal : Add 1050mL of product for 10L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L, 10L, 20L, 200L, 1000L, 250ML  PVC : 250ML (sachet), 3x250ML (3x sachets) |

 Table 41. Use # 6.21.8 – Disinfection of inner surfaces in human drinking water systems

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of inner surfaces in human drinking water systems |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Also : Legionella Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (meat, non alcoholic beverages, alcoholic beverages, dairy, agricultural), institutional area (homes, hotels, etc.) and medical area |
| Application method(s) | CIP, stand disinfection |
| Application rate(s) and frequency | Human drinking water systems in medical area, industries (general case), institutions:  Legionella : 0,05%a.c. (add 70mL of product for 10L of diluted solution)  Bactericidal : 0,1%a.c. (add 140mL of product for 10L of diluted solution)  Fongicidal : 0,3%a.c. (add 410mL of product for 10L of diluted solution)  Virucidal : 0,25%a.c. (add 340mL of product for 10L of diluted solution)  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L, 10L, 20L, 200L, 1000L, 250ML  PVC : 250ML (sachet), 3x250ML (3x sachets) |

Table 42. Use # 6.21.9 – Disinfection of inner surfaces in veterinary water systems

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of inner surfaces in veterinary water systems |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus) Also : Legionella  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary industry, animal farms, dairy farms, animal houses |
| Application method(s) | CIP, stand disinfection |
| Application rate(s) and frequency | Water systems in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings :  Legionella : 0,15%a.c. (add 200mL of product for 10L of diluted solution)  Bactericidal : 0,50%a.c. (add 670mL of product for 10L of diluted solution)  Fongicidal : 0,66%a.c. (add 890mL of product for 10L of diluted solution)  Virucidal : 0,78%a.c. (add 1050mL of product for 10L of diluted solution)  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L, 10L, 20L, 200L, 1000L, 250ML  PVC : 250ML (sachet), 3x250ML (3x sachets) |

Table 43. Use # 6.21.10 – Disinfection of water intended for human consumption

|  |  |
| --- | --- |
| Product Type(s) | 5 |
| Where relevant, an exact description of the authorised use | Disinfection of water intended for human consumption |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Also : Legionnella Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry, institutional area |
| Application method(s) | Transfer |
| Application rate(s) and frequency |  |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L, 10L, 20L, 200L, 1000L, 250ML  PVC : 250ML (sachet), 3x250ML (3x sachets) |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| meta SPC 6.21 | Produits à 9,6%c.a. | Min (%) | 9.6 | PPE (gloves - clothes - glasses - mask) - rinsing for PT3, and PT4 for professional users |
| Max (%) | 9.6 |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 6.21

Instructions for use

|  |
| --- |
| None |

Risk mitigation measures

|  |
| --- |
| Wear PPE. |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic bottle | 5L, 10L, 20L, 1000L, 250ML | HDPE | Cap | Professional | Yes |
| Flexible PVC | 250ML | PVC | Cap | Professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 6.22

Uses descriptions

Table 44. Use # 6.22.1 – Disinfection of surfaces in medical area

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces in medical area (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | healthcare |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | *Respective dilutions for products at 12,5%/13,5%a.c. :*  Disinfection of surfaces in medical area:  Bactericidal : Add 790/620mL of product for 10L of diluted solution.  Fongicidal/Yeasticidal : Add 720/560mL of product for 10L of diluted solution.  Virucidal : Add 300/240mL of product for 10L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 10L, 20L, 1000L |

Table 45. Use # 6.22.2 – Disinfection of surfaces in contact with food

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces in contact with food in institutions/industry (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural), institutions |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | *Respective dilutions for products at 12,5%/13,5%a.c. :*  Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries and alcoholic beverages industries) by wiping, mopping:  Bactericidal : Add 790/620mL of product for 10L of diluted solution.  Fongicidal/Yeasticidal : Add 720/560mL of product for 10L of diluted solution.  Virucidal : Add 300/240mL of product for 10L of diluted solution.  Disinfection of hard surfaces in agricultural and non-alcoholic beverages industries by wiping, mopping:  Bactericidal : Add 1120/940mL of product for 10L of diluted solution.  Fongicidal/Yeasticidal : Add 950/750mL of product for 10L of diluted solution.  Virucidal : Add 930/730mL of product for 10L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 10L, 20L, 1000L |

Table 46. Use # 6.22.3 – Disinfection of surfaces in institutions/industry

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces in institutions/industry (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (cosmetics, agricultural, general case, meat, milk, non-alcoholic, alcoholic beverages), institutions |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | *Respective dilutions for products at 12,5%/13,5%a.c. :*  Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by wiping, mopping:  Bactericidal : Add 790/620mL of product for 10L of diluted solution.  Fongicidal/Yeasticidal : Add 720/560mL of product for 10L of diluted solution.  Virucidal : Add 300/240mL of product for 10L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries by wiping, mopping:  Bactericidal : Add 1120/940mL of product for 10L of diluted solution.  Fongicidal/Yeasticidal : Add 950/750mL of product for 10L of diluted solution.  Virucidal : Add 930/730mL of product for 10L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 10L, 20L, 1000L |

Table 47. Use # 6.22.4 – Disinfection of surfaces by CIP

|  |  |
| --- | --- |
| Product Type(s) | 2, 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces by CIP |
| Target organism (including development stage) | Bactericidal (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (cosmetics, agricultural, general case, meat, milk, non-alcoholic, alcoholic beverages), institutions |
| Application method(s) | CIP |
| Application rate(s) and frequency | *Respective dilutions for products at 12,5%/13,5%a.c. :*  Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by CIP:  Bactericidal : Add 790/620mL of product for 10L of diluted solution.  Fongicidal/Yeasticidal : Add 720/560mL of product for 10L of diluted solution.  Virucidal : Add 300/240mL of product for 10L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries by CIP:  Bactericidal : Add 1120/940mL of product for 10L of diluted solution.  Fongicidal/Yeasticidal : Add 950/750mL of product for 10L of diluted solution.  Virucidal : Add 930/730mL of product for 10L of diluted solution.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 10L, 20L, 1000L |

 Table 48. Use # 6.22.5 – Laundry disinfection with hand soaking

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Laundry disinfection with hand soaking |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Healthcare, industry |
| Application method(s) | Hand soaking |
| Application rate(s) and frequency | *Respective dilutions for products at 12,5%/13,5%a.c. :*  Bactericidal : Add 120/100mL of product for 10L of diluted solution.  Fongicidal/Yeasticidal : Add 360/280mL of product for 10L of diluted solution.  Virucidal : Add 300/240mL of product for 10L of diluted solution.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 10L, 20L, 1000L |

 Table 49. Use # 6.22.6 – Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | *Respective dilutions for products at 12,5%/13,5%a.c. :*  Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings disinfection (non porous surfaces and in transportation vehicles) by wiping, mopping:  Bactericidal : Add 530/480mL of product for 10L of diluted solution.  Fongicidal : Add 810/640mL of product for 10L of diluted solution.  Yeasticidal : Add 710/560mL of product for 10L of diluted solution.  Virucidal : Add 930/730mL of product for 10L of diluted solution  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 10L, 20L, 1000L |

 Table 50. Use # 6.22.7 – Disinfection of non-porous hard surfaces in livestock transportation vehicles

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | *Respective dilutions for products at 12,5%/13,5%a.c. :*  Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings disinfection (non porous surfaces and in transportation vehicles) by wiping, mopping:  Bactericidal : Add 530/480mL of product for 10L of diluted solution.  Fongicidal : Add 810/640mL of product for 10L of diluted solution.  Yeasticidal : Add 710/560mL of product for 10L of diluted solution.  Virucidal : Add 930/730mL of product for 10L of diluted solution  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 10L, 20L, 1000L |

 Table 51. Use # 6.22.8 – Disinfection of inner surfaces in human drinking water systems

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of inner surfaces in human drinking water systems |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Also : Legionella Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (meat, non alcoholic beverages, alcoholic beverages, dairy, agricultural), institutional area (homes, hotels, etc.) and medical area |
| Application method(s) | CIP, stand disinfection |
| Application rate(s) and frequency | *Respective dilutions for products at 12,5%/13,5%a.c. :*  Human drinking water systems in medical area, industries (general case), institutions:  Legionella : 0,05%a.c. (add 60/50mL of product for 10L of diluted solution)  Bactericidal : 0,1%a.c. (add 120/100mL of product for 10L of diluted solution)  Fongicidal : 0,3%a.c. (add 360/280mL of product for 10L of diluted solution)  Virucidal : 0,25%a.c. (add 300/240mL of product for 10L of diluted solution)  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 10L, 20L, 1000L |

Table 52. Use # 6.22.9 – Disinfection of inner surfaces in veterinary water systems

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of inner surfaces in veterinary water systems |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Also : Legionella Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary industry, animal farms, dairy farms, animal houses |
| Application method(s) | CIP, stand disinfection |
| Application rate(s) and frequency | *Respective dilutions for products at 12,5%/13,5%a.c. :*  Water systems in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings :  Legionella : 0,15%a.c. (add 180/140mL of product for 10L of diluted solution)  Bactericidal : 0,50%a.c. (add 600/470mL of product for 10L of diluted solution)  Fongicidal : 0,66%a.c. (add 790/620mL of product for 10L of diluted solution)  Virucidal : 0,78%a.c. (add 930/730mL of product for 10L of diluted solution)  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 10L, 20L, 1000L |

Table 53. Use # 6.22.10 – Disinfection of water intended for human consumption

|  |  |
| --- | --- |
| Product Type(s) | 5 |
| Where relevant, an exact description of the authorised use | Disinfection of water intended for human consumption |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Also : Legionnella Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry, institutional area |
| Application method(s) | Transfer |
| Application rate(s) and frequency |  |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 10L, 20L, 1000L |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| meta SPC 6.22 | Produits à 12,5-13,5%c.a. | Min (%) | 12,5 | PPE (gloves - clothes - glasses - mask) - rinsing for PT3, and PT4 for professional users |
| Max (%) | 13,5 |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 6.22

Instructions for use

|  |
| --- |
| None |

Risk mitigation measures

|  |
| --- |
| Wear PPE. |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic bottle | 10L, 20L, 1000L | HDPE | Cap | Professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 7.11

Uses descriptions

Table 54. Use # 7.11.1 – Disinfection of surfaces in medical area

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces in medical area (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | healthcare |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Disinfection of surfaces in medical area:  Bactericidal : Add 230mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 210mL of product for 1L of diluted solution.  Virucidal : Add 90mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 120mL, 250mL, 5L |

Table 55. Use # 7.11.2 – Disinfection of surfaces in contact with food

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces in contact with food in institutions/industry (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural), institutions |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries and alcoholic beverages industries) by wiping, mopping:  Bactericidal : Add 230mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 210mL of product for 1L of diluted solution.  Virucidal : Add 90mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural, non-alcoholic beverages industries by wiping, mopping:  Bactericidal : Add 340mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 270mL of product for 1L of diluted solution.  Virucidal : Add 270mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 120mL, 250mL, 5L |

Table 56. Use # 7.11.3 – Disinfection of surfaces in institutions/industry

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces in institutions/industry (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (cosmetics, agricultural, general case, meat, milk, non-alcoholic, alcoholic beverages), institutions |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by wiping, mopping:  Bactericidal : Add 230mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 210mL of product for 1L of diluted solution.  Virucidal : Add 90mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries by wiping, mopping:  Bactericidal : Add 340mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 270mL of product for 1L of diluted solution.  Virucidal : Add 270mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 120mL, 250mL, 5L |

Table 57. Use # 7.11.4 – Disinfection of surfaces by CIP

|  |  |
| --- | --- |
| Product Type(s) | 2, 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces by CIP |
| Target organism (including development stage) | Bactericidal (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (cosmetics, agricultural, general case, meat, milk, non-alcoholic, alcoholic beverages), institutions, veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | CIP |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by CIP:  Bactericidal : Add 230mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 210mL of product for 1L of diluted solution.  Virucidal : Add 90mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries by CIP:  Bactericidal : Add 340mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 270mL of product for 1L of diluted solution.  Virucidal : Add 270mL of product for 1L of diluted solution.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 120mL, 250mL, 5L |

 Table 58. Use # 7.11.5 – Laundry disinfection with hand soaking

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Laundry disinfection with hand soaking |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Healthcare, industry |
| Application method(s) | Hand soaking |
| Application rate(s) and frequency | Bactericidal: Add 40mL of product for 1L of diluted solution.  Fongicidal: Add 110mL of product for 1L of diluted solution.  Virucidal: Add 90mL of product for 1L of diluted solution.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 120mL, 250mL, 5L |

 Table 59. Use # 7.11.6 – Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings disinfection (non porous surfaces and in transportation vehicles) by wiping, mopping:  Bactericidal: Add 170mL of product for 1L of diluted solution.  Fongicidal: Add 230mL of product for 1L of diluted solution.  Yeasticidal: Add 210mL of product for 1L of diluted solution.  Virucidal: Add 270mL of product for 1L of diluted solution.  Application rate: 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 120mL, 250mL, 5L |

 Table 60. Use # 7.11.7 – Disinfection of non-porous hard surfaces in livestock transportation vehicles

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings disinfection (non porous surfaces and in transportation vehicles) by wiping, mopping:  Bactericidal : Add 170mL of product for 1L of diluted solution.  Fongicidal : Add 230mL of product for 1L of diluted solution.  Yeasticidal : Add 210mL of product for 1L of diluted solution.  Virucidal : Add 270mL of product for 1L of diluted solution.  Application rate: 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 120mL, 250mL, 5L |

 Table 61. Use # 7.11.8 – Disinfection of inner surfaces in human drinking water systems

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of inner surfaces in human drinking water systems |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Also : Legionella Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (meat, non alcoholic beverages, alcoholic beverages, dairy, agricultural), institutional area (homes, hotels, etc.) and medical area |
| Application method(s) | CIP, stand disinfection |
| Application rate(s) and frequency | Human drinking water systems in medical area, industries (general case), institutions:  Legionella : 0,05%a.c. (add 170mL of product for 10L of diluted solution)  Bactericidal : 0,1%a.c. (add 340mL of product for 10L of diluted solution)  Fongicidal : 0,3%a.c. (add 1010mL of product for 10L of diluted solution)  Virucidal : 0,25%a.c. (add 840mL of product for 10L of diluted solution)  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 120mL, 250mL, 5L |

Table 62. Use # 7.11.9 – Disinfection of inner surfaces in veterinary water systems

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of inner surfaces in veterinary water systems |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus) Also : Legionella  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary industry, animal farms, dairy farms, animal houses |
| Application method(s) | CIP, stand disinfection |
| Application rate(s) and frequency | Water systems in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings :  Legionella : 0,15%a.c. (add 510mL of product for 10L of diluted solution)  Bactericidal : 0,50%a.c. (add 1680mL of product for 10L of diluted solution)  Fongicidal : 0,66%a.c. (add 2230mL of product for 10L of diluted solution)  Virucidal : 0,78%a.c. (add 2630mL of product for 10L of diluted solution)  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 120mL, 250mL, 5L |

Table 63. Use # 7.11.10 – Disinfection of water intended for human consumption

|  |  |
| --- | --- |
| Product Type(s) | 5 |
| Where relevant, an exact description of the authorised use | Disinfection of water intended for human consumption |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Also : Legionnella Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry, institutional area |
| Application method(s) | Transfer |
| Application rate(s) and frequency |  |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 120mL, 250mL, 5L |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Meta SPC | Product description | |  | RMM | | meta SPC 7.11 | Javel à 3,6%c.a. PRO | Min (%) | 3.6 | PPE (gloves - clothes - glasses - mask) | | Max (%) | 3.6 |   Always rinse after disinfection on hard surfaces in contact with food. |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 7.11

Instructions for use

|  |
| --- |
| Cleaning before disinfection is preferred. |

Risk mitigation measures

|  |
| --- |
| PPE (gloves - clothes - glasses - mask)  TP4 : rinse after disinfection |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic bottle | 120mL, 250mL, 5L | HDPE | Cap | Professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 7.12

Uses descriptions

Table 64. Use # 7.12.1 – Disinfection of surfaces in medical area

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces in medical area (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | healthcare |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Disinfection of surfaces in medical area:  Bactericidal: Add 150mL of product for 1L of diluted solution.  Fongicidal: Add 140mL of product for 1L of diluted solution.  Virucidal: Add 60mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 2L |

Table 65. Use # 7.12.2 – Disinfection of surfaces in contact with food

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces in contact with food in institutions/industry (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural), institutions |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries and alcoholic beverages industries) by wiping, mopping:  Bactericidal : Add 150mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 140mL of product for 1L of diluted solution.  Virucidal : Add 60mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural and non-alcoholic beverages industries by wiping, mopping:  Bactericidal : Add 230mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 180mL of product for 1L of diluted solution.  Virucidal : Add 180mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 2L |

Table 66. Use # 7.12.3 – Disinfection of surfaces in institutions/industry

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces in institutions/industry (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (cosmetics, agricultural, general case, meat, milk, non-alcoholic, alcoholic beverages), institutions |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by wiping, mopping:  Bactericidal : Add 150mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 140mL of product for 1L of diluted solution.  Virucidal : Add 60mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries by wiping, mopping:  Bactericidal : Add 230mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 180mL of product for 1L of diluted solution.  Virucidal : Add 180mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 2L |

Table 67. Use # 7.12.4 – Disinfection of surfaces by CIP

|  |  |
| --- | --- |
| Product Type(s) | 2, 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces by CIP |
| Target organism (including development stage) | Bactericidal (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (cosmetics, agricultural, general case, meat, milk, non-alcoholic, alcoholic beverages), institutions |
| Application method(s) | CIP |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by CIP:  Bactericidal : Add 150mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 140mL of product for 1L of diluted solution.  Virucidal : Add 60mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries by CIP:  Bactericidal : Add 230mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 180mL of product for 1L of diluted solution.  Virucidal : Add 180mL of product for 1L of diluted solution.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 2L |

 Table 68. Use # 7.12.5 – Laundry disinfection with hand soaking

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Laundry disinfection with hand soaking |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Healthcare, industry |
| Application method(s) | Hand soaking |
| Application rate(s) and frequency | Bactericidal: Add 30mL of product for 1L of diluted solution.  Fongicidal: Add 70mL of product for 1L of diluted solution.  Virucidal: Add 60mL of product for 1L of diluted solution.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 2L |

 Table 69. Use # 7.12.6 – Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings disinfection (non porous surfaces and in transportation vehicles) by wiping, mopping:  Bactericidal: Add 120mL of product for 1L of diluted solution.  Fongicidal: Add 160mL of product for 1L of diluted solution.  Yeasticidal: Add 140mL of product for 1L of diluted solution.  Virucidal: Add 180mL of product for 1L of diluted solution.  Application rate: 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 2L |

 Table 70. Use # 7.12.7 – Disinfection of non-porous hard surfaces in livestock transportation vehicles

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings disinfection (non porous surfaces and in transportation vehicles) by wiping, mopping:  Bactericidal: Add 120mL of product for 1L of diluted solution.  Fongicidal: Add 160mL of product for 1L of diluted solution.  Yeasticidal: Add 140mL of product for 1L of diluted solution.  Virucidal: Add 180mL of product for 1L of diluted solution.  Application rate: 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 2L |

 Table 71. Use # 7.12.8 – Disinfection of inner surfaces in human drinking water systems

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of inner surfaces in human drinking water systems |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Also : Legionella Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (meat, non alcoholic beverages, alcoholic beverages, dairy, agricultural), institutional area (homes, hotels, etc.) and medical area |
| Application method(s) | CIP, stand disinfection |
| Application rate(s) and frequency | Human drinking water systems in medical area, industries (general case), institutions:  Legionella: 0,05%a.c. (add 110mL of product for 10L of diluted solution)  Bactericidal: 0,1%a.c. (add 220mL of product for 10L of diluted solution)  Fongicidal: 0,3%a.c. (add 670mL of product for 10L of diluted solution)  Virucidal: 0,25%a.c. (add 560mL of product for 10L of diluted solution)  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 2L |

Table 72. Use # 7.12.9 – Disinfection of inner surfaces in veterinary water systems

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of inner surfaces in veterinary water systems |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Also : Legionella  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary industry, animal farms, dairy farms, animal houses |
| Application method(s) | CIP, stand disinfection |
| Application rate(s) and frequency | Water systems in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings:  Legionella: 0,15%a.c. (add 340mL of product for 10L of diluted solution)  Bactericidal: 0,50%a.c. (add 1110mL of product for 10L of diluted solution)  Fongicidal: 0,66%a.c. (add 1470mL of product for 10L of diluted solution)  Virucidal: 0,78%a.c. (add 1740mL of product for 10L of diluted solution)  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 2L |

Table 72.1. Use # 7.12.10 – Disinfection of water intended for human consumption

|  |  |
| --- | --- |
| Product Type(s) | 5 |
| Where relevant, an exact description of the authorised use | Disinfection of water intended for human consumption |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Also : Legionnella Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry, institutions |
| Application method(s) | Transfer |
| Application rate(s) and frequency |  |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 2L |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |
| --- |
| None |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 7.12

Instructions for use

|  |
| --- |
| Cleaning before disinfection is preferred. |

Risk mitigation measures

|  |
| --- |
| PPE (gloves - clothes - glasses - mask)  TP4 : rinse after disinfection |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic bottle | 2L | HDPE | Cap | Professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 7.2

Uses descriptions

Table 73. Use # 7.2.1 – Disinfection of surfaces in medical area

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces in medical area (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | healthcare |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Disinfection of surfaces in medical area:  Bactericidal : Add 300mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 270mL of product for 1L of diluted solution.  Virucidal : Add 120mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 250mL, 1L, 2L, 5L, 10L, 20L |

Table 74. Use # 7.2.2 – Disinfection of surfaces in contact with food

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces in contact with food in institutions/industry (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural), institutions |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries and alcoholic beverages industries) by wiping, mopping:  Bactericidal : Add 300mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 270mL of product for 1L of diluted solution.  Virucidal : Add 120mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural, non-alcoholic beverages industries by wiping, mopping:  Bactericidal : Add 450mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 360mL of product for 1L of diluted solution.  Virucidal : Add 350mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 250mL, 1L, 2L, 5L, 10L, 20L |

Table 75. Use # 7.2.3 – Disinfection of surfaces in institutions/industry

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces in institutions/industry (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (cosmetics, agricultural, general case, meat, milk, non-alcoholic, alcoholic beverages), institutions |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by wiping, mopping:  Bactericidal : Add 300mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 270mL of product for 1L of diluted solution.  Virucidal : Add 120mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries by wiping, mopping:  Bactericidal : Add 450mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 360mL of product for 1L of diluted solution.  Virucidal : Add 350mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 250mL, 1L, 2L, 5L, 10L, 20L |

Table 76. Use # 7.2.4 – Disinfection of surfaces by CIP

|  |  |
| --- | --- |
| Product Type(s) | 2, 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces by CIP |
| Target organism (including development stage) | Bactericidal (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (cosmetics, agricultural, general case, meat, milk, non-alcoholic, alcoholic beverages), institutions |
| Application method(s) | CIP |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by CIP:  Bactericidal : Add 300mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 270mL of product for 1L of diluted solution.  Virucidal : Add 120mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries by CIP:  Bactericidal : Add 450mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 360mL of product for 1L of diluted solution.  Virucidal : Add 350mL of product for 1L of diluted solution.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 250mL, 1L, 2L, 5L, 10L, 20L |

 Table 77. Use # 7.2.5 – Laundry disinfection with hand soaking

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Laundry disinfection with hand soaking |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Healthcare, industry |
| Application method(s) | Hand soaking |
| Application rate(s) and frequency | Bactericidal : Add 50mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 140mL of product for 1L of diluted solution.  Virucidal : Add 120mL of product for 1L of diluted solution.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 250mL, 1L, 2L, 5L, 10L, 20L |

 Table 78. Use # 7.2.6 – Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings disinfection (non porous surfaces and in transportation vehicles) by wiping, mopping:  Bactericidal : Add 230mL of product for 1L of diluted solution.  Fongicidal : Add 310mL of product for 1L of diluted solution.  Yeasticidal : Add 270mL of product for 1L of diluted solution.  Virucidal : Add 350mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 250mL, 1L, 2L, 5L, 10L, 20L |

 Table 79. Use # 7.2.7 – Disinfection of non-porous hard surfaces in livestock transportation vehicles

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus) Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | Wiping, mopping |
| Application rate(s) and frequency | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings disinfection (non porous surfaces and in transportation vehicles) by wiping, mopping:  Bactericidal: Add 230mL of product for 1L of diluted solution.  Fongicidal: Add 310mL of product for 1L of diluted solution.  Yeasticidal: Add 270mL of product for 1L of diluted solution.  Virucidal: Add 350mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 250mL, 1L, 2L, 5L, 10L, 20L |

 Table 80. Use # 7.2.8 – Disinfection of inner surfaces in human drinking water systems

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of inner surfaces in human drinking water systems |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Also : Legionella Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (meat, non alcoholic beverages, alcoholic beverages, dairy, agricultural), institutional area (homes, hotels, etc.) and medical area |
| Application method(s) | CIP, stand disinfection |
| Application rate(s) and frequency | Human drinking water systems in medical area, industries (general case), institutions:  Legionella: 0,05%a.c. (add 220mL of product for 10L of diluted solution)  Bactericidal: 0,1%a.c. (add 440mL of product for 10L of diluted solution)  Fongicidal: 0,3%a.c. (add 1330mL of product for 10L of diluted solution)  Virucidal: 0,25%a.c. (add 1110mL of product for 10L of diluted solution)  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 250mL, 1L, 2L, 5L, 10L, 20L |

Table 81. Use # 7.2.9 – Disinfection of inner surfaces in veterinary water systems

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of inner surfaces in veterinary water systems |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Also : Legionella Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary industry, animal farms, dairy farms, animal houses |
| Application method(s) | CIP, stand disinfection |
| Application rate(s) and frequency | Water systems in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings :  Legionella: 0,15%a.c. (add 660mL of product for 10L of diluted solution)  Bactericidal: 0,50%a.c. (add 2210mL of product for 10L of diluted solution)  Fongicidal: 0,66%a.c. (add 2930mL of product for 10L of diluted solution)  Virucidal: 0,78%a.c. (add 3460mL of product for 10L of diluted solution)  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 250mL, 1L, 2L, 5L, 10L, 20L |

Table 81.1. Use # 7.2.10 – Disinfection of water intended for human consumption

|  |  |
| --- | --- |
| Product Type(s) | 5 |
| Where relevant, an exact description of the authorised use | Disinfection of water intended for human consumption |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Also : Legionnella Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry, institutions |
| Application method(s) | Transfer |
| Application rate(s) and frequency |  |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 250mL, 1L, 2L, 5L, 10L, 20L |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |
| --- |
| None |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 7.2

Instructions for use

|  |
| --- |
| Cleaning before disinfection is preferred. |

Risk mitigation measures

|  |
| --- |
| TP4 : rinse after disinfection |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic bottle | 2L | HDPE | Cap | Professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 8

Uses descriptions

Table 82. Use #8.1 – Disinfection of surfaces (floors) by wiping with mop and bucket

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (floors) by wiping with mop and bucket (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Household |
| Application method(s) | mopping |
| Application rate(s) and frequency | For bactericidal activity: Add 1 volumes of bleach into 1 volume of water.  For fungicidal/yeasticidal activity: Add 1 volumes of bleach into 2 volumes of water.  For virucidal activity: Add 1 volumes of bleach into 4 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | 2L, 5L |

Table 83. Use #8.2 – Disinfection of surfaces (other than floors) by wiping with cloth and bucket

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (other than floors) by wiping with cloth and bucket (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Household |
| Application method(s) | Wiping |
| Application rate(s) and frequency | For bactericidal activity: Add 1 volumes of bleach into 1 volume of water.  For fungicidal/yeasticidal activity: Add 1 volumes of bleach into 2 volumes of water.  For virucidal activity: Add 1 volumes of bleach into 4 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | PEHD : 2L, 5L |

Table 84. Use #8.3 – Disinfection of toilet bowls

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of toilet bowls by wiping (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Household |
| Application method(s) | Wiping |
| Application rate(s) and frequency | For bactericidal activity: Add 1 volumes of bleach into 1 volume of water.  For fungicidal/yeasticidal activity: Add 1 volumes of bleach into 2 volumes of water.  For virucidal activity: Add 1 volumes of bleach into 4 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : up to 2 times per week. |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | PEHD : 2L, 5L |

Table 85. Use #8.4 – Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Household |
| Application method(s) | Wiping |
| Application rate(s) and frequency | For bactericidal activity: Add 1 volumes of bleach into 1 volume of water.  For fungicidal/yeasticidal activity: Add 1 volumes of bleach into 2 volumes of water.  For virucidal activity: Add 1 volumes of bleach into 4 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | PEHD : 2L, 5L |

 Table 86. Use #8.5 – Disinfection of companion animal housing and associated equipment

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of companion animal housing (such as kennels, hutches, cages) and associated equipment (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Household, companion animals |
| Application method(s) | Wiping |
| Application rate(s) and frequency | For bactericidal activity: Add 3 volumes of bleach into 5 volumes of water.  For a fungicidal activity: Add 1 volume of bleach into 1 volume of water.  For yeast activity: Add 4 volumes of bleach into 5 volumes of water.  For virucidal activity: Add 4 volumes of bleach into 3 volumes of water.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency: twice per year. |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | PEHD : 2L, 5L |

Table 87. Use #8.6 – Laundry disinfection with hand soaking

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Laundry disinfection with hand soaking |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Household |
| Application method(s) | Hand soaking |
| Application rate(s) and frequency | For bactericidal activity: Add 1 volume of bleach into 11 volumes of water.  For a fungicidal/yeasticidal activity: Add 2 volumes of bleach into 7 volumes of water.  For yeast activity: Add 1 volume of bleach into 9 volume of water.  For virucidal activity: Add 1 volume of bleach into 4 volume of water.  Frequency: once per day. |
| Category(ies) of user(s) | Non profesionnal |
| Pack sizes and packaging material | PEHD : 2L, 5L |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |
| --- |
| None |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 8

Instructions for use

|  |
| --- |
| Cleaning before disinfection is preferred. Always rinse after disinfection on hard surfaces in contact with food. |

Risk mitigation measures

|  |
| --- |
| Not required. |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic bottle | 2L, 5L | HDPE | Cap | Non-professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 9

Uses descriptions

Table 88. Use #9.1 – Algaecide and fungicide for outdoor surfaces

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Algaecide and fungicide for outdoor surfaces by spraying (without mechanical action) |
| Target organism (including development stage) | Algaecidal Fungicidal |
| Field of use | Household |
| Application method(s) | Spraying then rinsing |
| Application rate(s) and frequency | Dilution 25% Application rate: 5L of diluted solution per 100m²  Frequency: max. once every 3 months. |
| Category(ies) of user(s) | Non-professional |
| Pack sizes and packaging material | HDPE: 5L, 10L, 20L |

Use-specific instructions for use

|  |
| --- |
| Use this 25% diluted product (5L of product per 15L of cold water) mixing directly into the plastic spray tank used to apply the product to the surface to be treated. Always try the diluted product on a small surface. Protect the slabs, metal objects, soils and green areas around the surfaces that will be treated (using a plastic tarpaulin, for example). Sprinkle the surfaces slightly before application, apply the product until the surface is saturated, leave to act for 30 minutes and rinse with water at low pressure. Do not exceed one treatment every 3 months. |

Use-specific risk mitigation measures

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Fill 75% of the sprayer’s tank with water then add the product. Before application, protect flora and fauna with tarpaulin near the surfaces where the product will be applied.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Meta SPC | Product description | |  | RMM | | meta SPC 9 | Produits à 9,6%c.a. Parfumés | Min (%) | 9.6 | PPE (gloves - clothes - glasses - mask) - protection of soil | | Max (%) | 9.6 | |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 9

Instructions for use

|  |
| --- |
| Fill 75% of the sprayer’s tank with water then add the product. |

Risk mitigation measures

|  |
| --- |
| Fill 75% of the sprayer’s tank with water then add the product. Before application, protect flora and fauna with tarpaulin near the surfaces where the product will be applied. |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic bottle | 5L, 10L, 20L | HDPE | Cap | Non-professional | Yes |

Documentation

Data submitted in relation to product application

None.

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 10.1

Uses descriptions

Table 89. Use # 10.1.1 – Disinfection of hard surfaces in medical area

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of hard surfaces in medical area (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | healthcare |
| Application method(s) | Wiping, mopping, flooding |
| Application rate(s) and frequency | Bactericidal: Add 300mL of product for 1L of diluted solution.  Fongicidal: Add 270mL of product for 1L of diluted solution.  Virucidal: Add 120mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L |

Table 90. Use # 10.1.2 – Disinfection of hard surfaces in contact with food

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of hard surfaces in contact with food (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural), institutions |
| Application method(s) | Wiping, mopping, flooding |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries and alcoholic beverages industries):  Bactericidal: Add 300mL of product for 1L of diluted solution.  Fongicidal: Add 270mL of product for 1L of diluted solution.  Virucidal: Add 120mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural, non-alcoholic beverages industries:  Bactericidal: Add 450mL of product for 1L of diluted solution.  Fongicidal: Add 360mL of product for 1L of diluted solution.  Virucidal: Add 350mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L |

Table 91. Use # 10.1.3 – Disinfection of hard surfaces in industries/institutions

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of hard surfaces in industries/institutions (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural, cosmetics), institutions |
| Application method(s) | Wiping, mopping, flooding |
| Application rate(s) and frequency | Disinfection of surfaces institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries):  Bactericidal : Add 300mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 270mL of product for 1L of diluted solution.  Virucidal : Add 120mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries:  Bactericidal : Add 450mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 360mL of product for 1L of diluted solution.  Virucidal : Add 350mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L |

Table 92. Use # 10.1.4 – Disinfection of hard surfaces by CIP

|  |  |
| --- | --- |
| Product Type(s) | 2, 4 |
| Where relevant, an exact description of the authorised use | Disinfection of hard surfaces by CIP |
| Target organism (including development stage) | Bactericidal (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural, cosmetics), institutions |
| Application method(s) | CIP |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries):  Bactericidal : Add 300mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 270mL of product for 1L of diluted solution.  Virucidal : Add 120mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries:  Bactericidal : Add 450mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 360mL of product for 1L of diluted solution.  Virucidal : Add 350mL of product for 1L of diluted solution.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L |

Table 93. Use # 10.1.5 – Laundry disinfection with hand soaking

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Laundry disinfection with hand soaking |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Healthcare, industry (general case) |
| Application method(s) | Hand soaking |
| Application rate(s) and frequency | Bactericidal: Add 50mL of product for 1L of diluted solution.  Fongicidal: Add 140mL of product for 1L of diluted solution.  Virucidal: Add 120mL of product for 1L of diluted solution.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L |

Table 94. Use # 10.1.6 – Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | Wiping, mopping, flooding |
| Application rate(s) and frequency | Bactericidal: Add 230mL of product for 1L of diluted solution.  Fongicidal: Add 310mL of product for 1L of diluted solution.  Yeasticidal: Add 270mL of product for 1L of diluted solution.  Virucidal: Add 350mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L |

Table 95. Use # 10.1.7 – Disinfection of non-porous hard surfaces in livestock transportation vehicles

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | Wiping, mopping, flooding |
| Application rate(s) and frequency | Bactericidal : Add 230mL of product for 1L of diluted solution.  Fongicidal : Add 310mL of product for 1L of diluted solution.  Yeasticidal : Add 270mL of product for 1L of diluted solution.  Virucidal : Add 350mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Meta SPC | Product description | |  | RMM | | meta SPC 10.1 | Détergents à 2,6%c.a. | Min (%) | 2.6 | PPE (gloves - clothes - glasses - mask)  Always rinse after disinfection on hard surfaces in contact with food. | | Max (%) | 2.6 | |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 10.1

Instructions for use

|  |
| --- |
| Cleaning before disinfection is preferred. |

Risk mitigation measures

|  |
| --- |
| Wear PPE. Always rinse after disinfection on hard surfaces in contact with food. |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic bottle | 5L | HDPE | Cap | Professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 10.2

Uses descriptions

Table 96. Use # 10.2.1 – Disinfection of hard surfaces in medical area

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of hard surfaces in medical area (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | healthcare |
| Application method(s) | Wiping, mopping, flooding |
| Application rate(s) and frequency | Bactericidal: Add 150mL of product for 1L of diluted solution.  Fongicidal: Add 140mL of product for 1L of diluted solution.  Virucidal: Add 60mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L |

Table 97. Use # 10.2.2 – Disinfection of hard surfaces in contact with food

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of hard surfaces in contact with food (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural), institutions |
| Application method(s) | Wiping, mopping, flooding |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries and alcoholic beverages industries):  Bactericidal: Add 150mL of product for 1L of diluted solution.  Fongicidal: Add 140mL of product for 1L of diluted solution.  Virucidal: Add 60mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural, non-alcoholic beverages industries:  Bactericidal : Add 230mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 180mL of product for 1L of diluted solution.  Virucidal : Add 180mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L |

Table 98. Use # 10.2.3 – Disinfection of hard surfaces in industries/institutions

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of hard surfaces in industries/institutions (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural, cosmetics), institutions |
| Application method(s) | Wiping, mopping, flooding |
| Application rate(s) and frequency | Disinfection of surfaces institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries):  Bactericidal: Add 150mL of product for 1L of diluted solution.  Fongicidal: Add 140mL of product for 1L of diluted solution.  Virucidal: Add 60mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries:  Bactericidal: Add 230mL of product for 1L of diluted solution.  Fongicidal: Add 180mL of product for 1L of diluted solution.  Virucidal: Add 180mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L |

Table 99. Use # 10.2.4 – Disinfection of hard surfaces by CIP

|  |  |
| --- | --- |
| Product Type(s) | 2, 4 |
| Where relevant, an exact description of the authorised use | Disinfection of hard surfaces by CIP |
| Target organism (including development stage) | Bactericidal (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural, cosmetics), institutions, veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | CIP |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by CIP:  Bactericidal: Add 150mL of product for 1L of diluted solution.  Fongicidal: Add 140mL of product for 1L of diluted solution.  Virucidal: Add 60mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries by CIP:  Bactericidal: Add 230mL of product for 1L of diluted solution.  Fongicidal: Add 180mL of product for 1L of diluted solution.  Virucidal: Add 180mL of product for 1L of diluted solution.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L |

Table 100. Use # 10.2.5 – Laundry disinfection with hand soaking

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Laundry disinfection with hand soaking |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Healthcare, industry (general case) |
| Application method(s) | Hand soaking |
| Application rate(s) and frequency | Bactericidal: Add 30mL of product for 1L of diluted solution.  Fongicidal/Yeasts: Add 70mL of product for 1L of diluted solution.  Virucidal: Add 60mL of product for 1L of diluted solution.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L |

Table 101. Use # 10.2.6 – Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | Wiping, mopping, flooding |
| Application rate(s) and frequency | Bactericidal: Add 120mL of product for 1L of diluted solution.  Fongicidal: Add 160mL of product for 1L of diluted solution.  Yeasticidal: Add 140mL of product for 1L of diluted solution.  Virucidal: Add 180mL of product for 1L of diluted solution.  Application rate: 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L |

Table 102. Use # 10.2.7 – Disinfection of non-porous hard surfaces in livestock transportation vehicles

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | Wiping, mopping, flooding |
| Application rate(s) and frequency | Bactericidal: Add 120mL of product for 1L of diluted solution.  Fongicidal: Add 160mL of product for 1L of diluted solution.  Yeasticidal: Add 140mL of product for 1L of diluted solution.  Virucidal: Add 180mL of product for 1L of diluted solution.  Application rate: 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 5L |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |
| --- |
| Always rinse after disinfection on hard surfaces in contact with food. |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 10.2

Instructions for use

|  |
| --- |
| Cleaning before disinfection is preferred. |

Risk mitigation measures

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Wear PPE.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Meta SPC | Product description | |  | RMM | | meta SPC 10.2 | Détergents à 4,8%c.a. | Min (%) | 4.8 | PPE (gloves - clothes - glasses - mask)  Always rinse after disinfection on hard surfaces in contact with food. | | Max (%) | 4.8 | |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic bottle | 5L | HDPE | Cap | Professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 11

Uses descriptions

Table 103. Use # 11.1 – Disinfection of hard surfaces in medical area

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of hard surfaces in medical area (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | healthcare |
| Application method(s) | Wiping, mopping, flooding, spraying |
| Application rate(s) and frequency | Bactericidal: Add 160mL of product for 1L of diluted solution.  Fongicidal: Add 150mL of product for 1L of diluted solution.  Virucidal: Add 60mL of product for 1L of diluted solution.  Application rate: 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 20L, 200L, 1000L |

Table 104. Use # 11.2 – Disinfection of hard surfaces in contact with food

|  |  |
| --- | --- |
| Product Type(s) | 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces in contact with food (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural), institutions |
| Application method(s) | Wiping, mopping, flooding, spraying |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries and alcoholic beverages industries) by spraying, wiping, mopping, flooding:  Bactericidal : Add 160mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 150mL of product for 1L of diluted solution.  Virucidal : Add 60mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries by spraying, wiping, mopping, flooding:  Bactericidal : Add 240mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 200mL of product for 1L of diluted solution.  Virucidal : Add 190mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 20L, 200L, 1000L |

Table 105. Use # 11.3 – Disinfection of hard surfaces in institutions/industries

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of hard surfaces in institutions/industries (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Institutions, industries (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural, cosmetics) |
| Application method(s) | Wiping, mopping, flooding, spraying |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetics industries and alcoholic beverages industries) by spraying, wiping, mopping, flooding:  Bactericidal : Add 160mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 150mL of product for 1L of diluted solution.  Virucidal : Add 60mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries by spraying, wiping, mopping, flooding:  Bactericidal : Add 240mL of product for 1L of diluted solution.  Fongicidal/Yeasticidal : Add 200mL of product for 1L of diluted solution.  Virucidal : Add 190mL of product for 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 20L, 200L, 1000L |

Table 106. Use # 11.4 – Disinfection of surfaces by CIP

|  |  |
| --- | --- |
| Product Type(s) | 2, 4 |
| Where relevant, an exact description of the authorised use | Disinfection of surfaces by CIP |
| Target organism (including development stage) | Bactericidal (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Institutions, industries (general case, meat, milk, non-alcoholic, alcoholic beverages, agricultural, cosmetics) |
| Application method(s) | CIP |
| Application rate(s) and frequency | Disinfection of surfaces in institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries) by CIP:  Bactericidal: Add 160mL of product for 1L of diluted solution.  Fongicidal: Add 150mL of product for 1L of diluted solution.  Virucidal: Add 60mL of product for 1L of diluted solution.  Disinfection of hard surfaces in agricultural industries and non-alcoholic beverages industries by CIP:  Bactericidal: Add 240mL of product for 1L of diluted solution.  Fongicidal: Add 200mL of product for 1L of diluted solution.  Virucidal: Add 190mL of product for 1L of diluted solution.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 20L, 200L, 1000L |

 Table 107. Use # 11.5 – Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | Wiping, mopping, flooding, spraying |
| Application rate(s) and frequency | For bactericidal activity: Add 120mL of product per 1L of diluted solution.  For fungicidal activity: Add 170mL of product per 1L of diluted solution.  For yeasticidal activity: Add 150mL of product to 1L of diluted solution.  For virucidal activity: Add 190mL of product per 1L of diluted solution.  Application rate : 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency : once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 20L, 200L, 1000L |

Table 108. Use # 11.6 – Disinfection of non-porous hard surfaces in livestock transportation vehicles

|  |  |
| --- | --- |
| Product Type(s) | 3 |
| Where relevant, an exact description of the authorised use | Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings (without mechanical action) |
| Target organism (including development stage) | Bacteria (tests conducted on E.hirae, P.vulgaris, P.aeruginosa, S.aureus)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Viruses (tests conducted on ECBO) |
| Field of use | Veterinary healthcare facilities, animal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) buildings |
| Application method(s) | Wiping, mopping, flooding, spraying |
| Application rate(s) and frequency | For bactericidal activity: Add 120mL of product per 1L of diluted solution.  For fungicidal activity: Add 170mL of product per 1L of diluted solution.  For yeasticidal activity: Add 150mL of product to 1L of diluted solution.  For virucidal activity: Add 190mL of product per 1L of diluted solution.  Application rate: 100 mL of diluted product per m², equal to a film thickness of 0,1mm.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE : 20L, 200L, 1000L |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Meta SPC | Product description | |  | RMM | | meta SPC 11 | Détergents alcalins chlorés | Min (%) | 6 | PPE (gloves - clothes - glasses - mask) - rinsing treated surfaces (TP4) | | Max (%) | 6 | |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 11

Instructions for use

|  |
| --- |
| Cleaning before disinfection is preferred. |

Risk mitigation measures

|  |
| --- |
| Wear PPE. Always rinse after disinfection on hard surfaces in contact with food. |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic bottle | 20L, 200L, 1000L | HDPE | Cap | Professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 12

Use description

Table 109. Use # 12.1 – Disinfection of hard surfaces by spraying

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of hard surfaces by spraying |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Healthcare, institutions, industries (general case) |
| Application method(s) | Spraying |
| Application rate(s) and frequency | RTU product  Application rate: 1 squeeze every 10 centimeters (= to film thickness of 0,1mm).  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE: 500ML, 750ML |

Use-specific instructions for use

|  |
| --- |
| Trigger the spray 30cm away from the surface to be treated. |

Use-specific risk mitigation measures

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Meta SPC | Product description | |  | RMM | | meta SPC 12 | Produits Spray à 4,8%c.a. | Min (%) | 4.8 | PPE (gloves - clothes - glasses - mask) | | Max (%) | 4.8 | |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 12

Instructions for use

|  |
| --- |
| Switch mobile cap to “ON” before using the product and switch back to “OFF” after use. Push the trigger when at 20 to 30 cm from the surface to be disinfected. |

Risk mitigation measures

|  |
| --- |
| Wear PPE |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic bottle | 750ML, 500ML | HDPE | Cap with trigger spray and ON/OFF lock | Professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 13

Use description

Table 110. Use # 13.1 – Disinfection of toilet bowls in medical area

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of toilet bowls in medical area |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Healthcare |
| Application method(s) | Direct application of the product (by pressing on the packaging) and rinse with flush |
| Application rate(s) and frequency | RTU product  Application rate: 100 mL of product per m², equal to a film thickness of 0,1mm.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE: 750ML |

Table 111. Use # 13.2 – Disinfection of toilet bowls in institutions/industry

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Disinfection of toilet bowls in institutions/industry |
| Target organism (including development stage) | Bacteria (tests conducted on P.aeruginosa ; S.aureus ; E.hirae ; E.coli)  Fungi and Yeast (tests conducted on C.albicans ; A.brasiliensis) Virucidal (tests conducted on Norovirus murin ; Poliovirus ; Adénovirus) |
| Field of use | Industry (general case), institutions |
| Application method(s) | Direct application of the product (by pressing on the packaging) and rinse with flush |
| Application rate(s) and frequency | RTU product  Application rate: 100 mL of product per m², equal to a film thickness of 0,1mm.  Frequency: once per day. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE: 750ML |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Meta SPC | Product description | |  | RMM | | meta SPC 13 | Produits Gel WC à 4,5%c.a. | Min (%) | 4.5 | Formulation : Gel - gooseneck | | Max (%) | 4.5 |   Gel formulation and diameter reducer on caps to easily apply the product with accuracy. |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 13

Instructions for use

|  |
| --- |
| Remove cap and press bottle to direct the product into the surface to be disinfected. |

Risk mitigation measures

|  |
| --- |
| none |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

|  |
| --- |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

|  |
| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle with gooseneck | 750ML | HDPE | Caps | Non-professional | Yes |
| Plastic bottle (round) | 750ML | HDPE | Caps | Non-professional | Yes |

Documentation

Data submitted in relation to product application

*[Please indicate here whether any new data on the product or on the active substace(s) and substance(s) of concern contained in the product have been submitted. A reference to a reference list can be made.]*

Access to documentation

A LoA has been submitted giving access to the authorisation dossier submitted by Eurochlor.

Authorised use(s) for meta-SPC 14

Use description

Table 112. Use # 14.1 – Algaecide and fungicide for outdoor surfaces by spraying

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Algaecide and fungicide for outdoor surfaces by spraying |
| Target organism (including development stage) | Algaecidal, fungicidal |
| Field of use | Household |
| Application method(s) | Spraying then rinsing |
| Application rate(s) and frequency | Dilution 25%  Frequency: max. once every 3 months |
| Category(ies) of user(s) | Non-professional, professional |
| Pack sizes and packaging material | HDPE: 5L (with 4L gel SETS) + 1L (Bleach 9,6%a.c.) |

Use-specific instructions for use

|  |
| --- |
| None |

Use-specific risk mitigation measures

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Meta SPC | Product description | |  | RMM | | meta SPC 14 | Gel SETS + Javel BEC | Min (%) | 9.6 | PPE (gloves - clothes - glasses - mask) - Formulation : Gel | | Max (%) | 9.6 | |

Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| None |

Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| None |

Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| None |

General directions for use for meta-SPC 14

Instructions for use

|  |
| --- |
| Add the bleach water bundled with the product into the gel solution and mix appropriately the mixture until the solution is homogeneous. Apply the mixture immediately after on the surface with an “airless” sprayer. |

Risk mitigation measures

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| Please wear PPE (gloves - clothes - glasses - mask) |

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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| --- |
| Please refer to P-Mentions |

Instructions for safe disposal of the product and its packaging

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| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. |

Conditions of storage and shelf-life of the product under normal conditions of storage

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| Store in a cool place, away from light and sun. Do not store under 5°C. |

Other information

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| --- |
| Application codes |

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Jerrycan | 5L (with 4L gel) +1L (bleach) | HDPE | Cap | Non-professional | Yes |

### Physical, chemical and technical properties

Products of the family are ready to use formulations (SPC 3, 4, 5, 12, 13) and soluble concentrates to be diluted (other meta SPC). Meta SPC 5 and 12 are ready to use sprays.

Physico chemical properties have been provided for several formulation identified as worst cases by the applicant (please refer to excel sheet BPF DAAP19 for comparison of the products). Read across are detailed in confidential annex.

Products do not contain H304 compounds >10%, therefore H304 is not applicable for this family.

Packaging are made of HDPE (bottles, containers, drums, barrels, cuve) or PVC (berlingot). For meta SPC 5 and 12, products are sold with a spray trigger (PP/PE Trigger TS5 S).

Mentions EUH 206 and 031 are sometimes proposed by eCa:

* EUH206 is only applicable for non professional users and when active chlorine content in biocidal products is > 1% w/w.
* EU031 is applicable when sodium hypochlorite content in biocidal products is ≥ 5% w/w.

**Meta SPC 1.1 (soluble concentrate formulation)**

Tested formulation: physico chemical properties have been performed with product 1 from meta SPC 9. See read across in confidential annex.

Packaging claimed: HDPE bottle

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | 9,6% (product 1 SPC 1.1) | Liquid | SDS | acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | 9,6% (product 1 SPC 1.1) | Pale Yellow | SDS | acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | 9,6% (product 1 SPC 1.1) | Bleach water | SDS | Acceptable |
| Acidity / alkalinity | CIPAC MT31 | EAU DE JAVEL 9,6%C.A. SPECIAL PISCINE  Batch 2001230010  (product 1 of meta-SPC 1.1)  Product 1 of SPC 9, EAU DE JAVEL A 9.6% c.a parfumée eucalyptus batch 2010201416 (product 1 SPC 9) | 3,88%w/w NaOH eq  pH at 20°C: 12.20 | 20.503032.0001  CoA, 10/2020 | Acceptable. |
| Relative density / bulk density | OECD 109 | Eau de javel 9.6% C.A parfumee eucalyptus  Batch19\_0025  % (product 1 SPC 1.1) | 1,1542g/ml at 20°C (product 1 of meta SPC 9)  1.11-1.15 (SDS of product 1 of meta SPC 1.1) | RRCo-000338\_01  SDS | Cross reading with meta SPC 9 is acceptable. |
| Storage stability test – **accelerated storage** | No testing required. | | | | Product should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | This product is mainly covered by the stability tests of products of meta-SPC9 (AS loss over time, sodium chlorates and chlorites concentrations). Products in meta-SPC9 are considered worst case because they contain surfactants and perfume, which is known to increase AS content decaying over time. Also, as seen in report 20.503032.0001, alcalinity is similar to the alcalinity of the product used for cross-reading (from meta-SPC 9). | | | | Read across is performed with product of meta SPC 9. See confidential annex.  Product 1 of meta SPC 9 is compatible with HDPE packaging.  However the content of active chlorine after 10 months at 20°C decreases by more than 10% (-40%) and the ratio sodium chlorate/active chlorine exceeds 5.4% w/w. Please refer to human health, residues and environment sections regarding conclusion on chlorate content.  Efficacy data support a shelf life up to 6 months as claimed by the applicant.  Please refer to the results of meta SPC 9. |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | Acceptable. Products should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | Acceptable. Products should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | Acceptable. Products should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See results on the product 1 of meta SPC 9 (250 mL HDPE bottle)  « No crack, no swellling, no change of colour after 10 months of storage. » | | | | Compatibility has been demonstrated with product 1 of meta SPC 9. Extrapolation to meta SPC 1.1 is acceptable due to comparison of composition and type of packaging claimed (HDPE bottle). |
| Wettability | No data generated |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  |  |  | Not relevant |
| Disintegration time | No data generated |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  |  |  | Not relevant |
| Persistent foaming | No foaming expected as co-formulants used in those products do not generate foam. | | | | Product of this meta SPC does not contain surfactant. No foam is expected. |
| Flowability/Pourability/Dustability |  |  | No data generated |  | Not relevant |
| Burning rate — smoke generators |  |  | No data generated |  | Not relevant |
| Burning completeness — smoke generators |  |  | No data generated |  | Not relevant |
| Composition of smoke — smoke generators |  |  | No data generated |  | Not relevant |
| Spraying pattern — aerosols |  |  | No data generated |  | Not relevant |
| Physical compatibility |  |  | No data generated |  | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility |  |  | No data generated |  | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mentions EUH031 “contact with acids liberates toxic gas” and EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” are proposed for this meta SPC.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | CIPAC MT 41 | Eau de Javel 9.6% c.a parfum eucalyptus (product 1 meta SPC 9), batch 180817  9,55% | Before and after shelf life of product 1 meta SPC 9:  After dilution of the test item in water at 75 % v/v, no separated material was detected. | 18.644892.0002  18.644892.0007 | Acceptable results were provided for meta SPC 9. Extrapolation to meta SPC 1.1 is also acceptable since the differences in composition are not expected to affect this property. |
| Surface tension | No data generated | | | | Not acceptable. However, product of meta SPC 1.1 is not expected to be surface active since no surfactants are used. |
| Viscosity | No data generated | | | | Not acceptable. However, according to the composition, the viscosity is expected to be similar to water and to have a Newtonian behaviour. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 1.1** |
| Product of meta SPC 1.1 is a soluble concentrate formulation. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid.  No accelerated storage stability study was provided. Product should not be stored at a temperature higher than 30°C.  Shelf life was performed with similar product of meta SPC 9 (product 1). The stability of product 1 of meta SPC 9 was not fully demonstrated after storage 10 months at 20°C, since the active chlorine content decreased significantly (-40%) and the sodium chlorate content was found above the maximum limit of 5.4% of the active chlorine content (please refer to human health, residues and environment sections regarding conclusion on chlorate content). Efficacy data support a shelf life up to 6 months as claimed by the applicant.  Product 1 of meta SPC 1.1 is not expected to form foam since no surfactants are present.  Product 1 of meta SPC 9 forms clear solution when diluted. Extrapolation to meta SCP 1 is acceptable.  Compatibility of products with HDPE is acceptable with product 1 of meta SPC 9 and results can be extrapolated to product 1 of meta SPC 1.1.  **Implication concerning labelling for products of meta SPC1.1:**  Shelf life proposed by eCA: 6 months (shelf life claimed by the applicant: 6 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  EUH031 “contact with acids liberates toxic gas”  EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)”  Products should not be used in conjunction with acids or ammonia. |

**Meta SPC 1.2 (soluble concentrate formulation)**

Tested formulation: cross reading with product 1 of meta SPC6.22 is proposed. Read across is acceptable. Please refer to confidential annex.

Packaging claimed: HDPE bottle

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | 12,5% (product 1 SPC 1.2) | Liquid | SDS | Acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | 12,5% (product 1 SPC 1.2) | Pale Yellow | SDS | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | 12,5% (product 1 SPC 1.2) | Bleach water | SDS | Acceptable |
| Acidity / alkalinity | CIPAC MT191 | Eau de Javel 12.5%C.A batch 180101  (product 1 SPC 6.22)  Eau de Javel à 12.5% c.a, batch 2010121575 (product 1 SPC 6.22) | 5,13% NaOH  pH at 20°C: 12.10 | 18.649820.0001  CoA, 10/2020 | Read across with product of meta SPC 6.22 is acceptable. |
| Relative density / bulk density | OECD109 | Eau de Javel A 12.5% C.A  Batch 19-0061  (product 1 SPC 6.22) | 1,2261g/mL at 20°C | RRCo-000337\_01+ Amdt n#1 | Read across with product of meta SPC 6.22 is acceptable. |
| Storage stability test – **accelerated storage** | No testing required | | | | Product should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | This product is mainly covered by the stability tests of product 1 of meta-SPC6.22 (AS loss over time, sodium chlorates and chlorites concentrations) as it is the same AS concentration. Co-formulants added in this product are expected to have no impact on its long-term stability. | | | | Read across is performed with product of meta SPC 6.22. See confidential annex.  For product 1 of meta SPC 6.22, active substance content decreased by more than 10% after 5 months (-41.9%) and the ratio sodium chlorates/active chlorine exceeds 5.4%. Please refer to human health, residues and environment sections regarding conclusion on chlorate content.  Efficacy data support a shelf life up to 4 months as claimed by the applicant.    Please refer to the results of meta SPC 6.22. |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | Acceptable. Product should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | Acceptable. Product should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | Acceptable. Product should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report 19.530379.0001 :  After 3 months storage : PEHD white tank with blue plastic cap containing 5000ml of product ; no sign of deformation, leak or discolouration were observed.  After 5 months storage : PEHD white tank with blue plastic cap containing 5000ml of product ; no sign of deformation, leak or discolouration were observed. | | | | Compatibility with HDPE has been demonstrated with product 1 of meta SPC 6.22. Extrapolation to meta SPC 1.2 is acceptable. |
| Wettability | No data generated |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  |  |  | Not relevant |
| Disintegration time | No data generated |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  |  |  | Not relevant |
| Persistent foaming | No foaming expected as co-formulants used in those products do not generate foam. | | | | Product of this meta SPC does not contain surfactant. No foam is expected. |
| Flowability/Pourability/Dustability | No data generated |  |  |  | Not relevant |
| Burning rate — smoke generators | No data generated |  |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated |  |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated |  |  |  | Not relevant |
| Spraying pattern — aerosols | No data generated |  |  |  | Not relevant |
| Physical compatibility | No data generated |  |  |  | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated |  |  |  | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mentions EUH031 “contact with acids liberates toxic gas” is proposed for this meta SPC.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | CIPAC MT 41 | Eau de Javel 12.5% C.A batch 180101  Product 1 of meta-SPC6.22 (same AS concentration) | no separated material detected | T0 :  18.649820.0001  T5months :  18.649820.0002 | According to other meta SPC with similar ingredient, dilution stability is acceptable. No concerns are expected for this meta SPC. |
| Surface tension | No data generated | | | | Not acceptable. However, product 1 is not expected to be surface active since no surfactants are used. |
| Viscosity | No data generated | | | | Not acceptable. However, according to the composition, the viscosity is expected to be similar to water and to have a Newtonian behaviour. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 1.2** |
| Product of meta SPC 1.2 is a soluble concentrate formulation. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid.  No accelerated storage stability study was provided. Product should not be stored at a temperature higher than 30°C.  Shelf life was performed with similar product of meta SPC 6.22 (product 1). The stability of product 1 of meta SPC 6.22 was not fully demonstrated after storage 5 months at 20°C, since the active chlorine content decreased significantly (-42%) and the sodium chlorate content was found above the maximum limit of 5.4% of the active chlorine content (please refer to human health, residues and environment sections regarding conclusion on chlorate content). Efficacy data support a shelf life up to 4 months as claimed by the applicant..  Product 1 of meta SPC 1.2 is not expected to form foam since no surfactants are present.  Product 1 of meta SPC 6.22 forms clear solution when diluted. Extrapolation to meta SCP 1.2 is acceptable.  Compatibility of products with HDPE is acceptable with product 1 of meta SPC 6.22 and results can be extrapolated to product 1 of meta SPC 1.2.  **Implication concerning labelling for products of meta SPC1.2**:  Shelf life proposed by eCA: 4 months (shelf life claimed by the applicant: 4 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  EUH031 “contact with acids liberates toxic gas”  Products should not be used in conjunction with acids or ammonia. |

**Meta SPC 2.1(soluble concentrate formulation)**

Tested formulation : product 1 (Eau de Javel 2.6% c.a parfum eucalyptus) from meta SPC 2.1. This product covers the whole meta SPC. Refer to read across in condifential annex.

Packaging: HDPE bottle

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | Eau de javel 2.6% c.a parfum eucalyptus, Batch 180752  (product 1 of meta SPC 2.1) | Liquid | 18.644892.0004 | Acceptable. |
| Colour at 20 °C and 101.3 kPa | Internal method | Eau de javel 2.6% c.a parfum eucalyptus, Batch 180752  (product 1 of meta SPC 2.1) | Transparent yellow | 18.644892.0004 | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | 2 Eau de javel 2.6% c.a parfum eucalyptus, Batch 180752  (product 1 of meta SPC 2.1) | Hypochlorite + eucalyptus | 18.644892.0004 | Acceptable. Other products will present different odour since various perfumes are used. |
| Acidity / alkalinity | CIPAC MT 191 | Eau de javel 2.6% c.a parfum eucalyptus, Batch 180752 (product 1 of meta SPC 2.1)  Eau de javel 2.6% c.a nature (product 5 meta SPC 2.1) batch 2001230040  Eau de Javel à 2.6% c.a parfuméee eucalyptus, batch 201071707 and 1812130831 (product 1 SPC 2.1) | 1.20 as NaOH %w/w  1.08 as NaOH %w/w  pH at 20°C  before storage: 12.10  after storage (>11 months): 12.40 | 18.644892.0004  20.503032.0009  CoA, 10/2020 | Acceptable. Data were provided for representative products of this meta SPC. |
| Relative density / bulk density | OECD109 (pycnometer method) | Eau de javel 2.6% c.a parfum eucalyptus  Batch 191143 (product 1 of meta SPC 2.1) | 1,0397 g/mL at 20°C | RRCo-000334\_01 | Acceptable. Results can be considered similar for other products of this meta SPC due to similar composition. |
| Storage stability test – **accelerated storage** | No testing required | | | | Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17,  ANA\_MON\_102 ANA\_MON\_103  Internat method for sodium chlorides  Validated method in the study RRCo-000345\_01 | Eau de javel 2,6% c.a parfumee eucalyptus  Batch 191143 (product 1 of meta SPC 2.1) | GLP study  Packaging tested: HDPE bottle of 250mL  Storage conditions: darkness, at 20°C  **Appearance**  Before storage: slightly yellow transparent liquid, typical eucalyptus bleach odour  After storage 6 and 11 months at 20°C: slightly yellow transparent liquid, typical eucalyptus bleach odour  **Packaging**  Before storage: no crack, no swelling, no change of colour  After storage: no crack, no swelling, no change of colour  **T0:**  Active chlorine: 2,64% w/w  Sodium chlorates: 0,07% w/w  Sodium chlorides: 2,53% w/w  Ratio sodium chlorates/active chlorine: 2.6%  **T6 months:**  Active chlorine: 2,58% w/w  **T11 months:**  Active chlorine: 2,58% w/w  Sodium chlorates: 0,12% w/w  Sodium chlorides: 2,67% w/w  Ratio sodium chlorates/active chlorine: 4.65% | RRCo-000334\_01 | A storage stability study 24 months at 20°C has been launched. Only results after 11 months are available. If the applicant claims a longer shelf life, complete study should be submitted during a minor change application.  Product can be considered stable up to 11 months at 20°C. Active chlorine content decreases by less than 10% (-2.2%) and the ratio sodium chlorate/active chlorine remains below 5.4%.  A shelf life of 11 months can be proposed for this meta SPC.  The effect of perfumes has been discussed for meta SPC 2.21 and is applicable for meta SPC 2.1. For meta SPC 2.21 it has been demonstrated that products containing eucalyptus constitute the worst case. Consequently, the tested product is sufficiently representative for this meta SPC. However, it should be noticed that only citrus, lavender and eucalyptus perfumes were tested. No justification was provided for products with mandarine orange and mint perfumes. However it has been demonstrated that the influence of perfumes on the degradation rate of active chlorine is quite similar on a short period (-11.5% to 13.7% after 8 months for eucalyptus, lavande and citrus). According to this observation and the compositions of the perfumes in confidential PAR, eCA is of the opinion that no significant differences are expected for the untested perfumes mandarin/orange and mint. |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report RRCo-000334\_01 (mid-term report) :  No crack, no swelling, no change of colour. | | | | Compatiblity of HDPE with product 1 of meta SPC 2.1 has been demonstrated and results can be extrapolated to the whole meta SPC 2.1. |
| Wettability | No data generated |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  |  |  | Not relevant |
| Disintegration time | No data generated |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  |  |  | Not relevant |
| Persistent foaming | See results on products with 4,8%a.c. of meta-SPC 2.21 as they are considered worst case (higher surfactants concentrations).  See reports 18.644892.0003 (before shelf life) and 18.644892.0008 (after shelf life). | | | | Read across with product 1 of meta SPC 2.21 is acceptable since it contains the same surfactant at a higher level. Products are foaming formulations since the volume of foam exceeds 60mL after 1min. |
| Flowability/Pourability/Dustability | No data generated |  |  |  | Not relevant |
| Burning rate — smoke generators | No data generated |  |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated |  |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated |  |  |  | Not relevant |
| Spraying pattern — aerosols | No data generated |  |  |  | Not relevant |
| Physical compatibility | No data generated |  |  |  | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated |  |  |  | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mentions EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” is proposed for this Meta SPC.  Mention EUH031 is not applicable for this meta SPC since active substance content is below 5% w/w.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | No data generated | See results on product 1 of meta-SPC 2.21 as they are considered worst case (higher surfactants, higer perfume concentrations and higher after dilution concentrations).  See reports 18.644892.0003 (before shelf life) and 18.644892.0008 (after shelf life), results were the same : “For the test item diluted at 50 % v/v in standard water C, no separated material was detected.” | | | Read across with product 1 of meta SPC 2.21 is acceptable since it can be regarded as a worst case (similar composition with additional formulants than in products of meta SPC 2.1). Even if a higher content of surfactants is expected to improve dissolution, no specific concern is expected for products of this meta SPC 2.1 as components are soluble substances.  Results from meta SPC 2.21 are reliable and found acceptable. |
| Surface tension | EEC A.5 | Eau de javel 2.6% c.a eucalyptus (Product 1 meta SPC 2.1) batch 2001230045 | At 36%v/v, the mean surface tension at a temperature of 20 ± 0.5°C was 31.72 mN/m | 20.503032.0006 | Acceptable. All products of meta SPC 2.1 are considered to be surface active (expect product 5 due to its composition). |
| Viscosity | No data generated | | | | Not acceptable. However, according to the composition, the viscosity is expected to be similar to water. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 2.1** |
| Products of meta SPC 2.1 are soluble concentrate formulations. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid, with different odours (various perfumes are used).  No accelerated storage stability study was provided. Products should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 1 of meta SPC 2.1. The stability of this product was demonstrated after storage 11 months at 20°C, since the active chlorine content remains stable (variations below 10%) and the sodium chlorate content remains below the maximum limit of 5.4% of the active chlorine content. Results can be extrapolated to other products of meta SPC 2.1 since compositions are similar. No justification was provided for products with mandarine orange and mint perfumes. However it has been demonstrated that the influence of perfumes on the degradation rate of active chlorine is quite similar on a short period (-11.5% to 13.7% after 8 months for eucalyptus, lavande and citrus). According to this observation and the compositions of the perfumes in confidential PAR, eCA is of the opinion that no significant differences are expected for the untested perfumes mandarin/orange and mint.  Products of meta SPC 2.21 are foaming products and results can be extrapolated to products of meta SPC 2.1 due to their composition.  Products of meta SPC 2.21 form clear solution when diluted. Extrapolation to meta SCP 2.1 is acceptable.  Compatibility of products with HDPE is acceptable with product 1 of meta SPC 2.1 and results can be extrapolated to the whole meta SPC 2.1  **Implication concerning labelling for products of meta SPC2.1**:  Shelf life proposed by eCA: 11 months (shelf life claimed by the applicant: 24 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Foaming products  EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)”  Products should not be used in conjunction with acids or ammonia. |

**Meta SPC 2.21 (soluble concentrate formulation)**

Tested formulation : product 1 of meta SPC 2.21 (eau de javel 4.8% c.a parfum eucalyptus)

This product will cover the whole meta SPC. Please refer to read across in confidential annex.

Packaging claimed: PVC berlingot

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage: liquid, No phase separation or precipitation  After storage 10 months at 20°C: liquid, no phase separation or precipitation | 18.644892.0003  18.644892.0008 | Acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage: Transparent yellow  After storage 10 months at 20°C: transparent yellow | 18.644892.0003  18.644892.0008 | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage: characteristic odour of eucalyptus and hypochlorite  After storage 10 months at 20°C: characteristic odour of eucalyptus and hypochlorite | 18.644892.0003  18.644892.0008 | Acceptable. Products of this meta SPC have different odours since various perfumes are used. |
| Acidity / alkalinity | CIPAC MT 191 | Product with surfactant and perfume:  4,72%  Batch 180802 (product 1 of meta SPC 2.21)  Product without surfactants:  4,86%, Batch 2001230020 (product 4 of meta SPC 2.21)  eau de javel 4.8% c.a parfum eucalyptus  Batch 72010121504 and 191404 (product 1 of meta SPC 2.21) | Before storage: 2.32 % w/w NaOH eq  After storage 10 months at 20°C: 2.05% w/w NaOH eq  2.02 % NaOH eq w/w.  pH at 20°C  before storage: 12.20  after storage (>10 monhts): 12.30 | 18.644892.0003  18.644892.0008  20.503032.0003  CoA, 10/2020 | Acceptable. Data were provided for two representative products of this meta SPC.  pH provided for product 1 of meta SPC 2.21 covers the other products of this SPC, except for product 4 (simple TK solution without stabilizer). However extrapolation can be performed with product 1 of SPC 2.1 (no stabilizer and less content of a.i, pH>12). |
| Relative density / bulk density | OECD109 | eau de javel 4.8% c.a parfum eucalyptus Batch 191404 (product 1 of meta SPC 2.21) | Before storage: 1,0755g/mL  After storage 10 months at 20°C: 1.0743g/mL | RRCo-000335\_01 | Acceptable. Results can be extrapolated to other products of this meta SPC due to similar composition. |
| Storage stability test – **accelerated storage** | No testing required | | | | Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17,  ANA\_MON\_102, ANA\_MON\_103,  Internal method for sodium chlorides  Validated method in the study RRCo-000345\_01 | eau de javel 4.8% c.a parfum eucalyptus  Batch 191404 (product 1 of meta SPC 2.21) | GLP study :  Packaging tested: HDPE bottle 250mL  Storage conditions: 20°C for 10 months  **Appearance**  Before storage: slightly yellow transparent liquid, typical eucalyptus bleach odour  After storage: slightly yellow transparent liquid, typical eucalyptus bleach odour  **Packaging**  Before storage: no crack, no swelling, no change of coulour  After storage: no crack, no swelling, no change of colour, no change in weight  **T0:**  Active chlorine: 4,67% w/w  Sodium chlorates: 0,13%w/w  Sodium chlorides: 4,59%w/w  Ratio sodium chlorates/active chlorine: 2.8%  **T2 months:**  Active chlorine: 4,51% w/w  **T4 months:**  Active chlorine: 4,24% w/w  **T5 months:**  Sodium chlorates: 0,27%w/w  Sodium chlorides: 4,78%w/w  **T6 months:**  Active chlorine: 4,29% w/w  **T8 months:**  Active chlorine: 4,18% w/w  **T10 months:**  Active chlorine: 3,93% w/w  Sodium chlorates: 0,39%w/w  Sodium chlorides: 5,33%w/w  Ratio sodium chlorate/active chlorine: 9.9% | RRCo-000335\_01 | Final results of the shelf life study 10 months at 20°C are available.  The product is compatible with HDPE packaging.  Active chlorine content decreases by more than 10% (-15.9%) and the ratio sodium chlorates/active chlorine exceeds 5.4%. Please refer to human health, residues and environment sections regarding conclusion on chlorate content.A compatibility study of the products with PVC berlingot has been provided and is reported below. As results for berlingots are only available up to 8 months, only a shelf life of 8 months could be granted for this SPC.  Efficacy data are sufficient to support a shelf life of 8 months even if degradation of active substance exceeds 10% of initial content. A shelf life of 8 months is acceptable for this meta SPC.  The influence of perfumes on active chlorine content has been studied in the following study. |
| Internal studies from Pintaud | Sodium hypochloride with 4.8% a.c NATURE (product 4 of meta SPC 2.21), batch 1732J154 | Packaging tested: pvc berlingot  Storage conditions: 8 months at 25°C  **Active chlorine content (% w/w)**  T=0: 4.73%  T=8 month: 4.67% (-8.67%)  **Packaging stability after storage**: no leakage or migration was observed on packaging  **Test item aspect after storage**: yellow liquid with characteristic odour of bleach. No precipitation events or phase separation was observed. | RD-2017-020 | The products are compatible with PVC berlingot up to 8 months.  As expected, no significant loss is noticed for product without perfume. For the other ones, variations of active chlorine content is higher than 10% after 8 month storage. No information on chlorate levels is reported in this study. In the previous report, the variations after 10 months were slightly more significant (-15.9%) and the chlorate levels found was taken into account for risk assessment. Therefore, the previous study will cover results obtained with PVC berlingot. However, only a shelf life of 8 months can be granted for this SPC (supported with efficacy data).  All perfumes were tested in this study and variations remain quite similar with citrus, lavender and eucalyptus. Consequently, no significant differences are expected with the perfumes used. Addditionally, eucalyptus was identified as the worst case (the maximal loss of active ingredient content was observed in this specific case) and the applicant has chosen products with eucalyptus to assess stability. eCA considers that the choice is relevant considering the results observed and that the products with eucalyptus will be the most representative ones. |
| Internal studies from Pintaud | Sodium hypochloride with 4.8% a.c EUCALYPTUS (product 1 of meta SPC 2.21), batch 1732J856 | Packaging tested: pvc berlingot  Storage conditions: 8 months at 25°C  **Active chlorine content (% w/w)**  T=0: 4.61%  T=8 month: 3.98% (-13.67%)  **Packaging stability after storage**: no leakage or migration was observed on packaging  **Test item aspect after storage**: yellow liquid with eucalyptus odour. No precipitation events or phase separation was observed. | RD-2017-020 |
| Internal studies from Pintaud | Sodium hypochloride with 4.8% a.CITRUS (product 2 of meta SPC 2.21), batch 1731J13 | Packaging tested: pvc berlingot  Storage conditions: 8 months at 25°C  **Active chlorine content (% w/w)**  T=0: 4.74%  T=8 month: 4.11% (-13.29%)  **Packaging stability after storage**: no leakage or migration was observed on packaging  **Test item aspect after storage**: yellow liquid with citrus odour. No precipitation events or phase separation was observed. | RD-2017-020 |
| Internal studies from Pintaud | Sodium hypochloride with 4.8% a.c LAVANDER (product 3 of meta SPC 2.21), batch 1732J154 | Packaging tested: pvc berlingot  Storage conditions: 8 months at 25°C  **Active chlorine content (% w/w)**  T=0: 4.8%  T=8 month: 4.25% (-11.46%)  **Packaging stability after storage**: no leakage or migration was observed on packaging  **Test item aspect after storage**: yellow liquid with lavender odour. No precipitation events or phase separation was observed. | RD-2017-020 |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | Acceptable. Products should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | Acceptable. Products should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | Acceptable. Products should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report 200428\_RRCo-000335\_01\_RF\_V1. Products were in 250ML HDPE bottle. Packaging used for these products is PVC, however HDPE can be used for stability tests.  See report18.644892.0008: No weight change after 10 months at 20°C (HDPE bottle 250mL) | | | | Acceptable. The product is compatible with HDPE and PVC packaging. |
| Wettability | No data generated |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  |  |  | Not relevant |
| Disintegration time | No data generated |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  |  |  | Not relevant |
| Persistent foaming | CIPAC MT 47.2 | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage  After dilution of 50 % v/v, foam produced is 300 ml after 10 sec, 1 min, 3 min and 12 min.  After storage 10 months at 20°C:  At 50% v/v  10 sec : 830ml  1 min : 810ml  3 min : 800ml  12 min : 780ml | 18.644892.0003  18.644892.0008 | 50mL of product were diluted in 1L of water. Up to 1L of foam can be formed. The product is a foaming formulation.  No foam is expected for product 4 of this meta SPC since no surfactants are used. |
| Flowability/Pourability/Dustability | No data generated |  |  |  | Not relevant |
| Burning rate — smoke generators | No data generated |  |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated |  |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated |  |  |  | Not relevant |
| Spraying pattern — aerosols | No data generated |  |  |  | Not relevant |
| Physical compatibility | No data generated |  |  |  | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated |  |  |  | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mentions EUH031 “contact with acids liberates toxic gas” and EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” are proposed for this meta SPC.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | CIPAC MT 41.1 | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage: at 50% v/v, no separated material was noticed.  After storage 10 months at 20°C: at 50% v/v, no separated material was noticed. | 18.644892.0003  18.644892.0008 | Acceptable. Results can be extrapolated to other products of this meta SPC. |
| Surface tension | OECD Test Guideline 115 and EC method A.5 | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage (neat): 32.96 mN/m  After storage 10 months at 20°C (neat): 30.70 mN/m | 18.644892.0003  18.644892.0008 | Acceptable. The product is surface active. Other products of meta SPC 2.21 are expected to be surface active due to their similar composition.  Only product 4 is not expected to be surface active since no surfactants are used. |
| Viscosity | No data generated | | | | Not acceptable. However, according to the composition, the viscosity is expected to be similar to water. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 2.21** |
| Products of meta SPC 2.21 are soluble concentrate formulations. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid, with different odours (various perfumes are used).  No accelerated storage stability study was provided. Products should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 1 of meta SPC 2.21. The stability of this product was not fully demonstrated after storage 10 months at 20°C in HDPE bottle and 8 months in PVC berlingots, since the active chlorine content decreases by more than 10% and the sodium chlorate content is higher than the maximum limit of 5.4% of the active chlorine content (please refer to human health, residues and environment sections regarding conclusion on chlorate content). Results can be extrapolated to other products of meta SPC 2.21 since compositions are similar. Efficacy data are available and allow to support a shelf life of 8 months even if degradation of active substance is higher than 10% of initial content. Consequently, a shelf life of 8 months can be granted for this meta SPC.  Products of meta SPC 2.21 are foaming products.  Products of meta SPC 2.21 form clear solution when diluted.  Compatibility of products with HDPE and PVC is acceptable with product 1 of meta SPC 2.21 and results can be extrapolated to the whole meta SPC 2.21.  **Implication concerning labelling for products of meta SPC2.21**:  Shelf life proposed by eCA: 8 months (shelf life claimed by the applicant: 8 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Foaming products  Products should not be used in conjunction with acids or ammonia.  EUH031 “contact with acids liberates toxic gas”  EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” |

**Meta SPC 2.22 (soluble concentrate formulation)**

Tested formulation : product 1 of meta SPC 2.22 (eau de javel 3.6% c.a parfum eucalyptus)

This product will cover the whole meta SPC. Please refer to read across in confidential annex.

Packaging claimed: HDPE bottle

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | eau de javel 3.6% c.a parfum eucalyptus Batch 181411 (product 1 of meta SPC 2.22) | Before storage: Liquid, no phase separation or precipitation  After storage 15 months at 25°C: Liquid, no phase separation or precipitation | 18.646835.0003  18.646835.0009 | Acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | eau de javel 3.6% c.a parfum eucalyptus Batch 181411 (product 1 of meta SPC 2.22) | Before storage: Transparent yellow  After storage 15 months at 25°C: transparent yellow | 18.646835.0003  18.646835.0009 | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | eau de javel 3.6% c.a parfum eucalyptus Batch 181411 (product 1 of meta SPC 2.22) | Before storage: characteristic odour of eucalyptus and hypochlorite  After storage 15 months at 25°C: characteristic odour of eucalyptus and hypochlorite | 18.646835.0003  18.646835.0009 | Acceptable. Different odours are expected for other products of this meta SPC since various perfumes are used. |
| Acidity / alkalinity | CIPAC MT 191 | eau de javel 3.6% c.a parfum eucalyptus Batch 181411 (product 1 of meta SPC 2.22)  eau de javel 3.6% c.a nature, batch 2001230015 (product 6 of meta SPC 2.22)  eau de javel 3.6% c.a parfum eucalyptus Batch 2QZ032022 and 191153 (product 1 of meta SPC 2.22) | Before storage: 1.68 As NaOH %w/w  After storage 12 months at 25°C: 1.06 as NaOH eq %w/w  After storage 15 months at 25°C: 1.03 as NaOH eq %w/w  Before storage: 1.55 as NaoH eq % w/w  pH at 20°C:  before storage: 12.30  after storage (>11 months): 12.30 | 18.646835.0003  18.646835.0009  20.503032.0002  CoA, 10/2020 | Acceptable. Alkalinity was provided for two representative products of this meta SPC.  pH provided for product 1 of meta SPC 2.22 covers the other products of this SPC, except for product 6 (simple TK solution without stabilizers). However extrapolation can be performed with product 1 of SPC 2.1 (no stabilizer and less content of a.i). |
| Relative density / bulk density | OECD109 | eau de javel 3.6% c.a parfum eucalyptus Batch 191153 (product 1 of meta SPC 2.22) | 1,0559g/mL at 20°C | RRCo-000336\_01 | Acceptable. Results can be extrapolated to other products of this meta SPC since they have a similar composition. |
| Storage stability test – **accelerated storage** | No testing required | | | | Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17,  ANA\_MON\_102 ANA\_MON\_103  Internal method for sodium chlorides  Validated methods in the study RRCo-000345\_01 | eau de javel 3.6% c.a parfum eucalyptus Batch 191153 (product 1 meta SPC 2.22) | GLP study :  Packaging tested: 250mL HDPE bottle  storage conditions: 20°C, in darkness  **Appearance**  Before storage: slightly yellow transparent liquid, typical eucalyptus bleach odour  After storage: slightly yellow transparent liquid, typical eucalyptus bleach odour  **Packaging**  Before storage: no crack, no swelling, no change of coulour  After storage: no crack, no swelling, no change of colour, no change in weight  **T0:**  Active chlorine: 3,55% w/w  Sodium chlorates: 0,10%w/w  Sodium chlorides: 3,38%w/w  Ratio sodium chlorate/av. Chlorine: 2.8%  **T6 months:**  Active chlorine: 3,25% w/w  **T11 months:**  Active chlorine: 3,14% w/w  Sodium chlorates: 0,22%w/w  Sodium chlorides: 3,65%w/w  Ratio sodium chlorate/av. Chlorine: 7% | RRCo-000336\_01 | Results up to 11 months are available. Active chlorine content decreases by more than 10% (-11.5%) and the ratio sodium chlorates/active chlorine exceeds 5.4%. Please refer to human health, residues and environment sections regarding conclusion on chlorate content.  Efficacy data are available and allow to grant a shelf life of 11 months even if degradation of active ingredient is higher than 10% of initial content.  The effect of perfumes has been previously discussed for meta SPC 2.21 and it has been demonstrated that products containing eucalyptus constitute the worst case. Consequently, the tested product is sufficiently representative for this meta SPC.  No justification was provided for products with mandarine orange and mint perfumes. However it has been demonstrated that the influence of perfumes on the degradation rate of active chlorine is quite similar on a short period (-11.5% to 13.7% after 8 months for eucalyptus, lavander and citrus). According to this observation and the compositions of the perfumes in confidential PAR, eCA is of the opinion that no significant differences are expected for the untested perfumes mandarin/orange and mint. |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report RRCo-000336\_01 (mid-term results) :  « No crack, no swellling, no change of colour after 11 months of storage. » | | | | Compatibility of product 1 from meta SPC 2.22 has been demonstrated with HDPE. Extrapolation is acceptable to other products of this meta SPC. |
| Wettability | No data generated |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  |  |  | Not relevant |
| Disintegration time | No data generated |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  |  |  | Not relevant |
| Persistent foaming | CIPAC MT 47.2 | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage  After dilution of 50 % v/v, foam produced is 300 ml after 10 sec, 1 min, 3 min and 12 min.  After storage 10 months at 20°C:  At 50% v/v  10 sec : 830ml  1 min : 810ml  3 min : 800ml  12 min : 780ml | 18.644892.0003  18.644892.0008 | This property was assessed using produt 1 of meta SPC 2.21. As this product contains the same ingredient than in products of meta SPC 2.22 but at higher level, this product is a worst case and results can be extrapolated to meta SPC 2.22.    50mL of product were diluted in 1L of water. Up to 1L of foam can be formed. The product is a foaming formulation.  No foam is expected for product 6 of this meta SPC since no surfactants are used. |
| Tests on products with 4,8%a.c. of meta-SPC 2.21 are considered relevant since they are considered worst case (higher surfactants concentrations).  See reports 18.644892.0003 (before shelf life) and 18.644892.0008 (after shelf life). | | | |
| Flowability/Pourability/Dustability | No data generated |  |  |  | Not relevant |
| Burning rate — smoke generators | No data generated |  |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated |  |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated |  |  |  | Not relevant |
| Spraying pattern — aerosols | No data generated |  |  |  | Not relevant |
| Physical compatibility | No data generated |  |  |  | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated |  |  |  | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mention EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” is proposed for this meta SPC.  Mention EUH031 is not applicable for this meta SPC since active substance content is below 5% w/w.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | CIPAC MT 41.1 | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage: at 50% v/v, no separated material was noticed.  After storage 10 months at 20°C: at 50% v/v, no separated material was noticed. | 18.644892.0003  18.644892.0008 | Acceptable. Results provided for product 1 of meta SPC 2.21 can be extrapolated to products of meta SPC 2.22. Even if a higher content of surfactants is expected to improve dissolution, no specific concern is expected for products of this meta SPC 2.2 as components are soluble substances. |
| Test on product 1 of meta-SPC 2.21 is considered relevant since it is considered worst case (higher surfactants, higer perfume concentrations and higher after dilution concentrations).  See reports 18.644892.0003 (before shelf life) and 18.644892.0008 (after shelf life), results were the same : “For the test item diluted at 50 % v/v in standard water C, no separated material was detected.” | | | |
| Surface tension | OECD Test Guideline 115 and EC method A.5 | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage (neat): 32.96 mN/m  After storage 10 months at 20°C (neat): 30.70 mN/m | 18.644892.0003  18.644892.0008 | Acceptable. Results provided for product 1 of meta SPC 2.21 and product 1 of meta SPC 2.1 can be considered for products of meta SPC 2.22. The same surfactant is used in these products and its content in meta SPC 2.22 is between the ones of the tested products. It can be assumed that products of meta SPC 2.22 will be surface active.    So this confirms that products of meta SPC 2.22 will be surface active.  Product 6 is not expected to be surface active since no surfactants are used. |
| OECD Test Guideline 115 and EC method A.5 | Eau de javel 2.6% c.a eucalyptus (Product 1 meta SPC 2.1) batch 2001230045 | At 36%v/v, the mean surface tension at a temperature of 20 ± 0.5°C was 31.72 mN/m | 20.503032.0006 |
| Tests on products with 4,8%a.c. of meta-SPC 2.21 are considered relevant since they are considered worst case (higher surfactants concentrations).  See reports 18.644892.0003 (before shelf life) and 18.644892.0008 (after shelf life). | | | |
| Viscosity | No data generated | | | | Not acceptable. However, according to the composition, the viscosity is expected to be similar to water. |

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| **Conclusion on the physical, chemical and technical properties of the meta SPC 2.22** |
| Products of meta SPC 2.22 are soluble concentrate formulations. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid, with different odours (various perfumes are used).  No accelerated storage stability study was provided. Products should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 1 of meta SPC 2.22. The stability of this product was not fully demonstrated after storage 11 months at 20°C, since the active chlorine content decreases by more than 10% (-11.5%) and the sodium chlorate content is higher than the maximum limit of 5.4% of the active chlorine content (please refer to human health, residues and environement sections regarding conclusion on chlorate content). Results can be extrapolated to other products of meta SPC 2.22 since compositions are similar. No justification was provided for products with mandarine orange and mint perfumes. However it has been demonstrated that the influence of perfumes on the degradation rate of active chlorine is quite similar on a short period (-11.5% to 13.7% after 8 months for eucalyptus, lavande and citrus). According to this observation and the compositions of the perfumes in confidential PAR, eCA is of the opinion that no significant differences are expected for the untested perfumes mandarin/orange and mint. Efficacy data are available and allow to support a shelf life of 11 months even if degradation of active substance is higher than 10% of initial content. Consequently, a shelf life of 11 months can be granted for this meta SPC.  Products of meta SPC 2.22 are foaming products.  Products of meta SPC 2.22 form clear solution when diluted.  Compatibility of products with HDPE is acceptable with product 1 of meta SPC 2.22 and results can be extrapolated to the whole meta SPC 2.22.  **Implication concerning labelling for products of meta SPC2.22**:  Shelf life proposed by eCA: 11 months (shelf life claimed by the applicant: 18 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Foaming products.  Products should not be used in conjunction with acids or ammonia.  EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” |

**Meta SPC 3 (ready to use gel)**

Tested product: Product 3 (gel javel 2.6% c.a parfum eucalyptus) from meta SPC 3. Results provided for this product can be extrapolated to the whole meta SPC 3. Please refer to confidential annex.

Packaging: HDPE bottle

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | gel javel 2.6% c.a parfum eucalyptus Batch 180809 (product 3 of meta SPC 3) | Before storage: liquid, without phase separation or precipitation  After storage 15 months at 25°C: liquid, without phase separation or precipitation | 18.644892.0001  18.644892.0005 | Acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | gel javel 2.6% c.a parfum eucalyptus Batch 180809 (product 3 of meta SPC 3) | Before storage: yellow liquid  After storage 15 months at 25°C: yellow liquid | 18.644892.0001  18.644892.0005 | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | gel javel 2.6% c.a parfum eucalyptus Batch 180809 (product 3 of meta SPC 3) | Before storage: characteristic odour of eucalyptus and hypochlorite  After storage 15 months at 25°C: characteristic odour of eucalyptus and hypochlorite | 18.644892.0001  18.644892.0005 | Acceptable. Different odours are expected for other products of this meta SPC since various perfumes are used. |
| Acidity / alkalinity | CIPAC MT 191 | gel javel 2.6% c.a parfum eucalyptus Batch 180809 (product 3 of meta SPC 3)  gel javel 2.6% c.a parfum eucalyptus Batch 2009290704 and 180809 (product 3 of meta SPC 3) | Average 1.71 as NaOHeq %w/w  After storage 15 months at 25°C: 0.98 as NaOHeq %w/w  pH at 20°C  before storage: 12.60  after storage (>11months): 12.60 | 18.644892.0001  18.644892.0005  CoA, 10/2020 | Acceptable. Results can be extrapolated to other products of meta SPC 3 since compositions are similar (above all for stabilizer). |
| Relative density / bulk density | OECD109 (pycnometer) | gel javel 2.6% c.a parfum eucalyptus  Batch 191419 (product 3 of meta SPC 3) | 1,0461 g/mL at 20°C | RRCo-000339\_01 | Acceptable. Results can be extrapolated to other products of this meta SPC due to similar compositions. |
| Storage stability test – **accelerated storage** | No testing required | | | | Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17,  ANA\_MON\_102, ANA\_MON\_103,  internal method for chloride  All methods are validated method in the study RRCo-000345\_01 | gel javel 2.6% c.a parfum eucalyptus  Batch 191419 (product 3 meta SPC 3) | GLP study :  Packaging tested: HDPE bottle of 250mL  Storage conditions: in darkness at 20°C for 24 months  packaging  No deterioration of the packaging after 11 months storage. No crack, no sweeling, no change of colour  Appearance before and after 11 months: slightly yellow transparent viscous liquid, typical eucalyptus bleach odour  **T0:**  Active chlorine: 2,56% w/w  Sodium chlorates: 0,07%w/w  Sodium chlorides: 2,5%w/w  Ratio sodium chlorate/active chlorine: 2.7%  **T6 months:**  Active chlorine: 2,12% w/w  **T11 months:**  Active chlorine: 2,16% w/w  Sodium chlorates: 0,11%w/w  Sodium chlorides: 2,91%w/w  Ratio sodium chlorate/active chlorine: 5.09% | RRCo-000339\_01 | A 2 year shelf life study is ongoing and will be finished on April 2021. Only results up to 11 months are available.  According to the data provided, a shelf life of 11 months can be granted. If the applicant claims a longer shelf life, a dossier for minor change should be submitted.  Active chlorine content decreases by more than 10% (-15.6%). However, the ratio sodium chlorates/active chlorine remains below 5.4%.  Efficacy data allow to support a shelf life of 11 months even if degradation of active substance exceeds 10% of initial content.  The effect of perfumes has been previously discussed for meta SPC 2.21 and it has been demonstrated that products containing eucalyptus constitute the worst case. Consequently, the tested product is sufficiently representative for this meta SPC.  As products are ready to use, no specific property needs to be investigated during storage. |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | Acceptable. Products of this method SPC should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report RRCo-000339\_01 (mid term) :  « No crack, no swellling, no change of colour after 11 months of storage. » | | | | Acceptable. Product 3 of meta SPC 3 is compatible with HDPE bottle. Results can be extrapolated to other products of this meta SPC due to similar compositions. |
| Wettability | No data generated |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  |  |  | Not relevant |
| Disintegration time | No data generated |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  |  |  | Not relevant |
| Persistent foaming | RTO product, test considered not relevant | | | | Not relevant since products are ready to use. |
| Flowability/Pourability/Dustability | No data generated |  |  |  | Not relevant |
| Burning rate — smoke generators | No data generated |  |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated |  |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated |  |  |  | Not relevant |
| Spraying pattern — aerosols | No data generated |  |  |  | Not relevant |
| Physical compatibility | No data generated |  |  |  | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated |  |  |  | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mention EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” is proposed for this meta SPC.  Mention EUH031 is not applicable for this meta SPC since active substance content is below 5% w/w.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | RTO product, test considered not relevant | | | | Not relevant since products are ready to use. |
| Surface tension | Not performed because OECD115/A.5 ring method is applicable only to solutions having dynamic viscosity lower than 200 mPa, the product has a higher dynamic viscosity. | | | | Acceptable. The recommended method is not suitable for this method SPC. However, based on the compositions, the content of surfactants is significant and it can be assumed that products of this meta SPC will be surface active (i.e surface tension below 60mN/m). |
| Viscosity | OECD Test Guideline No.114 | gel javel 2.6% c.a parfum eucalyptus Batch 180809 (product 3 of meta SPC 3) | Before storage  1786 mm2\*s-1 at 20.0 ± 0.1°C (flow time: 1811s)  165 mm2\*s-1 at 40.0 ± 0.1°C (flow time: 167s)  After 12 months:  20 °C: 1666 mm2/sec (flow time 1690s)  40°C: 176 mm2/sec (flow time 178s) | 18.644892.0001  18.644892.0005 | Acceptable. Results can be extrapolated to other products of this meta SPC due to similar compositions. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 3** |
| Products of meta SPC 3 are ready to use gel formulation. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow viscous liquid, with different odours (various perfumes are used).  No accelerated storage stability study was provided. Products should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 3 of meta SPC 3. The stability of this product was not fully demonstrated after storage 11 months at 20°C, since the active chlorine content decreases by more than 10% (-15.6%). However, the sodium chlorate content remains below than the maximum limit of 5.4% of the active chlorine content. Results can be extrapolated to other products of meta SPC 3 since compositions are similar.Efficacy data allow to support a shelf life of 11 months.  No technical properties are needed since these products are ready to use.  Compatibility of products with HDPE is acceptable with product 3 of meta SPC 3 and results can be extrapolated to the whole meta SPC 3.  **Implication concerning labelling for products of meta SPC3**:  Shelf life proposed by eCA: 11 months (shelf life claimed by the applicant: 24 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Products should not be used in conjunction with acids or ammonia.  EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” |

**Meta SPC 4 (ready to use gel)**

Tested formulation: Product 3 (gel javel 2.6% c.a parfum eucalyptus) from meta SPC 3. Results for this product can be extrapolated to the whole meta SPC 4. Please refer to confidential annex.

Packaging: HDPE bottle.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | 1,5% (product 1 and 2 of meta SPC 4) | Liquid | SDS | Acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | 1,5% (product 1 and 2 of meta SPC 4) | Transparent green | SDS | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | 1,5% (product 1 and 2 of meta SPC 4) | Bleach with eucalyptus | SDS | Acceptable. Different odours are expected for other products of this meta SPC since various perfumes are used. |
| Acidity / alkalinity | CIPAC MT 191 | gel javel 2.6% c.a parfum eucalyptus Batch 180809 (product 3 of meta SPC 3)  gel javel 2.6% c.a parfum eucalyptus Batch 2009290704 (product 3 of meta SPC 3) | Average 1.71 as NaOHeq %w/w  After storage 15 months at 25°C: 0.98 as NaOHeq %w/w  pH at 20°C: 12.60 | 18.644892.0001  18.644892.0005  CoA, 10/2020 | Cross reading is acceptable for products of meta SPC 4 due to similar composition with product 3 of meta SPC 3. |
| Relative density / bulk density | OECD109 (pycnometer) | gel javel 2.6% c.a parfum eucalyptus  Batch 191419 (product 3 of meta SPC 3) | 1,0461 g/mL at 20°C | RRCo-000339\_01 | Acceptable. Results can be extrapolated to meta SPC 4 due to similar compositions. |
| Internal  method | 1,5% (product 1 and 2 of meta SPC 4) | 1,03 | SDS | Acceptable |
| Storage stability test – **accelerated storage** | Not required | | | | Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | Products in this meta-SPC have similar composition but with lower AS concentration than in meta-SPC3, therefore they are covered by the tests conducted on products of meta-SPC3. It is expected that the % of AS decay over time will be equal or lower than product of meta-SPC3. Shelf life will be based on results of products of meta-SPC3. | | | | Cross reading with product 3 of meta SPC 3 is acceptable since compositions are similar and the content of active chlorine is higher in the tested product.  Active chlorine content decreases by more than 10% (-15.6%) for product 3 of meta SPC 3. However, the ratio sodium chlorates/active chlorine remains below 5.4% for products of Meta SPC 3.  Efficacy data do not support a shelf life of 11 months for meta SPC 4 (this is due to a lower content of active chlorine when compared to meta SPC 3). However, degradation rate observed for tested product of Meta SPC 3 can be used to predict av. Cl content in product of meta SPC 4 after 11 months. Indeed, the only difference among products of Meta SPC 3 and 4 is related to the content of active substance that is lower in Meta SPC 4. Tested product from Meta SPC 3 is a worst case as the content is higher, meaning that the degradation rate will be faster. Based on this consideration and taking into account a worst case degradation rate of -15.6% after 11 months for tested product of Meta SPC 3, av Cl content after 11 months in products of Meta SPC 4 can be estimated as follow: 1.5% av. Cl x (100% – 15.6%) = 1.266% av. Cl. This content is still higher than the minimum efficacy dose (1.1% for these RTU products, see efficacy section). Consequently, a shelf life of 11 months can be granted for products of Meta SPC 4.  Sodium chlorate content is not known. A worst case approach is to considered the sodium chlorate content measured after 11M in tested product of Meta SPC3 (0,11% w/w) and the predicted content of available chlorine after 11M in products of Meta SPC4 (1.266% w/w). The ratio is higher than 5.4% w/w. Please refer to human health, residues and environment sections regarding conclusion on chlorate content.  As products are ready to use, no specific property needs to be investigated during storage.  Only eucalyptus fragrance is used for this meta SPC and the tested product already contains this perfume. No further data on the effect of perfumes is required for this meta SPC. |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Products in this meta-SPC have identical formulation but with lower AS concentration than in meta-SPC3, therefore they are covered by the tests conducted on products of meta-SPC3. Shelf life will be based on results of products of meta-SPC3. | | | | Compatibility with HDPE has been demonstrated for product 3 of meta SPC 3. Extrapolation is acceptable for products of meta SPC 4 due to similar compositions. |
| Wettability | No data generated |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  |  |  | Not relevant |
| Disintegration time | No data generated |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  |  |  | Not relevant |
| Persistent foaming | RTO product, test considered not relevant | | | | Not relevant as products are ready to use. |
| Flowability/Pourability/Dustability | No data generated |  |  |  | Not relevant |
| Burning rate — smoke generators | No data generated |  |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated |  |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated |  |  |  | Not relevant |
| Spraying pattern — aerosols | No data generated |  |  |  | Not relevant |
| Physical compatibility | No data generated |  |  |  | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated |  |  |  | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mention EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” is proposed for this meta SPC.  Mention EUH031 is not applicable for this meta SPC since active substance content is below 5% w/w.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | RTO product, test considered not relevant | | | | Not relevant as products are ready to use. |
| Surface tension | Not performed because OECD115/A.5 ring method is applicable only to solutions having dynamic viscosity lower than 200 mPa, the product has an higher dynamic viscosity. | | | | Acceptable. The recommended method is not suitable for this method SPC. However, based on the compositions, the content of surfactants is significant and it can be assumed that products of this meta SPC will be surface active (i.e surface tension below 60mN/m). |
| Viscosity | See results of meta-SPC3 as products have identical surfactants (viscosity modifier) concentrations. Therefore, viscosity is expected to be the same. | | | | Cross reading is acceptable. See SPC 3 |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 4** |
| Products of meta SPC 4 are ready to use gel formulation. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow viscous liquid, with different odours (eucalyptus or bleauc odour).  No accelerated storage stability study was provided. Products should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 3 of meta SPC 3. The stability of this product was not fully demonstrated after storage 11 months at 20°C, since the active chlorine content decreases by more than 10% (-15.6%). However, the sodium chlorate content remains lower than the maximum limit of 5.4% of the active chlorine content for Meta SPC 3. Results can be extrapolated to products of meta SPC 4 since compositions are similar.Only eucalyptus fragrance is used for this meta SPC and the tested product already contains this perfume.  Efficacy data of Meta SPC 3 do not allow to support the efficacy of aged products of Meta SPC 4 as the av. Cl content is lower than in products of Meta SPC 3. Indeed, it cannot be concluded if the content of av. Cl in products of Meta SPC 4 is still higher than the minimum efficacy dose. However, degradation rate observed after 11 months for tested products of Meta SPC 3 can be applied to Meta SPC 4 as this approach can be considered as a worst case (av. Cl content is higher in Meta SPC 3 and degradation rate of av. Cl is faster when the content increases). An estimation of av. Cl content in products of Meta SPC 4 after 11 months can be predicted and the content found (1.266% av. Cl) remains above the minimum efficacy dose (1.1% av. Cl). Consequently a shelf life of 11 months can be granted for products of Meta SPC 4.  Sodium chlorate content is not known after 11 months in products of Meta SPC 4. A worst case approach is to consider the sodium chlorate content measured after 11 months in tested product of Meta SPC3 (0,11% w/w) and the predicted content of available chlorine after 11 months in products of Meta SPC4 (1.266% w/w). The ratio is higher than 5.4% w/w. Please refer to human health, residues and environment sections regarding conclusion on chlorate content  No technical properties are needed since these products are ready to use.  Compatibility of products with HDPE is acceptable with product 3 of meta SPC 3 and results can be extrapolated to the whole meta SPC 4.  **Implication concerning labelling for products of meta SPC4**:  Shelf life proposed by eCA: 11 months (shelf life claimed by the applicant: 24 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Products should not be used in conjunction with acids or ammonia.  EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” |

**Meta SPC 5 (ready to use – spray)**

Test formulation: product 1 (Spray javel 1.5% c.a parfum eucalyptus) from meta SPC 5

As this meta SPC contains only one product, no read across is needed.

Packaging: HDPE bottle (ready to use spray)

| **Property** | **Guideline and Method** | | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | | Spray javel 1.5% c.a parfum eucalyptus  Batch 181530 (product 1 of meta SPC 5) | Liquid, no phase separation or precipitation | 18.646835.0005 | Acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | | Spray javel 1.5% c.a parfum eucalyptus  Batch 181530 (product 1 of meta SPC 5) | Transparent yellow | 18.646835.0005 | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | | Spray javel 1.5% c.a parfum eucalyptus  Batch 181530 (product 1 of meta SPC 5) | Hypochlorite + eucalyptus | 18.646835.0005 | Acceptable |
| Acidity / alkalinity | CIPAC MT 191 | | Spray javel 1.5% c.a parfum eucalyptus  Batch 181530 (product 1 of meta SPC 5)  Spray javel 1.5% c.a parfum eucalyptus  Batch 2010010604 and 181530 (product 1 of meta SPC 5) | 1.21 As NaOHeq %w/w  pH at 20°C:  before storage: 12.80  after storage (>11 months): 12.80 | 18.646835.0005  CoA, 10/2020 | Acceptable |
| Relative density / bulk density | OECD109 (pycnometer method) | | Spray javel 1.5% c.a parfum eucalyptus  Batch 190411 (product 1 of meta SPC 5) | 1,0282 g/mL at 20°C | RRCo-000340\_01 | Acceptable |
| Storage stability test – **accelerated storage** | No test required | | | | | Product should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17,  ANA\_MON\_102ANA\_MON\_103internal method for sodium chlorides  Validated methods in the study RRCo-000345\_01 | | Spray javel 1.5% c.a parfum eucalyptus  Batch 190411 (product 1 of meta SPC 5) | GLP study :  Packaging tested: HDPE bottle of 250mL with PP/PE trigger spray TS5 S  Storage conditions: 24 months at 20°C, in darkness (only results up to 11 months are available)  **Appearance**  Before storage: slightly yellow transparent liquid, typical eucalyptus bleach odour  After storage: slightly yellow transparent liquid, typical eucalyptus bleach odour  **Packaging**  Before storage: no crack, no swelling, no change of colour  After storage: no crack, no swelling, no change of colour, no significant change in weight  **T0:**  Active chlorine: 1,55% w/w  Sodium chlorates: 0,04%w/w  Sodium chlorides: 1,46%w/w  Ratio sodium chlorates/active chlorine: 2.58% w/w  **T6 months:**  Active chlorine: 1,36% w/w  **T11 months:**  Active chlorine: 1,28% w/w  Sodium chlorates: 0,05%w/w  Sodium chlorides: 1,77%w/w  Ratio sodium chlorates/active chlorine: 3.9% w/w | RRCo-000340\_01 | Only intermediate results up to 11 months were provided. If the applicant claims a longer shelf life, final results should be provided during a minor change application.  Ratio of sodium chlorate/active chlorine remains below 5.4% w/w. Active chlorine content decreases by more than 10% (-17.4%)**.**  Efficacy data are available and allow to support a shelf life of 11 months even if degradation of active substance is higher than 10% of initial content |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | | Acceptable. Product should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | | Acceptable. Product should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | | Acceptable. Product should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report RRCo-000340\_01 (mid-term) ;  « No crack, no swelling, no change of colour.” | | | | | Acceptable. The product is compatible with HDPE packaging. |
| Wettability | No data generated | |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated | |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated | |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated | |  |  |  | Not relevant |
| Disintegration time | No data generated | |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated | |  |  |  | Not relevant |
| Persistent foaming | RTO product, test considered not relevant | | | | | Not relevant as product is ready to use. |
| Flowability/Pourability/Dustability | No data generated | |  |  |  | Not relevant |
| Burning rate — smoke generators | No data generated | |  |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated | |  |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated | |  |  |  | Not relevant |
| Spraying pattern — aerosols | Internal method  CIPAC MT 187  FEA 643 | | Spray javel 1.5% c.a parfum eucalyptus  Batch 181530 (product 1 of meta SPC 5)  Spray javel 1.5% c.a parfum eucalyptus  Batch 2001230055 (product 1 of meta SPC 5)  Spray javel 1.5% c.a parfum eucalyptus  Batch 2001230055 (product 1 of meta SPC 5) | PP/PE Trigger TS5 S  Before storage  Amount of spray delivered (mean on 10 squeezes): 1.42g  Observation of nozzle after test: absence of residues and fouling  Spray diameter (mean on 6 squeezes at 30cm from the adsorbent paper): 10cm  Before storage  Amount of spray delivered (mean on 10 squeezes): 1.36g  Observation of nozzle after test: absence of residues and fouling  Spray diameter (mean on 6 squeezes at 30cm from the adsorbent paper): 10cm  MMAD was determined to be 480µm, 10% of particles were smaller than 200µm, 50% were smaller than 480 µm and 90% were smaller than 784 µm.  Discharge rate:  1.38g/stroke (mean on 3 samples with 10 tests per sample) | 18.646835.0005  20.503032.0008  20.503032.0008 | Data are acceptable before storage.  **Results after storage are available in report 18.646835.0011. According to the applicant, the draft report does not contain results after 15 months. Only results after 24 months will be available. The applicant should provide such data in post registration.** |
| Physical compatibility | No data generated | |  |  |  | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated | |  |  |  | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mention EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” is proposed for this meta SPC.  Mention EUH031 is not applicable for this meta SPC since active substance content is below 5% w/w.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | RTO product, test considered not relevant | | | | | Not relevant as product is ready to use. |
| Surface tension | OECD115 and EC method A.5 | Spray javel 1.5% c.a parfum eucalyptus  Batch 181530 (product 1 of meta SPC 5) | | Neat: 32.53 mN/m at 20°C | 18.646835.0005 | Acceptable. The product is surface active. |
| Viscosity | No data generated | | | | | Not acceptable. However, according to the composition, the viscosity is expected to be similar to water. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 5** |
| Product of meta SPC 5 are ready to use soluble concentrate spray formulation. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow viscous liquid, with eucalyptus odour.  No accelerated storage stability study was provided. Product should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 1 of meta SPC 5 (only one product for this meta SPC). The stability of this product was not fully demonstrated after storage 11 months at 20°C, since the active chlorine content decreases by more than 10% (-17.4%). However, the sodium chlorate content remains below than the maximum limit of 5.4% of the active chlorine content.Efficacy data are available and allow to support a shelf life of 11 months even if degradation of active substance is higher than 10% of initial content  Technical properties (size distribution of particles, MMAD, discharge rate, clogging, spray pattern) were provided for this meta SPC. However spraying pattern — aerosols data are missing after storage and they should be provided in post registration.  Compatibility of products with HDPE is acceptable with product 1 of meta SPC 5.  **Implication concerning labelling for products of meta SPC5**:  Shelf life proposed by eCA: 11 months (shelf life claimed by the applicant: 24 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Products should not be used in conjunction with acids or ammonia.  EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” |

**Meta SPC 6.1 and 6.21 (soluble concentrate)**

Only one product with the same composition is claimed in these two meta SPC.

Tested formulation: physico chemical properties have been performed with product 1 from meta SPC 9. This product will cover meta SPC 6.1 and 6.21. Please refer to the read across in confidential annex.

Packaging: HDPE bottle and PVC sachet/berlingot

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | 9,6% (product 1 of meta SPC 6.1/6.21) | Liquid | SDS | Acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | 9,6% (product 1 of meta SPC 6.1/6.21) | Transparent yellow | SDS | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | 9,6% (product 1 of meta SPC 6.1/6.21) | Bleach | SDS | Acceptable |
| Acidity / alkalinity | CIPAC MT191 | Eau de Javel 9.6% c.a parfum eucalyptus (product 1 meta SPC 9), batch 180817  Eau de javel 9.6% c.a nature batch 2001230030  Product 1 meta SPC 6.1/6.21  Eau de Javel 9.6% c.a parfum eucalyptus (product 1 meta SPC 9), batch 2010201416 | 3,98% w/w NaOH eq  pH>11.5 (SDS)  4% w/w NaOH eq  pH at 20°C: 12.20 | 18.644892.0002  SDS  20.503032.0004  CoA, 10/2020 | Acceptable |
| Relative density / bulk density | OECD 109 | Eau de Javel à 9.6% c.a parfumée eucalyptus  Batch 190402 (product 1 of meta SPC 9) | 1,1542g/mL at 20°C  1.1498g/ml after 10 months at 20°C | RRCo-000338\_01 | Acceptable. |
| Storage stability test – **accelerated storage** | This product is mainly covered by the stability tests of products of meta-SPC9 (AS loss over time, sodium chlorates and chlorites concentrations). Products in meta-SPC9 are considered worst case because they contain surfactants and perfume, which is known to increase AS content decaying over time. Also, as seen in report 20.503032.0004, pH of the product was higher than 11,5, alcalinity is similar to the alcalinity of the product used for cross-reading (from meta-SPC 9). | | | | Product should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17  ANA MON 102  ANA MON 103  Internal method for sodium chlorides  Validated method in the study RRCo-000345\_01 | Eau de Javel à 9.6% c.a parfumée eucalyptus  Batch 190402 (product 1 of meta SPC 9) | See results of product for meta SPC 9 | RRCo-000338\_01 | Results from product 1 of meta SPC 9 can be used for product 1 of meta SPC 6.1/6.21 due to similar compositions. Please refer to confidential annex for details.  Final report of the shelf life study is available for product 1 of meta SPC 9 (10 months at 20°C).  The product is compatible with HDPE packaging.  However the content of active chlorine decreases by more than 10% (-40%) and the ratio sodium chlorate/active chlorine exceeds 5.4% w/w. Please refer to human health, residues and environement sections regarding conclusion on chlorate content.  Efficacy data are available and allow to support a shelf life of 6 months even if degradation of active substance is higher than 10% of initial content  Please refer to meta SPC 9 for details on the results.  **PVC berlingot are claimed for meta SPC 6.21 (but not for meta SPC 6.1). A storage stability study with PVC is missing. Consequently, this packaging cannot be authorized for Meta SPC 6.21.** |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | Acceptable. Product of this meta SPC should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | Acceptable. Product of this meta SPC should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | Acceptable. Product of this meta SPC should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report RRCo-000338\_01, 18.644892.0002 and 18.644892.0007.  The determination of colour, physical state and odour was performed on 26th August 2019. The test item was a transparent yellow liquid without phase separation or precipitation events, with a characteristic odour of eucalyptus and hypochlorite. | | | | Compatibility has been demonstrated with product 1 of meta SPC 9 and results can be extrapolated to meta SPC 6.1/6.21.  **Extrapolation from HDPE bottle to PVC sachet is not possible. A storage stability study with PVC is missing. This packaging cannot be authorized yet for meta SPC 6.21.** |
| Wettability | No data generated |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  |  |  | Not relevant |
| Disintegration time | No data generated |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  |  |  | Not relevant |
| Persistent foaming | No data generated | | | | No foam is expeted for product 1 of meta SPC 6.1/6.21 since no surfactants are used. |
| Flowability/Pourability/Dustability | No data generated |  |  |  | Not relevant |
| Burning rate — smoke generators | No data generated |  |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated |  |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated |  |  |  | Not relevant |
| Spraying pattern — aerosols | No data generated |  |  |  | Not relevant |
| Physical compatibility | See “reactivity towards container material” assessed on reports RRCo-000338\_01, 18.644892.0002 and 18.644892.0007. | | | | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | See “reactivity towards container material” assessed on reports RRCo-000338\_01, 18.644892.0002 and 18.644892.0007. | | | | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mentions EUH031 “contact with acids liberates toxic gas” for both Meta SPC and EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” for Meta SPC 6.1 are proposed.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | CIPAC 41 MT | Eau de Javel 9.6% c.a parfum eucalyptus (product 1 meta SPC 9), batch 180817  9,55% | Before shelf life:  After dilution of the test item in water at 75 % v/v at t10, no separated material was detected.  After shelf life:  After dilution of the test item in water at 75 % v/v at t10, no separated material was detected. | Before storage:  18.644892.0002  After storage:  18.644892.0007 | See meta SPC 9 (and also 6.22 which is similar to meta SPC 6.1/6.21). Results are acceptable and can be extrapolated to meta SPC 6.1/6.21. |
| Surface tension | No data generated | | | | Product 1 of meta SPC 6.1/6.21 is not expected to be surface active since no surfactants are used. |
| Viscosity | No data generated | | | | Not acceptable. However, the viscosity of product 1 of meta SPC 6.1/6.21 is expected to be similar to the one of water according to its composition. No further data are required. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 6.1/6.21** |
| Product of meta SPC 6.1/6.21 is a soluble concentrate formulation. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid, with bleach odour.  No accelerated storage stability study was provided. Product should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 1 of meta SPC 9. The stability of this product was not fully demonstrated after storage 10 months at 20°C, since the active chlorine content decreases by more than 10% (-40%) and the sodium chlorate content is higher than the maximum limit of 5.4% of the active chlorine content (please refer to human health, residues and environement sections regarding conclusion on chlorate content). Results can be extrapolated to product 1 of meta SPC 6.1/6.21 since compositions are similar. Efficacy data are available and allow to support a shelf life of 6 months even if degradation of active substance is higher than 10% of initial content.  Product 1 of meta SPC 6.1/6.21 is not a foaming product.  Product 1 of meta SPC 6.1/6.21 forms a clear solution when diluted.  Compatibility of products with HDPE is acceptable with product 1 of meta SPC 9 and results can be extrapolated to meta SPC 6.1/6.21.PVC berlingot is claimed for Meta SPC 6.21. However, compatibility study is missing. This packaging cannot be authorized and the applicant should submit a dossier for minor change including a stability study with PVC berlingot.  **Implication concerning labelling for products of meta SPC6.1/6.21**:  Shelf life proposed by eCA: 6 months (shelf life claimed by the applicant: 6 months for both meta SPC)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  EUH031 “contact with acids liberates toxic gas”  Products should not be used in conjunction with acids or ammonia.  **Additional labelling mention for products of meta SPC 6.1 (due to non professional use)**  EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” |

**Meta SPC 6.22 (soluble concentrate)**

Tested formulation: physico chemical properties have been performed with product 1 of meta SPC 6.22. This product will cover the whole meta SPC. Please refer to the read across in confidential annex.

Packaging: HDPE bottle

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | Eau de javel 12,5%  13,5% c.a batch 180101  (product 1 of meta SPC 6.22) | | Liquid | 18.649820.0001 and SDS | Acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | Eau de javel 12,5%  13,5% c.a batch 180101  (product 1 of meta SPC 6.22) | | Transp. yellow | 18.649820.0001 and SDS | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | Eau de javel 12,5%  13,5% c.a batch 180101  (product 1 of meta SPC 6.22) | | Bleach water | 18.649820.0001 and SDS | Acceptable |
| Acidity / alkalinity | CIPAC MT191 | Eau de javel 12.5% c.a batch 180101 (product 1 of meta SPC 6.22)  Eau de javel 12.5% c.a batch 2010121575 and 2006081407(product 1 of meta SPC 6.22) | | 5,13% NaOH %w/w  pH at 20°C:  before storage: 12.10  after storage (>5 months): 12.20 | 18.649820.0001  CoA, 10/2020 | Acceptable. |
| Relative density / bulk density | OECD109 (pycnometer method) | eau de javel 12.5% c.a batch 191531 (product 1 meta SPC 6.22) | | Before storage: 1,2261g/mL at 20°C  After 5 months: 1.2201 g/mL at 20°C | RRCo-000337\_01+ Amdt n#1 | Acceptable. Results can be extrapolated to the whole meta SPC. |
| Storage stability test – **accelerated storage** | Tests not required | | | | | Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17  ANA MON 102 ANA MON 103 internal method for sodium chlorides  validated methods in the study RRCo-000345\_01 | eau de javel 12.5% c.a batch 191531 (product 1 meta SPC 6.22) | | GLP study:  Packaging tested: HDPE bottle 250mL  Storage conditions: 5 months at 20°C  **Appearance**  Before storage: yellow transparent liquid, typical odour of bleach  After storage 5 months at 20°C: yellow transparent liquid, typical odour of bleach  **Packaging**  Before storage: no crack, no swelling, no change of colour  After storage 5 months at 20°C: no crack, no swelling, no change of colour, no significant change in weight  **T0:**  Active chlorine: 12,59% w/w  Sodium chlorates: 1,01% w/w  Sodium chlorides: 13,92% w/w  Ratio sodium chlorate/active chlorine: 8%  **T2 months:**  Active chlorine: 9,70% w/w  Sodium chlorates: 2,35% w/w  Sodium chlorides: 15,00% w/w  Ratio sodium chlorate/active chlorine: 24.2%  **T3 months:**  Active chlorine: 7,48% w/w  **T4 months:**  Sodium chlorides: 7,68% w/w  **T5 months:**  Active chlorine: 7,32% w/w  Sodium chlorates: 3,66% w/w  Sodium chlorides: 16,72% w/w  Ratio sodium chlorate/active chlorine: 50% | RRCo-000337\_01+ Amdt n#1 | Active substance content decreased by more than 10% after 5 months (-41.9%) and the ratio sodium chlorates/active chlorine exceeds 5.4%. Please refer to human health, residues and environment sections regarding conclusion on chlorate content.  Product at 12.5% does not contain the maximum NaOCl content for this Meta SPC. However the maximum content is 13.5%. eCa considers that 1% difference is not significant on stability.  Efficacy data only allow to support a shelf life of 3 months for the product at 12.5% active chlorine.  Product at 13.5% NaOCl is not covered because doses are different than the ones claimed for the product at 12.5%. eCA has checked if sufficient NaOCl content remains in the dilution of an aged product at 13.5% (using stability results for a product at 12.5% that is a worst case for efficacy). However it does not cover the minimum efficacy dose (in opposition with a dilution of an aged product at 12.5%). Please refer to efficacy section for details on calculation.  Therefore this meta SPC is limited to a maximum content of 12.5% active chlorine and a shelf life of 3 months. |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | | Acceptable. Products of this meta SPC should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | | Acceptable. Products of this meta SPC should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | | Acceptable. Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Internal method | | Eau de javel 12.5% CA batch 1909101549 (produt 1 of meta SPC 6.22) | After 3 months storage : PEHD white tank with blue plastic cap containing 5000ml of product ; no sign of deformation, leak or discolouration were observed.  After 5 months storage : PEHD white tank with blue plastic cap containing 5000ml of product ; no sign of deformation, leak or discolouration were observed. | 19.530379.0001 | Acceptable. Compatibility with HDPE has been demonstrated. |
| Wettability | No data generated |  | |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  | |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  | |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  | |  |  | Not relevant |
| Disintegration time | No data generated |  | |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  | |  |  | Not relevant |
| Persistent foaming | No data generated | | | | | This meta SPC does not contain surfactants. Based on the composition, no foam is expected. |
| Flowability/Pourability/Dustability | No data generated |  | |  |  | Not relevant |
| Burning rate — smoke generators | No data generated |  | |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated |  | |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated |  | |  |  | Not relevant |
| Spraying pattern — aerosols | No data generated |  | |  |  | Not relevant |
| Physical compatibility | Reactivity towards container material assessed on products of meta-SPC6.2 (higher concentration). | | | | | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | Reactivity towards container material assessed on products of meta-SPC6.2 (higher concentration). | | | | | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mention EUH031 “contact with acids liberates toxic gas” is proposed for this meta SPC.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | CIPAC MT41 | | Eau de javel 12.5% c.a batch 180101 and 1810151519 (product 1 of meta SPC 6.22) | At 8.5%v/v, no separated material was detected after 24 hours. | T0 :  18.649820.0001 | Acceptable. Results after storage were not submitted. However, no critical concern are excepted regarging dilution stability. |
| Surface tension | No data generated | | | | | Products are not expected to be surface active since no surfactants are used in this meta SPC. |
| Viscosity | No data generated | | | | | Not acceptable. However, viscosity is expected to be similar to water due to the compositions of products from this meta SPC. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 6.22** |
| Products of meta SPC 6.22 are soluble concentrate formulations. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid, with bleach odour.  No accelerated storage stability study was provided. Products should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 1 of meta SPC 6.22. The stability of this product was not fully demonstrated after storage 5 months at 20°C, since the active chlorine content decreases by more than 10% (-41.9%) and the sodium chlorate content is higher than the maximum limit of 5.4% of the active chlorine content (please refer to human health, residues and environement section regarding conclusion on chlorate content). Results can be extrapolated to the whole meta SPC 6.22 since compositions are similar.Efficacy data only allow to support a shelf life of 3 months for the product at 12.5% active chlorine. Therefore this meta SPC is limited to a maximum content of 12.5% active chlorine and a shelf life of 3 months.  Product at 13.5% NaOCl is not covered because doses are different than the ones claimed for the product at 12.5%. eCA has checked if sufficient NaOCl content remains in the dilution of an aged product at 13.5% (using stability results for a product at 12.5% that is a worst case for efficacy). However it does not cover the minimum efficacy dose (in opposition with a dilution of an aged product at 12.5%). Please refer to efficacy section for details on calculation.  Products of meta SPC 6.22 are not a foaming product.  Products of meta SPC 6.22 form clear solutions when diluted.  Compatibility of products with HDPE is acceptable with product 1 of meta SPC 6.22 and results can be extrapolated to other products of meta SPC 6.22.  **Implication concerning labelling for products of meta SPC6.22**:  Shelf life proposed by eCA: 3 months with a maximum content of active chlorine of 12.5% for this meta SPC (shelf life claimed by the applicant: 3 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  EUH031 “contact with acids liberates toxic gas”  Products should not be used in conjunction with acids or ammonia. |

**Meta SPC 7.11 (soluble concentrate)**

Tested formulation : product 1 of meta SPC 2.22. This product will cover meta SPC 7.11. Please refer to read across in confidential annex.

Packaging: HDPE bottle

| **Property** | **Guideline and Method** | | **Purity of the test substance (% (w/w)** | **Results** | | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | | Eau de Javel 3.6% parfum eucalyptus  Batch 181411 (product 1 of meta SPC 2.22) | Liquid | | 18.646835.0003 | Acceptable. |
| Colour at 20 °C and 101.3 kPa | Internal method | | Eau de Javel 3.6% parfum eucalyptus  Batch 181411 (product 1 of meta SPC 2.22) | Transparent yellow | | 18.646835.0003 | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | | Eau de Javel 3.6% parfum eucalyptus  Batch 181411 (product 1 of meta SPC 2.22) | Hypochlorite + eucalyptus | | 18.646835.0003 | Acceptable. Product of meta SPC 7.11 is expected to have a bleach odour since no perfumes are added. |
| Acidity / alkalinity | CIPAC MT 191 | eau de javel 3.6% c.a parfum eucalyptus Batch 181411 (product 1 of meta SPC 2.22)  eau de javel 3.6% c.a nature, batch 2001230015 (product 6 of meta SPC 2.22)  Eau de javel à 2.6% ca parfumee eucalyptus, batch 2010171707 (product1 of meta SPC 2.1) | | | Before storage: 1.68 As NaOH %w/w  After storage 12 months at 25°C: 1.06 as NaOH eq %w/w  After storage 15 months at 25°C: 1.03 as NaOH eq %w/w  Before storage: 1.55 as NaoH eq % w/w  pH at 20°C: 12.10 | 18.646835.0003  18.646835.0009  20.503032.0002  CoA, 10/2020 | Acceptable. Results can be extrapolated to product 1 of meta SPC 7.11. pH may not be covered by SPC 2.22 due to the presence of stabilizer in the tested product of meta SPC 2.22. However pH provided for product 1 of SPC 2.1 (no stabilizer and similar content of a.i) can be used for read across. |
| Relative density / bulk density | OCDE109 | | Eau de Javel 3.6% parfum eucalyptus  Batch 191153  (product 1 of meta SPC 2.22) | 1,0559g/mL at 20°C | | RRCo-000336\_01 | Acceptable. Density is expected to be similar for product of meta SPC 7.11. |
| Storage stability test – **accelerated storage** | Testing not required | | | | | | Product of this meta SPC should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17,  ANA\_MON\_102, ANA\_MON\_103, Validated method in the study RRCo-000345\_01 | | Eau de Javel 3.6% parfum eucalyptus  Batch 191153  (product 1 of meta SPC 2.22) | See results of product 1 of meta SPC 2.22 | | RRCo-000336\_01 (mid-term results) | Results obtained for product 1 of meta SPC 2.22 can be used as a worst case due to the composition of the product. Active chlorine content decreases by more than 10% (-11.5% after 11 months) and the ratio sodium chlorates/active chlorine exceeds 5.4%. Please refer to human health, residues and environement sections regarding conclusion on chlorate content.  Efficacy data allow to support a shelf life of 11 months even if degradation of active substance is higher than 10% of initial content.  Extrapolation can be performed to product 1 of meta SPC 7.11. |
| Tests were conducted on products of meta-SPC2.22 as they have identical active substance concentrations with added co-formulants: surfactant and perfume, which are known to increase instability of the products. Therefore, they are considered worst case. | | | | | |  |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | | | Acceptable. Products of this meta SPC should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | | | Acceptable. Products of this meta SPC should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | | | Acceptable. Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report RRCo-000336\_01 (mid-term results):  « No crack, no swellling, no change of colour after 11 months of storage. » | | | | | | Compatibility has been demonstrated with HDPE packaging for product of meta SPC 2.22. Results can be extrapolated to meta SPC 7.11. |
| Wettability | No data generated | |  |  | |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated | |  |  | |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated | |  |  | |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated | |  |  | |  | Not relevant |
| Disintegration time | No data generated | |  |  | |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated | |  |  | |  | Not relevant |
| Persistent foaming | No foaming expected as no co-formulants are used in this product. | | | | | | No foam is expected since no surfactants are used. |
| Flowability/Pourability/Dustability | No data generated | |  |  | |  | Not relevant |
| Burning rate — smoke generators | No data generated | |  |  | |  | Not relevant |
| Burning completeness — smoke generators | No data generated | |  |  | |  | Not relevant |
| Composition of smoke — smoke generators | No data generated | |  |  | |  | Not relevant |
| Spraying pattern — aerosols | No data generated | |  |  | |  | Not relevant |
| Physical compatibility | No data generated | | | | | | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated | | | | | | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas.  Mention EUH031 is not applicable for this meta SPC since active substance content is below 5% w/w.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | Test on product 1 of meta-SPC 2.21 is considered relevant since it is considered worst case (higher surfactants, higer perfume concentrations and higher after dilution concentrations).  See reports 18.644892.0003 (before shelf life) and 18.644892.0008 (after shelf life), results were the same : “For the test item diluted at 50 % v/v in standard water C, no separated material was detected.” | | | | | | Acceptable. Results obtained for product 1 of meta 2.21 can be extrapolated to product 1 of meta SPC 7.11. No differences are expected. |
| Surface tension | No data generated | | | | | | Products of meta SPC 7.11 are not expected to be surface active since no surfactants are used. |
| Viscosity | No data generated | | | | | | Not acceptable. However, viscosity is expected to be similar to water due to the composition of product from this meta SPC 7.11. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 7.11** |
| Products of meta SPC 7.11 are soluble concentrate formulations. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid, with bleach odour.  No accelerated storage stability study was provided. Products should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 1 of meta SPC 2.22. The stability of this product was not fully demonstrated after storage 11 months at 20°C, since the active chlorine content decreases by more than 10% (-11.5%) and the sodium chlorate content is higher than the maximum limit of 5.4% of the active chlorine content (please refer to human health, residues and enviroment sections regarding conclusion on chlorate content). Results can be extrapolated to other products of meta SPC 7.11 since the tested product is a worst case**.** Efficacy data allow to support a shelf life of 11 months even if degradation of active substance is higher than 10% of initial content.  Products of meta SPC 7.11 are not foaming products.  Products of meta SPC 7.11 form clear solution when diluted.  Compatibility of products with HDPE is acceptable with product 1 of meta SPC 2.22 and results can be extrapolated to the whole meta SPC 7.11.  **Implication concerning labelling for products of meta SPC7.11**:  Shelf life proposed by eCA: 11 months (shelf life claimed by the applicant: 18 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Products should not be used in conjunction with acids or ammonia. |

**Meta SPC 7.12 (soluble concentrate)**

Tested formulation : product 1 of meta SPC 2.21. This product will cover meta SPC 7.12. Please refer to read across in confidential annex.

Packaging: HDPE bottle

| **Property** | **Guideline and Method** | | **Purity of the test substance (% (w/w)** | **Results** | | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage: liquid, No phase separation or precipitation  After storage 10 months at 20°C: liquid, no phase separation or precipitation | | 18.644892.0003  18.644892.0008 | Acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage: Transparent yellow  After storage 10 months at 20°C: transparent yellow | | 18.644892.0003  18.644892.0008 | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage: characteristic odour of eucalyptus and hypochlorite  After storage 10 months at 20°C: characteristic odour of eucalyptus and hypochlorite | | 18.644892.0003  18.644892.0008 | Acceptable. Products of meta SPC 7.12 are expected to have a bleach odour as no perfurmes are added. |
| Acidity / alkalinity | CIPAC MT 191 | Product with surfactant and perfume:  4,72%  Batch 180802 (product 1 of meta SPC 2.21)  Product without surfactants:  4,86%, Batch 2001230020 (product 4 of meta SPC 2.21)  Eau de javel à 2.6% c.a parfumee eucalyptus, batch 2010171707 (product 1 of meta SPC 2.1) | | | Before storage: 2.32 % w/w NaOH eq  After storage 10 months at 20°C: 2.05% w/w NaOH eq  2.02 % NaOH eq w/w.  pH at 20°C: 12.10 | 18.644892.0003  18.644892.0008  20.503032.0003  CoA, 10/2020 | Acceptable. Results can be extrapolated to products of meta SPC 7.12. pH may not be covered by SPC 2.21 due to the presence of stabilizer in the tested product of meta SPC 2.21. However pH provided for product 1 pf SPC 2.1 (no stabilizer and less content of a.i) can be used for read across. |
| Relative density / bulk density | OCDE109 | | eau de javel 4.8% c.a parfum eucalyptus Batch 191404 (product 1 of meta SPC 2.21) | Before storage: 1,0755g/mL  After storage 10 months at 20°C: 1.0743g/mL | | RRCo-000335\_01 | Acceptable. Relative density is expected to be similar for products of meta SPC 7.12. |
| Storage stability test – **accelerated storage** | Testing not required | | | | | | Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17,  ANA\_MON\_102ANA\_MON\_103  Internal method for sodium chlorides  Validated method in the study RRCo-000345\_01 | | eau de javel 4.8% c.a parfum eucalyptus  Batch 191404 (product 1 of meta SPC 2.21) | See results for product 1 of meta SPC 2.21 | | RRCo-000335\_01 | Results obtained for product 1 of meta SPC 2.21 can be extrapolated to meta SPC 7.12.  Active chlorine content decreases by more than 10% (-15.9% after 10 months) and the ratio sodium chlorates/active chlorine exceeds 5.4%. Please refer to human health, residues and environment sections regarding conclusion on chlorate content.  Efficacy data allow to support a shelf life of 8 months (as claimed by the applicant) even if degradation of active substance is higher than 10% of initial content. |
|  | | | | | |  |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | | | Acceptable. Products of this meta SPC should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | | | Acceptable. Products of this meta SPC should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | | | Acceptable. Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report 200428\_RRCo-000335\_01\_RF\_V1.  “No crack, no swellling, no change of colour after 11 months of storage.” | | | | | | Compatibility with HDPE material has been demonstrated for product 1 of meta SPC 2.21 and results can be extrapolated to meta SPC 7.12. |
| Wettability | No data generated | |  |  | |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated | |  |  | |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated | |  |  | |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated | |  |  | |  | Not relevant |
| Disintegration time | No data generated | |  |  | |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated | |  |  | |  | Not relevant |
| Persistent foaming | No foaming expected as no co-formulants are used in this product. | | | | | | No foam is expected since no surfactants are used. |
| Flowability/Pourability/Dustability | No data generated | |  |  | |  | Not relevant |
| Burning rate — smoke generators | No data generated | |  |  | |  | Not relevant |
| Burning completeness — smoke generators | No data generated | |  |  | |  | Not relevant |
| Composition of smoke — smoke generators | No data generated | |  |  | |  | Not relevant |
| Spraying pattern — aerosols | No data generated | |  |  | |  | Not relevant |
| Physical compatibility | No data generated | | | | | | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated | | | | | | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mention EUH031 “contact with acids liberates toxic gas” is proposed for this Meta SPC.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | See results of products of meta-SPC2.21 as they have identical active substance concentrations and are diluted in identical or higher concentrations (worst case).  Before storage: at 50% v/v, no separated material was noticed.  After storage 10 months at 20°C: at 50% v/v, no separated material was noticed. | | | | | | Acceptable. Results obtained for meta SP 2.21 can be extrapolated to meta SPC 7.12. |
| Surface tension | No data generated | | | | | | Products of meta SPC 7.12 are not expected to be surface active since no surfactants are used. |
| Viscosity | No data generated | | | | | | Not acceptable. However viscosity is expected to be similar to water due to the compositions of products from meta SPC 7.12. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 7.12** |
| Products of meta SPC 7.12 are soluble concentrate formulations. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid, with bleach odour.  No accelerated storage stability study was provided. Products should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 1 of meta SPC 2.21. The stability of this product was not fully demonstrated after storage 10 months at 20°C, since the active chlorine content decreases by more than 10% (-15.9%) and the sodium chlorate content is higher than the maximum limit of 5.4% of the active chlorine content (please refer to human health, residues and environment sections regarding conclusion on chlorate content). Results can be extrapolated to other products of meta SPC 7.12 since the tested product is a worst case**.** Efficacy data allow to support a shelf life of 8 months (as claimed by the applicant) even if degradation of active substance is higher than 10% of initial content.  Products of meta SPC 7.12 are not foaming products.  Products of meta SPC 7.12 form clear solution when diluted.  Compatibility of products with HDPE is acceptable with product 1 of meta SPC 2.21 and results can be extrapolated to the whole meta SPC 7.12.  **Implication concerning labelling for products of meta SPC7.12**:  Shelf life proposed by eCA: 8 months (shelf life claimed by the applicant: 8 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Products should not be used in conjunction with acids or ammonia.  EUH031 “contact with acids liberates toxic gas” |

**Meta SPC 7.2 (soluble concentrate)**

Tested formulation: product 1 from meta SPC 2.1. This product will cover meta SPC 7.2. Please refer to read across in confidential annex.

Packaging: HDPE bottle

| **Property** | **Guideline and Method** | | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | | Eau de javel 2.6% c.a parfum eucalyptus, Batch 180752  (product 1 of meta SPC 2.1) | Liquid | 18.644892.0004 | Acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | | Eau de javel 2.6% c.a parfum eucalyptus, Batch 180752  (product 1 of meta SPC 2.1) | Transparent yellow | 18.644892.0004 | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | | 2 Eau de javel 2.6% c.a parfum eucalyptus, Batch 180752  (product 1 of meta SPC 2.1) | Hypochlorite + eucalyptus | 18.644892.0004 | Acceptable. Product of meta SPC 7.2 is expected to have a bleach odour. |
| Acidity / alkalinity | CIPAC MT 191 | Eau de javel 2.6% c.a parfum eucalyptus, Batch 180752 (product 1 of meta SPC 2.1)  Eau de javel 2.6% c.a nature (product 5 meta SPC 2.1) batch 2001230040  Eau de javel 2.6% c.a parfum eucalyptus, Batch 2010171707 (product 1 of meta SPC 2.1) | | 1.20 as NaOH %w/w  1.08 as NaOH %w/w  pH at 20°C: 12.10 | 18.644892.0004  20.503032.0009  CoA, 10/2020 | Acceptable. Results can be extrapolated to meta SPC 7.2. |
| Relative density / bulk density | OECD109 | | Eau de javel 2.6% c.a parfum eucalyptus  Batch 191143 (product 1 of meta SPC 2.1) | 1,0397 g/mL at 20°C | RRCo-000334\_01 | Acceptable. Results can be extrapolated to meta SPC 7.2 |
| Storage stability test – **accelerated storage** | Testing not required | | | | | Product should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17,  ANA\_MON\_102ANA\_MON\_103internal method for sodium chlorides  Validated method in the study RRCo-000345\_01 | | 2,64%  Batch 191143 | Tests were conducted on products of meta-SPC2.1 as they have identical active substance concentrations with added co-formulants: surfactant and perfume, which are known to increase instability of the products. Therefore, they are considered worst case. | RRCo-000334\_01  (mid-term report) | Results obtained for meta SPC 2.1 can be used for meta SPC 7.2.  Product 1 of meta SPC 2.1 is considered stable up to 11 months at 20°C. Active chlorine content decreases by less than 10% (-2.2%) and the ratio sodium chlorate/active chlorine remains below 5.4%.  A shelf life of 11 months can be proposed for meta SPC 2.1 and 7.2. |
|  | | | | |  |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | | Acceptable. Products of this meta SPC should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | | Acceptable. Products of this meta SPC should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | | Acceptable. Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report RRCo-000334\_01 (mid-term report) :  No crack, no swelling, no change of colour. | | | | | Compatibility with HDPE material has been demonstrated with product 1 of meta SPC 2.1 and results can be extrapolated to meta SPC 7.2. |
| Wettability | No data generated | |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated | |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated | |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated | |  |  |  | Not relevant |
| Disintegration time | No data generated | |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated | |  |  |  | Not relevant |
| Persistent foaming | No foaming expected as no co-formulants are used in this product. | | | | | No foam is expected for this meta SPC since no surfactants are used. |
| Flowability/Pourability/Dustability | No data generated | |  |  |  | Not relevant |
| Burning rate — smoke generators | No data generated | |  |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated | |  |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated | |  |  |  | Not relevant |
| Spraying pattern — aerosols | No data generated | |  |  |  | Not relevant |
| Physical compatibility | No data generated | | | | | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated | | | | | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas.  Mention EHU031 is not applicable for this meta SPC since active substance content is below 5% w/w.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | See results on product 1 of meta-SPC 2.21 as they are considered worst case (higher surfactants, higer perfume concentrations and higher after dilution concentrations).  See reports 18.644892.0003 (before shelf life) and 18.644892.0008 (after shelf life), results were the same : “For the test item diluted at 50 % v/v in standard water C, no separated material was detected.” | | | | | Acceptable. Results can be extrapolated to meta SPC 7.2. |
| Surface tension | See results of products of meta-SPC2.2 as they have higher active substance concentrations with added co-formulants in low concentrations. | | | | | Product 1 is not expected to be surface active since no surfactants are used. |
| Viscosity | No data generated. | | | | | Not acceptable. However, viscosity is expected to be similar to water due to the composition of products from this meta SPC. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 7.2** |
| Products of meta SPC 7.2 are soluble concentrate formulations. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid, with bleach odour.  No accelerated storage stability study was provided. Products should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 1 of meta SPC 2.1. The stability of this product was fully demonstrated after storage 11 months at 20°C, since the active chlorine content remains stable and the sodium chlorate content is lower than the maximum limit of 5.4% of the active chlorine content. Results can be extrapolated to other products of meta SPC 7.2 since the tested product is a worst case**.** A shelf life if 11 months is acceptable for meta SPC 7.2.  Products of meta SPC 7.2 are not foaming products.  Products of meta SPC 7.2 form clear solution when diluted.  Compatibility of products with HDPE is acceptable with product 1 of meta SPC 2.1 and results can be extrapolated to the whole meta SPC 7.2.  **Implication concerning labelling for products of meta SPC7.2**:  Shelf life proposed by eCA: 11 months (shelf life claimed by the applicant: 24 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Products should not be used in conjunction with acids or ammonia. |

**Meta SPC 8 (soluble concentrate)**

Tested formulation: product 1 of meta SPC 2.1. Results obtained with this product can be used for meta SPC 8. Please refer to confidential annex for details.

Packaging: HDPE bottle

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | Product 6 of meta SPC 8  1,6% | | Liquid | SDS | Acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | Product 6 of meta SPC 8  1,6% | | Transparent yellow | SDS | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | Product 6 of meta SPC 8  1,6% | | Bleach water | SDS | Acceptable. Products of meta SPC 8 are expected to present different odours as various perfumes are used. |
| Acidity / alkalinity | CIPAC MT 31 | Without surfactants and perfume:  Batch 2001230035 (product 6 meta SPC 8)  With surfactant and perfume:  Eau de javel 1.6% eucalyptus  Batch 2001230050 (product 1 meta SPC 8)  Eau de javel à 2.6% c.a parfumee eucalyptus, batch 2010171707 (product 1 of meta SPC 2.1) | | 0.77 % w/w NaOH eq  0.71 % w/w NaOH eq  pH at 20°C: 12.10 | 20.503032.0005  20.503032.0007  CoA, 10/2020 | Acceptable. |
| Relative density / bulk density | OECD109 | Eau de javel 1.6% eucalyptus  Batch 2001230050 (product 1 meta SPC 8) | | 1,0262 g/cm3 at 20°C. | 20.503032.0007 | Acceptable. Results can be extrapolated to the whole meta SPC 8. |
| Storage stability test – **accelerated storage** | No test required | | | | | Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17,  ANA\_MON\_102ANA\_MON\_103internal methods for sodium chloride Validated method in the study RRCo-000345\_01 | Eau de javel 2,6% c.a parfumee eucalyptus  Batch 191143 (product 1 of meta SPC 2.1) | | See results for product 1 of meta SPC 2.1  Tests were conducted on product of meta-SPC2.1 as active substance concentration is higher. Stability tests on various products showed that higher AS concentration implies faster AS decaying over time. Therefore, stability tests done on product from meta-SPC 2.1 covers these products. | RRCo-000334\_01  (mid-term report) | Results obtained for product 1 of meta SPC 2.1 can be used for meta SPC 8.  Product 1 of meta SPC 2.1 can be considered stable up to 11 months at 20°C. Active chlorine content decreases by less than 10% (-2.2%) and the ratio sodium chlorate/active chlorine remains below 5.4%.  A shelf life of 11 months can be proposed for meta SPC 8.  The effect of perfumes has been previously discussed for meta SPC 2.21 and it has been demonstrated that products containing eucalyptus constitute the worst case. Consequently, the tested product is sufficiently representative for this meta SPC.  No justification was provided for products with mandarine orange and mint perfumes. However it has been demonstrated that the influence of perfumes on the degradation rate of active chlorine is quite similar on a short period (-11.5% to 13.7% after 8 months for eucalyptus, lavande and citrus). According to this observation and the compositions of the perfumes in confidential PAR, eCA is of the opinion that no significant differences are expected for the untested perfumes mandarin/orange and mint. |
|  | | | | |  |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | | Acceptable. Products of this meta SPC should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | | Acceptable. Products of this meta SPC should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | | Acceptable. Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report RRCo-000334\_01 (mid-term report) :  No crack, no swelling, no change of colour.  Tests were conducted on product of meta-SPC2.1 as active substance concentration is higher. | | | | | Compatibility with HDPE material has been demonstrated for product 1 of meta SPC 2.1. Results can be extrapolated to meta SPC 8. |
| Wettability | No data generated |  | |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  | |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  | |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  | |  |  | Not relevant |
| Disintegration time | No data generated |  | |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  | |  |  | Not relevant |
| Persistent foaming | See results of products with 4,8%a.c. of meta-SPC2.21 (higher surfactants concentrations (foaming agents)) | | | | | Read across with product 1 of meta SPC 2.21 is acceptable since it contains the same surfactant at a higher level. The products are foaming formulations since the volume of foam exceeds 60mL after 1min.  Product 6 of meta SPC 8 is not expected to be a foaming formulation. |
| Flowability/Pourability/Dustability | No data generated |  | |  |  | Not relevant |
| Burning rate — smoke generators | No data generated |  | |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated |  | |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated |  | |  |  | Not relevant |
| Spraying pattern — aerosols | No data generated |  | |  |  | Not relevant |
| Physical compatibility | No data generated | | | | | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated | | | | | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mention EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” are proposed for all products.  Mention EUH031 is not applicable for this meta SPC since active substance content is below 5% w/w.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | Test on product 1 of meta-SPC 2.21 is considered relevant since it is considered worst case (higher surfactants, higer perfume concentrations and higher after dilution concentrations).  See reports 18.644892.0003 (before shelf life) and 18.644892.0008 (after shelf life), results were the same : “For the test item diluted at 50 % v/v in standard water C, no separated material was detected.” | | | | | Read across with product 1 of meta SPC 2.21 is acceptable since it can be regarded as a worst case (similar composition with additional formulants than in products of meta SPC 8). Results from meta SPC 2.21 are reliable and found acceptable. |
| Surface tension | OECD 115 | | Eau de javel 1.6% eucalyptus  Batch 2001230050 (product 1 meta SPC 8) | At 59% v/v: 31.86 mN/m at 20°C | 20.503032.0007 | Acceptable. Results can be extrapolated to other products of meta SPC 8. Only product 6 of meta SPC 8 is not expected to be surface active due to its composition. |
| Viscosity | No data generated | | | | | Not acceptable. However, according to the composition, the viscosity is expected to be similar to water. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 8** |
| Products of meta SPC 8 are soluble concentrate formulations. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid, with different odours (various perfumes are used).  No accelerated storage stability study was provided. Products should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 1 of meta SPC 2.1. The stability of this product was demonstrated after storage 11 months at 20°C, since the active chlorine content remains stable (variations below 10% (-2.2%)) and the sodium chlorate content remains below the maximum limit of 5.4% of the active chlorine content. Results can be extrapolated to product of meta SPC 8 since compositions are similar. No justification was provided for products with mandarine orange and mint perfumes. However it has been demonstrated that the influence of perfumes on the degradation rate of active chlorine is quite similar on a short period (-11.5% to 13.7% after 8 months for eucalyptus, lavande and citrus). According to this observation and the compositions of the perfumes in confidential PAR, eCA is of the opinion that no significant differences are expected for the untested perfumes mandarin/orange and mint. A shelf life of 11 months is acceptable for Meta SPC 8.  Products of meta SPC 2.21 are foaming products and results can be extrapolated to products of meta SPC 8 due to their compositions.  Extrapolation to meta SCP 8 is acceptable.  Compatibility of products with HDPE is acceptable with product 1 of meta SPC 2.1 and results can be extrapolated to the whole meta SPC 8.  **Implication concerning labelling for products of meta SPC8**:  Shelf life proposed by eCA: 11 months (shelf life claimed by the applicant: 24 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Foaming products  Products should not be used in conjunction with acids or ammonia.  EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” |

**Meta SPC 9 (soluble concentrate)**

Testedformulation : product 1 (eau de javel 9.6% c.a eucalyptus) from meta SPC. Only one product is claimed for this meta SPC.

Packaging: HDPE bottle

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | eau de javel 9.6% c.a eucalyptus  Batch: 180817  (product 1 of meta SPC 9) | Before storage: Liquid, No phase separation or precipitation  After storage 10 months at 25°C: liquid, no phase separation | 18.644892.0002  18.644892.0007 | Acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | eau de javel 9.6% c.a eucalyptus  Batch: 180817  (product 1 of meta SPC 9) | Before storage: Transparent yellow  After storage 10 months at 25°C: transparent yellow | 18.644892.0002  18.644892.0007 | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | eau de javel 9.6% c.a eucalyptus  Batch: 180817  (product 1 of meta SPC 9) | Before storage: characteristic odour of eucalyptus and hypochlorite  After storage 10 months at 25°C: characteristic odour of eucalyptus and hypochlorite | 18.644892.0002  18.644892.0007 | Acceptable |
| Acidity / alkalinity | CIPAC MT 191 | eau de javel 9.6% c.a eucalyptus  Batch: 180817  (product 1 of meta SPC 9)  eau de javel 9.6% c.a eucalyptus  Batch: 2010201416 and 190402  (product 1 of meta SPC 9) | Before storage: 3.98 as NaOH %w/w  After storage 10 months at 25°C: 1.76% w/w NaOH eq  pH at 20°C:  before storage: 12.20  after storage (>10 months): 11.70 | 18.644892.0002  18.644892.0007  CoA 10/2020 | Acceptable |
| Relative density / bulk density | OECD 109 (pycnometer method) | eau de javel 9.6% c.a eucalyptus  Batch: 190402  (product 1 of meta SPC 9) | 1,1542 g/mL at 20°C  After 10 months at 20°C: 1.1498 g/mL at 20°C | RRCo-000338\_01 | Acceptable |
| Storage stability test – **accelerated storage** | Test not required | | | | Product should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17  ANA\_MON\_102ANA\_MON\_103  Internal method for sodium chloride  All methods validated in the study RRCo-000345\_01 | eau de javel 9.6% c.a eucalyptus  Batch: 190402  (product 1 of meta SPC 9) | GLP study :  Packaging tested: HDPE bottle 5L  Storage at 20°C for 10 months  **Appearance**  Before storage: yellow transparent liquid, typical of eucalyptus bleach  After storage: yellow transparent liquid, bitter smell, slightly eucalyptus bleach  **Packaging**  Before storage: no crack, no swelling  After storage: no crack, no swelling, no change of colour. No change in weights  **T0:**  Active chlorine: 9,91% w/w  Sodium chlorates: 0,35%w/w  Sodium chlorides: 8,83%w/w  Ratio sodium chlorates/active chlorine: 3.5%  **T2 months:**  Active chlorine: 8,68% w/w  **T4 months:**  Active chlorine: 7,45% w/w  **T5 months:**  Sodium chlorates: 1,63%w/w  Sodium chlorides: 10,11%w/w  **T6 months:**  Active chlorine: 7,04% w/w  **T8 months:**  Active chlorine: 6,62% w/w  **T10 months:**  Active chlorine: 5,96% w/w  Sodium chlorates: 2,22%w/w  Sodium chlorides: 11,11%w/w  Ratio sodium chlorates/active chlorine: 37.2% | RRCo-000338\_01 | Final report of the shelf life study is available (10 months at 20°C).  Product is compatible with HDPE packaging.  However the content of active chlorine decreases by more than 10% (-39.8%) and the ratio sodium chlorate/active chlorine exceeds 5.4% w/w. Please refer to human health, residues and environment sections regarding conclusion on chlorate content.  Efficacy data do not support a shelf life up to 8 months as claimed by the applicant. eCA has considered the limit of 10%. According to the results available for meta SPC 9, interpolation can be done using the graph 1/C NaOCl vs time (kinetic model order 2, 6 points, linear regression, R>0.99). eCA considers that the loss of active substance is still below 10% after 1 month. A shelf life of 1 month can be granted for this meta SPC. |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | Acceptable. Products of this meta SPCshould be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report RRCo-000338\_01, 18.644892.0002 and 18.644892.0007.  The determination of colour, physical state and odour was performed on 26th August 2019. The test item was a transparent yellow liquid without phase separation or precipitation events, with a characteristic odour of eucalyptus and hypochlorite. | | | | Acceptable. The product is compatible with HDPE packaging. |
| Wettability | No data generated |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  |  |  | Not relevant |
| Disintegration time | No data generated |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  |  |  | Not relevant |
| Persistent foaming | CIPAC MT 47.2 | eau de javel 9.6% c.a eucalyptus  Batch: 180817 (product 1 of meta SPC 9) | Before shelf life:  At 75%v/v: 850 ml after 10 sec and remained constant at 800 ml from 1 min to 12 min.  After shelf life 10 months at 20°C:  At 75% v/v  10 sec : 850ml  1 min : 830ml  3 min : 820ml  12 min : 800ml | Before storage:  18.644892.0002  After storage:  18.644892.0007 | The product is a foaming formulation. This product is intended to be used by spraying for outdoor surface. However, foaming is a property of interest for this type formulation (in order to increase of contact time and to see where product has been applied (especially for surfaces like walls).  Additionally, the users are only professionals and specific protection equipments are recommended for spraying application. Therefore no further data are necessary. |
| Flowability/Pourability/Dustability | No data generated |  |  |  | Not relevant |
| Burning rate — smoke generators | No data generated |  |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated |  |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated |  |  |  | Not relevant |
| Spraying pattern — aerosols | No data generated |  |  |  | Not relevant |
| Physical compatibility | No data generated | | | | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated | | | | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mentions EUH031 “contact with acids liberates toxic gas” and EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” are proposed for this Meta SPC.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | CIPAC MT 41.1 | eau de javel 9.6% c.a eucalyptus  Batch: 180817 (product 1 of meta SPC 9) | Before shelf life:  After dilution of the test item in water at 75 % v/v, no separated material was detected.  After shelf life 10 months at 20°C:  After dilution of the test item in water at 75 % v/v at t10, no separated material was detected. | 18.644892.0002  18.644892.0007 | Acceptable. |
| Surface tension | OECD Test Guideline 115 and EC method A.5 | eau de javel 9.6% c.a eucalyptus  Batch: 180817 (product 1 of meta SPC 9) | initial: 31.44 mN/m (neat)  After storage 10 months at 20°C: 30.69 mN/m (neat) | 18.644892.0002  18.644892.0007 | Acceptable. The product is surface active. |
| Viscosity | No data generated | | | | Not acceptable. However, according to the composition, the viscosity is expected to be similar to water. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 9** |
| Products of meta SPC 9 are soluble concentrate formulations. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid, with eucalyptus odour.  No accelerated storage stability study was provided. Products should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 1 of meta SPC 9. The stability of this product was not fully demonstrated after storage 10 months at 20°C, since the active chlorine content decreases by more than 10% (-39.8%) and the sodium chlorate content is higher than the maximum limit of 5.4% of the active chlorine content (please refer to human health, residues and environment sections regarding conclusion on chlorate content).  Efficacy data do not support a shelf life up to 8 months as claimed by the applicant. eCA has considered the limit of 10%. According to the results available for meta SPC 9, eCA considers that the loss of active substance is still below 10% after 1 month by interpolation. A shelf life of 1 month can be granted for this meta SPC.  Products of meta SPC 9 are foaming products. This product is intended to be used by spraying for outdoor surface. However, foaming is a property of interest for this type formulation (in order to increase of contact time and to see where product has been applied (especially for surfaces like walls).  Additionally, the users are only professionals and specific protection equipments are recommended for spraying application.  Products of meta SPC 9 form clear solution when diluted.  Compatibility of products with HDPE is acceptable with product 1 of meta SPC 9.  **Implication concerning labelling for products of meta SPC9**:  Shelf life proposed by eCA: 1 month (shelf life claimed by the applicant: 8 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Foaming products  EUH031 “contact with acids liberates toxic gas”  EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)”  Products should not be used in conjunction with acids or ammonia. |

**Meta SPC 10.1 (soluble concentrate)**

Tested formulation: product 1 from meta SPC 10.1. This product cover the whole meta SPC. Please refer to read across in confidential annex.

Packaging: HDPE bottle.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | Detergent 2.6% c.a parfum eucalyptus  Batch: 181404 (product 1 of meta SPC 10.1) | Before storage: Liquid, no precipition or phase separation  After storage 15 months at 25°C: liquid without phase separation or precipitation | 18.646835.0001  18.646835.0006 | Acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | Detergent 2.6% c.a parfum eucalyptus  Batch: 181404 (product 1 of meta SPC 10.1) | Before storage: Transparent yellow  After storage 15 months at 25°C: yellow liquid | 18.646835.0001  18.646835.0006 | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | Detergent 2.6% c.a parfum eucalyptus  Batch: 181404 (product 1 of meta SPC 10.1) | Before storage: characteristic odour of eucalyptus and hypochlorite  After storage 15 months at 25°C: characteristic odour of eucalyptus and hypochlorite | 18.646835.0001  18.646835.0006 | Acceptable. Other products of this meta SPC are expected to present different odours since various perfumes are used. |
| Acidity / alkalinity | CIPAC MT 191 | Detergent 2.6% c.a parfum eucalyptus  Batch: 181404 (product 1 of meta SPC 10.1)  Detergent 2.6% c.a parfum eucalyptus  Batch: 2010180558 and 181404 (product 1 of meta SPC 10.1) | Before storage: 1.20 as NaOHeq % w/w  After 12 months at 25°C: 0.349 as NaOH eq %w/w  After 15 months at 25°C: 0.12 as NaOH eq % w/w  pH at 20°C:  before storage: 12.30  after storage (>11 months): 12.20 | 18.646835.0001  18.646835.0006  CoA, 10/2020 | Acceptable. Results can be extrapolated to meta SPC 10.1. |
| Relative density / bulk density | OECD109 (pycnometer) | Detergent 2.6% c.a parfum eucalyptus  Batch: 181404 and 191111 (product 1 of meta SPC 10.1) | 1,040 g/mL at 20°C  1.0404 g/mL at 20°C | 18.646835.0001  RRCo-000344\_01 | Acceptable. Results can be extrapolated to meta SPC 10.1. |
| Storage stability test – **accelerated storage** | Test not required | | | | Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17,  ANA\_MON\_102ANA\_MON\_103  Internal method for sodium chlorides  Validated methods in the study RRCo-000345\_01 | Detergent 2.6% c.a parfum eucalyptus  Batch: 191111 (product 1 of meta SPC 10.1) | GLP study :  Packaging tested: HDPE bottle 250mL  Storage conditions: 24 months at 20°C in darkness (results available up to 11 months)  **Appearance**  Before storage: slightly yellow transparent liquid, typical odour  After storage 11 months at 20°C: slightly yellow transparent liquid, typical odour  **Packaging**  Before storage: no crack, no swelling, no change of colour  After storage 11 months at 20°C: no crack, no swelling, no change of colour, no significant change in weight  **T0:**  Active chlorine: 2,33% w/w  Sodium chlorate: 0,07%w/w  Sodium chlorides: 2,41%w/w  Ratio sodium chlorates/active chlorine: 3% w/w  **T6 months:**  Active chlorine: 2,32% w/w  **T11 months:**  Active chlorine: 2,33% w/w  Sodium chlorates: 0,12%w/w  Sodium chlorides: 2,89%w/w  Ratio sodium chlorates/active chlorine: 5.2% w/w | RRCo-000344\_01 | Intermediate results up to 11 months were provided.  The product is compatible with HDPE packaging and can be regarded stable up to 11 months at 20°C. Variations of active chlorine content is below 10% after storage and the ratio sodium chlorates/available chlorine remains below 5.4% w/w.  A shelf life of 11 months can be granted for this meta SPC.  The effect of perfumes has been previously discussed for meta SPC 2.21 and it has been demonstrated that products containing eucalyptus constitute the worst case. Consequently, the tested product is sufficiently representative for this meta SPC. |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report RRCo-000344\_01 (mid-term report):  “No crack, no swelling, no change of colour.” | | | | Acceptable. The product is compatible with HDPE packaging. Results can be extrapolated to other products of meta SPC 10.1. |
| Wettability | No data generated |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  |  |  | Not relevant |
| Disintegration time | No data generated |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  |  |  | Not relevant |
| Persistent foaming | CIPAC MT 47.2 | Detergent 2.6% c.a parfum eucalyptus  Batch: 181404 (product 1 of meta SPC 10.1) | Before storage: at 45%v/v, foam produced was 1010 ml after 10 sec and 1min, 1000mL after 3 and 12 min  After storage 15 months at 25°C: at 45%v/v, foam produced was 100mL after 10s, 90mL after 1 min, 80ml after 3 min and 60mL after 12min | 18.646835.0001  18.646835.0006 | The products are foaming formulation.  45mL of product were diluted in 1L of water and up to 1L of foam can be formed. |
| Flowability/Pourability/Dustability | No data generated |  |  |  | Not relevant |
| Burning rate — smoke generators | No data generated |  |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated |  |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated |  |  |  | Not relevant |
| Spraying pattern — aerosols | No data generated |  |  |  | Not relevant |
| Physical compatibility | No data generated | | | | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated | | | | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas.  Mention EUH 031 is not applicable for this meta SPC since active substance content is below 5% w/w.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | CIPAC MT 41.1 | Detergent 2.6% c.a parfum eucalyptus  Batch: 181404 (product 1 of meta SPC 10.1) | Before storage: at 45% v/v, no separated material detected after 24h  After storage 15 months at 25°C: at 45% v/v, no separated material detected after 24h | 18.646835.0001  18.646835.0006 | Acceptable. Results can be extrapolated to other products of meta SPC 10.1. |
| Surface tension | OECD Test Guideline 115 and EC method A.5 | Detergent 2.6% c.a parfum eucalyptus  Batch: 181404 (product 1 of meta SPC 10.1) | Before storage: 31.31 mN/m (at 45% v/v) at 20°C | 18.646835.0001 | Acceptable. The products are surface active formulations. |
| Viscosity | No data generated | | | | Not acceptable. However, according to the composition, the viscosity is expected to be similar to water. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 10.1** |
| Products of meta SPC 10.1 are soluble concentrate formulations. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid, with different odours (various perfumes are used).  No accelerated storage stability study was provided. Products should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 1 of meta SPC 10.1. The stability of this product was fully demonstrated after storage 11 months at 20°C, since the active chlorine content remains stable (no variations observed) and the sodium chlorate content is lower than the maximum limit of 5.4% of the active chlorine content. Results can be extrapolated to other products of meta SPC 10.1 since compositions are similar. A shelf life of 11 months can be granted for Meta SPC 10.1.  Products of meta SPC 10.1 are foaming products.  Products of meta SPC 10.1 form clear solution when diluted.  Compatibility of products with HDPE is acceptable with product 1 of meta SPC 10.1 and results can be extrapolated to the whole meta SPC 10.1.  **Implication concerning labelling for products of meta SPC10.1**:  Shelf life proposed by eCA: 11 months (shelf life claimed by the applicant: 24 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Foaming products  Products should not be used in conjunction with acids or ammonia. |

**Meta SPC 10.2 (soluble concentrate)**

Tested formulation: product 1 (eau de javel 4.8% c.a parfum eucalyptus) from meta SPC 2.21. This product covers meta SPC 10.2. Please refer to briding in confidential annex.

Packaging: HDPE bottle

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage: liquid, No phase separation or precipitation  After storage 10 months at 20°C: liquid, no phase separation or precipitation | 18.644892.0003  18.644892.0008 | Acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage: Transparent yellow  After storage 10 months at 20°C: transparent yellow | 18.644892.0003  18.644892.0008 | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage: characteristic odour of eucalyptus and hypochlorite  After storage 10 months at 20°C: characteristic odour of eucalyptus and hypochlorite | 18.644892.0003  18.644892.0008 | Acceptable. Other products are expected to present different odours since various perfumes are used. |
| Acidity / alkalinity | CIPAC MT 191 | Product with surfactant and perfume:  4,72%  Batch 180802 (product 1 of meta SPC 2.21)  Product without surfactants:  4,86%, Batch 2001230020 (product 4 of meta SPC 2.21)  Eau de javel à 4.8% c.a parfumee eucalypstus, Batch 180802 (product 1 of meta SPC 2.21) | Before storage: 2.32 % w/w NaOH eq  After storage 10 months at 20°C: 2.05% w/w NaOH eq  2.02 % NaOH eq w/w.  pH at 20°C: 12.20 | 18.644892.0003  18.644892.0008  20.503032.0003  CoA, 10/2020 | Read across is acceptable with product of meta SPC 2.21. |
| Relative density / bulk density | OECD109 | eau de javel 4.8% c.a parfum eucalyptus Batch 191404 (product 1 of meta SPC 2.21) | Before storage: 1,0755g/mL  After storage 10 months at 20°C: 1.0743g/mL | RRCo-000335\_01 | Acceptable. Results can be extrapoalted to other products of this meta SPC due to similar composition. |
| Storage stability test – **accelerated storage** | Test not required | | | | Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17,  ANA\_MON\_102ANA\_MON\_103internal method for sodium chlorides  Validated method in the study RRCo-000345\_01 | eau de javel 4.8% c.a parfum eucalyptus  Batch 191404 (product 1 of meta SPC 2.21) | See results for product 1 of meta SPC 2.21 | RRCo-000335\_01 | Results for product 1 of meta SPC 2.21 can be used for meta SPC 10.2.  For this product, active chlorine content decreases by more than 10% (-15.9% after 10 months) and the ratio sodium chlorates/active chlorine exceeds 5.4%. Please refer to human health, residues and environment sections regarding conclusion on chlorate content.  Efficacy data allow to support a shelf life of 8 months (as claimed by the applicant) even if degradation of active substance exceeds 10% of initial content.  The effect of perfumes has been previously discussed for meta SPC 2.21 and it has been demonstrated that products containing eucalyptus constitute the worst case. Consequently, the tested product is sufficiently representative for this meta SPC. |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report 200428\_RRCo-000335\_01\_RF\_V1. Products were in 250ML HDPE bottle. Packaging used for these products is PVC, however HDPE can be used for stability tests. | | | | Compatibility with HDPE material has been demonstrated for product 1 of meta SPC 2.21. Results are acceptable for meta SPC 10.2. |
| Wettability | No data generated |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  |  |  | Not relevant |
| Disintegration time | No data generated |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  |  |  | Not relevant |
| Persistent foaming | CIPAC MT 47.2 | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | After dilution of 50 % v/v, foam produced is 300 ml after 10 sec, 1 min, 3 min and 12 min.  After storage:  10 sec : 830ml  1 min : 810ml  3 min : 800ml  12 min : 780ml | 18.644892.0003  18.644892.0008 | Acceptable. The products are foaming formulation.  50mL of product were diluted in 1L of water. Up to 1L of foam can be formed. |
| Flowability/Pourability/Dustability | No data generated |  |  |  | Not relevant |
| Burning rate — smoke generators | No data generated |  |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated |  |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated |  |  |  | Not relevant |
| Spraying pattern — aerosols | No data generated |  |  |  | Not relevant |
| Physical compatibility | No data generated | | | | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated | | | | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mention EUH031 “contact with acids liberates toxic gas” is proposed for this Meta SPC.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | CIPAC MT 41.1 | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage: at 50% v/v, no separated material was noticed.  After storage 10 months at 20°C: at 50% v/v, no separated material was noticed. | 18.644892.0003  18.644892.0008 | Acceptable. Results can be extrapolated to other products of this meta SPC. |
| Surface tension | OECD Test Guideline 115 and EC method A.5 | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage (neat): 32.96 mN/m  After storage 10 months at 20°C (neat): 30.70 mN/m | 18.644892.0003  18.644892.0008 | Acceptable. The product is surface active. Other products of meta SPC 10.2 are expected to be surface active due to their similar composition. |
| Viscosity | No data generated | | | | Not acceptable. However, according to the composition, the viscosity is expected to be similar to water. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 10.2** |
| Products of meta SPC 10.2 are soluble concentrate formulations. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid, with different odours (various perfumes are used).  No accelerated storage stability study was provided. Products should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 1 of meta SPC 2.21. The stability of this product was not fully demonstrated after storage 10 months at 20°C, since the active chlorine content decreases by more than 10% (-15.9%) and the sodium chlorate content is higher than the maximum limit of 5.4% of the active chlorine content (please refer to human health, residues and environment sections regarding conclusion on chlorate content). Results can be extrapolated to other products of meta SPC 10.2 since compositions are similar.Efficacy data allow to support a shelf life of 8 months (as claimed by the applicant) even if degradation of active substance exceeds 10% of initial content.  Products of meta SPC 10.2 are foaming products.  Products of meta SPC 10.2 form clear solution when diluted.  Compatibility of products with HDPE is acceptable with product 1 of meta SPC 2.21 and results can be extrapolated to the meta SPC 10.2.  **Implication concerning labelling for products of meta SPC10.2**:  Shelf life proposed by eCA: 8 months (shelf life claimed by the applicant: 8 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Foaming products  Products should not be used in conjunction with acids or ammonia.  EUH031 “contact with acids liberates toxic gas” |

**Meta SPC 11 (soluble concentrate)**

Tested formulation: product 2 from meta SPC 11. This product will cover meta SPC 11. Please refer to read across in confidential annex.

Packaging: HDPE bottle

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | detergent alcalin chlore moussant 5.74%  Batch 181106 (product 2 of meta SPC 11) | Before storage: Liquid without phase separation or precipitation  After storage 10 months at 25°C: Liquid without phase separation or precipitation | 18.649896.0003  18.649896.0004 | Acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | detergent alcalin chlore moussant 5.74%  Batch 181106 (product 2 of meta SPC 11) | Before storage: transparent Yellow  After storage 10 months at 25°C: transparent yellow | 18.649896.0003  18.649896.0004 | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | detergent alcalin chlore moussant 5.74%  Batch 181106 (product 2 of meta SPC 11) | Before storage: characteristic odour of hypochlorite  After storage 10 months at 25°C: characteristic odour of hypochlorite | 18.649896.0003  18.649896.0004 | Acceptable |
| Acidity / alkalinity | CIPAC MT 31 | detergent alcalin chlore moussant 5.74%  Batch 181106 (product 2 of meta SPC 11)  detergent alcalin chlore moussant  Batch 2009241148 and 191521 (product 2 of meta SPC 11) | Before storage: 9.43 %w/w NaOH eq  After storage 5 months at 25°C: 8.36% w/w NaOH eq  After storage 10 months at 25°C: 8.37% w/w NaOH eq  pH at 20°C:  before storage: 12.80  after storage (>11 months): 12.50 | 18.649896.0003  18.649896.0004  18.649896.0005  CoA, 10/2020 | Acceptable |
| Relative density / bulk density | OECD 109 (pycnometer) | detergent alcalin chlore moussant 6,71% a.c  Batch 191521 (product 2 of meta SPC 11)  detergent alcalin chlore moussant 5.74%  Batch 181106 (product 2 of meta SPC 11) | 1,1920g/mL (neat)  At 20%v/v: 1.04g/cm3 | RRCo-000343\_01  18.649896.0003 | Acceptable |
| Storage stability test – **accelerated storage** | No testing required | | | | Product of this meta SPC should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17,  ANA\_MON\_102ANA\_MON\_103 internal method for chlorides  Validated methods in the study RRCo-000345\_01 | detergent alcalin chlore moussant 6,71% a.c  Batch 191521 (product 2 of meta SPC 11) | GLP study :  Packaging tested: HDPE 250mL  Storage conditions: 24 months, in darkness, 20°C  **Appearance**  Before storage: slightly yellow transparent, slightly viscous liquid, typical odour  After storage: slightly yellow transparent, slightly viscous liquid, bitter smell  **Packaging**  Before storage: no crack, no swelling, no change of colour  After storage: no crack, no swelling, no change of colour, no significant change in weight  **T0:**  Active chlorine: 6,16% w/w  Sodium chlorates: 0,23% w/w  Sodium chlorides: 6,84% w/w  Ratio sodium chlorates/active chlorine: 3.7%  **T6 months:**  Active chlorine: 4,11% w/w  **T11 months:**  Active chlorine: 3,32% w/w  Sodium chlorates: 1,61% w/w  Sodium chlorides: 10,1% w/w  Ratio sodium chlorates/active chlorine: 48.5% | RRCo-000343\_01 | A storage stability study 24 months at 20°C has been launched. Only results after 11 months are available. If the applicant claims a longer shelf life, complete data should be provided with a minor change application.  Active substance content decreases by more than 10% (-46.1%) and ratio of sodium chlorate/active chlorine exceeds 5.4% after 11 months. Please refer to human health, residues and environement sections regarding conclusion on chlorate content.  Efficacy data allow to support a shelf life of 6 months (as claimed by the applicant) even if degradation of active substance is higher that 10% of initial content. |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report RRCo-000343\_01 (mid-term report):  “No crack, no swelling, no change of colour.” | | | | Compatibility with HDPE has been demonstrated for product 2 of meta SPC 11. Results are acceptable for other products of this meta SPC. |
| Wettability | No data generated |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  |  |  | Not relevant |
| Disintegration time | No data generated |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  |  |  | Not relevant |
| Persistent foaming | CIPAC MT 47.2 | detergent alcalin chlore moussant 5.74%  Batch 181106 (product 2 of meta SPC 11) | Before storage:  At 20%v/v: >1000mL  After 10 months at 25°C  At 20%v/v: >1000mL | 18.649896.0003  18.649896.0004 | The product is a foaming formulation.  Product 1 is not expected to form foam due to absence of surfactants. However, the same mitigation measure is applicable to the entire meta SPC. |
|  | | | |  |
| Flowability/Pourability/Dustability | No data generated |  |  |  | Not relevant |
| Burning rate — smoke generators | No data generated |  |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated |  |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated |  |  |  | Not relevant |
| Spraying pattern — aerosols | No data generated |  |  |  | Not relevant |
| Physical compatibility | No data generated | | | | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated | | | | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mentions EUH031 “contact with acids liberates toxic gas” is proposed for this Meta SPC.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | CIPAC MT 41.1 | detergent alcalin chlore moussant 5.74%  Batch 181106 (product 2 of meta SPC 11) | Before storage:  At 20%v/v: No separated material detected after 24h.  After storage 10 months at 25°C:  At 20%v/v: No separated material detected after 24h. | 18.649896.0003  18.649896.0004 | Acceptable. Data can be extrapolated to other products of this meta SPC. |
| Surface tension | OECD Test Guideline 115 and EC method A.5 | detergent alcalin chlore moussant 5.74%  Batch 181106 (product 2 of meta SPC 11) | Before storage  At 20%v/v: 32,30mN/m at 20°C  After storage 10 months at 25°C  At 20%v/v: 32,47mN/m at 20°C | 18.649896.0003  18.649896.0004 | Acceptable. The diluted product is surface active.  However, product 1 is not expected to be surface active as no surfacants are used. |
| Viscosity | No data generated | | | | Not acceptable. However, according to the composition, the viscosity is expected to be similar to water. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 11** |
| Products of meta SPC 11 are soluble concentrate formulations. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid, with bleach odour.  No accelerated storage stability study was provided. Products should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 2 of meta SPC 11. The stability of this product was not fully demonstrated after storage 11 months at 20°C, since the active chlorine content decreases by more than 10% (-46.1%) and the sodium chlorate content is higher than the maximum limit of 5.4% of the active chlorine content (please refer to human health, residues and environment sections regarding conclusion on chlorate content). Results can be extrapolated to other products of meta SPC 11 since compositions are similar.Efficacy data allow to support a shelf life of 6 months (as claimed by the applicant) even if degradation of active substance is higher that 10% of initial content.  Products of meta SPC 11 are foaming products.  Products of meta SPC 11 form clear solution when diluted.  Compatibility of products with HDPE is acceptable with product 2 of meta SPC 11 and results can be extrapolated to the meta SPC 11.  **Implication concerning labelling for products of meta SPC11**:  Shelflife proposed by eCA: 6 months(shelf life claimed by the applicant: 6 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Foaming products  EUH031 “contact with acids liberates toxic gas”  Products should not be used in conjunction with acids or ammonia. |

**Meta SPC 12 (ready to use liquid – spray)**

Tested formulation: Product 1 from meta-SPC2.21 shares the exact same formula. Product of meta SPC 12 is the spray version. Some tests have been performed with product 1 of meta SPC12 spray javel 4.8% c.a parfum eucalyptus.

Packaging: HDPE botte

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21) | Before storage: liquid, No phase separation or precipitation  After storage 10 months at 20°C: liquid, no phase separation or precipitation | 18.644892.0003  18.644892.0008 | Acceptable (product 1 of meta SPC 2.21 is identical). |
| Colour at 20 °C and 101.3 kPa | Internal method | Internal method | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21)    Before storage: Transparent yellow  After storage 10 months at 20°C: transparent yellow | 18.644892.0003  18.644892.0008 | Acceptable (product 1 of meta SPC 2.21 is identical).  . |
| Odour at 20 °C and 101.3 kPa | Internal method | Internal method | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21)    Before storage: characteristic odour of eucalyptus and hypochlorite  After storage 10 months at 20°C: characteristic odour of eucalyptus and hypochlorite | 18.644892.0003  18.644892.0008 | Acceptable (product 1 of meta SPC 2.21 is identical). |
| Acidity / alkalinity | CIPAC MT 191 | eau de javel 4.8% c.a parfum eucalyptus Batch 180802 (product 1 of meta SPC 2.21)  eau de javel 4.8% c.a parfum eucalyptus Batch 72010121504 and 191404(product 1 of meta SPC 2.21 | Before storage: 2.32 % w/w NaOH eq  After storage 10 months at 20°C: 2.05% w/w NaOH eq  pH at 20°C:  before storage: 12.20  after storage (>10 months): 12.30 | 18.644892.0003  18.644892.0008  CoA, 10/2020 | Acceptable (product 1 of meta SPC 2.21 is identical). |
| Relative density / bulk density | OECD109 | eau de javel 4.8% c.a parfum eucalyptus Batch 191404 (product 1 of meta SPC 2.21) | Before storage: 1,0755g/mL  After storage 10 months at 20°C: 1.0743g/mL | RRCo-000335\_01 | Acceptable |
| Storage stability test – **accelerated storage** | No testing required | | | | Product should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17,  ANA\_MON\_102, ANA\_MON\_103,  Internal method for sodium chlorides  Validated method in the study RRCo-000345\_01 | eau de javel 4.8% c.a parfum eucalyptus  Batch 191404 (product 1 of meta SPC 2.21) | GLP study :  Packaging tested: HDPE bottle 250mL  Storage conditions: 20°C for 10 months  **Appearance**  Before storage: slightly yellow transparent liquid, typical eucalyptus bleach odour  After storage: slightly yellow transparent liquid, typical eucalyptus bleach odour  **Packaging**  Before storage: no crack, no swelling, no change of coulour  After storage: no crack, no swelling, no change of colour, no change in weight  **T0:**  Active chlorine: 4,67% w/w  Sodium chlorates: 0,13%w/w  Sodium chlorides: 4,59%w/w  Ratio sodium chlorates/active chlorine: 2.8%  **T2 months:**  Active chlorine: 4,51% w/w  **T4 months:**  Active chlorine: 4,24% w/w  **T5 months:**  Sodium chlorates: 0,27%w/w  Sodium chlorides: 4,78%w/w  **T6 months:**  Active chlorine: 4,29% w/w  **T8 months:**  Active chlorine: 4,18% w/w  **T10 months:**  Active chlorine: 3,93% w/w  Sodium chlorates: 0,39%w/w  Sodium chlorides: 5,33%w/w  Ratio sodium chlorate/active chlorine: 9.9% | RRCo-000335\_01 | Final results of the shelf life study 10 months at 20°C are available.  The product is compatible with HDPE packaging.  Active chlorine content decreases by more than 10% (-15.9%) and the ratio sodium chlorates/active chlorine exceeds 5.4%. Please refer to human health, residues and environment sections regarding conclusion on chlorate content.  Efficacy data allow to support a shelf life of 8 months (as claimed by the applicant) even if degradation of active substance is higher that 10% of initial content. |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | Acceptable. Products should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | Acceptable. Products should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | Acceptable. Products should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report 200428\_RRCo-000335\_01\_RF\_V1. Products were in 250ML HDPE bottle.  See report18.644892.0008: No weight change after 10 months at 20°C (HDPE bottle 250mL) | | | | Acceptable. The product is compatible with HDPE packaging. |
| Wettability | No data generated |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  |  |  | Not relevant |
| Disintegration time | No data generated |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  |  |  | Not relevant |
| Persistent foaming | Not relevant, RTO products | | | | Not relevant as product is ready to use |
| Flowability/Pourability/Dustability | No data generated |  |  |  | Not relevant |
| Burning rate — smoke generators | No data generated |  |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated |  |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated |  |  |  | Not relevant |
| Spraying pattern — aerosols | Internal method | spray javel 4.8% c.a parfum eucalyptus  batch 181224 | PP/PE trigger spray TS5 S  Before storage  Amount of spray delivered (mean on 10 squeezes): 1.42g  Observation of nozzle after test: absence of residues and fouling  Spray diameter (mean on 6 squeezes at 30cm from the adsorbent paper): 15cm  After storage 10 months at 25°C:  Amount of spray delivered (mean on 10 squeezes): 1.38g  Observation of nozzle after test: small quantity of white foam, not significant  Spray diameter (mean on 6 squeezes at 30cm from the adsorbent paper): 20cm | 18.649634.0004  18.649634.0005 | Acceptable.  Also results on MMAD and size drop provided for meta SP 5 can be used for meta SPC 12 since the trigger is the same according to the applicant (PP/PE trigger spray TS5 S). However size distribution and MMAD are requested after storage for Meta SPC 5 and should be provided in post registration. |
| Physical compatibility | No data generated |  |  |  | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated | | | | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mention EUH031 “contact with acids liberates toxic gas” is proposed for this Meta SPC.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | Not relevant, RTO products | | | | Not relevant as product is ready to use |
| Surface tension | OECD Test Guideline 115 and EC method A.5 | spray javel 4.8% c.a parfum eucalyptus  batch 181224 | Before storage: 29.90 mN/m at 20°C (neat)  After storage 10 months at 25°C: 28.73 mN/m at 20°C (neat) | 18.649634.0004  18.649634.0005 | Acceptable. The product is surface active. |
| Viscosity | Not relevant / liquid product | | | | Not acceptable. However, according to the composition, the viscosity is expected to be similar to water. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 12** |
| Products of meta SPC 12 are ready to use spray formulation. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid, with eucalyptus odour.  No accelerated storage stability study was provided. Products should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 1 of meta SPC 2.21 (same composition as for product 1 of meta SPC 12). The stability of this product was not fully demonstrated after storage 10 months at 20°C, since the active chlorine content decreases by more than 10% (-15.9%) and the sodium chlorate content is higher than the maximum limit of 5.4% of the active chlorine content (please refer to human health, residues and environment sections regarding conclusion on chlorate content). Results can be extrapolated to other products of meta 12 since composition is identical.Efficacy data allow to support a shelf life of 8 months (as claimed by the applicant) even if degradation of active substance is higher that 10% of initial content.  Technical properties for spray (clogging, spray pattern, amount delivered per stroke) have been provided before and after storage and found acceptable. MMAD and size distribution after storage are required in post authorisation. These data are requested for Meta SPC 5 and will be representative for Meta SPC 12 as the trigger is the same.  Compatibility of products with HDPE is acceptable with product 1 of meta SPC 2.21 and results can be extrapolated to product 1 of meta SPC 12.  **Implication concerning labelling for products of meta SPC 12**:  Shelf life proposed by eCA: 8 months (shelf life claimed by the applicant: 8 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Products should not be used in conjunction with acids or ammonia.  EUH031 “contact with acids liberates toxic gas” |

**Meta SPC 13 (ready to use gel)**

Tested formulation : product 2 from meta SPC 13. This product covers the whole meta SPC. Please refer to read across in confidential annex**.**

Packaging: HDPE bottle

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | gel javel 4.5% c.a parfum eucalyptus Batch 181118 (product 2 of meta SPC 13) | Before storage: Liquid gel, without precipitation or phase separation  After storage 15 months at 25°C: liquid gel without phase separation or precipitation | 18.649634.0001  18.649634.0002 | Acceptable |
| Colour at 20 °C and 101.3 kPa | Internal method | gel javel 4.5% c.a parfum eucalyptus Batch 181118 product 2 of meta SPC 13) | Before storage: Transparent yellow  After storage 15 months at 25°C: transparent yellow | 18.649634.0001  18.649634.0002 | Acceptable |
| Odour at 20 °C and 101.3 kPa | Internal method | gel javel 4.5% c.a parfum eucalyptus Batch 181118 product 2 of meta SPC 13) | Before storage: Bleach water with eucalyptus  After storage 15 months at 25°C: Bleach water with eucalyptus | 18.649634.0001  18.649634.0002 | Acceptable. Other product of this meta SPC is expected to have a bleach odour only (no perfume). |
| Acidity / alkalinity | CIPAC MT 31 | gel javel 4.5% c.a parfum eucalyptus Batch 181118 product 2 of meta SPC 13)  gel javel 4.5% c.a parfum eucalyptus Batch 2010201532 and 1904080547 product 2 of meta SPC 13) | Before storage: 2,56 NaOHeq %w/w  After storage 15 months at 25°C: 1.2 NaOH eq %w/w  pH at 20°C  before storage: 12.70  after storage (>11 months): 12.30 | 18.649634.0001  18.649634.0002  CoA: 10/2020 | Acceptable. |
| Relative density / bulk density | OECD 109 (pycnometer) | gel javel 4.5% c.a parfum eucalyptus 4,60%  Batch 191431 product 2 of meta SPC 13) | 1,0769g/mL at 20°C | RRCo-000341\_01 | Acceptable |
| Storage stability test – **accelerated storage** | No testing required | | | | Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17 ANA\_MON\_102,ANA\_MON\_103 Internal method for sodium chlorides  Validated methods in the study RRCo-000345\_01 | Gel javel wc power parfum eucalyptus 4,29% c.a, Batch 191431 product 2 of meta SPC 13) | GLP study :  packaging tested: HDPE bottle of 250mL  storage conditions: 24 months, in darkness, at 20°C  **Appearance**  Before storage: slightly yellow transparent viscous liquid, typical eucalyptus bleach odour  After 6 and 11 months at 20°C: slightly yellow transparent viscous liquid, typical eucalyptus bleach odour  **packaging**  before storage: no crack, no swelling, no change of colour  after storage: no crack, no swelling, no change of colour, no significant change in weight  **T0:**  Active chlorine: 4,60% w/w  Sodium chlorates: 0,13%w/w  Sodium chlorides: 4,46%w/w  Ratio sodium chlorate/active chlorine: 2.8%  **T6 months:**  Active chlorine: 3,81% w/w  **T11 months:**  Active chlorine: 3,46% w/w  Sodium chlorates: 0,35%w/w  Sodium chlorides: 5,36%w/w  Ratio sodium chlorate/active chlorine: 10.1% | RRCo-000341\_01 | A long term study 24 months at 20°C has been launched. Only results after 11 months are available.  The active substance content decreases by more than 10% after 11 months (-24.78%) and the ratio sodium chlorates/active chlorine exceeds 5.4%. Please refer to human health, residues and environment sections regarding conclusion on chlorate content.  Efficacy data allow to support a shelf life of 11 months (12 months was claimed by the applicant) even if degradation of active substance is higher that 10% of initial content. |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | Acceptable. Products of this meta SPC should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See report RRCo-000341\_01 (mid term) :  « No crack, no swellling, no change of colour after 11 months of storage. » | | | | Compatibility has been demonstrated with product 2 of meta SPC 13. |
| Wettability | No data generated |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  |  |  | Not relevant |
| Disintegration time | No data generated |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  |  |  | Not relevant |
| Persistent foaming | Not relevant, RTO products | | | | Not relevant as product is ready to use. |
| Flowability/Pourability/Dustability | No data generated |  |  |  | Not relevant |
| Burning rate — smoke generators | No data generated |  |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated |  |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated |  |  |  | Not relevant |
| Spraying pattern — aerosols | No data generated |  |  |  | Not relevant |
| Physical compatibility | No data generated | | | | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated | | | | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas.  Mention EUH031 is not applicable for this meta SPC since active substance content is below 5% w/w.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | Not relevant, RTO products | | | | Not relevant as product is ready to use. |
| Surface tension | OECD Test Guideline 115 and EC method A.5 | gel javel 4.5% c.a parfum eucalyptus Batch 181118 product 2 of meta SPC 13) | Could not be done because viscosity is too high. OECD115/A.5 ring method is applicable only to solutions having dynamic viscosity lower than 200 mPa.s. The product GEL JAVEL 4.5% c.a PARFUM EUCALYPTUS batch 181118 has a dynamic viscosity of 420 mPa.s | 18.649634.0001 | Acceptable. Cannot be measured due a high viscosity. However, according to the composition products are expected to be surface active due to the presence of surfactants at significant amount. |
| Viscosity | OECD 114 | gel javel 4.5% c.a parfum eucalyptus Batch 181118 product 2 of meta SPC 13) | Before shelf-life:  1266,02mm²/s at 20°C (flow time 1284s)  2.88 mm2/s at 40°C (flow time 565s)  After storage 12 months at 25°C:  775mm²/s at 20°C (flow time 767-805s)  3.38 mm2/s at 40°C (flow time 612-768s) | 18.649634.0001  18.649634.0002 | Acceptable |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 13** |
| Products of meta SPC 13 are ready to use gel formulation. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance is that of transparent yellow liquid, with eucalyptus or bleach odour.  No accelerated storage stability study was provided. Products should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 2 of meta SPC 13. The stability of this product was not fully demonstrated after storage 11 months at 20°C, since the active chlorine content decreases by more than 10% (-24.78%) and the sodium chlorate content is higher than the maximum limit of 5.4% of the active chlorine content (please refer to human health, residues and environment sections regarding conclusion on chlorate content). Results can be extrapolated to other products of meta 13 since the product is similar~~.~~ Efficacy data allow to support a shelf life of 11 months even if degradation of active substance is higher that 10% of initial content.  Compatibility of products with HDPE is acceptable with product 2 of meta SPC 13 and results can be extrapolated to this meta SPC.  **Implication concerning labelling for products of meta SPC 13**:  Shelf life proposed by eCA: 11 months (shelf life claimed by the applicant: 12 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Products should not be used in conjunction with acids or ammonia. |

**Meta SPC 14 (gel formulation)**

Tested formulation: this meta SPC is composed of one product composed of two separate liquids (one containing the active ingredient named “concentrated bleach 9.6% c.a” and a gel solution containing only formulants). These two liquids are mixed just before application (1L of concentrated bleach in 4L of gel solution). Physico chemical properties of the concentrated bleach are covered by studies provided for meta SPC 9/6.22 as product of these meta SPC constitute a worst case. Please refer to confidential annex. Data were also provided for the gel solution and the mixture gel solution + concentrated bleach 9.6% c.a.

Packaging: HDPE bottle for concentrated bleach and gel solution.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Internal method | Gel SETS EPAISSISSANT (gel solution), batch 10-35  GEL SETS EPAISSISSANT (gel solution), batch 12-75 + JAVEL BEC 9.6% batch 6201091454 | Gel  Mixture: 100g of gel with 25g of JAVEL 9.6%  White gel, opaque, homognenous with bleach odour | SDS  SETS STABILITESv1  SETS document 003 | Acceptable.  Physical state is not reported for the concentrated bleach. However, based on the composition, it is a liquid. |
| Colour at 20 °C and 101.3 kPa | Internal method | Gel SETS EPAISSISSANT (gel solution), batch 10-35  GEL SETS EPAISSISSANT (gel solution), batch 12-75 + JAVEL BEC 9.6% batch 6201091454 | White  White | SDS  SETS STABILITESv1  SETS document 003 | Acceptable  Colour is not reported for the concentrated bleach. However, based on the composition, it is expected to be a transparent yellow liquid as for meta SPC 6.22 |
| Odour at 20 °C and 101.3 kPa | Internal method | Gel SETS EPAISSISSANT (gel solution), batch 10-35  GEL SETS EPAISSISSANT (gel solution), batch 12-75 + JAVEL BEC 9.6% batch 6201091454 | No odour  Bleach odour | SDS  SETS STABILITESv1  SETS document 003 | Acceptable.  According to the composition, the concentrated bleach is expected to have a bleach odour. |
| Acidity / alkalinity | CIPAC MT 191  No method reported  No method reported | eau de javel 9.6% c.a eucalyptus  Batch: 180817  (product 1 of meta SPC 9)  SETS EPAISSISSANT, batch 10-35  Mixture gel solution SETS EPAISSISSANT/concentrated bleach 4 :1  eau de javel à 9.6% c.a parfumee eucalyptus, batch 2010201416 (product 1 of meta SPC 9) | Before storage: 3.98 as NaOH %w/w  After storage 10 months at 25°C: 1.76% w/w NaOH eq  pH of gel solution: 9  pH of mixture: 10.8  pH at 20°C: 12.20 | 18.644892.0002  18.644892.0007  SETS document 001v1  SETS document 001v1  CoA, 10/2020 | Acceptable for alkalinity.  pH has been provided for the gel solution and mixture 4:1 gel solution/concentrated bleach. |
| Relative density / bulk density | OECD 109 (pycnometer method) | eau de javel 9.6% c.a eucalyptus  Batch: 190402  (product 1 of meta SPC 9)  eau de javel 12.5% c.a batch 191531 (product 1 meta SPC 6.22) | 1,1542 g/mL at 20°C  After 10 months at 20°C: 1.1498 g/mL at 20°C  Before storage: 1,2261g/mL at 20°C  After 5 months: 1.2201 g/mL at 20°C | RRCo-000338\_01  RRCo-000337\_01+ Amdt n#1 | Results for meta SPC 9/6.22 are acceptable and can be extrapolated to the concentrated bleach of meta SPC 14. |
| Storage stability test – **accelerated storage** | Test not required | | | | Product should be stored at ambient temperature (below 30°C). |
| Storage stability test – **long term storage at ambient temperature** | T GIFAP Monograph 17  ANA\_MON\_102ANA\_MON\_103  Internal method for sodium chloride  All methods validated in the study RRCo-000345\_01 | eau de javel 9.6% c.a eucalyptus  Batch: 190402  (product 1 of meta SPC 9) | Refer to results of meta SPC 9 and meta-SPC6.22 | RRCo-000338\_01 | A storage stability 10 months at 20°C has been provided for product 1 of meta SPC 9 and results can be extrapolated to the concentrated bleach. Product 1 of meta SPC 9 is compatible with HDPE packaging. However the content of active chlorine decreases by more than 10% and the ratio sodium chlorate/active chlorine exceeds 5.4% w/w. Please refer to human health, residues and environement sections regarding conclusion on chlorate content.  Efficacy data do not support a shelf life up to 8 months as claimed by the applicant. eCA has considered the limit of 10%. According to the results available for meta SPC 9, interpolation can be done using the graph 1/C NaOCl vs time (kinetic model order 2, 6 points, linear regression, R>0.99). eCA considers that the loss of active substance is still below 10% after 1 month. A shelf life of 1 month can be granted for this meta SPC. |
| Internal method SETS RHE 001 (rotational viscometer AR 2000ex) | SETS EPAISSISSANT, batch 10-35 | Packaging tested: HDPE  T0:  Appearance: white, homogeneous gel  pH: between 8 and 10  Gel Viscosity:  At 10s-1: 3 - 5 Pa.s (no temperature reported)  At 0.1s-1: 45 - 80 Pa.s (no temperature reported)  T5months:  Appearance: white, homogeneous gel  pH: between 8 and 10  Gel viscosity  At 10s-1: 3 - 5 Pa.s (no temperature reported)  At 0.1s-1: 45 - 80 Pa.s (no temperature reported) | SETS STABILITESv1.pdf | Acceptable. The gel is compatible with HDPE packaging. |
| Internal method SETS RHE 001 (rotational viscometer AR 2000ex) | Mixture gel solution SETS EPAISSISSANT/concentrated bleach 4 :1 | T0  No exothermic reaction  viscosity  At 10s-1: 1-1.5 Pa.s (no temperature reported)  At 0.1s-1: 45 - 80 Pa.s (no temperature reported)  T5months  No exothermic reaction  At 10s-1: 1 – 1.5 Pa.s (no temperature reported)  At 0.1s-1: 45 - 80 Pa.s (no temperature reported) | SETS STABILITESv1.pdf | Mixture of the concentrated bleach with gel solution was assessed before and after 5 months. Viscosity remains in the range set. Even if not temperature is reported for the measure of viscosity, data are considered acceptable regarding the type of product.  Content of active chlorine and pH were measured on storage in HDPE container. Results shows that no av. Chlorine remains after 10 days in the container used for the preparation of the mixture. However, the mixture is not intended to be stored and should be used immediately. No shelf life is given for the mixture. |
| no method reported | Mixture gel solution SETS EPAISSISSANT/concentrated bleach 4 :1 | For the preparation: 1 berlingot to 250mL Javel 9.6% av. Chlorine is added in a curtec HDPE packaging containing 1.08kg of gel solution (theoretical av chlorine content in the mixture: 2.10%). The mixture is shaken vigorously. The container is closed and stored for 10 days.  The content of av. Chlorine and pH of the mixture was measured following 10 days in the HDPE container at 23°C and in darkness:  pH  0-15min: 10.8  4h: 10  24: 9  10 days: 6.0  Av. Chlorine content  0-15min: 1.94% w/w  4h: 1.85%  24h: 1.66%  29h: 1.17%  10 days: <0.1% (not detected) | SETS document 001v1 |
| Storage stability test – **low temperature stability test for liquids** | “Store away from low temperatures” will be labelled on the product. | | | | Acceptable. Products should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | “Store away from light” will be labelled on the product. | | | | Acceptable. Products should be kept away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | “Store at ambient temperature” will be labelled on the product. | | | | Acceptable. Products should be stored at ambient temperature (below 30°C). |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | See results on products of meta-SPC9 and meta SPC 6.22 (same or higher concentration of av. chlorine and presence of additional formulants, therefore considered worst cases). | | | | Compatibility of product 1 from meta SPC 9 and product 1 of meta SPC 6.22 with HDPE material has been demonstrated and results can be extrapolated to product 1 of meta SPC 14. |
| Wettability | No data generated |  |  |  | Not relevant |
| Suspensibility, spontaneity and dispersion stability | No data generated |  |  |  | Not relevant |
| Wet sieve analysis and dry sieve test | No data generated |  |  |  | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | No data generated |  |  |  | Not relevant |
| Disintegration time | No data generated |  |  |  | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | No data generated |  |  |  | Not relevant |
| Persistent foaming | Not specified | GEL SETS EPAISSISSANT (gel solution), batch 12-75 + JAVEL BEC 9.6% batch 6201091454 | At 50w/w% (25g of gel sets javel BEC = mixture into 26g of water): no foam was observed after 30 iversions during 60s | SETS document 003 | Acceptable. The mixture is not foaming. |
| Flowability/Pourability/Dustability | No data generated |  |  |  | Not relevant |
| Burning rate — smoke generators | No data generated |  |  |  | Not relevant |
| Burning completeness — smoke generators | No data generated |  |  |  | Not relevant |
| Composition of smoke — smoke generators | No data generated |  |  |  | Not relevant |
| Spraying pattern — aerosols | No data generated |  |  |  | Not relevant |
| Physical compatibility | No data generated | | | | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | No data generated | | | | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mentions EUH031 “contact with acids liberates toxic gas” and EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” are proposed for this Meta SPC.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | No specified | GEL SETS EPAISSISSANT (gel solution), batch 12-75 + JAVEL BEC 9.6% batch 6201091454 | At 50w/w% (50g of gel sets javel BEC = mixture into 50g of water): no phase separation after 24h | SETS document 003 | Acceptable. The mixture remains homogeneous after 24h. |
| Surface tension | No data generated | GEL SETS EPAISSISSANT (gel solution), batch 12-75 + JAVEL BEC 9.6% batch 6201091454 | The method recommende by OCDE is applicable to products with a viscosity below 0.2 Pa.s, which is not the case for the mixture. Consequently, surface tension cannot be measured with the recommended method. | SETS document 003 | Concentrated bleach is not expected to be surface active. Even if the test method is not applicable to the mixture due to its viscosity, the mixture is expected to be surface active due to the presence of emulsifier in the gel solution. |
| Viscosity | Internal method SETS RHE 001 (rotational viscometer AR 2000ex) | Gel solution, batch 10-35  Mixture gel solution:concentrated bleach 4:1, no batch reported  GEL SETS EPAISSISSANT (gel solution), batch 12-75 + JAVEL BEC 9.6% batch 6201091454 | At 10s-1 : between 3 and 5 Pa.s (no temperature reported)  At 0.1s-1 : between 45 and 80 Pa.s (no temperature reported)  No exothermic reaction when gel and concentration bleach are mixed  At 10s-1: between 1 and 1.5Pa.s (no temperature reported)  At 0.1s-1: between 45 and 80 Pa.s (no temperature reported)  At 0.01s-1: 1021 Pa (no temperature reported) | SETS STABILITESv1  SETS document  003 | Viscosity of the bleach concentrated is expected to be similar to water.  Viscosity was provided for the gel solution and mixture 4:1 gel solution/concentrated bleach. No significant difference are noticed. No temperature is reported and the method is not described. |
| Gel solution, | At 100s-1: 0.354 Pa.s  At 10s-1: 3.54 Pa.s  At 1s-1: 11Pa.s  At 0.1s-1: 55.27 Pa.s  At 0.01s-1: 765 Pa.s | SETS document 001v1 | Acceptable. |

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| **Conclusion on the physical, chemical and technical properties of meta SPC 14** |
| Product of meta SPC 14 is composed of a gel solution to be mixed with a concentrated bleach solution. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance of the concentrated bleach is that of transparent yellow liquid, with bleach. The appareance of the gel is that of a white gel without odour.  No accelerated storage stability study was provided. Product (gel and concentrated bleach) should not be stored at a temperature higher than 30°C.  Shelf life was performed with product 1 of meta SPC 9. The stability of this product was not fully demonstrated after storage 10 months at 20°C, since the active chlorine content decreases by more than 10% (-39.8%) and the sodium chlorate content is higher than the maximum limit of 5.4% of the active chlorine content (please refer to human health, residues and environment sections regarding conclusion on chlorate content). Product 1 of meta SPC 9 is a worst case and results can be extrapolated to the concentrated bleach of meta SPC 14. Efficacy data do not support a shelf life up to 8 months as claimed by the applicant. eCA has considered the limit of 10%. According to the results available for meta SPC 9, eCA considers that the loss of active substance is still below 10% after 1 month by interpolation. A shelf life of 1 month can be granted for this meta SPC.  The gel solution was stored 5 months. Appearance, viscosity and pH of the gel remain stable. The mixture of the gel solution with the bleach solution is not foaming and forms homogeneous white opaque solution. Even if results are only available up to 5 months for the gel solution, no significant differences are expected after 6 months. However an overall shelf life of 1 month is acceptable for this meta SPC (bottle of bleach product + bottle of gel solution)  Viscosity and pH of the mixture (gel solution/concentrated bleach 4:1) were provided. No exothermic reaction occurs when the two liquids are mixed.  Compatibility of products with HDPE is acceptable with product 1 of meta SPC 9. Results can be extrapolated to the concentrated bleach of meta SPC 14.  **Implication concerning labelling for products of meta SPC14**:  Shelf life proposed by eCA: 1 month (shelf life claimed by the applicant: 6 months)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  EUH031 “contact with acids liberates toxic gas”  EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)”  Products should not be used in conjunction with acids or ammonia. |

### Physical hazards and respective characteristics

No studies have been provided by the applicant.

Due to the similarity between formulations of the biocidal product family, a common table has been prepared since scientific cases/waivers are mainly proposed.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Explosives | No data generated | At the view of the products components composition, it is not expected for the products of the family to possess explosive properties. Indeed, the products are mostly composed of water and none of the ingredients is classified as explosive. Moreover, experience in manufacture and use shows that no explosiveness is expected from the products.  Based on these elements, it is therefore considered that the classification of the products according to the explosiveness hazard can be waived without further testing. | | | According to the CAR (confirmatory data peer reviewed in 2018), solutions of NaOCl (16.7%) are not explosive. Additionally, other compounds are not classified as explosive and the products are aqueous solution with a high proportion of water. Therefore, products of the family are not classified. |
| Flammable gases | No data  generated | Not applicable. The products are liquid formulations. | | | Not relevant. |
| Flammable aerosols | No data  generated | Not applicable. The products are liquid formulations  not intended to be used as aerosols. | | | Not relevant. |
| Oxidising gases | No data  generated | Not applicable. The products are liquid formulations. | | | Not relevant. |
| Gases under pressure | No data  generated | Not applicable. The products are liquid formulations. | | | Not relevant. |
| Flammable liquids | No data  generated | The products are mainly composed of water and inorganic substances. The only  components classifiedas flammable are some of the substances present in  the perfumes. None of the other components is volatile, making it unlikely for them to be present inthe product vapour. As perfumes are never found at  great concentrations in the formulations, their  presence in some of the products is not expected to  lead to flash points lower than 60°C or to lead to  combustions that would be sustained. Moreover,  experience in manufacture and handling has shown  no evidence of the products being flammable. Hence,  it is considered that the products are not flammable  liquids and this classification can be waived without  further testing. | | | Products contains less than 8% of organic compounds and none of them (except perfums at low content) are classified as flammable according to Brief Profile/C&L Inventory (ECHA). eCA considers that a test for flammability is not relevant and products are not classified as flammable according to CLP criteria and Reach regulation 1907/2006.  For the gel solution of SPC 14, one compound may be flammable (C&L inventory, ECHA) but its content is low (<1%). eCA considers that the gel solution is also not flammable.  This conclusion is confirmed with tests performed on 12 products of the family using closed cup method. None of them was considerd flammable. |
|  | ISO 3679 (closed cup method) | Detergent Alcalin Chloré Moussant  Spray Javel 1.5% ca Eucalyptus  Gel Javel 1.5% ca ca Eucalyptus  Gel Javel 2.6% ca Eucalyptus  Gel Javel 4.5% ca Eucalyptus  Detergent Javel 2.6% ca Eucalyptus  Eau de Javel 1.6% ca eucalyptus  Eau de Javel 2.6% ca eucalyptus  Eau de Javel 3.6% ca eucalyptus  Eau de Javel 4.8% ca eucalyptus  Eau de Javel 9.6% ca eucalyptus  Eau de Javel 12.5% ca | Flash point has been measured for 12 products of the family.  For all products, flahs point is > 100°C, meaning that none of them are classified as flammable. | J.C NEYT, 2020 |  |
| Flammable solids | No data  generated | Not applicable. The products are liquid formulations. | | | Not relevant |
| Self-reactive substances and mixtures | No data  generated | The mixtures are mostly composed of water. Examination of the structural formula of the components indicates few ingredients containing potentially self-reactive chemical groups.  The sum of those substances concentrations in the products never exceeds 5% and they are not classified as self-reactive, nor are any of the other components. Moreover, experience in manufacture and use shows no evidence that the products possess self-reactive properties.  Based on these elements, the products are not considered to be self-reactive and classification can be waived without further testing. | | | Not relevant since no compound is classified explosive or self reactive. Additionally, sodium hypochlorite does not decompose strongly exothermically.  According to Guidance on the application of the CLP criteria, “*substances and mixtures must be considered for classification in this hazard class unless there are no chemical groups present in the molecule associated with explosive or self-reactive properties. Examples of such groups are given in Tables A6.1 and A6.2 in Appendix 6 of the UN RTDG, Manual of Tests and Criteria”*.  For Meta SPCs containing only active substance and water, a waiving is acceptable. All other Meta SPCs may contain formulants as complexing agents, surfactants, perfumes and they do not satisfy the waiver for chemical group associated with self reactive properties. However, in view of very low concentrations of compounds and the absence of explosive properties, eCa is of opinion that requesting a full test is not appropriate. eCA rather proposes to request a DSC test in post registration to confirm the non classification in this hazard class for those meta-SPCs. |
| Pyrophoric liquids | No data  generated | Experience in manufacture and handling shows that  the products do not ignite spontaneously on coming  into contact with air at normal temperatures (i.e. the  liquids are known to be stable at room temperature  for prolonged periods of time). It is therefore  concluded that the products are not pyrophoric and  further testing is not necessary. | | | Acceptable. Based on the compositions, products are not pyrophoric liquids. |
| Pyrophoric solids | No data  generated | Not applicable. The products are liquid formulations. | | | Not relevant. |
| Self-heating substances and mixtures | No data  generated | The products are liquid at ambient temperature.  According to the Guidance on the Application of the  CLP Criteria (version 5.0, July 2017), "the  phenomenon of self-heating applies only to solids.  The surface of liquids is not large enough for reaction  with air and the test method is not applicable to  liquids. Therefore liquids are not classified as self-  heating." Based on this element, the products can  therefore be considered as not being self-heating  without further testing. | | | Not relevant due to the composition of the family product. Not applicable to products with a melting point below 160°C. |
| Substances and mixtures which in contact with water emit flammable gases | No data  generated | Experience in handling and use shows that the  mixtures do not react with water. The products are  water-based formulations. It is therefore concluded  that classification for substances or mixtures which in  contact with water emit flammable gas can be waived  without further testing. | | | Acceptable.  In water, sodium hypochlorite can be converted in chlorine gas. However, this is relevant at low pH (<4). In this case, the pH of the product is kept >11 due to stability of the active substance. Additionally, chlorine is not known to be a flammable gas. No further data are deemed necessary.  Furthermore, products are already water based formulation. |
| Oxidising liquids | No data  generated | The products are mainly composed of water. The only  component classified as oxidising is sodium chlorate.  No study of oxidising properties of sodium  hypochlorite has been detailed in the assessment  report but the REACH registration dossier shows  negative results according to UN Method A21, which  means that sodium hypocholorite is not  oxidising. None of the other components of the  products are oxidising. Moreover, experience in  manufacture and handling has shown no evidence of  the products being oxidising. Hence, it is considered  that the products are not oxidising liquids and this  classification can be waived without further testing. | | | According to the CAR (confirmatory data peer reviewed in 2018), solutions of NaOCl (25.3%) are not considered as oxidizing liquid. Additionally, other constituents are not classified or do not possess chemical groups related to oxidizing properties. Consequently, products of the family do not possess oxidizing properties. |
| Oxidising solids | No data  generated | Not applicable. The products are liquid formulations. | | | Not relevant. |
| Organic peroxides | No data  generated | Not applicable. The formulations do not contain organic peroxides. | | | Not relevant. |
| Corrosive to metals | No data generated | Products are classified H290 Corr. Met. 1. | | | All tested products are classified according to test C1 of manul UN RTDG. The products at 1.5-1.6% active chlorine is sufficiently representative to conclude that all products of the family are clearly corrosive to metals. Consequently, the classification H290 Met Corr I is applicable to the whole family. |
| Test C1, UN RTDG Manual of tests and criteria | Eau de Javel 3.6% ca eucalyptus, batch 201209-1  Eau de Javel à 2.6% ca eucalyptus, batch 201209-2  Eau de Javel à 1.6% ca eucalyptus, batch 201209-3  Gel Javel à 2.6% ca eucalytus, batch 201209-4  Gel javel à 1.5% ca eucalyptus, batch 201209-5  Spray javel à 1.5% ca eucalyptus batch 201209-6 | Conditions of the test: samples of steel (S235 JR+ CR) and aluminium (7075-T6) are exposed to formulations (immersed, half immersed, suspended in vapour phase), 14 days at 55°C  **Eau de Javel 3.6% ca eucalyptus:**  Worst case for steel sample: loss of 30.24% after 14 days (half immersed)  Worst case for aluminium sample: loss of 12.27% after 14 days (immersed), no intrusion depth  As the loss for steel is higher than 26.5% after 14 days (equivalent to a corrosive rate of 6.255 mm/y), the product is classified H290 Met. Corr. I.  **Eau de Javel à 2.6% ca eucalyptus**  Worst case for steel sample : loss of 24.57% after 14 days (immersed); intrusion depth higher than 240µm (970µm observed)  Worst case for aluminium sample: loss of 7.78% after 14 days (immersed), no intrusion depth  The loss for steel and aluminium is below 26.5% after 14 days (equivalent to a corrosive rate of 6.255 mm/y), but intrusion depth is higher than 240µm (limit for an exposition of 14 days). The product is classified H290 Met. Corr. I.  **Eau de Javel à 1.6% ca eucalyptus**  Worst case for steel sample: loss of 21.10% after 14 days (immersed), intrusion depth of 1440µm  Worst case for aluminium sample: loss of 3.82% after 14 days (immersed), intrusion depth of 620µm  The loss for steel and aluminium is below 26.5% after 14 days (equivalent to a corrosive rate of 6.255 mm/y), but intrusion depth is higher than 240µm (limit for an exposition of 14 days) for both samples. The product is classified H290 Met. Corr. I.  **Gel javel à 2.6% ca eucalyptus**  Worst case for steel sample : loss of 11.89% after 14 days (half immersed), intrusion depth of 930µm  Worst case for aluminium: loss of 20.40% after 14 days (immersed); no intrusion depth  The loss for steel and aluminium is below 26.5% after 14 days (equivalent to a corrosive rate of 6.255 mm/y), but intrusion depth is higher than 240µm for steel samples (limit for an exposition of 14 days). The product is classified H290 Met. Corr. I.  **Gel javel à 1.5% ca eucalyptus**  Worst case for steel : loss of 1.60% (vapour phase), intrusion depth of 950µm  Worst case for aluminium: loss of 33.88% (immersed)  The loss for aluminium is higher than 26.5% after 14 days (equivalent to a corrosive rate of 6.255 mm/y), and intrusion depth for steel is higher than 240µm (limit for an exposition of 14 days). The product is classified H290 Met. Corr. I.  **Spray javel à 1.5% ca eucalyptus**  Worst case for steel : loss of 10.40% after 14 days (half immersed), intrusion depth of 1100µm  Worst case for aluminium: loss of 25.44% (immersed), no intrusion depth  The loss for steel and aluminium is below than 26.5% after 14 days (equivalent to a corrosive rate of 6.255 mm/y), but intrusion depth for steel is higher than 240µm (limit for an exposition of 14 days). The product is classified H290 Met. Corr. I. | J-F Lacroix, 2021, report R2021128A, R2021128B, R2021128C, R2021128D, R2021128E, R2021128F |
| Auto-ignition temperatures of products (liquids and gases) | No data generated | This parameter is not relevant for liquid formulations not flammable in air. Based on the products compositions, they are not flammable in air: sodium hypochlorite solutions are non-flammable (as stated in the assessment report for the active substance), and the co-formulants are not expected to cause the products to be flammable as they are not flammable themselves. This parameter is therefore considered irrelevant and no testing is necessary. | | | In the CAR, it has been concluded that sodium hypochlorite is not auto-flammable. Additionally, as produts are aqueous solution with a high proportion of water, no specific concern is raised and products are not considered as auto flammable. |
| Relative self-ignition temperature for solids | No data  generated | Not applicable. The products are liquid formulations. | | | Not relevant. |
| Dust explosion hazard | No data  generated | Not applicable. The products are liquid formulations. | | | Not relevant. |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| Products of the family DAAP19 are not explosive, flammable or auto-flammable. They have no oxidizing properties.  According to the tests provided, all products of the DAAP19 family are classified H290 Met Corr. I. All other hazard categories are considered irrelevant based on the nature of the products constituents, without there being the need for further testing. **A DSC test on representative products of the BPF should be provided in post registration in order to confirm that products are not self reactive.**  **Labelling mention for all Meta SPC:** H290, GHS05 Met Corr. 1, Danger |

### Methods for detection and identification

GLP studies were developed to analyse sodium hypochlorite concentrations, sodium chlorates, sodiums chlorides and sodium hydroxide.

**Analytical method for active chlorine in formulation (ANA MON 102 and RRCo-000708\_01)**

Method: A neutral pH, active chlorine reacts with DPD and forms a coloured solution. Absorbance at 550 nm is measured by the spectrophotometer. Just after preparation in measuring cell, solutions were shaken during 30 second and absorbance at 550 nm was read quickly after preparation. The auto zero was performed with the blank.

Study ANA\_MON\_102: validation data are reported for liquid formulation containing 12.5%, 5.5% and 2.6% active chlorine. Please refer to confidential annex for details on the products tested and validation data.

Study RRCo-000708\_01: Additional validation data on representative products of the DAAP19 family are reported in study RRCo-000708\_01. Please refer to confidential annex for details on the products tested and validation data.

**Analytical method for active chlorine in algae and M4 test media (report RRCo-0000267\_01)**

This report is a validation of active chlorine in different test media (algae and M4). The test item (Eau javel parfumée à 2.6% (eucalyptus), batch 1820J14, meta SPC 2.1) has been used to fortified test media.

Method: A neutral pH, active chlorine reacts with DPD and forms a coloured solution. Absorbance at 550 nm is measured by the spectrophotometer. The auto zero was performed with the blank. To validate the method for test item, 5 series of experiments were repeated for distinct days or operators. Preparation of solutions are detailed for all series in the report. Please refer to confidential annex for details on the products tested and validation data.

**Analytical method for active chlorate (report ANA MON 103 and RRCo-000708\_01)**

Samples are diluted in water and homogenised by agitation. Chlorate content is determined by ionic chromatography with external calibration. The same conditions were used in each report:



Report ANA MON 103

Products tested (according to study ANA Mon 103):

* 12.5% active chlorine formulation
* 5.5% active chlorine formulation
* 2.6% active chlorine formulation

Please refer to confidential annex for details on the tested products and validation data.

Report RRCo-000708\_01

Only specificity was assessed in this report. The same products as listed above were tested for sodium chlorate specificity. The analytical conditions were the same as in report ANA MON 103. Please refer to confidential annex for details on the tested products and validation data.

Report RRCo-000866\_01

Further validation data regarding linearity, accuracy, precision and LOQ were provided in this report. The same products as listed above in report RRCo-000708\_01 were tested. The analytical conditions were the same as in report ANA MON 103. Please refer to confidential annex for details on the tested products and validation data. The method is considered validated for the determination of sodium chlorate in DAAP19 family.

**Analytical method for sodium chloride (report RRCo-000345\_01)**

Formulation pH is adjusted to 7.0 ± 0.2 with H2SO4 0.1 M prior to analysis. Sodium chloride is titrated by a silver nitrate solution with which forms a silver chloride precipitate. In presence of potassium chromate, end of titration (ie excess of silver nitrate) is detected by a coloration change form yellow to orange. Validation was performed on three representative products chosen during the study. Please refer to confidential annex for details on the tested products and validation data.

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| --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** |
| **Refer to confidential annex** |

|  |  |
| --- | --- |
| **Analytical methods for air** | |
| study scientifically not necessary / other information available | This method is already provided in the AS documents section III A (brought via LoA see attached LoA in section 13). no need to redevelop another one.  The CAR precise "Though not validated, the two available methods are published methods, so they can still be concluded to be acceptable for the purpose (determination of chlorine in workplace air)" |

|  |  |
| --- | --- |
| **Analytical methods for soil** | |
| study scientifically not necessary / other information available | This method is already provided in the AS documents section III A (brought via LoA see attached LoA in section 13). no need to redevelop another one.  The CAR precise "Active chlorine (HClO/ClO─) can reach the soil compartment only indirectly, via liquid manure application: rapid degradation occurs already with organic matter therein. In the event of contamination of soil, e.g. due to direct application of chlorinated water, hypochlorous acid/hypochlorite anion would react rapidly with organic matter in soil, anyway". |

|  |  |
| --- | --- |
| **Analytical methods for animal and human body fluids and tissues** | |
| study scientifically not necessary / other information available | Not required.  The CAR precise "Hypochlorous acid/ hypochlorite anion are oxidizing agents and degrade rapidly with organic matter. Besides, due to corrosive properties, systemic toxicity would be secondary to local effects". |

|  |  |
| --- | --- |
| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** | |
| study scientifically not necessary / other information available | BPC opinion precises "as active chlorine released from sodium hypochlorite degrades rapidly in contact with food and feed matrices, no methods are to be submitted". Analytical methods for determination of the relevant metabolite chlorate (ClO3─) in food/feed of animal origin were reviewed at EU level. |

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| Methods for the determination of active chlorine and sodium chlorate in products of the biocidal family DAAP19 are sufficiently validated according to the BPR.  Please refer to confidential annex for details.  For soil, air, surface water, body fluids and tissues, the applicant has access to the CAR of the active substance. According to the Assessment Report of Active chlorine released from sodium hypochlorite (January 2017), considering the reactivity of active chlorine with organic matter, no method is required for the determination of the active chlorine (HClO/ClO─) in soil, surface water and animal and human body fluids and tissues.  Fully validated methods for the determination of active chlorine in water and relevant impurity chlorate in drinking water, food and animal products have also been provided in the CAR of the active substance (confirmatory data assessed and peer reviewed by eCA IT in 2018) |

### Efficacy against target organisms

#### Function and field of use

MG 01: Disinfectants

PT2: Disinfectants and algaecides not intended for direct application to humans or animals

PT3: Veterinary hygiene.

PT4: Food and feed area.

PT5: Drinking water disinfectants.

The biocidal product family DAAP19 based on the active substance available chlorine released from sodium hypochlorite consists of 22 META-SPC and is intended for uses in Product Type (PT) 2, 3, 4 and 5 for the following applications:

**Product Type 2:**

* #1 – Disinfection of private swimming pools – continuous treatment for META-SPC 1.1 and META-SPC 1.2.
* #2 – Disinfection of private swimming pools – shock treatment for META-SPC 1.1 and META-SPC 1.2.
* #3 – Disinfection of footbaths in private swimming pools for META-SPC 1.1 and META-SPC 1.2.
* #4 – Disinfection of household surfaces (floors) by wiping with mop and bucket (without mechanical action) for META-SPC 2.1, META-SPC 2.21, META-SPC 2.22, META-SPC 6.1 and META-SPC 8.
* #5 – Disinfection of surfaces (other than floors) by wiping with cloth and bucket (without mechanical action) in household areas for META-SPC 2.1, META-SPC 2.21, META-SPC 2.22, META-SPC 3, META-SPC 6.1 and META-SPC 8; and for household/institutions/healthcare/industries areas for META-SPC 4.
* #6 – Disinfection of toilet bowls (without mechanical action) in household areas for META-SPC 2.1, META-SPC 2.21, META-SPC 2.22, META-SPC 4 and META-SPC 8; and in household/institutions/industries/healthcare areas for META-SPC 3.
* #7 – Laundry disinfection with hand soaking in household areas for META-SPC 2.1, META-SPC 2.21, META-SPC 2.22, META-SPC 6.1, META-SPC 6.21 and META-SPC 8; and in healthcare/industry areas for META-SPC 6.22, META-SPC 7.11, META-SPC 7.12, META-SPC 7.2, META-SPC 10.1 and META-SPC 10.2.
* #8 – Disinfection of surfaces by spraying (without mechanical action) for META-SPC 5 (household/institutions/industry/healthcare areas) and META-SPC 12 (institutions /industry/healthcare areas).
* #9 – Disinfection of surfaces in medical area (without mechanical action) for META-SPC 6.21, META-SPC 6.22, META-SPC 7.11, META-SPC 7.12, META-SPC 7.2, META-SPC 10.1, META-SPC 10.2 and META-SPC 11.
* #10 - Disinfection of surfaces in institutions/industry (without mechanical action) for META-SPC 6.21, META-SPC 6.22, META-SPC 7.11, META-SPC 7.12, META-SPC 7.2, META-SPC 10.1, META-SPC 10.2 and META-SPC 11.
* #11 - Disinfection of surfaces by CIP in industry/institutions areas, for META-SPC 6.21, META-SPC 6.22, META-SPC 7.11, META-SPC 7.12, META-SPC 7.2, META-SPC 10.1, META-SPC 10.2 and META-SPC 11.
* #12 - Algaecide and fungicide for outdoor surfaces (without mechanical action) for META-SPC 9 and META-SPC 14.
* #13 - Disinfection of toilet bowls in medical area (without mechanical action) for META-SPC 13
* #14 - Disinfection of toilet bowls in institutions/industry area (without mechanical action) for META-SPC 13.

**Product Type 3:**

* #1 – Disinfection of companion animal housing and associated equipment (without mechanical action) for META-SPC 2.1, META-SPC 2.21, META-SPC 2.22, META-SPC 6.1 and META-SPC 8.
* #2 - Disinfection of non-porous hard surfaces in veterinary healthcare facilities, ani-mal housings (such as kennels, hutches, cages, bee hives, stables, etc.), livestocks (poultry, bovine, etc.) buildings (without mechanical action) for META-SPC 6.21, META-SPC 6.22, META-SPC 7.11, META-SPC 7.12, META-SPC 7.2, META-SPC 10.1, META-SPC 10.2 and META-SPC 11.
* #3 - Disinfection of non-porous hard surfaces in livestock transportation vehicles (without mechanical action) for META-SPC 6.21, META-SPC 6.22, META-SPC 7.11, META-SPC 7.12, META-SPC 7.2, META-SPC 10.1, META-SPC 10.2 and META-SPC 11.

**Product Type 4:**

* #1 – Disinfection of household surfaces (other than floors) in contact with food by wiping with cloth and bucket (without mechanical action) for META-SPC 2.1, META-SPC 2.21, META-SPC 2.22, META-SPC 6.1 and META-SPC 8.
* #2 - Disinfection of surfaces in contact with food (without mechanical action) in institutions/industry areas, for META-SPC 6.21, META-SPC 6.22, META-SPC 7.11, META-SPC 7.12, META-SPC 7.2, META-SPC 10.1, META-SPC 10.2 and META-SPC 11.
* #3 - Disinfection of surfaces by CIP in industry/institutions areas), for META-SPC 6.21, META-SPC 6.22, META-SPC 7.11, META-SPC 7.12, META-SPC 7.2, META-SPC 10.1, META-SPC 10.2 and META-SPC 11.
* #4 - Disinfection of inner surfaces in human drinking water systems by CIP, stand desinfection in industry/institutions/medical areas, for META-SPC 6.21, META-SPC 6.22, META-SPC 7.11, META-SPC 7.12) and META-SPC 7.2.
* #5 - Disinfection of inner surfaces in veterinary water systems by CIP, stand disinfection for META-SPC 6.21, META-SPC 6.22, META-SPC 7.11, META-SPC 7.12 and META-SPC 7.2.

**Product Type 5:**

* #1 - Disinfection of water intended for human consumption by transfer in industries/institutions areas, for META-SPC 6.21 META-SPC 6.22, META-SPC 7.11, META-SPC 7.12 and META-SPC 7.2.

The products are for non-professional, professional or industrial users.

#### Organisms to be controlled and products, organisms or objects to be protected

The biocidal products are intended to be used to control bacteria, yeasts, fungal spores, viruses and algae. The product family is used for the purpose of the protection of human and animal health.

#### Effects on target organisms, including unacceptable suffering

The products are intended to produce a reduction in the number of viable bacterial cells (bactericidal activity), yeasts cells (yeasticidal activity), fungal spores (fungicidal activity), algae cells (algicidal activity) and of infectious virus particles (virucidal activity) of relevant test organisms under defined conditions.

#### Mode of action, including time delay

According to the Assessment Report of the active substance, the hypochlorite ion is in equilibrium with hypochlorous acid (HOCl) and chlorine (sum: active chlorine or available chlorine) depending on the pH value: below pH 4 chlorine is available, in the neutral pH range hypochlorous acid is the predominant species and at pH values higher then 10, the only species present is the hypochlorite ion.

Hypochlorite reacts actively by chlorination of nitrogen with compounds like amino acids. The disinfecting efficiency of hypochlorite aqueous solution is dependent on the active chlorine concentration and decreases with an increase in pH. It is irrelevant whether available chlorine is generated from chlorine gas, calcium hypochlorite or sodium hypochlorite.

Contact times for the different activities claimed are determined in the efficacy tests (see tables below).

The mode of action of available chlorine released from sodium hypochlorite is non-specific. Microorganisms are inactivated by chlorination and oxidative reactions attacking multiple molecular sites on the cell surface as well as the cell interior.

#### Efficacy data

* **Efficacy requirements:**

The biocidal product family DAAP19 consists of products containing the active substance active chlorine in the range of 1.5 to 13.5 % w/w.

Laboratory studies were conducted with reference formulations in accordance with the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C). The results are summarized in Section 6.7 of the IUCLID file and the main efficacy data are summarized in the tables below.

According to the Efficacy Guidance Volume II part B/C:

* **for PT2:**
* For disinfection of footbaths (# 3) and private swimming pools (#1 and 2): phase 2 step 1 and SU test (including capacity test for footbath) or field test (monitoring data) on bacteria and viruses are basic requirements
* For disinfection of hard surfaces other than in healthcare by spraying, wiping, pouring, mopping (# 4, 5, 8 and 10): phase 2 step 1 and phase 2 step 2 tests on bacteria are basic requirements; yeasts, fungal spores and viruses are optional organisms for wich phase 2 step 1 and phase 2 step 2 tests are needed.
* For disinfection of hard surfaces in healthcare (# 9) by spraying, wiping, mopping (# 3): phase 2 step 1 and phase 2 step 2 tests on bacteria and yeasts are basic requirements; fungal spores and viruses are optional organisms for which phase 2 step 1 and phase 2 step 2 tests are needed.
* For disinfection of toilet bowls (# 6 and 14): phase 2 step 1 and phase 2 step 2 tests on bacteria are basic requirements; fungal spores, viruses and yeasts are optional organisms for wich phase 2 step 1 and phase 2 step 2 tests are needed.
* For disinfection of toilet bowls in medical areas (# 13): phase 2 step 1 and phase 2 step 2 tests on bacteria and yeasts are basic requirements; fungal spores, and viruses are optional organisms for which phase 2 step 1 and phase 2 step 2 tests are needed.
* For disinfection of Laundry disinfection with hand soaking (# 7): phase 2 step 1 and 2 step 2 tests on bacteria and yeasts are basic requirements; fungal spores, viruses are optional organisms for which phase 2 step 1 and phase 2 step 2 tests are needed.
* For disinfection of surfaces by CIP (#11): phase 2 step 1 tests on bacteria and yeasts are basic requirements; fungal spores and viruses are optional organisms for which requirements are the same as for hard surfaces disinfection i.e. phase 2 step 1 and phase 2 step 2 tests.
* For algaecidal and fungicidal activities for outdoor surfaces (#12): no specific requirements are presented in the guidance. Nevertheless, SU or field test are appropriate.
* **for PT3:**
* For disinfection of hard surfaces (#1 and 2): phase 2 step 1 and phase 2 step 2 tests on bacteria and yeasts are basic requirements; fungal spores and viruses are optional organisms for wich phase 2 step 1 and phase 2 step 2 tests are needed.
* For disinfection of non-porous hard surfaces in livestock transportation vehicles (without mechanical action) (#3): phase 2 step 1 and phase 2 step 2 tests on bacteria, yeasts and viruses are basic requirements; fungal spores are optional organisms for wich phase 2 step 1 and phase 2 step 2 tests are needed.
* **for PT4:**
* For disinfection of hard surfaces (#1 an 2): phase 2 step 1 and phase 2 step 2 tests on bacteria and yeasts are basic requirements; fungal spores and viruses are optional organisms for wich phase 2 step 1 and phase 2 step 2 tests are needed.
* For disinfection of inner surfaces by CIP (#3): phase 2 step 1 tests on bacteria and yeasts are basic requirements; fungal spores and viruses are optional organisms for wich requirements are the same as for hard surfaces disinfection i.e. phase 2 step 1 and phase 2 step 2 tests.
* For disinfection of inner surfaces without circulation in human drinking water system, requirements are the same as for hard surfaces (#4): phase 2 step 1 and phase 2 step 2 tests on bacteria are basic requirements; fungal spores, viruses and yeasts are optional organisms for which phase 2 step 1 and phase 2 step 2 tests are needed (field test is also needed in case of claim against *Legionella*).
* For disinfection of inner surfaces in veterinary water systems (# 5): phase 2 step 1 and phase 2 step 2 tests on bacteria are basic requirements; fungal spores, viruses and yeasts are optional organisms for which phase 2 step 1 and phase 2 step 2 are needed.
* **for PT5:**
* For disinfection of water intended for human consumption (#1): phase 2 step 1 and SU tests on bacteria and viruses are basic requirements.
* **Representative products tested - Effects of coformulants**

1. **Swimming pools/footbaths disinfections: Meta SPC 1.1 and 1.2**

Efficacy tests provided to support the efficacy for swimming pools/footbaths disinfections (Meta SPC 1.1 and 1.2) were done on product 1 of meta-SPC1.1 (sodium hypochlorite with 9.6% a.c., with anti-limescale agent). It is considered that the results of efficacy tests done on this product covers Meta 1.1 and 2.2 product as the coformulants claimed are the same are this product contains the minimal active concentration claimed for these Meta SPC.

Additional tests from another product were also provided. Considering that this product does not contain any other co-formulant, eCA considers these data also acceptable to support the application rates claimed (in mg avalaible chlorine/L) for the META SPC 1.1 and 1.2.

1. **SL Formulations: Meta SPC 2.1, 2.21, 2.22, 6.1, 6.21, 6.22, 7.11, 7.12, 7.2, 8, 10.1, 10.2 and 11**

All the efficacy tests provided to support the efficacy for SL formulations (Meta SPC 2.1, 2.21, 2.22, 6.1, 6.21, 6.22, 7.11, 7.12, 7.2, 8, 10.1, 10.2, 11) were performed with the product 1 of meta-SPC7.2 (2.6% available chlorine without surfactants or perfumes).

Meta-SPC 6.1, 6.21, 6.22, 7.11, 7.12 and 7.2, products do not contain any co-formulants, only sodium hypochlorite concentration vary between each meta-SPC. All dilution instructions consider the AS concentration of the product, therefore, efficacy tests with minimal active concentration determination are considered relevant for all these products.

Meta-SPCs 2.1, 2.21, 2.22, 8, 10.1, 10.2, 11 contain in addition other coformulants (such as surfactant, perfumes, and stabilizer). Perfumes and stabilizer are not expected to influence efficacy.

Surfactants are expected to increase disinfection efficacy of products in soiled conditions, consequently a product without surfactant is normally considered worst case. To support the non-efficacy of the surfactant, the applicant has provided an additional phase 1 test with the co-formulant alone (see confidential section of the PAR).

This study demonstrates that surfactant alone is not effective against fungi. No explanation was provided by the applicant regarding the relevance of testing fungi for this additional efficacy study and depending of the soiling conditions provided for SL formulations, fungi were not always the worst case target organisms.

However, considering that the maximum % of surfactant claimed fort these META SPC has been tested in this test and without dilution (whereas all SL products are claimed to be diluted to a minimum of 50% (worst case)), we consider that this test as acceptable despite this deviation.

1. **Gel Formulations: Meta SPC 3, 4 and 13**

All the efficacy tests provided to support the efficacy for gel formulations (Meta SPC 3, 4 and 13) were performed with the product 1 of meta-SPC4 (sodium hypochlorite with 1.5% a.c.). As this product has the minimal AS concentration, it is considered that the results of efficacy tests done on this product covers all gel formulation from meta-SPC3, 4 and 13 (all meta-SPC have same co-formulants to very close %, higher AS concentration, and all products are ready-to-use products).

1. **Spray formulations: Meta SPC 5 and 12**

All the efficacy tests provided to support the efficacy for spray formulations (Meta SPC 5 and 12) were performed with the product 1 of meta-SPC5 (sodium hypochlorite with 1.5%a.c.). As this product has the minimal AS concentration, the applicant consider that the results of efficacy tests done on this product can covers all spray formulations (meta-SPC 5 and 12, only ready-to-use products).

The Meta SPC 12 contains higher AS concentration than Meta SPC 5 products but also less coformulants (surfactant and stabilizer). However, considering that the claimed formulations for meta SPC 12 is the same as Meta SPC 10.2 which is supported by efficacy data with product 1 of Meta SPC 7.2 (2.6% available chlorine without surfactants or perfumes), eCa consider that the proposed cross reading with product 1 of meta-SPC5 is acceptable (worst cas effective concentration demonstrated in efficacy studies provided).

1. **Algaecidal and fungicidal activities for outdoor surfaces: Meta SPC 9 and 14**

Efficacy tests provided to support the efficacy for algaecidal and fungicidal activities for outdoor surfaces (Meta SPC 9 and 14) were done on product 1 of meta-SPC9 and product 1 of META SPC 14.

* **Efficacy of aged products**

All the efficacy tests have been carried out with fresh representative products.

However, based on stability data provided for APCP assessment, active substance concentration loss between before and after shelf life is higher than 10% for some meta-SPCs.

According to the Technical Agreements for Biocides (TAB, point 12):

- efficacy shelf life test should preferably be performed with aged products that have been stored for the complete claimed shelf life.

- In some cases, it is also acceptable when efficacy shelf life tests are performed with  
fresh product with an active substance concentration comparable to the  
concentration measured in a stored product after the claimed shelf life. In those  
cases, a robust justification and/or a clear indication from the physico-chemical  
assessment is required which explains why age-related changes in co-formulants  
would not have an effect on efficacy of the aged product, and why reduction in the  
quantity of active substance would be the only issue to be addressed.

1. **Products for swimming pools/footbaths disinfections: Meta SPC 1.1 and 1.2**

No efficacy data for aged products was provided and the shelf life is only based on APCP data.

1. **SL Formulations: Meta SPC 2.1, 2.21, 2.22, 6.1, 6.21, 6.22, 7.11, 7.12, 7.2, 8, 10.1, 10.2 and 11**

For Meta-SPCs 6.1, 6.21, 6.22, 7.11, 7.12 and 7.2, no co-formulants are added in the composition, therefore efficient concentrations should cover the loss of active substance at the end of the shelf life.

For Meta-SPCs 2.1, 2.21, 2.22, 8, 10.1, 10.2, 11, surfactant and perfumes are added in the composition. Some of the products also contain a stabilizer. The applicant has provided additional justifications (see table XX in confidential PAR) concerning the physico-chemical parameters after storage of these Meta SPC.

We considered these arguments to be acceptable and agree to use efficacy data with representative fresh product to support the efficacy at the shelf-life validated in APCP section (if efficient concentrations cover the loss of active substance at the end of the shelf-life).

1. **Gel Formulations: Meta SPC 3, 4 and 14**

Meta-SPC 3, 4, 13 contain the same co-formulants (soap, thickners, stabilisers and perfumes) at similar concentrations. The applicant has provided additional justifications (see table XX in confidential PAR) concerning the physico-chemical parameters after storage of these Meta SPC.

We considered these arguments to be acceptable and agree to use efficacy data with representative fresh product to support the efficacy at the shelf-life validated in APCP section (if efficient concentrations cover the loss of active substance at the end of the shelf-life).

1. **Spray formulations: Meta SPC 5 and 12**

For Meta-SPCs 5 and 12, contain the same coformulant (surfactant, perfume and stabilizer).

The applicant has provided additional justifications (see table XX in confidential PAR) concerning the physico-chemical parameters after storage of these Meta SPC.

We considered these arguments to be acceptable and agree to use efficacy data with representative fresh product to support the efficacy at the shelf-life validated in APCP section (if efficient concentrations cover the loss of active substance at the end of the shelf-life).

1. **Algaecidal and fungicidal activities for outdoor surfaces: Meta SPC 9 and 14**

No efficacy data for aged products was provided and the shelf life is ony based on APCP data (shelf-life with <10% AS decrease).

* **Efficacy data assessment: Swimming pool disinfections – META SPC 1.1 and 1.2: shock treatment**

**Efficacy against bacteria and virus**

Efficacy studies have been provided by the applicant in accordance with the Efficacy guidance and the discussions of Efficacy WG (WG-III 2020).

* For P2S1 tests (bacteria and virus), some modifications on the OECD No 170 methodology (composition of the soiling, temperature, and implementation of the product/soiling/inoculum) have been agreed by Efficacy WG.
* Simulated-use tests have been carried out in 15-litres tanks containing 10 litres of tap water at 20°C, for bacteria only. Indeed according to discussion at Efficacy WG-III 2020, it was agreed for virus, that either a modified phase 2, step 1 test or a simulated use test should be submitted.
* Phase 3: As stated in the OECD guidance, and as ethical considerations would suggest it, no test microorganismsn can deliberately be added to a public swimming pool to assess the efficacy of a disinfectant via shock dosing treatment. Therefore, it seems technically impossible to perform field tests for shock dosing treatments.

There is no field data either through monitoring data measured by the employees of the swimming pool or through French sanitary authorities Agences régionales de santé (ARS) that can be used to justify the type of shock dosing treatment applied. Indeed, when a non-compliance is identified by an ARS, the ARS only tells the pool operator to apply sufficient treatment to restore the situation but does not give a specific recommendation of treatment conditions. The only information that can be obtained from ARS is the result of the control that is carried out after the treatment to confirm the return to normal and re-authorize the opening of the pool. Pool operators mainly apply shock dosing treatments with active available chlorine concentrations generally around 10-12 mg/L if *Staphylococcus aureus* is present. It has not been possible to collect monitoring data from swimming pool with the real applied conditions for a shock dosing treatment as the operator just increases the concentration set point for a few hours out of the presence of the bathers, generally during the night, but does not carry out a control during the treatment to check the concentration obtained, the control is mainly done after the treatment to ensure the return to the normal concentration for using the pool again.

Note also that the presence of virus is generally not monitored by the authorities when controlling the quality of water in swimming pools and spas, as a consequence there is no official field data on the virucidal load in swimming pools. Also, the shock dosing treatment is not nearly as relevant for viruses as it is for bacteria and algae because it is not expected that a pool operator initiates a shock treatment against virus contamination.

**Efficacy against algae**

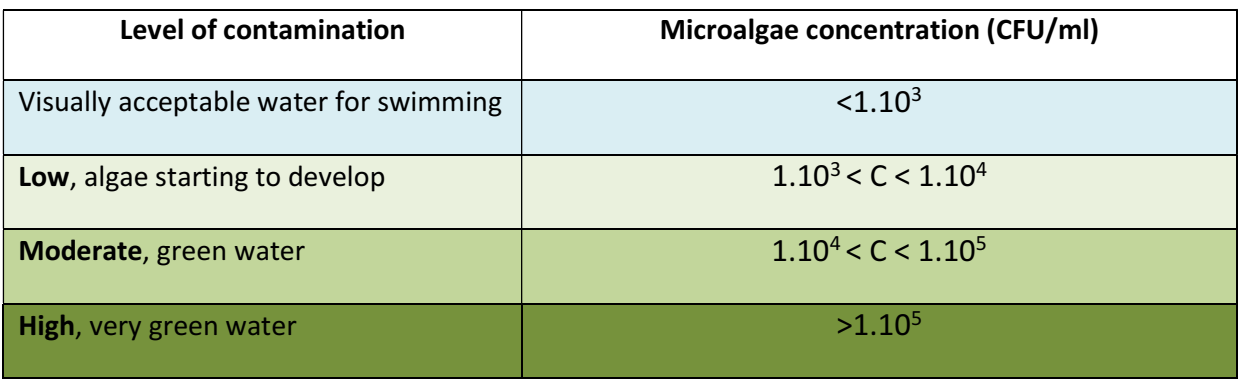
Efficacy studies have been provided by the applicant in accordance with the Efficacy guidance and the discussions of Efficacy WG (WG-III 2020).

* + Phase 2 step 1: No phase 2 step 1 tests were performed on algae because phase 2 step 2 tests are much more representative of what can occur in real swimming pools and also because there is no guidance for such tests.
* Phase 2 step 2: these tests are intended to provide reliable data on the efficacy of a product in practical tests that mimic real-life conditions.

Different parameters have been taken into account to make these conditions as real as possible: concentration of microalgae found in swimming-pools with green water, intended concentration of active chlorine, temperature, hydraulicity, light conditions and even the addition of a small-scale sand filtration system. Field observations were first carried out to determine the above-mentioned parameters under real conditions.

Algae species most commonly found in the contaminated swimming pool water samples are chosen: *Chlorella vulgaris* (SAG 211.12)*, Raphidocelis subcapitata* (SAG 61.81) (also called *Pseudokirchneriella subcapitata*)*, Chlamydomonas noctigama* (23.87) (also called *Chlamydomonas reinhardtii*). Based on the standard curves determined for each species (see in IUCLID “Study Summary Report of The Efficacy Testing In Swimming Pool” document: page 23 to 27), it was possible to calculate the proportion of each microalga to add to the mix. There is an equal proportion of Chl-a in this mixture of the three microalgae, i.e. 33%.

Swimming pool water samples with different levels of contamination were taken and analyzed, the aim being to determine the target concentrations to be used in the tests.From these analyses and observations, a scale of different levels of contamination and their corresponding microalgae concentrations was established:



* Phase 3: the effects of a shock treatment were studied in three infected outdoor swimming pools showing different levels of green coloration.

Water samples were collected to determine the number and the identity of algae. Chlorophyll a was used as a marker of algae density (standard curve to establish a relationship between chlorophyll a concentration and algae density).

The following criteria were used to define a swimming pool that it is ready to be reused by swimmers: No visual detection of algae; Visible liner and bottom of the pool; Clear and limpid water.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| Function | Field of use envisaged | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | PT2-  Swimming pool disinfection (public and private): shock treatment | Active available chlorine | Bacteria  *Staphylococcus aureus* (ATCC 6538)  *Enterococcus hirae* (ATCC 10541)  *Pseudomonas aeruginosa* (ATCC 15442)  *Escherichia coli* (ATCC 10536) | OECD 170 modified | Quantitative suspension test (Phase 2/Step 1)  Test concentrations:  0.1 - 1 – 2 - 5 mg/L available chlorine  Test temperatures:  25°C  pH at 20°C: in the range of  6.89 – 7.40.  Contact times:  5 & 15 min  Interfering substance:  Body-Fluid Analog (BFA) 6.432 mg/L  Required reduction factor:  ≥ 4 log (OECD criteria) | Log reduction ≥ 4 at 2 mg/L available chlorine after 5 & 15 min contact time. | STUDY SUMMARY REPORT OF THE EFFICACY TESTING FOR BIOCIDAL PRODUCT IN SWIMMING POOL  R.I.: 2 |
| Bactericide | PT2-  Swimming pool disinfection (public and private): shock treatment | Active available chlorine | Bacteria  *Staphylococcus aureus* (ATCC 6538)  *Enterococcus faecium* (ATCC 10541)  *Pseudomonas aeruginosa*  (ATCC 15442)  *Escherichia coli* (ATCC 10536) | Simulated use test (Phase 2/Step 2)  Shock treatment | 15-litre tanks containing 10 litres of tap water buffered to a pH of between 6.8 and 7.2  Pump for continuous circulation and movement of the water  Test concentrations:  5 - 10 mg/L available chlorine  Test temperature:  20°C  pH: in the range of  6.8 – 7.2.  Interfering substance:  Body-Fluid Analog (BFA) 6.432 mg/L  Bacterial inoculum: 105 & 106 CFU/ml  24H exposure, log reduction assessed at 2min/60min/120min/300min/1440min | Log reduction ≥ 5 at 5 & 10 mg/L available chlorine after 2 min contact time.  No bacteria are detected in the 24 hours following the shock dosing treatment. At the end of each experiment (except for *E. coli* which was too sensitive to the filtration process), a final analysis has demonstrated that not a single bacterium was found in a sample of 100 mL of water | STUDY SUMMARY REPORT OF THE EFFICACY TESTING FOR BIOCIDAL PRODUCT IN SWIMMING POOL  R.I.: 2 |
| Virucide | PT2-  Swimming pool disinfection (public and private): shock treatment | Active available chlorine | Virus  Type 5 adenovirus (strain Adenoid 75, ATCC VR-5)  Murine norovirus (strain S99 Berlin) | OECD 170 modified | Quantitative suspension test  Test concentrations:  0.1 – 1 mg/L available chlorine  Test temperature:  25°C  Contact times:  2 min, 10 min  Interfering substance:  Body-fluid analog 6.432mg/L  Required reduction factor: ≥3 log (OECD criteria) | Log reduction >3 at 1 mg/L after 10 min contact time. | STUDY SUMMARY REPORT OF THE EFFICACY TESTING FOR BIOCIDAL PRODUCT IN SWIMMING POOL  R.I.:2 |
| Algaecide | PT2-  Swimming pool disinfection (public and private): shock treatment | Active available chlorine | Simulated-use test (Phase 2/Step 2):  Tests were conducted in 15-litres tanks containing 10 litres of tap water buffered to a pH of between 6.8 and 7.2  Pump and sand water system  3 replicates  Microalgae tested  *Chlorella vulgaris* (SAG 211.12);  *Raphidocelis subcapitata* (SAG 61.81) (also called *Pseudokirchneriella subcapitata*);  *Chlamydomonas noctigama* (23.87) (also called *Chlamydomonas reinhardtii*)  Visual assessment of the green tone of the water as a function of the concentration of microalgae (fixed depth of 1.2 m):    Test temperature: 21 ± 1°C  Interfering substance: Body-fluid analog 6.432 mg/L  Artificial lighting (12h/12h light/dark)  Test concentrations:  Moderately contaminated water (green): 104 CFU/ml: 5 and 10 mg/L  Heavily contaminated water (very green): 105 CFU/ml: 10 & 15 mg/L  The effect of adding chlorine stabilizer to the water was also studied. Chlorine stabilizer (cyanuric acid) was added (final concentration of 75 mg/L) during the 15 mg/L treatment (concentration of microalgae 105 CFU/ml).  Monitoring period: 48 hours  Results:  Efficacy criteria: % Efficacy (effect of active chlorine on viable microalgae) after contact time of 1 H, 4 H, 24 H and 48 H  **Moderate contaminated water (104 CFU/ml) at 5 and 10 mg/L**    **Heavily contaminated water (105 CFU/ml) at 10 mg/L**    **Heavily contaminated water (105 CFU/ml) at 15 mg/L with and without stabilizer**    **Conclusion**  Inoculum 104 CFU/ml:  At 5 mg/L: 93.6% efficacy after 1 H, 98.6% after 48 H  At 10 mg/L: 95.3% efficacy after 1 H, 99.01% after 48 H  NB: control stable  Inoculum 105 CFU/ml:  At 10 mg/L: 98.2% efficacy after 1 H, 99.7% after 48 H  At 15 mg/L: 98.5% efficacy after 1 H, 99.1% after 48 H  At 15 mg/L + stabilizer: 98.5% efficacy after 1 H, 99.1% after 48 H  NB: slight decrease in the control | | | | STUDY SUMMARY REPORT OF THE EFFICACY TESTING FOR BIOCIDAL PRODUCT IN SWIMMING POOL  R.I.: 2 |
| Algaecide | PT2-  Swimming pool disinfection (public and private): shock treatment | Active available chlorine | Phase 3: field monitoring data  Tests have been conducted in three infected outdoor swimming pools showing different levels of green coloration.  **Swimming pool n°1** - Private pool. - Active available chlorine concentration regulated with automatic continuous monitoring system (Off-line for this field testing). - Sand filtration system with a granulometry of 0.6 to 1.6 mm - Capacity: 20m3 - Renewal rate: 10m3/h - Season of observation: beginning of winter  Visual appearance of the swimming pool before treatment and after treatment (Single shock treatment with NaOCl 12 mg/L in 20 m3 of water)    **Swimming pool n°2** - Private pool. - Active available chlorine concentration regulated with automatic continuous monitoring system (Off-line for this field testing). - Sand filtration system with a granulometry of 0.6 to 1.6 mm - Capacity: 52 m3 - Renewal rate: 15m3/h - Season of observation: end of winter  Visual appearance of the swimming pool before treatment and after treatment (Single shock treatment with NaOCl 15 mg/L in 52 m3 of water)    **Swimming pool n°3** - Private pool. - Active available chlorine concentration regulated with automatic continuous monitoring system (Offline for this field testing). - Sand filtration system with a granulometry of 0.6 to 1.6 mm - Capacity: 52 m3 - Renewal rate: 15m3/h - Season of observation: spring  Visual appearance of the swimming pool before treatment and after treatment (Single shock treatment with NaOCl 10 mg/L in 52 m3 of water      **Conclusion**  Results showed that from 10 to 15 mg/L of active available chlorine, the chemical treatment in addition with an appropriate physical action allow to recover blue swimming water in a few hours. | | | | STUDY SUMMARY REPORT OF THE EFFICACY TESTING FOR BIOCIDAL PRODUCT IN SWIMMING POOL  R.I.: 2 |

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
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| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | Swimming pool disinfection  Shock treatment | Eau de Javel à 9,6% c.a Bec Special Piscine  Batch: 2001200626 | **Bacteria**  *S. aureus*  *P. aeruginosa*  *E. coli*  *L. pneumophilla* | EN 1276:2019 modified | Phase 2 step 1 test (suspension test)  Concentration tested: 0.0001%, 0.0003%, 0.0005% v/v product. Temperature: 27°C Contact time: 30 seconds Soilling conditions: BFA (5mL BFA /100L)  pH 7.2  Criteria: at least a 5 log reduction | Bactericidal activity not demonstrated (no effective concentration). | RE20-0611-1  R.I: 3 (*E. hirae* not testing) |
| Virucide | Swimming pool disinfection  Shock treatment | Eau de Javel à 9,6% c.a Bec Special Piscine  Batch: 2001200626 | Human adenovirus type 5 (Ad5) | EN 14476:2015 modified | Phase 2 step 1 test (suspension test)  Concentration tested: 0,0001%, 0,0003%, 0,0005% v/v of product  Temperature: 27°C  Contact time: 10 min  Soilling conditions: 1 mL of BFA per 10 mL  Criteria: at least a 4 log reduction | No virucidal activity demonstrated. | RE20-381-1  R.I.: 3 |
| Virucide | Swimming pool disinfection  Shock treatment | Eau de Javel à 9,6% c.a Bec Special Piscine  Batch: 2001200626 | Rotavirus | EN 14476:2015 modified | Phase 2 step 1 test (suspension test)  Concentration tested: 1, 3 et 5 mg/L a.c  Temperature: 27°C  Contact time: 2 min  Soilling conditions: BFA (1mL BFA /100L)  Criteria: at least a 4 log reduction | Activity against rotavirus demonstrated at 3 mg/L a.c. | RE20-382-1  R.I.: 1 |
| Bactericide | Swimming pool disinfection  Shock treatment | Javel Bec Special Piscine  9.6% w/w a.c.  Batch: 1811081517 | **Bacteria**  *P. aeruginosa*  *S. aureus*  *Escherichia coli*  *Enterococcus hirae* | Simulated use tests | PE tank (101 L: 95 L in the tank and 6 L in the recirculating loop), maintained at atmospheric pressure with recirculation (pump with no filter), chlorine injection (pump) and pH regulation (sufuric acid)  pH: 7,2  Temperature: 27°C  Flow rate: 246,8 ± 246,8 L /h  **Negative controls:**   * After 2 minutes: between 1.3 and 2.3 log reduction (depending on the species) * after 30 minutes <3 log reduction * after 2 hours: between 2.6 and 5.3 log reduction (depending on the species)   Criteria: at least a 4 log reduction  **Shock treatment**  - addition of 500 mL of waste water into the system to simulate abnormal pollution (vomiting, faeces,…): *P.aeruginosa, E.coli, Enterococcus*, anaerobic sulphide-reducing bacteria (spores)  - Concentration tested: 50 mg/L a.c. (one injection)  - Contact time: 3h30 (after shock treatment)  - 3 replicates | **Shock treatment**  **-** *P. aeruginosa:* 2.57 log reduction after 3h30 (1 log in the tank after treatment)  - *E. coli:* 4.46 log reduction after 3h30  - *Enterococcus:* 4.36 log reduction after 3h30  - anaerobic sulphide-reducing bacteria (spores): 3.79 log reduction after 3h30 | EN-CAPE 19.034 C – V1  R.I.: 1 |

* **Efficacy data assessment: Swimming pool disinfections – META SPC 1.1 and 1.2: continuous/maintenance treatment**

**Efficacy against bacteria and virus:**

Efficacy studies have been provided by the applicant in accordance with the Efficacy guidance and the discussions of Efficacy WG (WG-III 2020).

* For P2S1 tests (bacteria and virus), some modifications on the OECD methodology (composition of the soiling, temperature, and implementation of the product/soiling/inoculum) have been agreed by Efficacy WG.

Moreover for virus, these assays are considered to cover both continuous treatment and shock dosing treatment.

* Simulated-use tests have been carried out in 15-litres tanks containing 10 litres of tap water at 20°C, for bacteria only. Indeed according to discussion at Efficacy WG-III 2020, it was agreed for virus, that either a modified phase 2, step 1 test or a simulated use test should be submitted.
* Phase 3: Monitoring data: the monitoring data (on 1 or 2 years according to the sites) of 5 French swimming pools in which chlorination is used to disinfect water have been provided.

The available data show that the concentration of active available chlorine was essentially maintained within the authorized range in France of 0.4 to 1.4 mg/L.

During those two years, the official sanitary authorities (Agence régionale de santé, ARS) have analyzed the quality of the water from the pool once per month. These analyses included a microbiological assessment and a physical-chemical assessment (concentration of active available chlorine, pH, temperature…). All the results of these physical-chemical and microbiological analyses were in compliance with the requirements.

For information, in France, microbiological analysis are obligatory and the following criteria should not be exceeded:

* *E. coli*: absence in 100 mL
* Coliform bacteria: 10 UFC / mL maximum
* Aerobic bacteria at 37°C: 100 UFC / mL maximum
* *Staphylocoques* pathogenes / 100 mL: absence (for at least 90 % of samples)

Virus, protozoa and algae are not sampled.

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| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | PT2-  Swimming pool disinfection (public and private): continuous dosing treatment | Active available chlorine | Bacteria  *Staphylococcus aureus* (ATCC 6538)  *Enterococcus hirae* (ATCC 10541)  *Pseudomonas aeruginosa* (ATCC 15442)  *Escherichia coli* (ATCC 10536) | OECD 170 modified | Quantitative suspension test (Phase 2/Step 1)  Test concentrations:  1 mg/L available chlorine  Test temperature:  25°C  pH at 20°C: in the range of  6.89 – 7.40.  Contact time:  30 sec  Interfering substance:  Body-Fluid Analog (BFA) 6.432 mg/L  Required reduction factor:  ≥ 4 log (OECD criteria) | Log reduction ≥ 4 at 1 mg/L available chlorine after 30 secondes | STUDY SUMMARY REPORT OF THE EFFICACY TESTING FOR BIOCIDAL PRODUCT IN SWIMMING POOL  R.I.: 2 |
| Bactericide | PT2-  Swimming pool disinfection (public and private): continuous dosing treatment | Active available chlorine | Bacteria  *Staphylococcus aureus*  (ATCC 6538)  *Enterococcus faecium (*ATCC 10541)  *Pseudomonas aeruginosa*  (ATCC 15442)  *Escherichia coli (*ATCC 10536) | Simulated use test (Phase 2/Step 2)  Continuous treatment | 15-litre tanks containing 10 litres of tap water buffered to a pH of between 6.8 and 7.2  Pump for continuous circulation and movement of the water  Test concentrations:  0,8 - 1,2 mg/L range available chlorine  Test temperature:  20°C  pH: in the range of  6.8 – 7.2.  Interfering substance:  Body-Fluid Analog (BFA) defined by AWPF at 6.432 mg/L  Bovin Serum Albumin (BSA): 0.3 g/L  Bacterial inoculum: 105 & 106 CFU/ml  Exposure  105 CFU/ml: 96h  106 CFU/ml: 48h  To simulate a new contamination due to additional bathers, a second addition of bacterial inoculum and interfering substance occurred after 48 h (for the concentration of 105 CFU/ml) or 24 h (for the concentration of 106 CFU/ml).  log reduction assessed at 2min/60min/120min/300min/1440min/2880min | After 48 H and 96 H:  At 1 mg/L - BFA 6.432 mg/L (Bacteria: 105 CFU/ml)  => results <1 CFU/ml (>5 log) within 2 min exposure (after 1 or 2 inoculations)  NB: growth in the control is shown  At 1 mg/L - BSA 0.3 g/L (Bacteria: 106 CFU/ml)  => results <1 CFU/ml within generally 1 to 2 H exposure (after 1 or 2 inoculations) or 3 to 4 log within 20 min.  NB: growth in the control is shown | STUDY SUMMARY REPORT OF THE EFFICACY TESTING FOR BIOCIDAL PRODUCT IN SWIMMING POOL  R.I.: 2 |
| Bactericide | PT2-  Swimming pool disinfection (public and private): continuous dosing treatment | Active available chlorine | Phase 3: Monitoring data   * Two pools are located in Portet, Haute-Garonne, France: a leisure pool and a sports pool. For these two pools, data are available for two years: 2016 and 2017. * Three other pools are located in Valence, Drôme, France: a large sports pool, a large leisure pool and a small leisure pool. For these pools, data are available for one year: from July 2017 to July 2018.   Results  Leisur pool, Sports pool  - capacity: 500 bathers / day  - leisure pool, indoor - 125m² - 125m3  - sports pool, indoor - 313m² - 594m³  - Filtration: glass filtering (Garo®filtre)  - Flocculation: Preventive action when high bather presence or shock treatment at night without bather if preventive action is not sufficient when high bather presence  Large leisure pool, small leisure pool and large sports pool  - capacity: 1000 bathers / day  - large pool, indoor - 375m² - 543m3  - small leisure pool, indoor - 120m² - 102m3  - large sports pool, indoor - 500m² - 1250m3  - Filtration: Sand filtering  - Flocculation : Preventive action when high bather presence or shock treatment at night without bather if preventive action is not sufficient when high bather  During those two years, the official sanitary authorities (Agence régionale de santé, ARS) have analyzed the quality of the water from the pool once per month. These analyses included a microbiological assessment (counting of *E. coli*, counting of pathogenic *Staphylococcus* strains and counting of total coliforms in 100 mL…) and a physical-chemical assessment (concentration of active available chlorine, pH, temperature…). All the results of these physical-chemical and microbiological analyses were in compliance with the requirements.  Therefore, the available data show that the concentration of active available chlorine was essentially maintained within the authorized range in France of 0.4 to 1.4 mg/L, keeping the water of a swimming pool disinfected and suitable for bathing. | | | | STUDY SUMMARY REPORT OF THE EFFICACY TESTING FOR BIOCIDAL PRODUCT IN SWIMMING POOL  R.I.: 2 |
| Virucide | PT2-  Swimming pool disinfection (public and private): continuous dosing treatment | Active available chlorine | Virus  Type 5 adenovirus (strain Adenoid 75, ATCC VR-5)  Murine norovirus (strain S99 Berlin) | OECD 170 modified | Quantitative suspension test  Test concentrations:  0.1 – 1 mg/L available chlorine  Test temperature:  25°C  Contact times:  2 min, 10 min  Interfering substance:  Body-fluid analog 6.432mg/L  Required reduction factor: ≥3 log (OECD criteria) | Log reduction ≥3 at 1 mg/L, with 10 min contact time | STUDY SUMMARY REPORT OF THE EFFICACY TESTING FOR BIOCIDAL PRODUCT IN SWIMMING POOL  R.I.: 2 |

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
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| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | maintenance/  continuous treatment of private swimming pools | Javel Bec Special Piscine  9.6% w/w a.c.    Batch: 1811081517 | **Bacteria**  *P. aeruginosa*  *S. aureus*  *Escherichia coli*  *Enterococcus hirae* | Simulated use tests | PE tank (101 L: 95 L in the tank and 6 L in the recirculating loop), maintained at atmospheric pressure with recirculation (pump with no filter), chlorine injection (pump) and pH regulation (sufuric acid)  pH: 7,2  Temperature: 27°C  Flow rate: 246,8 ± 246,8 L /h  **Negative controls:**   * After 2 minutes: between 1.3 and 2.3 log reduction (depending on the species) * after 30 minutes <3 log reduction * after 2 hours: between 2.6 and 5.3 log reduction (depending on the species)   Criteria: at least a 4 log reduction  **Maintenance treatment**  - Inoculum: between 107 and 108 cfu/L for each species  - Concentration tested: 1 and 3 mg/L a.c. (continuously maintained)  - With or without soiling (1 mL BFA).  - 4 repliactes per condition tested  - TC: 2 min, 30 min and 2 hours (after bacterial inoculation) | **Maintenance treatment**  > 4 log reduction after 2 min with and without soiling at 1 mg/L a.c. | EN-CAPE 19.034 C – V1  R.I.: 1 |

* **Efficacy data assessment: footbaths disinfections – META SPC 1.1 and 1.2**

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
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| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | Disinfection of footbaths in private swimming pools | Javel Bec Special Piscine  9.6% w/w a.c.    Batch: 1811081517 | **Bacteria**  *P. aeruginosa*  *S. aureus*  *Escherichia coli*  *Enterococcus hirae* | Simulated use tests | PE tank (101 L: 95 L in the tank and 6 L in the recirculating loop), maintained at atmospheric pressure with recirculation (pump with no filter), chlorine injection (pump) and pH regulation (sufuric acid)  pH: 7,2  Temperature: 27°C  Flow rate: 246,8 ± 246,8 L /h  **Negative controls:**   * After 2 minutes: between 1.3 and 2.3 log reduction (depending on the species) * after 30 minutes <3 log reduction * after 2 hours: between 2.6 and 5.3 log reduction (depending on the species)   Criteria: at least a 4 log reduction  **Capacity test (footbaths)**  - Inoculum: between 107 and 108 cfu/L for each species  - Soiling: 1 mL BFA  - Concentration tested: 5 mg/L a.c. (only one injection)  - 5 successive bacterial inoculation.  - With or without soiling  - TC: 2 min, 30 min and 2 hours (after bacterial inoculation) | **Capacity test (footbaths)**  > 4 log reduction after 2 min with and without soiling at 5 mg/L a.c. | EN-CAPE 19.034 C – V1  R.I.: 1 |

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| **Conclusion on the efficacy for the meta SPC 1.1 and 1.2** |
| The META SPC 1.1. and META SPC 1.2 of the biocidal product family DAAP19 have shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C) for the following uses:   * use 1: Disinfection of private swimming pools (continuous treatment) by professional and non professional users at the application rate of 3 mg of available chlorine in water against bacteria and virus. * use 2: Shock disinfection of private swimming pools by professional and non professional users at the application rate of 50 mg of available chlorine in water against bacteria (TC: 2 min, 20°C), virus (TC: 10 minutes, 25°C) and algae (TC: 48 hours, 21°C).   However, no efficacy data (capacity tests) against virus has been submitted to support the claimed use disinfection of footbaths in public and private swimming pools. Therefore, as both bacteria and viruses are mandatory organisms (same requirement as swimming pools), the claimed use disinfection of footbaths in private swimming pools is not demonstrated based on the efficacy data provided. |

* **Efficacy data assessment: SL formulations - META SPC 2.1, 2.21, 2.22, 6.1, 6.21, 6.22, 7.11, 7.12, 7.2, 8, 10.1, 10.2 and 11**

**Introduction:**

For PT2, PT3 and PT4 surface disinfection uses, the applicant has provided a set of efficacy tests appropriate for the medical area, for the veterinary area, and for some kind of industries areas (milk, cosmetics, non alcoholic and alcoholic beverages).

Some other studies have been performed with veterinary conditions of soiling for agricultural area (10 g/L BSA + 10 g/L yeasts extract), but considered as not appropriate by the eCA, as only general disinfection occurs in such area (for a control of plant pests, PPP regulation applies). However, even if this soiling conditions is higher than requirement for general disinfection in dirty conditions (3 g/L BSA), these studies are considered acceptable as worst case.

It has to be noted that no specific efficacy data has been provided for domestic and institutional areas and also general desinfection in food industries or agricultural areas. Therefore eCA has been taken into account results from medical conditions for these uses.

For PT5 disinfection at the drinking water suppliers and their water distribution systems and disinfection in collective drinking water systems uses, no efficacy data has been provided by the applicant. Therefore efficacy for these PT5 uses have not been validated

Below, all the efficacy testings are presented related to the soiling conditions performed (medical, vet, specific industries) with conclusions on efficient concentrations. Then a summary of results is proposed and an independent conclusion per Meta SPC.

* Experimental data: medical area

Representative products tested Eau de Javel, BEC eau de Javel ORIGINAL and Eau de Javel Hypochlorite de sodium are identical and contain 2,6 % available chlorine, without any coformulant.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
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| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | Disinfection of surfaces in medical area | Eau de Javel 2.6% a.c.  Batch: 2002J118758 | Bacteria  *Enterococcus hirae ATCC 10541  Staphylococcus aureus ATCC 6538* | EN 13727+A2:2015 | Phase 2 step 1 (suspension test)   Concentrations tested: 0.005%, 0.01%, 0.05%, 0.075%, 0.1% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions (3 g/L BSA+3 mL/L sheep erythrocytes) Criteria: at least a 5 log reduction | Activity against *E. hirae* and *S. aureus* demonstrated at 0.10% a.c. | RE20-010-1  R.I: 1 |
| Bactericide | Disinfection of surfaces in medical area | Eau de Javel 2.6% a.c.  Batch: 2002J118758 | Bacteria  *P. aeruginosa*  *E. coli K12* | EN 13727+A2:2015 | Phase 2 step 1 (suspension test)   Concentrations tested: 0.01%, 0.03%, 0.05% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions (3 g/L BSA+3 mL/L sheep erythrocytes) Criteria: at least a 5 log reduction | Activity against *P. aeruginosa* and *E. coli* demonstrated at 0.05% a.c. | RE20-040-1  R.I: 1 |
| Bactericide | Disinfection of surfaces in medical area | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Bacteria  *Legionella pneumophila DSM 7513* | EN13623:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.01%, 0.05%, 0.10%, 0.15%, 0.20% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA + 3mL/L sheep erythrocytes Criteria: at least a 4 log reduction | Activity against *L. pneumophila* demonstrated at 0.05 % a.c. | RE18-727-1  R.I: 1 |
| Bactericide | Disinfection of surfaces in medical area | Eau de Javel 2.6% a.c  Batch: 2002J118758 | Bacteria  *Enterococcus hirae ATCC 10541  Staphylococcus aureus ATCC 6538* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.64%, 0.66%, 0.68% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA+3 mL/L sheep erythrocytes Criteria: at least a 4 log reduction | Activity against *E. hirae* and *S. aureus* demonstrated at 0.66% a.c. | RE20-012-1  R.I: 1 |
| Bactericide | Disinfection of surfaces in medical area | Eau de Javel 2.6% a.c  Batch: 2002J118758 | Bacteria  *P. aeruginosa*  *E. coli* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.001%, 0.005%, 0.01%, 0.03% 0.05%, a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA+3 mL/L sheep erythrocytes Criteria: at least a 4 log reduction | Activity against *P. aeruginosa* and *E. coli* demonstrated at 0.03% a.c. | RE20-043-1  R.I: 1 |
| Yeasticide | Disinfection of surfaces in medical area | Eau de Javel 2.6% a.c.  Batch: 2002J118758 | Yeasts  *Candida albicans DSM 1386* | EN 13624:2013 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.07%, 0.10%, 0.13%, 0.15%, 0.20% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA+3 mL/L erythrocytes Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 0.13% a.c. | RE20-166-1  R.I: 1 |
| Yeasticide | Disinfection of surfaces in medical area | Eau de Javel 2.6% a. c.  Batch: 2002J118758 | Yeasts  *Candida albicans DSM 1386* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.05%, 0.10%, 0.15% 0.17% 0.19% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA+3 mL/L sheep erythrocytes Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 0.17% a.c. | RE20-168-1  R.I: 1 |
| Fungicide | Disinfection of surfaces in medical area | Javel 2.6% a.c  Batch: 180406 | Fungi  *Aspergillus brasiliensis DSM 1988* | EN 13624:2013 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.1%, 0.2%, 0.3%, 0.4%, 0.5% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA+3 mL/L erythrocytes Criteria: at least a 4 log reduction | Fungicidal activity demonstrated at 0.30% a.c. | RE18-177-2  R.I: 1 |
| Fungicide | Disinfection of surfaces in medical area | Eau de Javel 2.6% a. c.  Batch: 2002J118758 | Fungi  *Aspergillus brasiliensis DSM 1988* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.46%, 0.48%, 0.50% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA+3 mL/L sheep erythrocytes Criteria: at least a 3 log reduction | Fungicidal activity demonstrated at 0.50% a.c. | RE20-045-1  R.I: 1 |
| Virucide | Disinfection of surfaces in medical area | Eau de Javel Hypochlorite de sodium 2.6% a. c.  Batch: 1814J46 | Virus  *Murine*  *norovirus (MNV-1)  Human*  *adenovirus type 5 (Ad5)  Poliovirus type 1 (LSc-2ab)* | EN14476:2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.20%, 0.25%, 0.50% v/v Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/l bovine albumin + 3 ml/L sheep erythrocytes Criteria: at least a 4 log reduction | Virucidal activity demonstrated at 0.25% a.c. | 093V12-2018-01  R.I: 2 (minor deviations) |

In these efficacy studies with fresh samples of the representative product at 2.6% a.c:

* bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 13727 and EN 13697), at 20°C, with a contact time of 5 minutes with medical dirty conditions (3.0 g/L BSA + 3 mL/L sheep erythrocytes). In these conditions, bactericidal activity is shown at the in-use concentration of 0.66 % a.c..
* bactericidal activity against *Legionella* *pneumophila* is also demonstrated in phase 2, step 1 test (EN 13623), at 20°C, with a contact time of 5 minutes with medical dirty conditions (3.0 g/L BSA + 3 mL/L sheep erythrocytes). In these conditions, activity against *Legionella* *pneumophila* is shown at the in-use concentration of 0.05 % a.c.. Phase 2 step 2 test is missing for this target organism.
* yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 13624 and EN 13697), at 20°C, with a contact time of 5 minutes with medical dirty conditions (3.0 g/L BSA + 3 mL/L sheep erythrocytes). In these conditions, yeasticidal activity is shown at the in-use concentration of 0.17 % a.c..
* fungicidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 13624 and EN 13697), at 20°C, with a contact time of 5 minutes with medical dirty conditions (3.0 g/L BSA + 3 mL/L sheep erythrocytes). In these conditions, fungicidal activity is shown at the in-use concentration of 0.50 % a.c..
* virucidal activity is demonstrated according to phase 2, step 1 test (EN 14476) – (no surface test is available at the submission of the dossier for medical, food, industrial, domestic and institutional areas), at 20°C, with a contact time of 5 minutes with medical dirty conditions (3.0 g/L BSA + 3.0 mL/L sheep erythrocytes). In these conditions, virucidal activity is shown at the in-use concentration of 0.25 % a.c..
* Experimental data: veterinary area

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactéricide | Disinfection of empty breeding buildings and equipment (PT3) | Javel 2.6% a.c  Batch: 1820J14 | Bacteria  *Staphylococcus aureus ATCC 6538   Enterococcus hirae ATCC 10541* | EN 1656:2010 | Phase 2 step 1 (suspension test)   Concentration tested: 0.40%, 0.44%, 0.46%, 0.48%, 0.50% a.c. Temperature: 10°C ± 1 °C  Contact time: 5 min Dirty conditions:10 g/L BSA +10 g/L yeast extract Criteria: at least a 5 log reduction | Activity against *S. aureus* and *E. hirae* demonstrated at 0.50% a.c.. | RE18-278-1  R.I: 2 (product diluted in distilled water instead of hard water) |
| Bactéricide | Disinfection of empty breeding buildings and equipment (PT3) | Javel 2.6% a.c  Batch: 1820J14 | Bacteria  *Pseudomonas aeruginosa ATCC 10145   Proteus vulgaris DSM 13387* | EN 1656:2010 | Phase 2 step 1 (suspension test)   Concentration tested: 0.10%, 0.12%, 0.14%, 0.16%, 0.18% a.c Temperature: 10°C ± 1 °C  Contact time: 5 min Dirty conditions: 10 g/L BSA+10 g/L yeast extract Criteria: at least a 5 log reduction | Activity against *P. aeruginosa* and *P. vulgaris* demonstrated at 0.18% a.c.. | RE18-278-2  R.I: 2 (product diluted in distilled water instead of hard water) |
| Bactericide | Disinfection of empty breeding buildings and equipment (PT3) | Eau de Javel 2.6% a.c  Batch: 1820J14 | Bacteria  *Pseudomonas aeruginosa ATCC 10145   Staphylococcus aureus ATCC 6538   Proteus vulgaris DSM 13387  Enterococcus hirae ATCC 10541* | EN16437: 2014 | Phase 2 step 2 test (porous surface test)  Concentration tested: 0.60%, 1%, 1.6%, 2%, 2.6% a.c. Temperature: 10°C Contact time: 5 min Dirty conditions: 10 g/L BSA+10 g/L yeast extract  Criteria: at least a 4 log reduction | No bactericidal activity demonstrated. | RE18-276-1  R.I: 2 (product diluted in distilled water instead of hard water) |
| Bactericide | Disinfection of empty breeding buildings and equipment (PT3) | Eau de Javel 2.6% a.c  Batch: 180406 | Bacteria  *Staphylococcus aureus ATCC 6538   Enterococcus hirae ATCC 10541* | EN14349: 2012 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.40%, 0.44%, 0.46%, 0.48%, 0.50% a.c. Temperature: 10°C Contact time: 5 min Dirty conditions: 10 g/L BSA +10 g/L yeast extract  Criteria: at least a 4 log reduction | Activity against *S. aureus* and *E. hirae* demonstrated at 0.50% a.c.. | RE18-277-1  R.I: 2 (product diluted in distilled water instead of hard water) |
| Bactericide | Disinfection of empty breeding buildings and equipment (PT3) | Eau de Javel 2.6% a.c  Batch: 180406 | Bacteria  *Pseudomonas aeruginosa ATCC 10145   Proteus vulgaris DSM 13387* | EN14349: 2012 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.10%, 0.14%, 0.16%, 0.18%, 0.20% a.c. Temperature: 10°C Contact time: 5 min Dirty conditions: 10 g/L BSA +10 g/L yeast extract  Criteria: at least a 4 log reduction | Activity against *P. aeruginosa* and *P. vulgaris* demonstrated at 0.16% a.c.. | RE18-277-2  R.I: 2 (product diluted in distilled water instead of hard water) |
| Yeasticide | Disinfection of empty breeding buildings and equipment (PT3) | Javel 2.6% a.c  Batch: 1820J14 | Yeasts  *C.albicans* | EN 1657:2006 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.52%, 0.54%, 0.56%, 0.58%, 0.60% a.c Temperature: 10°C Contact time: 5 min Dirty conditions: 10 g/L BSA+10 g/L yeast extract Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 0.58 % a.c.. | RE18-275-1  R.I: 2 (product diluted in distilled water instead of hard water) |
| Yeasticide | Disinfection of empty breeding buildings and equipment (PT3) | Eau de Javel 2.6% a.c  Batch: 180406 | Yeasts  *Candida albicans DSM 1386* | EN 16438:2014 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.54%, 0.56%, 0.58%, 0.60%, 0.62% a.c. Temperature: 10°C Contact time: 5 min Dirty conditions: 10 g/L BSA +10 g/L yeast extract  Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 0.60% a.c.. | RE18-274-1  R.I: 2 (product diluted in distilled water instead of hard water) |
| Fungicide | Disinfection of empty breeding buildings and equipment (PT3) | Javel 2.6% a.c  Batch: 1820J14 | Fungi  *Aspergillus brasiliensis DSM 1988* | EN 1657:2006 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.58%, 0.60%, 0.64%, 0.66%, 0.68% a.c Temperature: 10°C Contact time: 5 min Dirty conditions: 10 g/L BSA+10 g/L yeast extract Criteria: at least a 4 log reduction | Fungicidal activity demonstrated at 0.66 % a.c.. | RE18-275-2  R.I: 2 (product diluted in distilled water instead of hard water) |
| Fungicide | Disinfection of empty breeding buildings and equipment (PT3) | Eau de Javel 2.6% a.c  Batch: 180406 | Fungi  *Aspergillus brasiliensis DSM 1988* | EN 16438:2014 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.62%, 0.64%, 0.66%, 0.68%, 0.70% a.c. Temperature: 10°C Contact time: 5 min Dirty conditions: 10 g/L BSA+10 g/L yeast extract  Criteria: at least a 3 log reduction | Fungicidal activity demonstrated at 0.68% a.c.. | RE18-274-2  R.I: 2 (product diluted in distilled water instead of hard water) |
| Virucidie | Disinfection of empty breeding buildings and equipment (PT3) | Eau de Javel 2.6% a.c  Batch: 1820J14 | Virus  ECBO | EN 14675:2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.70%, 0.72%, 0.75%, 0.78%, 0.80% a.c. Temperature: 10 °C Contact time: 5 min Dirty conditions: 10 g/L BSA +10 g/L yeast extract Criteria: at least a 4 log reduction | Virucidal activity demonstrated at 0.78 % a.c.. | RE 18-273  R.I: 2 (product diluted in distilled water instead of hard water) |

In these efficacy tests with fresh samples of the representative product Eau de Javel 2.6% a.c:

* bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1656 and EN 14349), at 10°C, with a contact time of 5 minutes with dirty conditions (10 g/L BSA +10 g/L yeast extract). In these conditions, bactericidal activity is shown at the in-use concentration of 0.50 % a.c. on non porous surfaces. Efficacy is not demonstrated on porous surfaces (EN 16437).
* yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1657 and EN 16438), at 10°C, with a contact time of 5 minutes with dirty conditions (10 g/L BSA +10 g/L yeast extract). In these conditions, yeasticidal activity is shown at the in-use concentration of 0.60 % a.c..
* fungicidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1657 and EN 13697), at 10°C, with a contact time of 5 minutes with dirty conditions (10 g/L BSA +10 g/L yeast extract). In these conditions, fungicidal activity is shown at the in-use concentration of 0.68 % a.c..
* virucidal activity is demonstrated according to phase 2, step 1 test (EN 14675) – (no surface test is available at the submission of the dossier for veterinary area), at 10°C, with a contact time of 5 minutes with dirty conditions (10 g/L BSA +10 g/L yeast extract). In these conditions, virucidal activity is shown at the in-use concentration of 0.78 % a.c..
* **Experimental data: milk industries**

Representative products tested BEC eau de Javel ORIGINAL and Eau de Javel Hypochlorite de sodium are identical and contain 2,6 % available chlorine.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | Disinfection of surfaces (milk industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Bacteria  *Staphylococcus aureus ATCC 6538   Enterococcus hirae ATCC 10541* | EN 1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.005%, 0.01%, 0.5%, 0,10%, 0.40% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions:10 g/L skimmed milk Criteria: at least a 5 log reduction | Activity against *S. aureus* and *E. hirae* demonstrated at 0.05 % a.c.. | RE18-706-1  R.I: 1 |
| Bactericide | Disinfection of surfaces (milk industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Bacteria  *Pseudomonas aeruginosa ATCC 10145   Escherichia coli ATCC 10536* | EN 1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.01%, 0.05%, 0.10%, 0.40% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions:10 g/L skimmed milk Criteria: at least a 5 log reduction | Activity against *P. aeruginosa* and *E. coli* demonstrated at 0.05 % a.c.. | RE18-706-2  R.I: 1 |
| Bactericide | Disinfection of surfaces (milk industries) | BEC eau de Javel ORIGINAL, 2.6 % a.c.   Batch: 1812030857 | Bacteria  *Legionella pneumophila DSM 7513* | EN13623: 2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.01%, 0.05%, 0.10%, 0.15%, 0.20% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L reconstituted skimmed milk Criteria: at least a 4 log reduction | Activity against *L. pneumophila* demonstrated at 0.05 % a.c.. | RE18-721-1  R.I: 1 |
| Bactericide | Disinfection of surfaces (milk industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Bacteria  *Enterococcus hirae ATCC 10541  Staphylococcus aureus ATCC 6538* | EN13697: 2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.05%, 0.1%, 0.5% 1% 2%, a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L reconstituted skimmed milk Criteria: at least a 4 log reduction | Activity against *E. hirae* and *S. aureus* demonstrated at 0.50% a.c.. | RE18-711-1  R.I: 1 |
| Bactericide | Disinfection of surfaces (milk industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Bacteria  *Pseudomonas aeruginosa ATCC 10145   Escherichia coli ATCC 1053* | EN13697: 2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.01%, 0.05%, 0.07% 0.1% 0.15%, a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L reconstituted skimmed milk Criteria: at least a 4 log reduction | Activity against *P. aeruginosa* and *E. coli* demonstrated at 0.15% a.c.. | RE18-711-2  R.I: 1 |
| Yeasticide | Disinfection of surfaces (milk industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Yeasts  *Candida albicans DSM 1386* | EN 1650:2008 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.005%, 0.025%, 0.05%, 0.10%, 0.20% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L reconstituted skimmed milk Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 0.025 % a.c.. | RE18-281-1  R.I: 1 |
| Yeasticide | Disinfection of surfaces (milk industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Yeasts  *Candida albicans DSM 1386* | EN13697: 2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.01%, 0.03%, 0.05%, 0.07%, 1% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L reconstituted skimmed milk Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 0.07% a.c.. | RE18-716-2  R.I: 1 |
| Fungicide | Disinfection of surfaces (milk industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Fungi  *Aspergillus brasiliensis DSM 1988* | EN 1650:2008 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.001%, 0.10%, 0.20%, 0.40%, 0.80% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L reconstituted skimmed milk Criteria: at least a 4 log reduction | Fungicidal activity demonstrated at 0.40 % a.c.. | RE18-281-2  R.I: 1 |
| Fungicide | Disinfection of surfaces (milk industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Fungi  *Aspergillus brasiliensis DSM 1988* | EN13697: 2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0,20%, 0.40%, 0.60%, 0.80%, 1% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L reconstituted skimmed milk Criteria: at least a 3 log reduction | Fungicidal activity demonstrated at 0.60% a.c.. | RE18-716-1  R.I: 1 |
| Virucide | Disinfection of surfaces (milk industries) | Eau de Javel Hypochlorite de sodium (chlore actif), 2.5%  Batch : 1901071535 | Virus  *Poliovirus type 1 (LSc-2ab)*  *Murine norovirus (MNV-1)  Human adenovirus type 5 (Ad5)* | EN14476: 2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.20%, 0.25%, 0.50% v/v Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L reconstituted skimmed milk Criteria: at least a 4 log reduction | Virucidal activity demonstrated at 0.25% a.c.. | 338D30-2018-01 LAITERIES  R.I: 2  (product diluted in distilled water instead of hard water) |

in these efficacy tests with fresh samples of the representative products at 2.6 % a.c.:

* bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (10 g/L skimmed milk). In these conditions, bactericidal activity is shown at the in-use concentration of 0.50 % a.c..
* bactericidal activity against *Legionella* is also demonstrated in phase 2, steps 1 test (EN 13623), at 20°C, with a contact time of 5 minutes with dirty conditions (10 g/L skimmed milk). In these conditions, bactericidal activity against *Legionella* is shown at the in-use concentration of 0.05 % a.c.. Phase 2 step 2 test is missing.
* yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (10 g/L skimmed milk). In these conditions, yeasticidal activity is shown at the in-use concentration of 0.07 % a.c..
* fungicidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (10 g/L skimmed milk). In these conditions, fungicidal activity is shown at the in-use concentration of 0.60 % a.c..
* virucidal activity is demonstrated according to phase 2, step 1 test (EN 14476) – (no surface test is available at the submission of the dossier for medical, food, industrial, domestic and institutional areas), at 20°C, with a contact time of 5 minutes with dirty conditions (10 g/L skimmed milk). In these conditions, virucidal activity is shown at the in-use concentration of 0.25 % a.c..
* Experimental data: agricultural areas

Studies have been performed with veterinary conditions of soiling for agricultural area (10 g/L BSA + 10 g/L yest extract). This soiling condtion is higher than the requirement for general dinsifection in dirty conditions (3 g/L BSA) but are considered acceptable as worst case.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | General Disinfection of surfaces (agricultural area) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Bacteria  *Pseudomonas aeruginosa ATCC 10145   Enterococcus hirae ATCC 10541  Staphylococcus aureus ATCC 6538   Escherichia coli ATCC 1053* | EN 1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.05%, 0.5%, 1%, 1.5%, 2% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L yeast extract + 10 g/L bovine albumin Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 1 % a.c.. | RE18-710-1  R.I: 1 |
| Bactericide | General Disinfection of surfaces (agricultural area) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Bacteria  *L.pneumophila DSM 7513* | EN13623:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.01%, 0.05%, 0.10%, 0.15%, 0.20% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L yeast extract + 10 g/L bovine albumin Criteria: at least a 4 log reduction | Activity against *L. pneumophila* demonstrated at 0.15 % a.c.. | RE18-725-1  R.I: 1 |
| Bactericide | General Disinfection of surfaces (agricultural area) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Bacteria  *Pseudomonas aeruginosa ATCC 10145   Enterococcus hirae ATCC 10541  Staphylococcus aureus ATCC 6538   Escherichia coli ATCC 1053* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.005%, 0.01%, 0.05% 0.1% 0.4%, a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L yeast extract + 10 g/L BSA Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 0.40% a.c.. | RE18-715-1  R.I: 1 |
| Yeasticide | General Disinfection of surfaces (agricultural area) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Yeasts  *Candida albicans DSM 1386* | EN 1650:2008 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.005%, 0.025%, 0.05%, 0.10%, 0.20% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L yeast extract + 10 g/L bovine albumin Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 0.20 % a.c.. | RE18-285-1  R.I: 1 |
| Yeasticide | General Disinfection of surfaces (agricultural area) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Yeasts  *Candida albicans DSM 1386* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.03%, 0.05%, 0.10%, 0.20%, 0.40% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L yeast extract + 10 g/L bovine albumin Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 0.10% a.c.. | RE18-720-1  R.I: 1 |
| Fungicide | General Disinfection of surfaces (agricultural area) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Fungi  *Aspergillus brasiliensis DSM 1988* | EN 1650:2008 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.001%, 0.10%, 0.20%, 0.40%, 0.80% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L yeast extract + 10 g/L bovine albumin Criteria: at least a 4 log reduction | Fungicidal activity demonstrated at 0.40 % a.c.. | RE18-285-2  R.I: 1 |
| Fungicide | General Disinfection of surfaces (agricultural area) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | *Aspergillus brasiliensis DSM 1988* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.10%, 0.20%, 0.30%, 0.40%, 0.50% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L yeast extract + 10 g/L bovine albumin Criteria: at least a 3 log reduction | Fungicidal activity demonstrated at 0.40% a.c.. | RE18-720-2  R.I: 1 |

In these efficacy tests with fresh samples of the product BEC eau de Javel ORIGINAL 2.6 % a.c:

* bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (10 g/L yeast extract + 10 g/L bovine albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 1 % a.c..
* bactericidal activity against *Legionella pneumophila* is also demonstrated in phase 2, step 1 test (EN 13623), at 20°C, with a contact time of 5 minutes with dirty conditions (10 g/L yeast extract + 10 g/L bovine albumin). In these conditions, bactericidal activity against *Legionella pneumophila* is shown at the in-use concentration of 0.15 % a.c.. Phase 2 step 2 test is missing.
* yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (10 g/L yeast extract + 10 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 0.20 % a.c..
* fungicidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (10 g/L yeast extract + 10 g/L bovine albumin). In these conditions, fungicidal activity is shown at the in-use concentration of 0.40 % a.c..
* Experimental data: comestics industries

Representative products tested BEC eau de Javel ORIGINAL and Eau de Javel Hypochlorite de sodium are identical and contain 2,6 % available chlorine.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | Disinfection of surfaces (cosmetics industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Bacteria  *Staphylococcus aureus ATCC 6538   Enterococcus hirae ATCC 10541* | EN 1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.001%, 0.002%, 0.005%, 0.01%, 0.05% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 5 g/L Sodium dodecyl sulfate  Criteria: at least a 5 log reduction | Activity against *S. aureus* and *E. hirae* demonstrated at 0.002 % a.c.. | RE18-709-1  R.I: 1 |
| Bactericide | Disinfection of surfaces (cosmetics industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Bacteria  *Pseudomonas aeruginosa ATCC 10145   Escherichia coli ATCC 10536* | EN 1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.0001%, 0.001%, 0.01%, 0.05%, 0.10% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 5 g/L Sodium dodecyl sulfate  Criteria: at least a 5 log reduction | Activity against *P. aeruginosa* and *E. coli* demonstrated at 0.10 % a.c.. | RE18-709-2  R.I: 1 |
| Bactericide | Disinfection of surfaces (cosmetics industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Bacteria  *L. pneumophila DSM 7513* | EN13623:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.01%, 0.05%, 0.10%, 0.15%, 0.20% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 5 g/L Sodium dodecyl sulfate  Criteria: at least a 4 log reduction | Activity against *L. pneumophila* demonstrated at 0.05 % a.c.. | RE18-724-1  R.I: 1 |
| Bactericide | Disinfection of surfaces (cosmetics industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Bacteria  *Pseudomonas aeruginosa ATCC 10145   Enterococcus hirae ATCC 10541  Staphylococcus aureus ATCC 6538   Escherichia coli ATCC 1053* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.05%, 0.01%, 0.05%, 0.1%, 0.40% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 5 g/L lauryl sulfate de sodium Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 0.05% a.c.. | RE18-714-1  R.I: 1 |
| Yeasticide | Disinfection of surfaces (cosmetics industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Yeasts  *Candida albicans DSM 1386* | EN 1650:2008 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.005%, 0.025%, 0.05%, 0.10%, 0.20% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 5 g/L sodium dodecyl sulfate Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 0.05 % a.c.. | RE18-284-1  R.I: 1 |
| Yeasticide | Disinfection of surfaces (cosmetics industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Yeasts  *Candida albicans DSM 1386* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.03%, 0.05%, 0.10%, 0.20%, 0.40% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 5 g/L lauryl sulfate de sodium Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 0.10% a.c.. | RE18-719-1  R.I: 1 |
| Fungicide | Disinfection of surfaces (cosmetics industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Fungi  *Aspergillus brasiliensis DSM 1988* | EN 1650:2008 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.001%, 0.10%, 0.20%, 0.40%, 0.80% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 5 g/L sodium dodecyl sulfate Criteria: at least a 4 log reduction | Fungicidal activity demonstrated at 0.20 % a.c.. | RE18-284-2  R.I: 1 |
| Fungicide | Disinfection of surfaces (cosmetics industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Fungi  *Aspergillus brasiliensis DSM 1988* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.10%, 0.20%, 0.30%, 0.40%, 0.50% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 5 g/L lauryl sulfate de sodium Criteria: at least a 3 log reduction | Fungicidal activity demonstrated at 0.30% a.c.. | RE18-719-2  R.I: 1 |
| Virucide | Disinfection of surfaces (cosmetics industries) | Eau de Javel Hypochlorite de sodium 2.5% a.c.  Batch: 1901071535 | Virus  *Murine norovirus (MNV-1)  Human adenovirus type 5 (Ad5)  Poliovirus type 1 (LSc-2ab)* | EN14476:2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.20%, 0.25%, 0.50% v/v Temperature: 20°C Contact time: 5 min Dirty conditions: 5 g/L lauryl sulfate Criteria: at least a 4 log reduction | Virucidal activity demonstrated at 0.25% a.c.. | 338D30-2018-04  R.I: 2 (product diluted in distilled water instead of hard water) |

In these efficacy tests with fresh samples of the representative products at 2.6 % a.c.:

* bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (5 g/L Sodium dodecyl sulfate). In these conditions, bactericidal activity is shown at the in-use concentration of 0.10 % a.c..
* bactericidal activity against *Legionella pneumophila* is also demonstrated in phase 2, step 1 test (EN 13623), at 20°C, with a contact time of 5 minutes with dirty conditions (5 g/L Sodium dodecyl sulfate). In these conditions, bactericidal activity against *Legionella pneumophila* is shown at the in-use concentration of 0.05 % a.c.. Phase 2 step 2 is missing.
* yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (5 g/L Sodium dodecyl sulfate). In these conditions, yeasticidal activity is shown at the in-use concentration of 0.10 % a.c..
* fungicidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (5 g/L Sodium dodecyl sulfate). In these conditions, fungicidal activity is shown at the in-use concentration of 0.30 % a.c..
* virucidal activity is demonstrated according to phase 2, step 1 test (EN 14476) – (no surface test is available at the submission of the dossier for medical, food, industrial, domestic and institutional areas), at 20°C, with a contact time of 5 minutes with dirty conditions (5 g/L Sodium dodecyl sulfate). In these conditions, virucidal activity is shown at the in-use concentration of 0.25 % a.c..
* Experimental data: non-alcoholic beverages industries

Representative products tested BEC eau de Javel ORIGINAL and Eau de Javel Hypochlorite de sodium are identical and contain 2,6 % available chlorine.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | Disinfection of surfaces (non-alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Bacteria  *Enterococcus hirae ATCC 10541  Pseudomonas aeruginosa ATCC 10145   Escherichia coli ATCC 10536* | EN 1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.001%, 0.005%, 0.01%, 0.05%, 0.10% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L saccharose Criteria: at least a 5 log reduction | Activity against *E. hirae, P. aeruginosa, E. coli* demonstrated at 0.05 % a.c.. | RE18-708-1  R.I: 1 |
| Bactericide | Disinfection of surfaces (non-alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Bacteria  *Staphylococcus aureus DSM 799* | EN 1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.01%, 0.05%, 0.07%, 0.010% 0.15% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions:10 g/L saccharose Criteria: at least a 5 log reduction | Activity against *S. aureus* demonstrated at 0.01 % a.c.. | RE18-708-2  R.I: 1 |
| Bactericide | Disinfection of surfaces (non-alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Bacteria  *L.pneumophila DSM 7513* | EN13623:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.01%, 0.05%, 0.10%, 0.15%, 0.20% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L saccharose Criteria: at least a 4 log reduction | Activity against *L. pneumophila* demonstrated at 0.05 % a.c.. | RE18-723-1  R.I: 1 |
| Bactericide | Disinfection of surfaces (non-alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Bacteria  *Pseudomonas aeruginosa ATCC 10145   Enterococcus hirae ATCC 10541  Staphylococcus aureus ATCC 6538   Escherichia coli ATCC 1053* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.05%, 0.01%, 0.05%, 0.1%, 0.40% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L sucrose Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 0.10% a.c.. | RE18-713-1  R.I: 1 |
| Yeasticide | Disinfection of surfaces (non-alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Yeasts  *Candida albicans DSM 1386* | EN 1650:2008 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.005%, 0.025%, 0.05%, 0.10%, 0.20% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L saccharose Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 0.05 % a.c.. | RE18-283-1  R.I: 1 |
| Yeasticide | Disinfection of surfaces (non-alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Yeasts  *Candida albicans DSM 1386* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.01%, 0.03%, 0.05%, 0.07%, 0.10% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L sucrose Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 0.07% a.c.. | RE18-718-1  R.I: 1 |
| Fungicide | Disinfection of surfaces (non-alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Fungi  *Aspergillus brasiliensis DSM 1988* | EN 1650:2008 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.001%, 0.10%, 0.20%, 0.40%, 0.80% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L saccharose Criteria: at least a 4 log reduction | Fungicidal activity demonstrated at 0.80 % a.c.. | RE18-283-2  R.I: 1 |
| Fungicide | Disinfection of surfaces (non-alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.  Batch: 1812030857 | Fungi  *Aspergillus brasiliensis DSM 1988* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.10%, 0.20%, 0.30%, 0.40%, 0.50% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L sucrose Criteria: at least a 3 log reduction | Fungicidal activity demonstrated at 0.30% a.c.. | RE18-718-2  R.I: 1 |
| Virucide | Disinfection of surfaces (non-alcoholic beverages industries) | Eau de Javel Hypochlorite de sodium 2,5% a.c.  Batch: 1901071535 | Virus  *Murine norovirus (MNV-1)  Human adenovirus type 5 (Ad5)  Poliovirus type 1 (LSc-2ab)* | EN14476:2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.20%, 0.25%, 0.50% v/v Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L sucrose Criteria: at least a 4 log reduction | Virucidal activity demonstrated at 0.25% a.c.. | 338D30-2018-03 BOISSONS SANS ALCOOL  R.I: 2 (product diluted in distilled water instead of hard water) |

In these efficacy tests with fresh samples of the representative products at 2.6 % a.c:

* bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (10 g/L saccharose). In these conditions, bactericidal activity is shown at the in-use concentration of 0.10 % a.c..
* bactericidal activity against *Legionella pneumophila* is also demonstrated in phase 2, step 1 test (EN 13623), at 20°C, with a contact time of 5 minutes with dirty conditions (10 g/L saccharose). In these conditions, bactericidal activity against *Legionella* *pneumophila* is shown at the in-use concentration of 0.05 % a.c.. Phase 2 step 2 test is missing.
* yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (10 g/L saccharose). In these conditions, yeasticidal activity is shown at the in-use concentration of 0.07 % a.c..
* fungicidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (10 g/L saccharose). In these conditions, fungicidal activity is shown at the in-use concentration of 0.80 % a.c..
* virucidal activity is demonstrated according to phase 2, step 1 test (EN 14476) – (no surface test is available at the submission of the dossier for medical, food, industrial, domestic and institutional areas), at 20°C, with a contact time of 5 minutes with dirty conditions (10 g/L saccharose). In these conditions, virucidal activity is shown at the in-use concentration of 0.25 % a.c..
* Experimental data: alcoholic beverages industries

Representative products tested BEC eau de Javel ORIGINAL and Eau de Javel Hypochlorite de sodium are identical and contain 2,6 % available chlorine.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | Disinfection of surfaces (alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.   Batch: 1812030857 | Bacteria  *Staphylococcus aureus ATCC 6538   Enterococcus hirae ATCC 10541* | EN 1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.001%, 0.01%, 0.10%, 0.20%, 0.40% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions:10 g/L yeast extract Criteria: at least a 5 log reduction | Activity against *S. aureus* and *E. hirae* demonstrated at 0.40 % a.c.. | RE18-701-1  R.I: 1 |
| Bactericide | Disinfection of surfaces (alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.   Batch: 1812030857 | Bacteria  *Pseudomonas aeruginosa ATCC 10145   Escherichia coli ATCC 10536* | EN 1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.01%, 0.05%, 0.07%, 0.10% 0,15% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions:10 g/L yeast extract Criteria: at least a 5 log reduction | Activity against *P. aeruginosa* and *E. coli* demonstrated at 0.05 % a.c.. | RE18-701-2  R.I: 1 |
| Bactericide | Disinfection of surfaces (alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.   Batch: 1812030857 | Bacteria  *L. pneumophila DSM 7513* | EN13623: 2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.01%, 0.05%, 0.10%, 0.15%, 0.20% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L yeast extract Criteria: at least a 4 log reduction | Activity against *L. pneumophila* demonstrated at 0.10 % a.c.. | RE18-722-1  R.I: 1 |
| Bactericide | Disinfection of surfaces (alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.   Batch: 1812030857 | Bacteria  *Pseudomonas aeruginosa ATCC 10145   Escherichia coli ATCC 1053* | EN13697: 2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.01%, 0.05%, 0.07% 0.1% 0.15%, a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L yeast extract Criteria: at least a 4 log reduction | Activity against *P. aeruginosa* and *E. coli* demonstrated at 0.07% a.c.. | RE18-712-1  R.I: 1 |
| Bactericide | Disinfection of surfaces (alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.   Batch: 1812030857 | Bacteria  *Enterococcus hirae ATCC 10541  Staphylococcus aureus ATCC 6538* | EN13697: 2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.05%, 0.1%, 0.4% 0.6%, 0.8%, a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L yeast extract Criteria: at least a 4 log reduction | Activity against *E. hirae* and *S. aureus* demonstrated at 0.40% a.c.. | RE18-712-2  R.I: 1 |
| Yeasticide | Disinfection of surfaces (alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.   Batch: 1812030857 | Yeasts  *Candida albicans DSM 1386* | EN 1650:2008 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.005%, 0.025%, 0.05%, 0.10%, 0.20% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L yeast extract Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 0.20 % a.c.. | RE18-282-1  R.I: 1 |
| Yeasticide | Disinfection of surfaces (alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.   Batch: 1812030857 | Yeasts  *Candida albicans DSM 1386* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.03%, 0.05%, 0.10%, 0.20%, 0.30% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L yeast extract Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 0.10% a.c.. | RE18-717-1  R.I: 1 |
| Fungicide | Disinfection of surfaces (alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.   Batch: 1812030857 | Fungi  *Aspergillus brasiliensis DSM 1988* | EN 1650:2008 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.001%, 0.10%, 0.20%, 0.40%, 0.80% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L yeast extract Criteria: at least a 4 log reduction | Fungicidal activity demonstrated at 0.40 % a.c.. | RE18-282-2  R.I: 1 |
| Fungicide | Disinfection of surfaces (alcoholic beverages industries) | BEC eau de Javel ORIGINAL 2.6 % a.c.   Batch: 1812030857 | Fungi  *Aspergillus brasiliensis DSM 1988* | EN13697: 2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.10%, 0.20%, 0.30%, 0.40%, 0.50% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L yeast extract Criteria: at least a 3 log reduction | Fungicidal activity demonstrated at 0.30% a.c.. | RE18-717-2  R.I: 1 |
| Virucide | Disinfection of surfaces (alcoholic beverages industries) | Eau de Javel Hypochlorite de sodium 2.5% a.c.  Batch: 1901071535 | Virus  *Murine norovirus (MNV-1)  Human adenovirus type 5 (Ad5)* | EN14476: 2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.20%, 0.25%, 0.50% v/v Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L yeast extract Criteria: at least a 4 log reduction | Activity against *Murine norovirus* and adenovirus demonstrated at 0.25% a.c.. | 338D30-2018-02 BOISSONS ALCOOLISEES  R.I: 2 (product diluted in distilled water instead of hard water) |
| Virucide | Disinfection of surfaces (alcoholic beverages industries) | Eau de Javel Hypochlorite de sodium 2.5% a.c.  Batch: 1901071535 | Virus  *Poliovirus type 1 (LSc-2ab)* | EN14476: 2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.20%, 0.25%, 0.50% v/v Temperature: 20°C Contact time: 5 min Dirty conditions: 10 g/L yeast extract Criteria: at least a 4 log reduction | Activity against *Poliovirus* demonstrated at 0.25% a.c.. | 338D30-2018-02 BOISSONS ALCOOLISEES poliovirus  R.I: 2 (product diluted in distilled water instead of hard water) |

In these efficacy tests with fresh samples of the representative products at 2.6 % a.c.:

* bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 5 minutes with specific dirty conditions (10 g/L yeast extract). In these conditions, bactericidal activity is shown at the in-use concentration of 0.40 % a.c. on non porous surfaces.
* bactericidal activity against *Legionella* is also demonstrated in phase 2, step 1 test (EN 13623), at 20°C, with a contact time of 5 minutes with specific dirty conditions (10 g/L yeast extract). In these conditions, bactericidal activity against *Legionella* is shown at the in-use concentration of 0.10 % a.c..
* yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 5 minutes with specific dirty conditions (10 g/L yeast extract). In these conditions, yeasticidal activity is shown at the in-use concentration of 0.20 % a.c..
* fungicidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 5 minutes with specific dirty conditions (10 g/L yeast extract). In these conditions, fungicidal activity is shown at the in-use concentration of 0.40 % a.c..
* virucidal activity is demonstrated according to phase 2, step 1 test (EN 14476) – (no surface test is available at the submission of the dossier for medical, food, industrial, domestic and institutional areas), at 20°C, with a contact time of 5 minutes with specific dirty conditions (10 g/L yeast extract). In these conditions, virucidal activity is shown at the in-use concentration of 0.25 % a.c..

The applicant has also submitted additional EN 13697 tests in dirty conditions (3 g/L BSA) for bacteria, yeasts and fungi, with the product Javel 2,6%. These tests were considered as supportive data and are presented below only for information.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | Disinfection of surfaces | Javel 2,6% c.a  Batch: 180406 | Bacteria  *Pseudomonas aeruginosa ATCC 10145   Escherichia coli ATCC 10536* | EN13697: 2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0,01%, 0.05%, 0.07%, 0.10%, 0.15% c.a. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA Criteria: at least a 4 log reduction | Activity against *P. aeruginosa* and *E; coli* demonstrated at 0.07% a.c.. | RE18-178-1  R.I: 2  (supportive data) |
| Bactericide | Disinfection of surfaces | Javel 2,6% c.a  Batch: 180406 | Bacteria  *Staphylococcus aureus ATCC 6538   Enterococcus hirae ATCC 10541* | EN13697: 2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.05%, 0.10%, 0.40%, 0.60%, 0.80% c.a. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA Criteria: at least a 4 log reduction | Activity against *S. aureus* and *E. hirae* demonstrated at 0.40% a.c.. | RE18-178-2  R.I: 2  (supportive data) |
| Yeasticide | Disinfection of surfaces | Javel 2,6% c.a  Batch: 180406 | Yeasts  *Candida albicans DSM 1386* | EN13697: 2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.03%, 0.05%, 0.07%, 0.10%, 0.13% c.a. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 0,07% v/v. | RE18-179-1  R.I: 2  (supportive data) |
| Fungicide | Disinfection of surfaces | Javel 2,6% c.a  Batch: 180406 | Fungi  *Aspergillus brasiliensis DSM 1988* | EN13697: 2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.10%, 0.20%, 0.30%, 0.40%, 0.50% c.a. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA Criteria: at least a 3 log reduction | Fungicidal activity demonstrated at 0.40% a.c.. | RE18-179-2  R.I: 2  (supportive data) |

Summary of efficacy studies performed on the representative product for SL formulations for the biocidal family DAAP19:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Field of use** | **Test method** | **Function** | **Soiling conditions** | **Contact time** | **Minimum efficacy (% a.c.)** |
| Medical area | EN 13727 | Bactericide | 3 g/L BSA+3 mL/L sheep erythrocytes | 5 min | 0.10% |
| Medical area | EN 13623 | Bactericide (Legionella) | 3 g/L BSA+3 mL/L sheep erythrocytes | 5 min | 0.05% |
| Medical area | EN 13697 | Bactericide | 3 g/L BSA+3 mL/L sheep erythrocytes | 5 min | 0.66% |
| Medical area | EN 13624 | Yeasticide | 3 g/L BSA+3 mL/L sheep erythrocytes | 5 min | 0.13% |
| Medical area | EN13697 | Yeasticide | 3 g/L BSA+3 mL/L sheep erythrocytes | 5 min | 0.17% |
| Medical area | EN 13624 | Fungicide | 3 g/L BSA+3 mL/L sheep erythrocytes | 5 min | 0.30% |
| Medical area | EN13697 | Fungicide | 3 g/L BSA+3 mL/L sheep erythrocytes | 5 min | 0.50% |
| Medical area | EN14476 | Virucide | 3 g/L BSA+3 mL/L sheep erythrocytes | 5 min | 0.25% |
| Veterinary area | EN 1656 | Bactericide | 10 g/L BSA +10 g/L yeast extracts | 5 min | 0.50% |
| Veterinary area | EN16437 | Bactericide | 10 g/L BSA +10 g/L yeast extracts | 5 min | No efficient |
| Veterinary area | EN14349 | Bactericide | 10 g/L BSA +10 g/L yeast extracts | 5 min | 0.50% |
| Veterinary area | EN 1657 | Yeasticide | 10 g/L BSA +10 g/L yeast extracts | 5 min | 0.58% |
| Veterinary area | EN 16438 | Yeasticide | 10 g/L BSA +10 g/L yeast extracts | 5 min | 0.60% |
| Veterinary area | EN 1657 | Fungicide | 10 g/L BSA +10 g/L yeast extracts | 5 min | 0.66% |
| Veterinary area | EN 16438 | Fungicide | 10 g/L BSA +10 g/L yeast extracts | 5 min | 0.68% |
| Veterinary area | EN 14675 | Virucide | 10 g/L BSA +10 g/L yeast extracts | 5 min | 0.78% |
| Milk industries | EN 1276 | Bactericide | 10 g/L reconstituted skim milk | 5 min | 0.05% |
| Milk industries | EN 13623 | Bactericide (Legionella) | 10 g/L reconstituted skim milk | 5 min | 0.05% |
| Milk industries | EN 13697 | Bactericide | 10 g/L reconstituted skim milk | 5 min | 0.50% |
| Milk industries | EN 1650 | Yeasticide | 10 g/L reconstituted skim milk | 5 min | 0.025% |
| Milk industries | EN13697 | Yeasticide | 10 g/L reconstituted skim milk | 5 min | 0.07% |
| Milk industries | EN 1650 | Fungicide | 10 g/L reconstituted skim milk | 5 min | 0.40% |
| Milk industries | EN13697 | Fungicide | 10 g/L reconstituted skim milk | 5 min | 0.60% |
| Milk industries | EN14476 | Virucide | 10 g/L reconstituted skim milk | 5 min | 0.25% |
| Agricultural area (general disinfection) | EN 1276 | Bactericide | 10 g/L yeast extract + 10 g/L bovine albumin | 5 min | 1% |
| Agricultural  area (general disinfection) | EN 13623 | Bactericide (Legionnella) | 10 g/L yeast extract + 10 g/L bovine albumin | 5 min | 0.15% |
| Agricultural  area (general disinfection) | EN 13697 | Bactericide | 10 g/L yeast extract + 10 g/L bovine albumin | 5 min | 0.40% |
| Agricultural  area (general disinfection) | EN 1650 | Yeasticide | 10 g/L yeast extract + 10 g/L bovine albumin | 5 min | 0.20% |
| Agricultural  area (general disinfection) | EN13697 | Yeasticide | 10 g/L yeast extract + 10 g/L bovine albumin | 5 min | 0.10% |
| Agricultural  area (general disinfection) | EN 1650 | Fungicide | 10 g/L yeast extract + 10 g/L bovine albumin | 5 min | 0.40% |
| Agricultural  area (general disinfection) | EN13697 | Fungicide | 10 g/L yeast extract + 10 g/L bovine albumin | 5 min | 0.40% |
| Cosmestics industries | EN 1276 | Bactericide | 5 g/L Sodium dodecyl sulfate | 5 min | 0.10% |
| Cosmestics industries | EN 13623 | Bactericide (Legionella) | 5 g/L Sodium dodecyl sulfate | 5 min | 0.05% |
| Cosmestics industries | EN 13697 | Bactericide | 5 g/L Sodium dodecyl sulfate | 5 min | 0.05% |
| Cosmestics industries | EN 1650 | Yeasticide | 5 g/L Sodium dodecyl sulfate | 5 min | 0.05% |
| Cosmestics industries | EN13697 | Yeasticide | 5 g/L Sodium dodecyl sulfate | 5 min | 0.10% |
| Cosmestics industries | EN 1650 | Fungicide | 5 g/L Sodium dodecyl sulfate | 5 min | 0.20% |
| Cosmestics industries | EN13697 | Fungicide | 5 g/L Sodium dodecyl sulfate | 5 min | 0.30% |
| Cosmestics industries | EN14476 | Virucide | 5 g/L Sodium dodecyl sulfate | 5 min | 0.25% |
| non-alcoholic beverages industries | EN 1276 | Bactericide | 10 g/L saccharose | 5 min | 0.05% |
| non-alcoholic beverages industries | EN 13623 | Bactericide (Legionella) | 10 g/L saccharose | 5 min | 0.05% |
| non-alcoholic beverages industries | EN 13697 | Bactericide | 10 g/L saccharose | 5 min | 0.10% |
| non-alcoholic beverages industries | EN 1650 | Yeasticide | 10 g/L saccharose | 5 min | 0.05% |
| non-alcoholic beverages industries | EN13697 | Yeasticide | 10 g/L saccharose | 5 min | 0.07% |
| non-alcoholic beverages industries | EN 1650 | Fungicide | 10 g/L saccharose | 5 min | 0.80% |
| non-alcoholic beverages industries | EN13697 | Fungicide | 10 g/L saccharose | 5 min | 0.30% |
| non-alcoholic beverages industries | EN14476 | Virucide | 10 g/L saccharose | 5 min | 0.25% |
| alcoholic beverages industries | EN 1276 | Bactericide | 10 g/L yeast extract | 5 min | 0.40% |
| alcoholic beverages industries | EN 13623 | Bactericide (Legionella) | 10 g/L yeast extract | 5 min | 0.10% |
| alcoholic beverages industries | EN 13697 | Bactericide | 10 g/L yeast extract | 5 min | 0.40% |
| alcoholic beverages industries | EN 1650 | Yeasticide | 10 g/L yeast extract | 5 min | 0.20% |
| alcoholic beverages industries | EN13697 | Yeasticide | 10 g/L yeast extract | 5 min | 0.10% |
| alcoholic beverages industries | EN 1650 | Fungicide | 10 g/L yeast extract | 5 min | 0.40% |
| alcoholic beverages industries | EN13697 | Fungicide | 10 g/L yeast extract | 5 min | 0.30% |
| alcoholic beverages industries | EN14476 | Virucide | 10 g/L yeast extract | 5 min | 0.25% |

* + **Conclusion on the efficacy for the META SPC 2.1**

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| **Conclusion on the efficacy for the meta SPC 2.1** |
| For meta SPC 2.1, available chlorine concentration is at 2.6% w/w (fresh product).  For meta SPC 2.1, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test). No efficacy tests have been performed with aged products for Meta SPC 2.1. However, available chlorine content based storage based on APCP data (11 months, 2.58 % a.c. w/w) was compared to the one demonstrated in the efficacy studies in the following table, as it is not expected that age-related changes in co-formulants would have an effect on efficacy of the aged product:   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2/4 | **# 1 - Disinfection of household surfaces (floors) by wiping with mop and bucket (non mechanical action)**  **# 2 - Disinfection of household surfaces (other than floors) by wiping with cloth and bucket**  **(non mechanical action)**  **# 4 Disinfection of household surfaces (other than floors) in contact with food by wiping with cloth and bucket**  **(non mechanical action)** | Mandatory:  Bacteria | Dirty | 5 min | 30% v/v  (0.81% a.c.) | 0.66% a.c. | 30% v/v  (0.80% a.c after 11 months) | 30% v/v | **Validated**  **30 % v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 25% v/v  (0.68% a.c.) | 0.17% a.c. | 25% v/v  (0.68% a.c. after 11 months) | 25% v/v | | Optional:  Fungal spores | Dirty | 5 min | 25% v/v  (0.68% a.c.) | 0.50% a.c. | 25% v/v  (0.68% a.c. after 11 months) | 25% v/v | | Optional:  Virus | Dirty | 5 min | 11.1% v/v  (0.30% a.c.) | 0.25% a.c. | 11.1% v/v  (0.30% a.c. after 11 months) | 11.1% v/v | | 2 | **# 3 - Disinfection of toilet bowls in household areas (non mechanical action)** | Mandatory:  Bacteria | Dirty | 5 min | 30% v/v  (0.81% a.c.) | 0.66% a.c. | 30% v/v  (0.80% a.c after 11 months) | 30% v/v | **Validated**  **30% v/v** | | Optional:  Yeasts | Dirty | 5 min | 25% v/v  (0.68% a.c.) | 0.17% a.c. | 25% v/v  (0.68 a.c. after 11 months) | 25% v/v | | Optional:  Fungal spores | Dirty | 5 min | 25% v/v  (0.68% a.c.) | 0.50% a.c. | 25% v/v  (0.68% a.c. after 11 months) | 25% v/v | | Optional:  Virus | Dirty | 5 min | 11.1% v/v  (0.30% a.c.) | 0.25% a.c. | 11.1% v/v  (0.30% a.c. after 11 months) | 11.1% v/v | | 2 | **# 6 - Laundry disinfection with hand soaking (household areas)** | Bacteria  Yeasts  Fungi  Virus |  |  |  |  |  |  | **Not validated, no phase 2 step 2 test submitted.** | | 3 | **# 5 Disinfection of companion animal housing and associated equipment**  **(non mechanical action)** | Mandatory:  Bacteria | Dirty | 5 min | 25% v/v  (0.68% a.c.) | 0.50% a.c. | 25% v/v  (0.68% a.c after 11 months) | 25% v/v | **Validated**  **28.6% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 28.6% v/v  (0.77% a.c.) | 0.60% a.c. | 28.6% v/v  (0.75 a.c. after 11 months) | 28.6% v/v | | Optional:  Fungal spores | Dirty | 5 min | 33,3% v/v  (0.88% a.c.) | 0.68% a.c. | 33.3% v/v  (0.89% a.c. after 11 months) | 33.3% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 37.5 % v/v  (1% a.c.) | 0.78% a.c. | 37.5% v/v  (1% a.c. after 11 months) | 37.5% v/v | **Validated** |   Regarding use #1, 2 and 4 “disinfection of hard surfaces”, for wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted, and only “non mechanical action is claimed by the applicant.. Therefore the eCA consider that wiping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by wiping with mop/cloth. A specific instruction for use is added in the SPC.  Regarding use #6 “Laundry disinfection with hand soaking”, in absence of P2S2 tests (e.g. ASTM E4206 or ASTM E2274) which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.2.10.2), efficacy for this use is not demonstrated. |

* + **Conclusion on the efficacy for the META SPC 2.21**

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| **Conclusion on the efficacy for the meta SPC 2.21** |
| For meta SPC 2.21, available chlorine concentration is at 4.8% w/w (fresh product).  For meta SPC 2.21, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test). No efficacy tests have been performed with aged products for Meta SPC 2.21. However, available chlorine content based storage based on APCP data (8 months, 4.18% a.c.) was compared to the one demonstrated in the efficacy studies in the following table, as it is not expected that age-related changes in co-formulants would have an effect on efficacy of the aged product:   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2/4 | **# 1 - Disinfection of household surfaces (floors) by wiping with mop and bucket (non mechanical action)**  **# 2 - Disinfection of household (other than floors) by wiping with cloth and bucket**  **(non mechanical action)**  **# 4 Disinfection of houseold surfaces (other than floors) in contact with food by wiping with cloth and bucket (non mechanical action)** | Mandatory:  Bacteria | Dirty | 5 min | 15% v/v  (0.77% a.c.) | 0.66% a.c. | 15% v/v  (0.67% a.c. after 8 months) | 15% v/v | **Validated**  **15% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 12.5% v/v  (0.64% a.c.) | 0.17% a.c. | 12.5% v/v  (0.56% a.c. after 8 months) | 12.5% v/v | | Optional:  Fungal spores | Dirty | 5 min | 12.5% v/v  (0.64% a.c.) | 0.50% a.c. | 12.5% v/v  (0.56% a.c. after 8 months) | 12.5% v/v | | Optional:  Virus | Dirty | 5 min | 5.5% v/v  (0.28% a.c.) | 0.25% a.c. | 5.5% v/v  (0.25% a.c. after 8 months) | 5.5% v/v | | 2 | **# 3 - Disinfection of toilet bowls in houhold areas (non mechanical action)** | Mandatory:  Bacteria | Dirty | 5 min | 15% v/v  (0.77% a.c.) | 0.66% a.c. | 15% v/v  (0.67% a.c. after 8 months) | 15% v/v | **Validated**  **15% v/v** | | Optional:  Yeasts | Dirty | 5 min | 12.5% v/v  (0.64% a.c.) | 0.17% a.c. | 12.5% v/v  (0.56% a.c. after 8 months) | 12.5% v/v | | Optional:  Fungal spores | Dirty | 5 min | 12.5% v/v  (0.64% a.c.) | 0.50% a.c. | 12.5% v/v  (0.56% a.c. after 8 months) | 12.5% v/v | | Optional:  Virus | Dirty | 5 min | 5.5% v/v  (0.28% a.c.) | 0.25% a.c. | 5.5% v/v  (0.25% a.c. after 8 months) | 5.5% v/v | | 2 | **# 6 - Laundry disinfection with hand soaking (household areas)** | Bacteria  Yeasts  Fungi  Virus |  |  |  |  |  |  | **Not validated, no phase 2 step 2 test submitted.** | | 3 | **# 5 Disinfection of companion animal housing and associated equipment**  **(non mechanical action)** | Mandatory:  Bacteria | Dirty | 5 min | 12.5% v/v  (0.64% a.c.) | 0.50% a.c. | 12.5% v/v  (0.56% a.c. after 8 months) | 12.5% v/v | **Validated**  **14.3% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 14.3% v/v  (0.74% a.c.) | 0.60% a.c. | 14.3% v/v  (0.64% a.c. after 8 months) | 14.3% v/v | | Optional:  Fungal spores | Dirty | 5 min | 16.6% v/v  (0.85% a.c.) | 0.68% a.c. | 16.6% v/v  (0.74% a.c. after 8 months) | 16.6% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 18.7% v/v  (0.96% a.c.) | 0.78% a.c. | 18.7% v/v  (0.84% a.c. after 8 months) | 17.8% v/v | **Validated** |   Regarding use #1, 2 and 4 “disinfection of hard surfaces”, for wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted, and only “non mechanical action is claimed by the applicant.. Therefore the eCA consider that wiping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by wiping with mop/cloth. A specific instruction for use is added in the SPC.  Regarding use #6 “Laundry disinfection with hand soaking”, in absence of P2S2 tests (e.g. ASTM E4206 or ASTM E2274) which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.2.10.2), efficacy for this use is not demonstrated. |

* + Conclusion on the efficacy for the META SPC 2.22

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| **Conclusion on the efficacy for the meta SPC 2.22** |
| For meta SPC 2.22, available chlorine concentration is at 3.6% w/w (fresh product).  For meta SPC 2.22, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test). No efficacy tests have been performed with aged products for Meta SPC 2.22. However, available chlorine content based storage based on APCP data (11 months, 3.14% a.c. w/w) was compared to the one demonstrated in the efficacy studies in the following table as it is not expected that age-related changes in co-formulants would have an effect on efficacy of the aged product:   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2/4 | **# 1 - Disinfection of household surfaces (floors) by wiping with mop and bucket**  **(non mechanical action)**  **# 2 - Disinfection of household surfaces (other than floors) by wiping with cloth and bucket**  **(non mechanical action)**  **# 4 Disinfection of household surfaces (other than floors) in contact with food by wiping with cloth and bucket (non mechanical action)** | Mandatory:  Bacteria | Dirty | 5 min | 22.2% v/v  (0.84% a.c.) | 0.66% a.c. | 22.2% v/v  (0.74% a.c after 11 months) | 22.2% v/v | **Validated**  **22.2% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 18.2% v/v  (0.69% a.c.) | 0.17% a.c. | 18.2% v/v  (0.60% a.c. after 11 months) | 18.2% v/v | | Optional:  Fungal spores | Dirty | 5 min | 18.2% v/v  (0.69% a.c.) | 0.50% a.c. | 18.2% v/v  (0.60% a.c. after 11 months) | 18.2% v/v | | Optional:  Virus | Dirty | 5 min | 8.3% v/v  (0.32% a.c.) | 0.25% a.c. | 8.3% v/v  (0.28% a.c. after 11 months) | 8.3% v/v | | 2 | **# 3 - Disinfection of toilet bowls in houhold areas (non mechanical action** | Mandatory:  Bacteria | Dirty | 5 min | 22.2% v/v  (0.84% a.c.) | 0.66% a.c. | 22.2% v/v  (0.74% a.c after 11 months) | 22.2% v/v | **Validated 22.2% v/v** | | Optional:  Yeasts | Dirty | 5 min | 18.2% v/v  (0.69% a.c.) | 0.50% a.c. | 18.2% v/v  (0.60% a.c. after 11 months) | 18.2% v/v | | Optional:  Fungal spores | Dirty | 5 min | 18.2% v/v  (0.69% a.c.) | 0.50% a.c. | 18.2% v/v  (0.60% a.c. after 11 months) | 18.2% v/v | | Optional:  Virus | Dirty | 5 min | 8.3% v/v  (0.32% a.c.) | 0.25% a.c. | 8.3% v/v  (0.28% a.c. after 11 months) | 8.3% v/v | | 2 | **# 6 - Laundry disinfection with hand soaking (household areas)** | Bacteria  Yeasts  Fungi  Virus |  |  |  |  |  |  | **Not validated, no phase 2 step 2 test submitted.** | | 3 | **# 5 Disinfection of companion animal housing and associated equipment (non mechanical action)** | Mandatory:  Bacteria | Dirty | 5 min | 18.2% v/v  (0.69% a.c.) | 0.50% a.c. | 18.2% v/v  (0.60% a.c. after 11 months) | 18.2% v/v | **Validated**  **18.2% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 15.4% v/v  (0.58% a.c.) | 0.60% a.c. | 15.4% v/v  (0.51% a.c. after 11 months) | **Not validated** | | Optional:  Fungal spores | Dirty | 5 min | 25% v/v  (0.95% a.c.) | 0.68% a.c. | 25% v/v  (0.83% a.c. after 11 months) | 25% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 28.6% v/v  (1% a.c.) | 0.78% a.c. | 50% v/v  (0.95% a.c. after 11 months) | 28.6% v/v | **Validated** |   Regarding use #1, 2 and 4 “disinfection of hard surfaces”, for wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted, and only “non mechanical action is claimed by the applicant.. Therefore the eCA consider that wiping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by wiping with mop/cloth. A specific instruction for use is added in the SPC.  Regarding use #6 “Laundry disinfection with hand soaking”, in absence of P2S2 tests (e.g. ASTM E4206 or ASTM E2274) which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.2.10.2), efficacy for this use is not demonstrated. |

* + **Conclusion on the efficacy for the META SPC 6.1**

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| **Conclusion on the efficacy for the meta SPC 6.1** |
| For meta SPC 6.1, available chlorine concentration is at 9.6% w/w (fresh product).  For meta SPC 6.1, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test. No efficacy tests have been performed with aged products for Meta SPC 6.1, However, available chlorine content based storage based on APCP data (Meta SPC 9, after 6 months storage 7.04% w/w a.c.) was compared to the one demonstrated in the efficacy studies in the following table:   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2/4 | **# 1 - Disinfection of household surfaces (floors) by wiping with mop and bucket (non mechanical action)**  **# 2 - Disinfection of household surfaces (other than floors) by wiping with cloth and bucket (non mechanical action)**  **# 3 Disinfection of household surfaces (other than floors) in contact with food by wiping with cloth and bucket**  **(non mechanical action)** | Mandatory:  Bacteria | Dirty | 5 min | 9.1% v/v  (1% a.c.) | 0.66% a.c. | 9.1% v/v  (0.74% a.c after 6 months) | 9.1% v/v | **Validated**  **9.1% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 7.1% v/v  (0.79% a.c.) | 0.17% a.c. | 7.1% v/v  (0.58% a.c after 6 months) | 7.1% v/v | | Optional:  Fungal spores | Dirty | 5 min | 7.1% v/v  (0.79% a.c.) | 0.50% a.c. | 7.1% v/v  (0.58% a.c after 6 months) | 7.1% v/v | | Optional:  Virus | Dirty | 5 min | 3.6% v/v  (0.39% a.c.) | 0.25% a.c. | 3.6% v/v  (0.29% a.c after 6 months) | 3.6% v/v | | 2 | **# 5 - Laundry disinfection with hand soaking (household areas)** | Bacteria  Yeasts  Fungi  Virus |  |  |  |  |  |  | **Not validated, no phase 2 step 2 test submitted.** | | 3 | **# 4 Disinfection of companion animal housing and associated equipment**  **(non mechanical action)** | Mandatory:  Bacteria | Dirty | 5 min | 7.1% v/v  (0.79% a.c.) | 0.50% a.c. | 7.1% v/v  (0.58% a.c after 6 months) | 7.1% v/v | **Validated**  **8.3% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 8.3% v/v  (0.92% a.c.) | 0.60% a.c. | 8.3% v/v  (0.68% a.c after 6 months) | 8.3% v/v | | Optional:  Fungal spores | Dirty | 5 min | 9.5% v/v  (1.05% a.c.) | 0.68% a.c. | 9.5% v/v  (0.77% a.c after 6 months) | 9.5% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 11.1% v/v  (1.22% a.c.) | 0.78% a.c. | 11.1% v/v  (0.90% a.c after 6 months) | 11.1% v/v | **Validated** |   Regarding use #1, 2 and 3 “disinfection of hard surfaces”, for wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted, and only “non mechanical action is claimed by the applicant.. Therefore the eCA consider that wiping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by wiping with mop/cloth. A specific instruction for use is added in the SPC.  Regarding use #5 “Laundry disinfection with hand soaking”, in absence of P2S2 tests (e.g. ASTM E4206 or ASTM E2274) which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.2.10.2), efficacy for this use is not demonstrated. |

* + **Conclusion on the efficacy for the META SPC 6.21**

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| **Conclusion on the efficacy for the meta SPC 6.21** |
| For meta SPC 6.21, available chlorine concentration is at 9.6% w/w (fresh product).  For meta SPC 6.21, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test).No efficacy tests have been performed with aged products for Meta SPC 6.21, However, available chlorine content based storage based on APCP data (Meta SPC 9, after 6 months storage, 7.04% w/w a.c.) was compared to the one demonstrated in the efficacy studies in the following table:   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | Contact time | Application rate/dilution claimed  in % of product  (% m/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% m/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2/4 | **Surfaces in medical area, institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries):**  **# 1 - Disinfection of hard surfaces in medical area**  **# 2 - Disinfection of hard surfaces in contact with food**  **# 3 Disinfection of hard surfaces in institutions, industries**  **# 4 Disinfection of hard surfaces by CIP\*** | Mandatory:  Bacteria | Dirty | 5 min | 8.9% v/v  (0.98% a.c.) | 0.66% a.c. (medical)  0.50% a.c. (milk indutries) | 8.9% v/v  (0.72% a.c after 6 months) | 8.9% v/v | **Validated**  **8.9% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 8.1% v/v  (0.89% a.c.) | 0.17% a.c. (medical)  0.07% a.c. (milk industries) | 8.1% v/v  (0.67% a.c after 6 months) | 8.1% v/v | | Optional:  Fungal spores | Dirty | 5 min | 8.1% v/v  (0.89% a.c.) | 0.50 % a.c. (medical)  0.60% a.c. (milk industries) | 8.1% v/v  (0.66% a.c after 6 months) | 8.1% v/v | | Optional:  Virus | Dirty | 5 min | 3.4% v/v  (0.37% a.c.) | 0.25% a.c. (medical and milk industries) | 3.4% v/v  (0.27% a.c after 6 months) | 3.4% v/v | | 2/4 | **Hard surfaces in agricultural industries and non-alcoholic beverages industries by wiping, mopping:**    **# 2 - Disinfection of hard surfaces in contact with food**  **# 3 Disinfection of hard surfaces in institutions, industries**  **# 4 Disinfection of hard surfaces by CIP\*** | Mandatory:  Bacteria | Dirty | 5 min | 13.5% v/v  (1.49% a.c.) | 1.00% a.c. (agricultural area (general disinfection))  0.10% a.c. (non-alcoholic beverages industries) | 13.5% v/v  (1.09% a.c after 6 months) | 13.5% v/v | **Validated**  **13.5% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 10.8% v/v  (1.19% a.c.) | 0.20% a.c. (agricultural area (general disinfection))  0.07% a.c. (non-alcoholic beverages industries) | 10.8% v/v  (0.87% a.c after 6 months) | 10.8% v/v | | Optional:  Fungal spores | Dirty | 5 min | 10.8% v/v  (1.19% a.c.) | 0.40% a.c. (agricultural area (general disinfection))  0.80% a.c. (non-alcoholic beverages industries) | 10.8% v/v  (0.87% a.c after 6 months) | 10.8% v/v | | Optional:  Virus | Dirty | 5 min | 10.5% v/v  (1.15% a.c.) | 0.25% a.c. (non-alcoholic beverages industries) | 10.5% v/v  (0.85% a.c after 6 months) | 10.5% v/v | | **Not validated for** **agricultural area** | | 3 | **# 6 Disinfection of non-porous hard surfaces in veterinary area** | Mandatory:  Bacteria | Dirty | 5 min | 7% v/v  (0.77% a.c.) | 0.50% a.c. | 7% v/v  (0.57% a.c after 6 months) | 7% v/v | **Validated**  **8.1% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 8.1% v/v  (0.89% a.c.) | 0.60% a.c. | 8.1% v/v  (0.66% a.c after 6 months) | 8.1% v/v | | Optional:  Fungal spores | Dirty | 5 min | 9.2% v/v  (1.01% a.c.) | 0.68% a.c. | 9.2% v/v  (0.75% a.c after 6 months) | 9.2% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 10.5% v/v  (1.16% a.c.) | 0.78% a.c. | 10.5% v/v  (0.85% a.c after 6 months) | 10.5% v/v | **Validated** | | 3 | **# 7 Disinfection of non-porous hard surfaces in livestock transportation vehicles** | Mandatory:  Bacteria | Dirty | 5 min | 7% v/v  (0.77% a.c.) | 0.50% a.c. | 7% v/v  (0.57% a.c after 6 months) | 7% v/v | **Validated**  **10.5% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 8.1% v/v  (0.89% a.c.) | 0.60% a.c. | 8.1% v/v  (0.66% a.c after 6 months) | 8.1% v/v | | Mandatoryl:  Virus | Dirty | 5 min | 10.5% v/v  (1.16% a.c.) | 0.78% a.c. | 10.5% v/v  (0.85% a.c after 6 months) | 10.5% v/v | | Optional:  Fungal spores | Dirty | 5 min | 9.2% v/v  (1.01% a.c.) | 0.68% a.c. | 9.2% v/v  (0.75% a.c after 6 months) | 9.2% v/v | | 4 | **# 8 Disinfection of inner surfaces in human drinking water systems** | Mandatory:  Bacteria | Dirty | 5 min | 1.4% v/v  (0.15% a.c.) | 0.10% a.c. | 1.4% v/v  (0.11% a.c after 6 months) | 1.4% v/v | **Validated** | | Optional:  Yeasts | Dirty | 5 min | 4.1% v/v  (0.45% a.c.) | 0.13% a.c. | 4.1% v/v  (0.33% a.c after 6 months) | 4.1% v/v | **Validated** | | Optional:  *Legionnella* | Dirty | 5 min | 0.7% v/v  (0.07% a.c.) | 0.05% a.c. | 0.7% v/v  (0.06% a.c after 6 months) | 0.7% v/v | **Not validated as no field test provided** | | Optional:  Fungal spores | Dirty | 5 min | 4.1% v/v  (0.45% a.c.) | 0.30% a.c. | 4.2% v/v  (0.33% a.c after 6 months) | 4.1% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 3.4% v/v  (0.37% a.c.) | 0.25% a.c. | 3.4% v/v  (0.28% a.c after 6 months) | 3.4% v/v | **Validated** | | 4 | **# 9 Disinfection of inner surfaces in veterinary water systems** | Mandatory:  Bacteria | Dirty | 5 min | 6.7% v/v  (0.73% a.c.) | 0.66% a.c. (medical) | 6.7% v/v  (0.54% a.c after 6 months) | **Not validated** | **Validated**  **8.9% v/v** | | Optional:  *Legionnella* | Dirty | 5 min | 2% v/v  (0.22% a.c.) |  |  |  | **Not validated, no phase 2 step 2 test submitted.** | | Optional:  Yeasts | Dirty | 5 min | 8.9% v/v  (0.98% a.c.) | 0.17% a.c. (medical) | 8.9% v/v  (0.72% a.c after 6 months) | 8.9% v/v | **Validated** | | Optional:  Fungal spores | Dirty | 5 min | 8.9% v/v  (0.98% a.c.) | 0.60% a.c. (medical) | 8.9% v/v  (0.72% a.c after 6 months) | 8.9% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 10.5% v/v  (1.16% a.c.) | 0.25% a.c. (medical) | 10.5% v/v  (0.85% a.c after 6 months) | 10.5% v/v | **Validated** | | 2 | **# 5 - Laundry disinfection with hand soaking** | Bacteria  Yeasts  Fungi  Virus |  |  |  |  |  |  | **Not validated, no phase 2 step 2 test submitted.** | | 5 | **# 10 - Disinfection of water intended for human consumption** | Bacteria  Yeasts  Fungi  Virus |  |  |  |  |  |  | **Not validated, no SU test submitted.** |   Regarding use #1, 2 and 3 “disinfection of hard surfaces”, for wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted, and only “non mechanical action is claimed by the applicant.. Therefore the eCA consider that wiping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by wiping with mop/cloth. A specific instruction for use is added in the SPC.  Regarding use #4 “Disinfection of hard surfaces by CIP”, suspension tests only should be used to determinate minimal active concentration. Nevertheless, this use was added with other hard surface disinfection uses as the same dilutions are claimed and it is considered as a worst case scenario.  Regarding use #5 “Laundry disinfection with hand soaking”, in absence of P2S2 tests (e.g. ASTM E4206 or ASTM E2274) which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.2.10.2), efficacy for this use is not demonstrated.  Regarding use #8 “Disinfection of inner surfaces in human drinking water systems” by CIP, in absence of field tests which are mandatory to support this use against *Legionela* according to the requirement of the efficacy guidance (section 5.4.4.6.2), efficacy for this target organism for this use is not demonstrated.  Regarding use #9 “Disinfection of inner surfaces in veterinary water systems” by CIP in absence of P2S2 tests representative of the conditions of use and which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.4.7.2), efficacy against *Legionella* for this use is not demonstrated.  Regarding use #10 “Disinfection of water intended for human consumption”, in absence of P2S1 and SU tests representative of the conditions of use and which are mandatory to support this use according to the requirement of the efficacy guidance, efficacy for this use is not demonstrated. |

* + Conclusion on the efficacy for the META SPC 6.22

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| **Conclusion on the efficacy for the meta SPC 6.22** |
| For meta SPC 6.21, available chlorine concentration is between 12.5 and 13.5% w/w (fresh product).  For meta SPC 6.22, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test). No efficacy tests have been performed with aged products for Meta SPC 6.22, However, available chlorine content based storage based on APCP data (after 3 months storage, 7.48% w/w a.c. for product with 12.5% w/w a.c. (fresh)) was compared to the one demonstrated in the efficacy studies in the following table. Please note that no available chlorine content after storage are available for products with 13.5% w/w a.c. (fresh).   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2/4 | **Surfaces in medical area, institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries):**  **# 1 - Disinfection of hard surfaces in medical area**  **# 2 - Disinfection of hard surfaces in contact with food**  **# 3 Disinfection of hard surfaces in institutions, industries**  **# 4 Disinfection of hard surfaces by CIP\*** | Mandatory:  Bacteria | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 7.9% v/v  (1.19% a.c.)  Product with 13.5 % w/w a.c. (fresh): 6.2% v/v  (1.01% a.c.) | 0.66% a.c. (medical)  0.50% a.c. (milk indutries) | Product with 12.5 % w/w a.c. (fresh): 7.9% v/v  (0.71% a.c. after 3 months) | 7.9% v/v | **Validated**  **7.9% v/v (product at 12.5 % w/w a.c. (fresh) only)** | | Mandatory:  Yeasts | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 7.2% v/v  (1.09% a.c.)  Product with 13.5 % w/w a.c. (fresh): 5.6% v/v  (0.91% a.c.) | 0.17% a.c. (medical)  0.07% a.c. (milk industries) | Product with 12.5 % w/w a.c. (fresh): 7.2% v/v (0.65% a.c. after 3 months) | 7.2% v/v | | Optional:  Fungal spores | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 7.2% v/v  (1.09% a.c.)  Product with 13.5 % w/w a.c. (fresh): 5.6% v/v  (0.91% a.c.) | 0.50 % a.c. (medical)  0.60% a.c. (milk industries) | Product with 12.5 % w/w a.c. (fresh): 7.2% v/v  (0.65% a.c. after 3 months) | 7.2% v/v | | Optional:  Virus | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 3% v/v  (0.45% a.c.)  Product with 13.5 % w/w a.c. (fresh): 2.4% v/v  (0.39% a.c.) | 0.25% a.c. (medical and milk industries) | Product with 12.5 % w/w a.c. (fresh): 3% v/v (0.27% a.c. after 3 months) | 3% v/v | | 2/4 | **Hard surfaces in agricultural industries and non-alcoholic beverages industries by wiping, mopping:**  **# 2 - Disinfection of hard surfaces in contact with food**  **# 3 Disinfection of hard surfaces in institutions, industries**  **# 4 Disinfection of hard surfaces by CIP\*** | Mandatory:  Bacteria | Dirty | 5 min | Product with 12,5 % w/w a.c. (fresh): 11.2% v/v  (1.69% a.c.)  Product with 13.5% w/w a.c. (fresh): 9.4% v/v  (1.53% a.c.) | 1.00% a.c. (agricultural area (general disinfection))  0.10% a.c. (non-alcoholic beverages industries) | Product with 12.5 % w/w a.c. (fresh): 11.2% v/v  (1.01% a.c. after 3 months) | 11.2% v/v | **Validated**  **11.2% v/v (product at 12.5 % w/w a.c. (fresh) only)** | | Mandatory:  Yeasts | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 9.5% v/v  (1.43% a.c.)  Product with 13.5 % w/w a.c. (fresh): 7.5% v/v  (1,22% a.c.) | 0.20% a.c. (agricultural area (general disinfection))  0.07% a.c. (non-alcoholic beverages industries) | Product with 12.5 % w/w a.c. (fresh): 9.5% v/v  (0.86% a.c. after 3 months) | 9.5% v/v | | Optional:  Fungal spores | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 9.5% v/v  (1.43% a.c.)  Product with 13.5 % w/w a.c. (fresh): 7.5% v/v  (1.22% a.c.) | 0.40% a.c. (agricultural area (general disinfection))  0.80% a.c. (non-alcoholic beverages industries) | Product with 12.5 % w/w a.c. (fresh): 9.5% v/v  (0.86% a.c. after 3 months) | 9.5% v/v | | Optional:  Virus | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 9.3% v/v  (1.40% a.c.)  Product with 13.5 % w/w a.c. (fresh): 7.3% v/v  (1.19% a.c.) | 0.25% a.c. (non-alcoholic beverages industries) | Product with 12.5 % w/w a.c. (fresh): 9.3% v/v  (0.84% a.c. after 3 months) | 9.3% v/v | | **Not validated for** **agricultural area** | | 3 | **# 6 Disinfection of non-porous hard surfaces in veterinary area** | Mandatory:  Bacteria | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 5.3% v/v  (0.80% a.c.)  Product with 13.5 % w/w a.c. (fresh): 4.8% v/v  (0.78% a.c.) | 0.50% a.c. | Product with 12.5 % w/w a.c. (fresh): 5.3% v/v  (0.48% a.c. after 3 months) | 5.3% v/v | **Validated**  **7.1% v/v (product at 12.5 % w/w a.c. (fresh) only)** | | Mandatory:  Yeasts | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 7.10% v/v  (1.07% a.c.)  Product with 13.5 % w/w a.c. (fresh): 5.6% v/v  (0.91% a.c.) | 0.60% a.c. | Product with 12.5 % w/w a.c. (fresh): 7.10% v/v  (0.64% a.c. after 3 months) | 7.1% v/v | | Optional:  Fungal spores | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 8.1% v/v  (1.22% a.c.)  Product with 13.5 % w/w a.c. (fresh): 6.4% v/v  (1,04% a.c.) | 0.68% a.c. | Product with 12.5 % w/w a.c. (fresh): 8.1% v/v  (0.73% a.c. after 3 months) | 8.1% v/v | **Validated**  **8.1% v/v (product at 12.5 % w/w a.c. (fresh) only)** | | Optional:  Virus | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 9.3% v/v  (1.40% a.c.)  Product with 13.5 % w/w a.c. (fresh): 7.3% v/v  (1.19% a.c.) | 0.78% a.c. | Product with 12.5 % w/w a.c. (fresh): 9.3% v/v  (0.84% a.c. after 3 months) | 9.3% v/v | **Validated9.3% v/v (product at 12.5 % w/w a.c. (fresh) only)** | | 3 | **# 7 Disinfection of non-porous hard surfaces in livestock transportation vehicles** | Mandatory:  Bacteria | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 5.3% v/v  (0.80% a.c.)  Product with 13.5 % w/w a.c. (fresh): 4.8% v/v  (0.78% a.c.) | 0.50% a.c. | Product with 12.5 % w/w a.c. (fresh): 5.3% v/v (0.48% a.c. after 3 months) | 5.3% v/v | **Validated9.3% v/v (product at 12.5 % w/w a.c. (fresh) only)** | | Mandatory:  Yeasts | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 7.10% v/v  (1.07% a.c.)  Product with 13.5 % w/w a.c. (fresh): 5.6% v/v  (0.91% a.c.) | 0.60% a.c. | Product with 12.5 % w/w a.c. (fresh): 7.10% v/v  (0.64% a.c. after 3 months) | 7.10% v/v | | Mandatory:  Virus | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 9.3% v/v  (1.40% a.c.)  Product with 13.5 % w/w a.c. (fresh): 7.3% v/v  (1.19% a.c.) | 0.78% a.c. | Product with 12.5 % w/w a.c. (fresh): 9.3% v/v  (0.84% a.c. after 3 months) | 9.3% v/v | | Optional:  Fungal spores | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 8.1% v/v  (1.22% a.c.)  Product with 13.5 % w/w a.c. (fresh): 6.4% v/v  (1,04% a.c.) | 0.68% a.c. | Product with 12.5 % w/w a.c. (fresh): 8.1% v/v  (0.73% a.c. after 3 months) | 8.1% v/v | | 4 | **# 8 Disinfection of inner surfaces in human drinking water systems** | Mandatory:  Bacteria | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 1.2% v/v  (0.18% a.c.)  Product with 13.5 % w/w a.c. (fresh): 1% v/v  (0.16% a.c.) | 0.10% a.c. | Product with 12.5 % w/w a.c. (fresh): 1.2% v/v  (0.11% a.c. after 3 months) | 1.2% v/v | **Validated1.2% v/v (product at 12.5 % w/w a.c. (fresh) only)** | | Optional:  *Legionnella* | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 0.6% v/v  (0.09% a.c.)  Product with 13.5 % w/w a.c. (fresh): 0.5% v/v  (0.08% a.c.) | 0.05% a.c. | Product with 12.5 % w/w a.c. (fresh): 0.6% v/v  (0.05% a.c. after 3 months) |  | **Not validated, no phase 2 test 2 test and field test submitted.** | | Optional:  Yeasts | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 3.6% v/v  (0.54% a.c.)  Product with 13.5 % w/w a.c. (fresh): 2.8% v/v  (0.46% a.c.) | 0.13% a.c. | Product with 12.5 % w/w a.c. (fresh): 3.6% v/v (0.32% a.c. after 3 months) | 3.6% v/v | **Validated3.6% v/v (product at 12.5 % w/w a.c. (fresh) only)** | | Optional:  Fungal spores | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 3.6% v/v  (0.54% a.c.)  Product with 13.5 % w/w a.c. (fresh): 2.8% v/v  (0.46% a.c.) | 0.30% a.c. | Product with 12.5 % w/w a.c. (fresh): 3.6% v/v  (0.32% a.c. after 3 months) | 3.6% v/v | **Validated3.6% v/v (product at 12.5 % w/w a.c. (fresh) only)** | | Optional:  Virus | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 3% v/v  (0.45% a.c.)  Product with 13.5 % w/w a.c. (fresh): 2.4% v/v  (0.39% a.c.) | 0.25% a.c. | Product with 12.5 % w/w a.c. (fresh): 3% v/v  (0.27% a.c. after 3 months) | 3% v/v | **Validated3% v/v (product at 12.5 % w/w a.c. (fresh) only)** | | 4 | **# 9 Disinfection of inner surfaces in veterinary water systems** | Mandatory:  Bacteria | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 6% v/v  (0.91% a.c.)  Product with 13.5 % w/w a.c. (fresh): 4.7% v/v  (0.77% a.c.) | 0.66% a.c. (medical) | Product with 12.5 % w/w a.c. (fresh): 6% v/v  (0.54% a.c. after 3 months) | 6% v/v | **Validated7.9% v/v (product at 12.5 % w/w a.c. (fresh) only)** | | Optional:  *Legionnella* | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 1.8% v/v  (0.27% a.c.)  Product with 13.5 % w/w a.c. (fresh): 1.4% v/v  (0.22% a.c.) |  | Product with 12.5 % w/w a.c. (fresh): 1.8% v/v  (0.16% a.c. after 3 months) |  | **Not validated, no phase 2 step 2 test submitted.** | | Optinal:  Yeasts | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 7.9% v/v  (1.19% a.c.)  Product with 13.5 % w/w a.c. (fresh): 6.2% v/v  (1.01% a.c.) | 0.17% a.c. (medical) | Product with 12.5 % w/w a.c. (fresh): 7.9% v/v  (0.71% a.c. after 3 months) | 7.9% v/v | **Validated7.9% v/v (product at 12.5 % w/w a.c. (fresh) only)** | | Optional:  Fungal spores | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 7.9% v/v  (1.19% a.c.)  Product with 13.5 % w/w a.c. (fresh): 6.2% v/v  (1.01% a.c.) | 0.60% a.c. (medical) | Product with 12.5 % w/w a.c. (fresh): 7.9% v/v  (0.71% a.c. after 3 months) | 7.9% v/v | **Validated7.9% v/v (product at 12.5 % w/w a.c. (fresh) only)** | | Optional:  Virus | Dirty | 5 min | Product with 12.5 % w/w a.c. (fresh): 9.3% v/v  (1.40% a.c.)  Product with 13.5 % w/w a.c. (fresh): 7.3% v/v  (1.19% a.c.) | 0.25% a.c. (medical) | Product with 12.5 % w/w a.c. (fresh): 9.3% v/v  (0.83% a.c. after 3 months) | 9.3% v/v | **Validated9.3% v/v (product at 12.5 % w/w a.c. (fresh) only)** | | 2 | **# 5 - Laundry disinfection with hand soaking** | Bacteria  Yeasts  Fungi  Virus |  |  |  |  |  |  | **Not validated, no phase 2 step 2 test submitted.** | | 5 | **# 10 - Disinfection of water intended for human consumption** | Bacteria  Yeasts  Fungi  Virus |  |  |  |  |  |  | **Not validated, no SU test submitted.** |   Regarding use #1, 2 and 3 “disinfection of hard surfaces”, for wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted, and only “non mechanical action is claimed by the applicant.. Therefore the eCA consider that wiping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by wiping with mop/cloth. A specific instruction for use is added in the SPC.  Regarding use #5 “Laundry disinfection with hand soaking”, in absence of P2S2 tests (e.g. ASTM E4206 or ASTM E2274) which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.2.10.2), efficacy for this use is not demonstrated.  Regarding use #8 “Disinfection of inner surfaces in human drinking water systems” by CIP, in absence of field tests which are mandatory to support this use against *Legionela* according to the requirement of the efficacy guidance (section 5.4.4.6.2), efficacy for this target organism for this use is not demonstrated.  Regarding use #9 “Disinfection of inner surfaces in veterinary water systems” by CIP in absence of P2S2 tests representative of the conditions of use and which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.4.7.2 page 115), efficacy against *Legionella* for this use is not demonstrated.  Regarding use #10 “Disinfection of water intended for human consumption”, in absence of P2S1 and SU tests representative of the conditions of use and which are mandatory to support this use according to the requirement of the efficacy guidance, efficacy for this use is not demonstrated. |

* + **Conclusion on the efficacy for the META SPC 7.11**

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| **Conclusion on the efficacy for the meta SPC 7.11** |
| For meta SPC 7.11, available chlorine concentration is at 3.6% w/w (fresh product).  For meta SPC 7.11, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test). Therefore for some uses, activities or target organisms claimed, the application rate validated are higher than claimed and then restrictions in the use conditions are applied. No efficacy tests have been performed with aged products for Meta SPC 7.11, However, available chlorine content based storage based on APCP data (Meta SPC 2.22, 11 months after storage, 3.14% w/w a.c.) was compared to the one demonstrated in the efficacy studies in the following table:   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2/4 | **Surfaces in medical area, institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries):**  **# 1 - Disinfection of hard surfaces in medical area**  **# 2 - Disinfection of hard surfaces in contact with food**  **# 3 Disinfection of hard surfaces in institutions, industries**  **# 4 Disinfection of hard surfaces by CIP\*** | Mandatory:  Bacteria | Dirty | 5 min | 23% v/v  (0.87% a.c.) | 0.66% a.c. (medical)  0.50% a.c. (milk indutries) | 23% v/v  (0.76% a.c after 11 months) | 23% v/v | **Validated**  **23% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 21% v/v  (0.80% a.c.) | 0.17% a.c. (medical)  0.07% a.c. (milk industries) | 21% v/v  (0.69% a.c. after 11 months) | 21% v/v | | Optional:  Fungal spores | Dirty | 5 min | 21% v/v  (0.80% a.c.) | 0.50 % a.c. (medical)  0.60% a.c. (milk industries) | 21% v/v  (0.69% a.c. after 11 months | 21% v/v | | Optional:  Virus | Dirty | 5 min | 9% v/v  (0.34% a.c.) | 0.25% a.c. (medical and milk industries) | 9% v/v  (0.30% a.c. after 11 months) | 9% v/v | | 2/4 | **Hard surfaces in agricultural industries and non-alcoholic beverages industries by wiping, mopping:**  **# 2 - Disinfection of hard surfaces in contact with food**  **# 3 Disinfection of hard surfaces in institutions, industries**  **# 4 Disinfection of hard surfaces by CIP\*** | Mandatory:  Bacteria | Dirty | 5 min | 34% v/v  (1.29% a.c.) | 1.00% a.c. (agricultural area (general disinfection))  0.10% a.c. (non-alcoholic beverages industries) | 34% v/v  (1.12% a.c after 11 months) | 34% v/v | **Validated**  **34% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 27% v/v  (1.02% a.c.) | 0.20% a.c. (agricultural area (general disinfection))  0.07% a.c. (non-alcoholic beverages industries) | 27% v/v  (0.89% a.c. after 11 months) | 27% v/v | | Optional:  Fungal spores | Dirty | 5 min | 27% v/v  (1.02% a.c.) | 0.40% a.c. (agricultural area (general disinfection))  0.80% a.c. (non-alcoholic beverages industries) | 27% v/v  (0.89% a.c. after 11 months | 27% v/v | | Optional:  Virus | Dirty | 5 min | 27% v/v  (1.02% a.c.) | 0.25% a.c. (non-alcoholic beverages industries) | 27% v/v  (0.89% a.c. after 11 months) | 27% v/v | | **Not validated for** **agricultural area** | | 3 | **# 6 Disinfection of non-porous hard surfaces in veterinary area** | Mandatory:  Bacteria | Dirty | 5 min | 17% v/v  (0.64% a.c.) | 0.50% a.c. | 17% v/v  (0.56% a.c. after 11 months) | 17% v/v | **Validated**  **21% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 21% v/v  (0.80% a.c.) | 0.60% a.c. | 21% v/v  (0.69% a.c. after 11 months) | 21% v/v | | Optional:  Fungal spores | Dirty | 5 min | 23% v/v  (0.87% a.c.) | 0.68% a.c. | 23% v/v  (0.76% a.c. after 11 months) | 23% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 27% v/v  (1.02% a.c.) | 0.78% a.c. | 27% v/v  (0.89% a.c. after 11 months) | 27% v/v | **Validated** | | 3 | **# 7 Disinfection of non-porous hard surfaces in livestock transportation vehicles** | Mandatory:  Bacteria | Dirty | 5 min | 17% v/v  (0.64% a.c.) | 0.50% a.c. | 17% v/v  (0.56% a.c. after 11 months) | 17% v/v | **Validated**  **27% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 21% v/v  (0.80% a.c.) | 0.60% a.c. | 21% v/v  (0.69% a.c. after 11 months) | 21% v/v | | Mandatory:  Virus | Dirty | 5 min | 27% v/v  (1.02% a.c.) | 0.78% a.c. | 27% v/v  (0.89% a.c. after 11 months) | 27% v/v | | Optional:  Fungal spores | Dirty | 5 min | 23% v/v  (0.87% a.c.) | 0.68% a.c. | 23% v/v  (0.76% a.c. after 11 months) | 23% v/v | | 4 | **# 8 Disinfection of inner surfaces in human drinking water systems** | Mandatory:  Bacteria | Dirty | 5 min | 3.4% v/v  (0.13% a.c.) | 0.10% a.c. | 3.4% v/v  (0.11% a.c. after 11 months) | 3.4% v/v | **validated** | | Optional:  *Legionnella* | Dirty | 5 min | 1.7% v/v  (0.06% a.c.) | 0.05% a.c. | 1.7% v/v  (0.06% a.c. after 11 months) | 1.7% v/v | **Not validated as no P2S2 test and fied test provided** | | Optional:  Yeasts | Dirty | 5 min | 10.1% v/v  (0.38% a.c.) | 0.13% a.c. | 10.1% v/v  (0.33% a.c. after 11 months) | 10.1% v/v | **validated** | | Optional:  Fungal spores | Dirty | 5 min | 10.1% v/v  (0.38% a.c.) | 0.30% a.c. | 10.1% v/v  (0.33% a.c. after 11 months) | 10.1% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 8.4.% v/v  (0.32% a.c.) | 0.25% a.c. | 8.4% v/v  (0.28% a.c. after 11 months) | 8.4% v/v | **Validated** | | 4 | **# 9 Disinfection of inner surfaces in veterinary water systems** | Mandatory:  Bacteria | Dirty | 5 min | 16.8% v/v  (0.64% a.c.) | 0.66% a.c. (medical) | 16.8% v/v  (0.55% a.c. after 11 months) | **Not validated** | **Validated**  **22.3% v/v** | | Optional:  *Legionnella* | Dirty | 5 min | 5.1% v/v  (0.19% a.c.) |  | 5.1% v/v  (0.17% a.c. after 11 months) | 5.1% v/v | **Not validated as no P2S2 test provided** | | Optional:  Yeasts | Dirty | 5 min | 22.3% v/v  (0.85% a.c.) | 0.17% a.c. (medical) | 22.3% v/v  (0.74% a.c. after 11 months) | 22.3% v/v | **Validated** | | Optional:  Fungal spores | Dirty | 5 min | 22.3% v/v  (0.85% a.c.) | 0.60% a.c. (medical) | 22.3% v/v  (0.74% a.c. after 11 months) | 22.3% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 26.3% v/v  (1% a.c.) | 0.25% a.c. (medical) | 26.3% v/v  (0.87% a.c. after 11 months) | 26.3% v/v | **Validated** | | 2 | **# 5 - Laundry disinfection with hand soaking** | Bacteria  Yeasts  Fungi  Virus |  |  |  |  |  |  | **Not validated, no phase 2 step 2 test submitted.** | | 5 | **# 10 - Disinfection of water intended for human consumption** | Bacteria  Yeasts  Fungi  Virus |  |  |  |  |  |  | **Not validated, no SU test submitted.** |   Regarding use #1, 2 and 3 ““disinfection of hard surfaces”, for wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted, and only “non mechanical action is claimed by the applicant.. Therefore the eCA consider that wiping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by wiping with mop/cloth. A specific instruction for use is added in the SPC.  Regarding use #4 “Disinfection of hard surfaces by CIP”, suspension tests only should be used to determinate minimal active concentration. Nevertheless, this use was added with other hard surface disinfection uses as the same dilutions are claimed and it is considered as a worst case scenario.  Regarding use #5 “Laundry disinfection with hand soaking”, in absence of P2S2 tests (e.g. ASTM E4206 or ASTM E2274) which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.2.10.2), efficacy for this use is not demonstrated.  Regarding use #8 “Disinfection of inner surfaces in human drinking water systems” by CIP, in absence of field tests which are mandatory to support this use against *Legionela* according to the requirement of the efficacy guidance (section 5.4.4.6.2), efficacy for this target organism for this use is not demonstrated.  Regarding use #9 “Disinfection of inner surfaces in veterinary water systems” by CIP in absence of P2S2 tests representative of the conditions of use and which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.4.7.2 page 115), efficacy against *Legionella* for this use is not demonstrated.  Regarding use #10 “Disinfection of water intended for human consumption”, in absence of P2S1 and SU tests representative of the conditions of use and which are mandatory to support this use according to the requirement of the efficacy guidance, efficacy for this use is not demonstrated. |

* + Conclusion on the efficacy for the META SPC 7.12

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| **Conclusion on the efficacy for the meta SPC 7.12** |
| For meta SPC 7.12, available chlorine concentration is at 4.8% w/w (fresh product).  For meta SPC 7.12, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test). No efficacy tests have been performed with aged products for Meta SPC 7.12, However, available chlorine content based storage based on APCP data (Meta SPC 2.21, after 8 months of storage, 4.18% w/w a.c.) was compared to the one demonstrated in the efficacy studies in the following table:   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2/4 | **Surfaces in medical area, institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries):**  **# 1 - Disinfection of hard surfaces in medical area**  **# 2 - Disinfection of hard surfaces in contact with food**  **# 3 Disinfection of hard surfaces in institutions, industries**  **# 4 Disinfection of hard surfaces by CIP\*** | Mandatory:  Bacteria | Dirty | 5 min | 15% v/v  (0.77% a.c.) | 0.66% a.c. (medical)  0.50% a.c. (milk indutries) | 15% v/v  (0.67% a.c. after 8 months) | 15% v/v | **Validated**  **15% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 14% v/v  (0.72% a.c.) | 0.17% a.c. (medical)  0.07% a.c. (milk industries) | 14% v/v  (0.63% a.c. after 8 months) | 14% v/v | | Optional:  Fungal spores | Dirty | 5 min | 14% v/v  (0.72% a.c.) | 0.50 % a.c. (medical)  0.60% a.c. (milk industries) | 14% v/v  (0.63% a.c. after 8 months) | 14% v/v | | Optional:  Virus | Dirty | 5 min | 6% v/v  (0.31% a.c.) | 0.25% a.c. (medical and milk industries) | 6% v/v  (0.27% a.c. after 8 months) | 6% v/v | | 2/4 | **Hard surfaces in agricultural industries and non-alcoholic beverages industries by wiping, mopping:**  **# 2 - Disinfection of hard surfaces in contact with food**  **# 3 Disinfection of hard surfaces in institutions, industries**  **# 4 Disinfection of hard surfaces by CIP** | Mandatory:  Bacteria | Dirty | 5 min | 23% v/v  (1.18% a.c.) | 1.00% a.c. (agricultural area (general disinfection))  0.10% a.c. (non-alcoholic beverages industries) | 23% v/v  (1.02% a.c. after 8 months) | 23% v/v | **Validated**  **23% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 18% v/v  (0.93% a.c.) | 0.20% a.c. (agricultural area (general disinfection))  0.07% a.c. (non-alcoholic beverages industries) | 18% v/v  (0.80% a.c. after 8 months) | 18% v/v | | Optional:  Fungal spores | Dirty | 5 min | 18% v/v  (0.93% a.c.) | 0.40% a.c. (agricultural area (general disinfection))  0.80% a.c. (non-alcoholic beverages industries) | 18% v/v  (0.80% a.c. after 8 months) | 18% v/v | | Optional:  Virus | Dirty | 5 min | 18% v/v  (0.93% a.c.) | 0.25% a.c. (non-alcoholic beverages industries) | 18% v/v  (0.80% a.c. after 8 months) | 18% v/v | | **Not validated for** **agricultural area** | | 3 | **# 6 Disinfection of non-porous hard surfaces in veterinary area** | Mandatory:  Bacteria | Dirty | 5 min | 12% v/v  (0.62% a.c.) | 0.50% a.c. | 12% v/v  (0.54% a.c. after 8 months) | 12% v/v | **Validated**  **14% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 14% v/v  (0.72% a.c.) | 0.60% a.c. | 14% v/v  (0.63% a.c. after 8 months) | 14% v/v | | Optional:  Fungal spores | Dirty | 5 min | 16% v/v  (0.82% a.c.) | 0.68% a.c. | 16% v/v  (0.72% a.c. after 8 months) | 16% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 18% v/v  (0.93% a.c.) | 0.78% a.c. | 18% v/v  (0.80% a.c. after 8 months) | 18% v/v | **Validated** | | 3 | **# 7 Disinfection of non-porous hard surfaces in livestock transportation vehicles** | Mandatory:  Bacteria | Dirty | 5 min | 12% v/v  (0.62% a.c.) | 0.50% a.c. | 12% v/v  (0.54% a.c. after 8 months) | 12% v/v | **Validated**  **18% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 14% v/v  (0.72% a.c.) | 0.60% a.c. | 14% v/v  (0.63% a.c. after 8 months) | 14% v/v | | Mandatory:  Virus | Dirty | 5 min | 18% v/v  (0.93% a.c.) | 0.78% a.c. | 18% v/v  (0.80% a.c. after 8 months) | 18% v/v | | Optional:  Fungal spores | Dirty | 5 min | 16% v/v  (0.82% a.c.) | 0.68% a.c. | 16% v/v  (0.72% a.c. after 8 months) | 16% v/v | | 4 | **# 8 Disinfection of inner surfaces in human drinking water systems** | Mandatory:  Bacteria | Dirty | 5 min | 2.2% v/v  (0.11% a.c.) | 0.10% a.c. | 2.2% v/v  (0.10% a.c. after 8 months) | 2.2% v/v | **Validated** | | Optional:  L*egionnella* | Dirty | 5 min | 1.1% v/v  (0.06% a.c.) |  |  |  | **Not validated as no P2S2 and fied test provided** | | Optional:  Yeasts | Dirty | 5 min | 6.7% v/v  (0.34% a.c.) | 0.13% a.c. | 6.7% v/v  (0.30% a.c. after 8 months) | 6.7% v/v | **Validated** | | Optional:  Fungal spores | Dirty | 5 min | 6.7% v/v  (0.34% a.c.) | 0.30% a.c. | 6.7% v/v  (0.30% a.c. after 8 months) | 6.7% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 5.6% v/v  (0.29% a.c.) | 0.25% a.c. | 5.6% v/v  (0.25% a.c. after 8 months) | 5.6% v/v | **Validated** | | 4 | **# 9 Disinfection of inner surfaces in veterinary water systems** | Mandatory:  Bacteria | Dirty | 5 min | 11.1% v/v  (0.57% a.c.) | 0.66% a.c. (medical) | 11.1 % v/v  (0.50% a.c. after 8 months) | **Not validated** | **Validated**  **14.7% v/v** | | Optional:  *Legionnella* | Dirty | 5 min | 3.4% v/v  (0.17% a.c.) |  | 3.4% v/v  (0.15% a.c. after 8 months) | 3.4% v/v | **Not validated as no P2S2 test provided** | | Optional:  Yeasts | Dirty | 5 min | 14.7% v/v  (0.76% a.c.) | 0.17% a.c. (medical) | 14.7% v/v  (0.66% a.c. after 8 months) | 14.7% v/v | **Validated** | | Optional:  Fungal spores | Dirty | 5 min | 14.7% v/v  (0.76% a.c.) | 0.60% a.c. (medical) | 14.7% v/v  (0.66% a.c. after 8 months) | 14.7% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 17.4% v/v  (0.89% a.c.) | 0.25% a.c. (medical) | 17.4% v/v  (0.78% a.c. after 8 months) | 17.4% v/v | **Validated** | | 2 | **# 5 - Laundry disinfection with hand soaking** | Bacteria  Yeasts  Fungi  Virus |  |  |  |  |  |  | **Not validated, no phase 2 step 2 test submitted.** | | 5 | **# 10 - Disinfection of water intended for human consumption** | Bacteria  Yeasts  Fungi  Virus |  |  |  |  |  |  | **Not validated, no SU test submitted.** |   Regarding use #1, 2 and 3 “disinfection of hard surfaces”, for wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted, and only “non mechanical action is claimed by the applicant.. Therefore the eCA consider that wiping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by wiping with mop/cloth. A specific instruction for use is added in the SPC.  Regarding use #4 “Disinfection of hard surfaces by CIP”, suspension tests only should be used to determinate minimal active concentration. Nevertheless, this use was added with other hard surface disinfection uses as the same dilutions are claimed and it is considered as a worst case scenario.  Regarding use #5 “Laundry disinfection with hand soaking”, in absence of P2S2 tests (e.g. ASTM E4206 or ASTM E2274) which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.2.10.2), efficacy for this use is not demonstrated.  Regarding use #8 “Disinfection of inner surfaces in human drinking water systems” by CIP, in absence of field tests which are mandatory to support this use against *Legionela* according to the requirement of the efficacy guidance (section 5.4.4.6.2), efficacy for this target organism for this use is not demonstrated.  Regarding use #9 “Disinfection of inner surfaces in veterinary water systems” by CIP in absence of P2S2 tests representative of the conditions of use and which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.4.7.2), efficacy against *Legionella* for this use is not demonstrated.  Regarding use #10 “Disinfection of water intended for human consumption”, in absence of P2S1 and SU tests representative of the conditions of use and which are mandatory to support this use according to the requirement of the efficacy guidance, efficacy for this use is not demonstrated. |

* + **Conclusion on the efficacy for the META SPC 7.2**

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| **Conclusion on the efficacy for the meta SPC 7.2** |
| For meta SPC 6.21, available chlorine concentration is at 2.6% w/w (fresh product).  For meta SPC 7.2, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test). No efficacy tests have been performed with aged products for Meta SPC 7.2, However, available chlorine content based storage based on APCP data (Meta SPC 2.1, after 11 months of storage) was compared to the one demonstrated in the efficacy studies in the following table:   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2/4 | **Surfaces in medical area, institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries):**  **# 1 - Disinfection of hard surfaces in medical area**  **# 2 - Disinfection of hard surfaces in contact with food**  **# 3 Disinfection of hard surfaces in institutions, industries**  **# 4 Disinfection of hard surfaces by CIP\*** | Mandatory:  Bacteria | Dirty | | 5 min | 30% v/v  (0.81% a.c.) | 0.66% a.c. (medical)  0.50% a.c. (milk indutries) | 30% v/v  (0.80% a.c after 11 months) | 30% v/v | **Validated**  **30% v/v** | | Mandatory:  Yeasts | | Dirty | 5 min | 27% v/v  (0.73% a.c.) | 0.17% a.c. (medical)  0.07% a.c. (milk industries) | 27% v/v  (0.72% a.c. after 11 months) | 27% v/v | | Optional:  Fungal spores | | Dirty | 5 min | 27% v/v  (0.73% a.c.) | 0.50 % a.c. (medical)  0.60% a.c. (milk industries) | 27% v/v  (0.72% a.c. after 11 months | 27% v/v | | Optional:  Virus | | Dirty | 5 min | 12% v/v  (0.32% a.c.) | 0.25% a.c. (medical and milk industries) | 12% v/v  (0.32% a.c. after 11 months) | 12% v/v | | 2/4 | **Hard surfaces in agricultural industries and non-alcoholic beverages industries by wiping, mopping:**  **# 2 - Disinfection of hard surfaces in contact with food**  **# 3 Disinfection of hard surfaces in institutions, industries**  **# 4 Disinfection of hard surfaces by CIP\*** | Mandatory:  Bacteria | Dirty | | 5 min | 45% v/v  (1.21% a.c.) | 1.00% a.c. (agricultural area (general disinfection))  0.10% a.c. (non-alcoholic beverages industries) | 45% v/v  (1.20% a.c after 11 months) | 45% v/v | **Validated**  **45% v/v** | | Mandatory:  Yeasts | Dirty | | 5 min | 36% v/v  (0.97% a.c.) | 0.20% a.c. (agricultural area (general disinfection))  0.07% a.c. (non-alcoholic beverages industries) | 36% v/v  (0.96% a.c. after 11 months) | 36% v/v | | Optional:  Fungal spores | Dirty | | 5 min | 36% v/v  (0.97% a.c.) | 0.40% a.c. (agricultural area (general disinfection))  0.80% a.c. (non-alcoholic beverages industries) | 36% v/v  (0.96% a.c. after 11 months | 36% v/v | | Optional:  Virus | Dirty | | 5 min | 35% v/v  (0.94% a.c.) | 0.25% a.c. (non-alcoholic beverages industries) | 35% v/v  (0.93% a.c. after 11 months) | 35% v/v | | **Not validated for** **agricultural area** | | 3 | **# 6 Disinfection of non-porous hard surfaces in veterinary area** | Mandatory:  Bacteria | Dirty | | 5 min | 23% v/v  (0.62% a.c.) | 0.50% a.c. | 23% v/v  (0.61% a.c. after 11 months) | 23% v/v | **Validated**  **27% v/v** | | Mandatory:  Yeasts | Dirty | | 5 min | 27% v/v  (0.73% a.c.) | 0.60% a.c. | 27% v/v  (0.72% a.c. after 11 months) | 27% v/v | | Optional:  Fungal spores | Dirty | | 5 min | 31% v/v  (0.83% a.c.) | 0.68% a.c. | 31% v/v  (0.83% a.c. after 11 months) | 31% v/v | **Validated** | | Optional:  Virus | Dirty | | 5 min | 35% v/v  (0.94% a.c.) | 0.78% a.c. | 35% v/v  (0.93% a.c. after 11 months) | 35% v/v | **Validated** | | 3 | **7 Disinfection of non-porous hard surfaces in livestock transportation vehicles** | Mandatory:  Bacteria | Dirty | | 5 min | 23% v/v  (0.62% a.c.) | 0.50% a.c. | 23% v/v  (0.61% a.c. after 11 months) | 23% v/v | **Validated**  **35%** | | Mandatory:  Yeasts | Dirty | | 5 min | 27% v/v  (0.73% a.c.) | 0.60% a.c. | 27% v/v  (0.72% a.c. after 11 months) | 27% v/v | | Mandatoryl:  Virus | Dirty | | 5 min | 35% v/v  (0.94% a.c.) | 0.78% a.c. | 35% v/v  (0.93% a.c. after 11 months) | 35% v/v | | Optional:  Fungal spores | Dirty | | 5 min | 31% v/v  (0.83% a.c.) | 0.68% a.c. | 31% v/v  (0.83% a.c. after 11 months) | 31% v/v | | 4 | **# 8 Disinfection of inner surfaces in human drinking water systems** | Mandatory:  Bacteria | Dirty | | 5 min | 4.4% v/v  (0.12% a.c.) | 0.10% a.c. | 3.4% v/v  (0.12% a.c. after 11 months) | 4.4% v/v | **Validated** | | Optional: *Legionnella* | Dirty | | 5 min | 2.2% v/v  (0.06% a.c.) | 0.05% a.c. | 1.7% v/v  (0.06% a.c. after 11 months) | 2.2% v/v | **Not validated as no fied test provided** | | Optional:  Yeasts | Dirty | | 5 min | 13.3% v/v  (0.36% a.c.) | 0.13% a.c. | 13.3% v/v  (0.36% a.c. after 11 months) | 13.3% v/v | **Validated** | | Optional:  Fungal spores | Dirty | | 5 min | 13.3% v/v  (0.36% a.c.) | 0.30% a.c. | 13.3% v/v  (0.36% a.c. after 11 months) | 13.3% v/v | **Validated** | | Optional:  Virus | Dirty | | 5 min | 11.1% v/v  (0.30% a.c.) | 0.25% a.c. | 11.1% v/v  (0.30% a.c. after 11 months) | 11.1% v/v | **Validated** | | 4 | **# 9 Disinfection of inner surfaces in veterinary water systems** | Mandatory:  Bacteria | Dirty | | 5 min | 22.1% v/v  (0.60% a.c.) | 0.50% a.c. | 22.1% v/v  (0.59% a.c. after 11 months) | 22.1% v/v | **Validated** | | Optional:  *Legionnella* | Dirty | | 5 min | 6.6% v/v  (0.18% a.c.) | 0.15% a.c. | 6.6% v/v  (0.18% a.c. after 11 months) | 6.6% v/v | **Not validated as no P2S2 test provided** | | Optional:  Yeasts | Dirty | | 5 min | 29.3% v/v  (0.79% a.c.) | 0.58% a.c. | 29.3% v/v  (0.78% a.c. after 11 months) | 29.3% v/v | **validated** | | Optional:  Fungal spores | Dirty | | 5 min | 29.3% v/v  (0.79% a.c.) | 0.66% a.c. | 22.3% v/v  (0.78% a.c. after 11 months) | 29.3% v/v | **Validated** | | Optional:  Virus | Dirty | | 5 min | 34.6% v/v  (0.93% a.c.) | 0.78% a.c. | 34.6% v/v  (0.92% a.c. after 11 months) | 34.6% v/v | **Validated** | | 2 | **# 5 - Laundry disinfection with hand soaking** | Bacteria  Yeasts  Fungi  Virus |  | |  |  |  |  |  | **Not validated, no phase 2 step 2 test submitted.** | | 5 | **# 10 - Disinfection of water intended for human consumption** | Bacteria  Yeasts  Fungi  Virus |  | |  |  |  |  |  | **Not validated, no SU test submitted.** |   Regarding use #1, 2 and 3 disinfection of hard surfaces”, for wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted, and only “non mechanical action is claimed by the applicant.. Therefore the eCA consider that wiping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by wiping with mop/cloth. A specific instruction for use is added in the SPC.  Regarding use #4 “Disinfection of hard surfaces by CIP”, suspension tests only should be used to determinate minimal active concentration. Nevertheless, this use was added with other hard surface disinfection uses as the same dilutions are claimed and it is considered as a worst case scenario.  Regarding use #5 “Laundry disinfection with hand soaking”, in absence of P2S2 tests (e.g. ASTM E4206 or ASTM E2274) which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.2.10.2), efficacy for this use is not demonstrated.  Regarding use #8 “Disinfection of inner surfaces in human drinking water systems” by CIP, in absence of field tests which are mandatory to support this use against *Legionela* according to the requirement of the efficacy guidance (section 5.4.4.6.2), efficacy for this target organism for this use is not demonstrated.  Regarding use #9 “Disinfection of inner surfaces in veterinary water systems” by CIP in absence of P2S2 tests representative of the conditions of use and which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.4.7.2), efficacy against *Legionella* for this use is not demonstrated.  Regarding use #10 “Disinfection of water intended for human consumption”, in absence of P2S1 and SU tests representative of the conditions of use and which are mandatory to support this use according to the requirement of the efficacy guidance, efficacy for this use is not demonstrated. |

* + **Conclusion on the efficacy for the META SPC 8**

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| **Conclusion on the efficacy for the meta SPC 8** |
| For meta SPC 8, available chlorine concentration is at 1.6% w/w (fresh product).  For meta SPC 8, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test).   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2/4 | **# 1 - Disinfection of household surfaces (floors) by wiping with mop and bucket**  **(non mechanical action)**  **# 2 - Disinfection of household surfaces (other than floors) by wiping with cloth and bucket(non mechanical action)**  **# 4 Disinfection of house hold surfaces (other than floors) in contact with food by wiping with cloth and bucket (non mechanical action)** | Mandatory:  Bacteria | Dirty | 5 min | 50% v/v  (0.82% a.c.) | 0.66% a.c. |  | 50% v/v | **Validated**  **50% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 33.3% v/v  (0.55% a.c.) | 0.17% a.c. |  | 33.3% v/v | | Optional:  Fungal spores | Dirty | 5 min | 33.3% v/v  (0.55% a.c.) | 0.50% a.c. |  | 33.3% v/v | | Optional:  Virus | Dirty | 5 min | 20% v/v  (0.33% a.c.) | 0.25% a.c. |  | 20% v/v | | 2 | **# 3 - Disinfection of toilet bowls in household areas (non mechanical action)** | Mandatory:  Bacteria | Dirty | 5 min | 50% v/v  (0.82% a.c.) | 0.66% a.c. |  | 50% v/v | **Validated**  **50% v/v** | | Optional:  Yeasts | Dirty | 5 min | 33.3% v/v  (0.55% a.c.) | 0.50% a.c. |  | 33.3% v/v | | Optional:  Fungal spores | Dirty | 5 min | 33.3% v/v  (0.55% a.c.) | 0.50% a.c. |  | 33.3% v/v | | Optional:  Virus | Dirty | 5 min | 20% v/v  (0.33% a.c.) | 0.25% a.c. |  | 20% v/v | | 2 | **# 6 - Laundry disinfection with hand soaking (household areas)** | Bacteria  Yeasts  Fungi  Virus |  |  |  |  |  |  | **Not validated, no phase 2 step 2 test submitted.** | | 3 | **# 5 Disinfection of companion animal housing and associated equipment**  **(non mechanical action)** | Mandatory:  Bacteria | Dirty | 5 min | 37.5% v/v  (0.62% a.c.) | 0.50% a.c. |  | 37.5% v/v | **Validated**  **44.4% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 44.4% v/v  (0.73% a.c.) | 0.60% a.c. |  | 44.4% v/v | | Optional:  Fungal spores | Dirty | 5 min | 50% v/v  (0.82% a.c.) | 0.68% a.c. |  | 50% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 57.1% v/v  (0.94% a.c.) | 0.78% a.c. |  | 57.1% v/v | **Validated** |   Regarding use #1, 2 and 4 “disinfection of hard surfaces”, for wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted, and only “non mechanical action is claimed by the applicant.. Therefore the eCA consider that wiping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by wiping with mop/cloth. A specific instruction for use is added in the SPC.  Regarding use #6 “Laundry disinfection with hand soaking”, in absence of P2S2 tests (e.g. ASTM E4206 or ASTM E2274) which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.2.10.2), efficacy for this use is not demonstrated. |

* + **Conclusion on the efficacy for the META SPC 10.1**

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| **Conclusion on the efficacy for the meta SPC 10.1** |
| For meta SPC 10.1, available chlorine concentration is at 2.6% w/w (fresh product).  For meta SPC 10.1, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test). No efficacy tests have been performed with aged products for Meta SPC 10.1, However, available chlorine content based storage based on APCP data (after 11 months of storage, 2.33 % w/w a.c.) was compared to the one demonstrated in the efficacy studies in the following table, as it is not expected that age-related changes in co-formulants would have an effect on efficacy of the aged product:   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2/4 | **Surfaces in medical area, institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries):**  **# 1 - Disinfection of hard surfaces in medical area**  **# 2 - Disinfection of hard surfaces in contact with food**  **# 3 Disinfection of hard surfaces in institutions, industries**  **# 4 Disinfection of hard surfaces by CIP\*** | Mandatory:  Bacteria | Dirty | 5 min | 30% v/v  (0.81% a.c.) | 0.66% a.c. (medical)  0.50% a.c. (milk indutries) | 30% v/v  (0.73% a.c after 11 months) | 30% v/v | **Validated**  **30% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 27% v/v  (0.73% a.c.) | 0.17% a.c. (medical)  0.07% a.c. (milk industries) | 27% v/v  (0.65% a.c. after 11 months) | 27% v/v | | Optional:  Fungal spores | Dirty | 5 min | 27% v/v  (0.73% a.c.) | 0.50 % a.c. (medical)  0.60% a.c. (milk industries) | 27% v/v  (0.65% a.c. after 11 months | 27% v/v | | Optional:  Virus | Dirty | 5 min | 12% v/v  (0.32% a.c.) | 0.25% a.c. (medical and milk industries) | 12% v/v  (0.29% a.c. after 11 months) | 12% v/v | | 2/4 | **Hard surfaces in agricultural industries and non-alcoholic beverages industries by wiping, mopping:**  **# 2 - Disinfection of hard surfaces in contact with food**  **# 3 Disinfection of hard surfaces in institutions, industries**  **# 4 Disinfection of hard surfaces by CIP\*** | Mandatory:  Bacteria | Dirty | 5 min | 45% v/v  (1.21% a.c.) | 1.00% a.c. (agricultural area (general disinfection))  0.10% a.c. (non-alcoholic beverages industries) | 45% v/v  (1.09% a.c after 11 months) | 45% v/v | **Validated**  **45% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 36% v/v  (0.97% a.c.) | 0.20% a.c. (agricultural area (general disinfection))  0.07% a.c. (non-alcoholic beverages industries) | 36% v/v  (0.0.87% a.c. after 11 months) | 36% v/v | | Optional:  Fungal spores | Dirty | 5 min | 36% v/v  (0.97% a.c.) | 0.40% a.c. (agricultural area (general disinfection))  0.80% a.c. (non-alcoholic beverages industries) | 36% v/v  (0.87% a.c. after 11 months | 36% v/v | | Optional:  Virus | Dirty | 5 min | 35% v/v  (0.94% a.c.) | 0.25% a.c. (non-alcoholic beverages industries) | 35% v/v  (0.85% a.c. after 11 months) | 35% v/v | | **Not validated for** **agricultural area** | | 3 | **# 6 Disinfection of non-porous hard surfaces in veterinary area** | Mandatory:  Bacteria | Dirty | 5 min | 23% v/v  (0.62% a.c.) | 0.50% a.c. | 23% v/v  (0.56% a.c. after 11 months) | 23% v/v | **Validated**  **27% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 27% v/v  (0.73% a.c.) | 0.60% a.c. | 27% v/v  (0.65% a.c. after 11 months) | 27% v/v | | Optional:  Fungal spores | Dirty | 5 min | 31% v/v  (0.83% a.c.) | 0.68% a.c. | 31% v/v  (0.75% a.c. after 11 months) | 31% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 35% v/v  (0.94% a.c.) | 0.78% a.c. | 35% v/v  (0.85% a.c. after 11 months) | 35% v/v | **Validated** | | 3 | **# 7 Disinfection of non-porous hard surfaces in livestock transportation vehicles** | Mandatory:  Bacteria | Dirty | 5 min | 23% v/v  (0.62% a.c.) | 0.50% a.c. | 23% v/v  (0.56% a.c. after 11 months) | 23% v/v | **Validated**  **35% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 27% v/v  (0.73% a.c.) | 0.60% a.c. | 27% v/v  (0.65% a.c. after 11 months) | 27% v/v | | Mandatory:  Virus | Dirty | 5 min | 35% v/v  (0.94% a.c.) | 0.78% a.c. | 35% v/v  (0.85% a.c. after 11 months) | 35% v/v | | Optional:  Fungal spores | Dirty | 5 min | 31% v/v  (0.83% a.c.) | 0.68% a.c. | 31% v/v  (0.75% a.c. after 11 months) | 31% v/v | | 2 | **# 5 - Laundry disinfection with hand soaking** | Bacteria  Yeasts  Fungi  Virus |  |  |  |  |  |  | **Not validated, no phase 2 step 2 test submitted.** |   Regarding use #1, 2 and 3 “disinfection of hard surfaces”, for wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted, and only “non mechanical action is claimed by the applicant.. Therefore the eCA consider that wiping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by wiping with mop/cloth. A specific instruction for use is added in the SPC.  Regarding use #5 “Laundry disinfection with hand soaking”, in absence of P2S2 tests (e.g. ASTM E4206 or ASTM E2274) which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.2.10.2), efficacy for this use is not demonstrated. |

* + **Conclusion on the efficacy for the META SPC 10.2**

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| **Conclusion on the efficacy for the meta SPC 10.2** |
| For meta SPC 10.2, available chlorine concentration is at 4.8% w/w (fresh product).  For meta SPC 10.2, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test). No efficacy tests have been performed with aged products for Meta SPC 10.2, However, available chlorine content based storage based on APCP data (Meta SPC 2.21, after 8 months of storage, 3.93% w/w a.c.) was compared to the one demonstrated in the efficacy studies in the following table:   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2/4 | **Surfaces in medical area, institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries):**  **# 1 - Disinfection of hard surfaces in medical area**  **# 2 - Disinfection of hard surfaces in contact with food**  **# 3 Disinfection of hard surfaces in institutions, industries**  **# 4 Disinfection of hard surfaces by CIP\*** | Mandatory:  Bacteria | Dirty | 5 min | 15% v/v  (0.77% a.c.) | 0.66% a.c. (medical)  0.50% a.c. (milk indutries) | 15% v/v  (0.67% a.c. after 8 months) | 15% v/v | **Validated**  **15% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 14% v/v  (0.72% a.c.) | 0.17% a.c. (medical)  0.07% a.c. (milk industries) | 14% v/v  (0.63% a.c. after 8 months) | 14% v/v | | Optional:  Fungal spores | Dirty | 5 min | 14% v/v  (0.72% a.c.) | 0.50 % a.c. (medical)  0.60% a.c. (milk industries) | 14% v/v  (0.63% a.c. after 8 months) | 14% v/v | | Optional:  Virus | Dirty | 5 min | 6% v/v  (0.31% a.c.) | 0.25% a.c. (medical and milk industries) | 6% v/v  (0.27% a.c. after 8 months) | 6% v/v | | 2/4 | **Hard surfaces in agricultural industries and non-alcoholic beverages industries by wiping, mopping:**  **# 2 - Disinfection of hard surfaces in contact with food**  **# 3 Disinfection of hard surfaces in institutions, industries**  **# 4 Disinfection of hard surfaces by CIP** | Mandatory:  Bacteria | Dirty | 5 min | 23% v/v  (1.18% a.c.) | 1.00% a.c. (agricultural area (general disinfection))  0.10% a.c. (non-alcoholic beverages industries) | 23% v/v  (1.03% a.c. after 8 months) | 23% v/v | **Validated**  **23% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 18% v/v  (0.93% a.c.) | 0.20% a.c. (agricultural area (general disinfection))  0.07% a.c. (non-alcoholic beverages industries) | 18% v/v  (0.81% a.c. after 8 months) | 18% v/v | | Optional:  Fungal spores | Dirty | 5 min | 18% v/v  (0.93% a.c.) | 0.40% a.c. (agricultural area (general disinfection))  0.80% a.c. (non-alcoholic beverages industries) | 18% v/v  (0.81% a.c. after 8 months) | 18% v/v | | Optional:  Virus | Dirty | 5 min | 18% v/v  (0.93% a.c.) | 0.25% a.c. (non-alcoholic beverages industries) | 18% v/v  (0.81% a.c. after 8 months) | 18% v/v | | **Not validated for** **agricultural area** | | 3 | **# 6 Disinfection of non-porous hard surfaces in veterinary area** | Mandatory:  Bacteria | Dirty | 5 min | 12% v/v  (0.61% a.c.) | 0.50% a.c. | 12% v/v  (0.53% a.c. after 8 months) | 12% v/v | **Validated**  **14% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 14% v/v  (0.72% a.c.) | 0.60% a.c. | 14% v/v  (0.63% a.c. after 8 months) | 14% v/v | | Optional:  Fungal spores | Dirty | 5 min | 16% v/v  (0.82% a.c.) | 0.68% a.c. | 16% v/v  (0.72% a.c. after 8 months) | 16% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 18% v/v  (0.93% a.c.) | 0.78% a.c. | 18% v/v  (0.81% a.c. after 8 months) | 18% v/v | **Validated** | | 3 | **# 7 Disinfection of non-porous hard surfaces in livestock transportation vehicles** | Mandatory:  Bacteria | Dirty | 5 min | 12% v/v  (0.61% a.c.) | 0.50% a.c. | 12% v/v  (0.53% a.c. after 8 months) | 12% v/v | **Validated**  **18% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 14% v/v  (0.72% a.c.) | 0.60% a.c. | 14% v/v  (0.63% a.c. after 8 months) | 14% v/v | | Mandatory:  Virus | Dirty | 5 min | 18% v/v  (0.93% a.c.) | 0.78% a.c. | 18% v/v  (0.81% a.c. after 8 months) | 18% v/v | | Optional:  Fungal spores | Dirty | 5 min | 16% v/v  (0.82% a.c.) | 0.68% a.c. | 16% v/v  (0.72% a.c. after 8 months) | 16% v/v | | 2 | **# 5 - Laundry disinfection with hand soaking** | Bacteria  Yeasts  Fungi  Virus |  |  |  |  |  |  | **Not validated, no phase 2 step 2 test submitted.** |   Regarding use #1, 2 and 3 “disinfection of hard surfaces”, for wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted, and only “non mechanical action is claimed by the applicant.. Therefore the eCA consider that wiping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by wiping with mop/cloth. A specific instruction for use is added in the SPC.  Regarding use #4 “Disinfection of hard surfaces by CIP”, suspension tests only should be used to determinate minimal active concentration. Nevertheless, this use was added with other hard surface disinfection uses as the same dilutions are claimed and it is considered as a worst case scenario.  Regarding use #5 “Laundry disinfection with hand soaking”, in absence of P2S2 tests (e.g. ASTM E4206 or ASTM E2274) which are mandatory to support this use according to the requirement of the efficacy guidance (section 5.4.2.10.2), efficacy for this use is not demonstrated. |

* + **Conclusion on the efficacy for the META SPC 11**

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| **Conclusion on the efficacy for the meta SPC 11** |
| For meta SPC 11, available chlorine concentration is at 6% w/w (fresh product).  For meta SPC 11, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test). Therefore for some uses, activities or target organisms claimed, the application rate validated are higher than claimed and then restrictions in the use conditions are applied. No efficacy tests have been performed with aged products for Meta SPC 11, However, available chlorine content based storage based on APCP data (Meta SPC 11, after 6 months of storage, 4.18% w/w a.c.) was compared to the one demonstrated in the efficacy studies in the following table, as it is not expected that age-related changes in co-formulants would have an effect on efficacy of the aged product:   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2/4 | **Surfaces in medical area, institutions, industries (general case), meat industries, milk industries, cosmetic industries and alcoholic beverages industries):**  **# 1 - Disinfection of hard surfaces in medical area**  **# 2 - Disinfection of hard surfaces in contact with food**  **# 3 Disinfection of hard surfaces in institutions, industries**  **# 4 Disinfection of hard surfaces by CIP\*** | Mandatory:  Bacteria | Dirty | 5 min | 16% v/v  (1.12% a.c.) | 0.66% a.c. (medical)  0.50% a.c. (milk indutries) | 16% v/v  (0.77% a.c. after 6 months) | 16% v/v | **Validated**  **16% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 15% v/v  (1.05% a.c.) | 0.17% a.c. (medical)  0.07% a.c. (milk industries) | 15% v/v  (0.72% a.c. after 6 months) | 15% v/v | | Optional:  Fungal spores | Dirty | 5 min | 15% v/v  (1.05% a.c.) | 0.50 % a.c. (medical)  0.60% a.c. (milk industries) | 15% v/v  (0.72% a.c. after 6 months) | 15% v/v | | Optional:  Virus | Dirty | 5 min | 6% v/v  (0.42% a.c.) | 0.25% a.c. (medical and milk industries) | 6% v/v  (0.29% a.c. after 6 months) | 6% v/v | | 2/4 | **Hard surfaces in agricultural industries and non-alcoholic beverages industries by wiping, mopping:**  **# 2 - Disinfection of hard surfaces in contact with food**  **# 3 Disinfection of hard surfaces in institutions, industries**  **# 4 Disinfection of hard surfaces by CIP\*** | Mandatory:  Bacteria | Dirty | 5 min | 24% v/v  (1.68% a.c.) | 1.00% a.c. (agricultural area (general disinfection))  0.10% a.c. (non-alcoholic beverages industries) | 24% v/v  (1.15% a.c. after 6 months) | 24% v/v | **Validated**  **24% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 20% v/v  (1.40% a.c.) | 0.20% a.c. (agricultural area (general disinfection))  0.07% a.c. (non-alcoholic beverages industries) | 20% v/v  (0.58% a.c. after 6 months) | 20% v/v | | Optional:  Fungal spores | Dirty | 5 min | 20% v/v  (1.40% a.c.) | 0.40% a.c. (agricultural area (general disinfection))  0.80% a.c. (non-alcoholic beverages industries) | 20% v/v  (0.96% a.c. after 6 months) | 20% v/v | | Optional:  Virus | Dirty | 5 min | 19% v/v  (1.33% a.c.) | 0.25% a.c. (non-alcoholic beverages industries) | 19% v/v  (0.91% a.c. after 6 months) | 19% v/v | | **Not validated for** **agricultural area** | | 3 | **# 5 Disinfection of non-porous hard surfaces in veterinary area** | Mandatory:  Bacteria | Dirty | 5 min | 12% v/v  (0.84% a.c.) | 0.50% a.c. | 12% v/v  (0.58% a.c. after 6 months) | 12% v/v | **Validated**  **15% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 15% v/v  (1.05% a.c.) | 0.60% a.c. | 15% v/v  (0.72% a.c. after 6 months) | 15% v/v | | Optional:  Fungal spores | Dirty | 5 min | 17% v/v  (1.19% a.c.) | 0.68% a.c. | 17% v/v  (0.82% a.c. after 6 months) | 17% v/v | **Validated** | | Optional:  Virus | Dirty | 5 min | 19% v/v  (1.33% a.c.) | 0.78% a.c. | 19% v/v  (0.92% a.c. after 6 months) | 19% v/v | **Validated** | | 3 | **# 6 Disinfection of non-porous hard surfaces in livestock transportation vehicles** | Mandatory:  Bacteria | Dirty | 5 min | 12% v/v  (0.84% a.c.) | 0.50% a.c. | 12% v/v  (0.58% a.c. after 6 months) | 12% v/v | **Validated**  **19% v/v** | | Mandatory:  Yeasts | Dirty | 5 min | 15% v/v  (1.05% a.c.) | 0.60% a.c. | 15% v/v  (0.72% a.c. after 6 months) | 15% v/v | | Mandatory:  Virus | Dirty | 5 min | 19% v/v  (1.33% a.c.) | 0.78% a.c. | 19% v/v  (0.92% a.c. after 6 months) | 19% v/v | | Optional:  Fungal spores | Dirty | 5 min | 17% v/v  (1.19% a.c.) | 0.68% a.c. | 17% v/v  (0.82% a.c. after 6 months) | 17% v/v |   Regarding use #1, 2 and 3 “disinfection of hard surfaces”, for wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted, and only “non mechanical action is claimed by the applicant.. Therefore the eCA consider that wiping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by wiping with mop/cloth. A specific instruction for use is added in the SPC.  Regarding use #4 “Disinfection of hard surfaces by CIP”, suspension tests only should be used to determinate minimal active concentration. Nevertheless, this use was added with other hard surface disinfection uses as the same dilutions are claimed and it is considered as a worst case scenario. |

* **Gel formulations: efficacy data to support Meta SPC3, 4 and Meta SPC 13**

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | Disinfection of PT2 surfaces | Gel Javel 2.6% a.c  Batch: 183 | Bacteria  *P. aeruginosa S. aureus E. hirae E. coli K12* | EN 13727+A2:2015 | Phase 2 step 1 (suspension test)   Concentrations tested: 0.01%, 0.8%, 1.1%, a.c. Temperature: 20°C Contact time: 5 min Dirty conditions ( 3 g/L BSA+3 mL/L sheep erythrocytes) Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 0.80% a.c.. | RE18-188-1  R.I: 1 |
| Bactericide | Disinfection of surfaces | Gel Javel 2.6% a.c  Batch : 1806141102 | Bacteria  *Pseudomonas aeruginosa ATCC 10145   Enterococcus hirae ATCC 10541  Staphylococcus aureus ATCC 6538   Escherichia coli ATCC 1053* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.05%, 0.8%, 1.1%, a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA + 3 ml/l sheep erythrocytes Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 1.1% a.c.. | RE18-290-1  R.I: 1 |
| Yeasticide Fungicide | Disinfection of PT2 surfaces (medical areas) | Gel Javel 2.6% a.c  Batch: 183 | Yeasts  *Candida albicans DSM 1386*  Fungi  *Aspergillus brasiliensis DSM 1988* | EN 13624:2013 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.1%, 0.8%, 1.1% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA +3 mL/L erythrocytes Criteria: at least a 4 log reduction | Fungicidal and yeasticidal activity demonstrated at 0.8% a.c.. | RE18-187-1  R.I: 1 |
| Yeasticide Fungicide | Disinfection of surfaces | Gel Javel 2.6% a.c  Batch: 1806141102 | Yeasts  *Candida albicans DSM 1386*  Fungi  *Aspergillus brasiliensis DSM 1988* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.05%, 0.8%, 1.1%, a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA + 3 ml/l sheep erythrocytes Criteria: at least a 4 log reduction | Yeasticidal and fungicidal activity demonstrated at 1.1% a.c.. | RE18-291-1  R.I: 1 |
| Virucide | Disinfection of PT2&PT4 surfaces | Gel Javel Hypochlorite de sodium 2,6% a.c.  Batch: 180491555 | Virus  *Murine norovirus (MNV-1)  Human adenovirus type 5 (Ad5)  Poliovirus type 1 (LSc-2ab)* | EN14476:2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.05%, 0.80%, 1% v/v Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/l bovine albumin + 3 ml/L sheep erythrocytes Criteria: at least a 4 log reduction | Virucidal activity demonstrated at 1% a.c.. | 093V12-2018-02  R.I: 1 |
| Bactericide | Disinfection of surfaces | Gel Javel 2,6% c.a  Batch: 183 | Bacteria  *Pseudomonas aeruginosa ATCC 10145   Enterococcus hirae ATCC 10541  Staphylococcus aureus ATCC 6538   Escherichia coli ATCC 1053* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0,05%, 0,8%, 1,1%, c.a. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 0,8% a.c.. | RE18-186-1  R.I: 1  **(supportive data)** |
| Yeasticide Fungicide | Disinfection of surfaces | Gel Javel 2,6% c.a  Batch: 183 | Yeasts  *Candida albicans DSM 1386*  Fungi  *Aspergillus brasiliensis DSM 1988* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0,01%, 0,80%, 1,1% c.a. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA Criteria: at least a 3 log reduction | Yeasticidal and fungicidal activity demonstrated at 0,8% a.c.. | RE18-189-1  R.I: 1  **(supportivedata)** |

For PT2 uses (disinfection for medical areas), with fresh samples of the product Gel Javel 2.6% a.c

* bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 13727, and EN 13697), at 20°C, with a contact time of 5 minutes with medical dirty conditions (3 g/L BSA+3 mL/L sheep erythrocytes). In these conditions, bactericidal activity is shown at the in-use concentration of 1.10 % a.c. on non porous surfaces.
* Yeasticidal and fugicidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 13624 and EN 13697), at 20°C, with a contact time of 5 minutes with medical dirty conditions (3 g/L BSA+3 mL/L sheep erythrocytes). In these conditions, yeasticidal and fungicidal activity is shown at the in-use concentration of 1.10 % a.c..
* virucidal activity is demonstrated according to phase 2, step 1 test (EN 14476) – (no surface test is available at the submission of the dossier for medical, food, industrial, domestic and institutional areas), at 20°C, with a contact time of 5 minutes with medical dirty conditions (3 g/L BSA+3 mL/L sheep erythrocytes). In these conditions, virucidal activity is shown at the in-use concentration of 1 % a.c..
  + **Conclusion on the efficacy for the META SPC 3**

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| **Conclusion on the efficacy for the meta SPC 3** |
| For meta SPC 3, available chlorine concentration is at 2.6% w/w (fresh product).  For meta SPC 3, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test). No efficacy tests have been performed with aged products for Meta SPC 3, However, available chlorine content based storage based on APCP data (after 11 months of storage, 2.16 % w/w a.c.) was compared to the one demonstrated in the efficacy studies in the following table:   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2 | **# 1 - Disinfection of household, intitutions, industries and medical surfaces (other than floors) by wiping with cloth and bucket (without mechanical action)**  **# 2 - Disinfection of toilet bowls inhousehold, intitutions, industries and medical areas (without mechanical action)** | Mandatory:  Bacteria | Dirty | | 5 min | 100% v/v  (2.71% a.c.) | 1.1% a.c. | 100% v/v  (2.25% a.c. after 11 moths of storage) | 100% v/v | **Validated** | | Mandatory (only for medical areas):  Yeasts | | Dirty | 5 min | 100% v/v  (2.71% a.c.) | 1.1% a.c. | 100% v/v  (2.25% a.c. after 11 moths of storage) | 100% v/v | | Optional:  Fungal spores | | Dirty | 5 min | 100% v/v  (2.71% a.c.) | 1.1% a.c. | 100% v/v  (2.25% a.c. after 11 moths of storage) | 100% v/v | **Validated** | | Optional:  Virus | | Dirty | 5 min | 100% v/v  (2.71% a.c.) | 1% a.c. | 100% v/v  (2.25% a.c. after 11 moths of storage) | 100% v/v | **Validated** |   Regarding use #1 “disinfection of hard surfaces”, for wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted, and only “non mechanical action is claimed by the applicant.. Therefore the eCA consider that wiping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by wiping with mop/cloth. A specific instruction for use is added in the SPC |

* + **Conclusion on the efficacy for the META SPC 4**

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| **Conclusion on the efficacy for the meta SPC 4** |
| For meta SPC 4, available chlorine concentration is at 1.5% w/w (fresh product).  For meta SPC 4, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test).   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2 | **# 1 - Disinfection of household, intitutions, industries and medi-cal surfac-es (other than floors) by wiping with cloth and bucket (without mechanical action)**  **# 2 - Disinfection of toilet bowls in household (without mechanical action)** | Mandatory:  Bacteria | Dirty | | 5 min | 100% v/v  (1.53% a.c.) | 1.1% a.c. |  | 100% v/v | **Validated** | | Mandatory (only for medical areas):  Yeasts | | Dirty | 5 min | 100% v/v  (1.53% a.c.) | 1.1% a.c. |  | 100% v/v | **Validated** | | Optional:  Fungal spores | | Dirty | 5 min | 100% v/v  (1.53% a.c.) | 1.1% a.c. |  | 100% v/v | **Validated** | | Optional:  Virus | | Dirty | 5 min | 100% v/v  (1.53% a.c.) | 1% a.c. |  | 100% v/v | **Validated** |   Regarding use #1 disinfection of hard surfaces”, for wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted, and only “non mechanical action is claimed by the applicant.. Therefore the eCA consider that wiping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by wiping with mop/cloth. A specific instruction for use is added in the SPC. |

* + **Conclusion on the efficacy for the META SPC 13**

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| **Conclusion on the efficacy for the meta SPC 13** |
| For meta SPC 13 available chlorine concentration is at 4.5% w/w (fresh product).  For meta SPC 13, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test). No efficacy tests have been performed with aged products for Meta SPC 13, However, available chlorine content based storage based on APCP data (after 11 months, 3.46% a.c.) was compared to the one demonstrated in the efficacy studies in the following table as it is not expected that age-related changes in co-formulants would have an effect on efficacy of the aged product:   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2 | **# 1 - Disinfection of toilet bowls in medical area**  **# 2 - Disinfection of toilet bowls** **in institutions/industry** | Mandatory:  Bacteria | Dirty | | 5 min | 100% v/v  (4.81% a.c.) | 1.1% a.c. | 100% v/v  (3.7% a.c.) | 100% v/v | **Validated** | | Mandatory (only for medical areas):  Yeasts | | Dirty | 5 min | 100% v/v  (4.81% a.c.) | 1.1% a.c. | 100% v/v  (3.7% a.c.) | 100% v/v | **Validated** | | Optional:  Fungal spores | | Dirty | 5 min | 100% v/v  (4.81% a.c.) | 1.1% a.c. | 100% v/v  (3.7% a.c.) | 100% v/v | **Validated** | | Optional:  Virus | | Dirty | 5 min | 100% v/v  (4.81% a.c.) | 1% a.c. | 100% v/v  (3.7% a.c.) | 100% v/v | **Validated** | |

* **Spray formulations: efficacy data to support Meta SPC 5 and Meta SPC 12**

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | Disinfection of PT2 surfaces (medical areas) | Spray Javel 1.5% a.c  Batch: 182 | Bacteria  *P. aeruginosa S. aureus E. hirae E.coli K12* | EN 13727+A2:2015 | Phase 2 step 1 (suspension test)   Concentrations tested: 0.01%, 0.8%, 1.1%, a.c. Temperature: 20°C Contact time: 5 min Dirty conditions ( 3 g/L BSA+3 mL/L sheep erythrocytes) Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 0.8% a.c.. | RE18-192-1  R.I: 1 |
| Bactericide | Disinfection of PT2 surfaces (medical areas) | Spray Javel 1.5% a.c  Batch: 182 | Bacteria  *Pseudomonas aeruginosa ATCC 10145   Enterococcus hirae ATCC 10541  Staphylococcus aureus ATCC 6538   Escherichia coli ATCC 1053* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.05%, 0.8%, 1.1%, a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA +3 mL/L erythrocytes Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 1.1% a.c.. | RE18-190-1  R.I: 1 |
| Yeasticide Fungicide | Disinfection of PT2 surfaces (medical areas) | Spray Javel 1,5% a.c  Batch: 182 | Yeasts  *Candida albicans DSM 1386*  Fungi  *Aspergillus brasiliensis DSM 1988* | EN 13624:2013 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.01%, 0.8%, 1.1% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA+3 mL/L erythrocytes Criteria: at least a 4 log reduction | Fungicidal and yeasticidal activity demonstrated at 0.8% a.c.. | RE18-191-1  R.I: 1 |
| Yeasticide Fungicide | Disinfection of PT2 surfaces (medical areas) | Spray Javel 1.5% a.c  Batch: 182 | Yeasts  *Candida albicans DSM 1386*  Fungi  *Aspergillus brasiliensis DSM 1988* | EN13697:2015 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.05%, 0.80%, 1.1% a.c. Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/L BSA +3 mL/L erythrocytes Criteria: at least a 3 log reduction | Yeasticidal and fungicidal activity demonstrated at 0.8% a.c.. | RE18-193-1  R.I: 1 |
| Virucide | Disinfection of PT2 surfaces (medical areas) | Spray Javel Hypochlorite de sodium 1,5% a.c.  Bacth: 180491147 | Virus  *Murine norovirus (MNV-1)  Human adenovirus type 5 (Ad5)  Poliovirus type 1 (LSc-2ab)* | EN14476:2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.05%, 0.80%, 1% v/v Temperature: 20°C Contact time: 5 min Dirty conditions: 3 g/l bovine albumin + 3 ml/L sheep erythrocytes Criteria: at least a 4 log reduction | Virucidal activity demonstrated at 1% a.c.. | 093V12-2018-03  R.I: 1 |

For PT2 uses (disinfection for medical areas), with fresh samples of the product Spray Javel 1.5% a.c:

* bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 13727, and EN 13697), at 20°C, with a contact time of 5 minutes with medical dirty conditions (3 g/L BSA+3 mL/L sheep erythrocytes). In these conditions, bactericidal activity is shown at the in-use concentration of 1.10 % a.c..
* Yeasticidal and fugicidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 13624 and EN 13697), at 20°C, with a contact time of 5 minutes with medical dirty conditions (3 g/L BSA+3 mL/L sheep erythrocytes). In these conditions, yeasticidal and fungicidal activity is shown at the in-use concentration of 0.80 % a.c..
* virucidal activity is demonstrated according to phase 2, step 1 test (EN 14476) – (no surface test is available at the submission of the dossier for medical, food, industrial, domestic and institutional areas), at 20°C, with a contact time of 5 minutes with medical dirty conditions (3 g/L BSA+3 mL/L sheep erythrocytes). In these conditions, virucidal activity is shown at the in-use concentration of 1 % a.c..
  + Conclusion on the efficacy for the META SPC 5

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| **Conclusion on the efficacy for the meta SPC 5** |
| For meta SPC 5, available chlorine concentration is at 1.5% w/w (fresh product).  For meta SPC 5, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test). Therefore for some uses, activities or target organisms claimed, the application rate validated are higher than claimed and then restrictions in the use conditions are applied. No efficacy tests have been performed with aged products for Meta SPC 5, However, available chlorine content based storage based on APCP data (after 11 months of storage, 1.28% w/w a.c.) was compared to the one demonstrated in the efficacy studies in the following table as it is not expected that age-related changes in co-formulants would have an effect on efficacy of the aged product:   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2 | **# 1 - Disinfection of houehols, institutions, industries and medical surfaces by spraying with trigger spray** | Mandatory:  Bacteria | Dirty | | 5 min | 100% v/v  (1.54% a.c.) | 1.1% a.c. | 100% v/v  (1.31% a.c. after 11 months) | 100% v/v | **Validated** | | Mandatory (only for medical areas):  Yeasts | | Dirty | 5 min | 100% v/v  (1.54% a.c.) | 0.8% a.c. | 100% v/v  (1.31% a.c. after 11 months) | 100% v/v | | Optional:  Fungal spores | | Dirty | 5 min | 100% v/v  (1.54% a.c.) | 0.8% a.c. | 100% v/v  (1.31% a.c. after 11 months) | 100% v/v | **Validated** | | Optional:  Virus | | Dirty | 5 min | 100% v/v  (1.54% a.c.) | 1% a.c. | 100% v/v  (1.31% a.c. after 11 months) | 100% v/v | **Validated** | |

* + Conclusion on the efficacy for the META SPC 12

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| **Conclusion on the efficacy for the meta SPC 12** |
| For meta SPC 12, available chlorine concentration is at 4.8% w/w (fresh product).  For meta SPC 12, the application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted (phase 2 step 1 test versus phase 2 step 2 test). Therefore for some uses, activities or target organisms claimed, the application rate validated are higher than claimed and then restrictions in the use conditions are applied. No efficacy tests have been performed with aged products for Meta SPC 12, However, available chlorine content based storage based on APCP data (Meta SPC 2.21, after 10 months of storage, 3.93% w/w a.c.) was compared to the one demonstrated in the efficacy studies in the following table:   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Field of use envisaged | Target organism | Soiling conditions (worst case) | | Contact time | Application rate/dilution claimed  in % of product  (% w/v of available chlorine) (worst case) | Minimum effective concentration in % of available chlorine (worst case based on efficacy data) | Application rate claimed  in % of product  (% w/v of available chlorine) after storage (based on APCP data) | Validated application rate  in % of product | Conclusion on the use | | 2 | **# 1 - Disinfection of healthcare, institutions, industries surfaces by spraying with trigger spray** | Mandatory:  Bacteria | Dirty | | 5 min | 100% v/v  (5.15% a.c.) | 1.1% a.c. | 100% v/v  (4.21% a.c. after 10 months) | 100% v/v | **Validated** | | Mandatory (only for medical areas):  Yeasts | | Dirty | 5 min | 100% v/v  (5.15% a.c.) | 0.8% a.c. | 100% v/v  (4.21% a.c. after 10 months) | 100% v/v | **Validated** | | Optional:  Fungal spores | | Dirty | 5 min | 100% v/v  (5.15% a.c.) | 0.8% a.c. | 100% v/v  (4.21% a.c. after 10 months) | 100% v/v | **Validated** | | Optional:  Virus | | Dirty | 5 min | 100% v/v  (5.15% a.c.) | 1% a.c. | 100% v/v  (4.21% a.c. after10 months) | 100% v/v | **Validated** | |

* **Meta SPC 9 and Meta SPC 14**

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Algicide | Algaecide for outdoor surfaces | **Meta SPC 9 product:**  J.NET NETTOYANT EXTERIEUR (9.6 % a.c.) Batch: 1811151714  **Meta SPC 14 product:**  GEL SETS EPAISSISSANT + EAU DE JAVEL BEC 9,6%  Bactch: J1811160713 | Algae | Field test  house method | **JNET NETTOYANT EXTERIEUR**  Application on painted and unpainted concrete (1 m2) covered with algae by spraying  Concentration tested: 25% (dilution in water) Rinsing and observation of the surface 30 minutes after application.  Second observation after 24 hours.  Replicate: none  **GEL SETS EPAISSISSANT + EAU DE JAVEL BEC 9,6%**  Application on painted and unpainted concrete (1 m2) covered with algae by brushing (mechanical)  Concentration tested: 250 mL of EAU DE JAVEL BEC 9.6% in 1.5L of GEL SETS EPAISSISSANT  Rinsing and observation of the surface 4 hours after application.  Second application of the product and second observation after 24 hours.  Replicate: none | Not acceptable to support algaecidal efficacy. | BEB6.I.  306061/1  R.I: 4 |

To demonstrate biocidal activity of the META SPC 9 and 14 product againt algae for outdoor surfaces simulated used tests have been provided by the appliquant.

However, considering that:

* the species present on surfaces are not identified (sometimes indicated as algae and sometimes as mosses)
* the % coverage of algae before and after application is not measured.
* only 2 surfaces were tested per product (painted and non painted)
* the quality of the picture is very poor and some information is not consistent between photos (very light green colouration of the control zone at T0 and fluorescent green colouration for the same zone at T4 hours).
* the meta SPC 14 product was applied by brushing and so applied with mechanical action and therefore the control surface should have been brushed as well. In addition, only spraying application is claimed for méta SPC 14 product and therefore the mode of application tested is not representative of the claimed use (and only one one application is claimed, not two as tested).

we consider that the efficacy against algae of the META SPC 9 and 14 of the DAAP19 product family is not demonstrated based on this study.

To demonstrate biocidal activity of the META SPC 9 and 14 product againt fungi for outdoor surfaces, the applicant indicated that laboratory studies submitted with product 1 of meta-SPC7.2 (SL formulations) under soilling conditions should be used to support the efficacy.

However, eCA consider that the conditions in these studies are not relevant/representative to support fungicidal activity for outdoor surfaces. We are of the opinion that laboratory surfaces tests (P2S2) are not representative of this use (temperature, humidity,…) which is claimed for outdoor surfaces to “Protect the slabs, metal objects, soils and green areas around the surfaces that will be treated (using a plastic tarpaulin, for example).” At least a SU or a field test should have been provided. Theferefore, fungicidal activity for oudoor surfaces is not demonstrated based on the efficacy data provided.

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| **Conclusion on the efficacy for the meta SPC 9 and 14** |
| Considering that:  - simulated uses tests provided against algae is not acceptable to support algaecidal  - no representative SU or field tests have been provided to support fungicidal activity for oudoor surfaces  French competent authorities (FR CA) consider that the efficacy of the META SPC 9 and 14 of the DAAP19 product family is not demonstrated based on the effiacy data provided. |

#### Occurrence of resistance and resistance management

Although different species of target organisms vary in their sensitivity to available chlorine, the development of resistance is not expected due to the unspecific mode of action. The acquisition of resistance of biocidal products is in principle most feasible if the biocidal product operates against a specific cellular target and where the biocidal product is stable such that low, sub-lethal concentrations of the biocide can persist to which viable organisms remain continuously exposed over long time periods. Active chlorine is in fact regarded by experts [see IFH (International Scientific Forum on Home Hygiene) review October 2003, Doc. No.: 392-070 and Submission to SCENIHR, February 2008, Doc. No.: 392-069)] as one of the biocides where acquired resistance is least likely to develop. For the same reasons cross-resistance is not to be expected, nor has it been observed. Despite the use for almost a century in purifying drinking water, where very low (sub ppm) concentrations are continuously maintained, the development of acquired resistance has not been observed.

Due to its reactive nature and unspecific mode of action, no management strategies have been developed since an acquired resistance to active chlorine is not expected. Some temporary adaptation giving modestly reduced susceptibility is sometimes observed in organisms exposed continuously at low concentrations (e.g. in water pipes through formation of biofilms) but this is readily managed e.g. by control / removal of the biofilm. Sabyet al, (1999, Appl Environ Microbiol. 65(12): 5600–5603, Doc. No.: 392-068) reported that oxidative stress, independent of the nature of the oxidant, lead to a development of resistance of bacteria probably by GSH homeostasis. Industries using hypochlorite at low concentrations already routinely manage their operations to cope with such temporarily reduced susceptibility. [from Assessment Report of Active chlorine released from sodium hypochlorite (January 2017), section 2.1.2.]

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

#### Known limitations

None.

#### Evaluation of the label claims

The uses assessed in this dossier belong to the Product Type 2, 3, 4 and the Product Type 5.

The products are used by professional and non-professional users.

Please refer to conclusion on efficacy regarding the accordance of the label claimed with the submitted efficacy data and uses claimed.

#### Relevant information if the product is intended to be authorised for use with other biocidal product(s)

### Risk assessment for human health

For each meta SPC, when no study was available or deemed not reliable, classification has been determined using the calculation method described in the Guidance on the Application of the CLP Criteria Version 5.0 (July 2017).

For more details, please see confidential annex.

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

| **Summary table of *in vitro* studies on skin corrosion/irritation** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method,Guideline,**  **GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks** *(e.g. major deviations)* | **Reference** |
| *In vitro* Transcutaneous Electrical Resistance (TER) for Skin Corrosion  OECD 430    GLP  Reliability 2 | Eau de Javel à 2.6%ca Parfumée (product 1 of meta SPC 2.1)  150 µL onto 3 epidermal surfaces of skin disc  Dye: sulforhodamine | **TER:**  Positive control = hydrochloric acid 10M  Negative control = water  Application time: 24 hours  **Dye application:**  Positive control = hydrochloric acid 10M  Negative control = water  Application time: 2 hours | **Mean TER:**  Test item: 4.68 ± 1.56 kΩ  Positive control: 1.71 ± 0.09 kΩ  Negative control: 21.50 ± 1.49 kΩ  **Mean dye content:**  Test item: 819 µg/disc  Positive control: 44.8 µg/disc  Negative control: 32.8 µg/disc  **Conclusion:**  According to the OECD 430 guideline, due to a  TER < 5 kΩ and a mean dye content above those of positive control (819 µg/disc vs 44.8 µg/disc), Gel avec Javel à 2.6%ca Parfumée is corrosive to skin. | **Major deviation:**   * Acceptability criteria of positive control (0.5-1 kΩ) are not met for TER; * The properties and dimensions of the test apparatus are not reported; * No observation of the integrity of the skin disc is reported.   **Minor deviation:**  Positive control = hydrochloric acid 10M 36% instead of hydrochloric acid 10M 32% | Richeux F. (2018)  Study Number:  TER-PH-18/0208 |
| *In vitro* Transcutaneous Electrical Resistance (TER) for Skin Corrosion  OECD 430    GLP  Reliability 3 | Gel avec Javel à 2.6%ca (product 3 of meta SPC 3)  150 µL onto 3 epidermal surfaces of skin disc | Positive control = hydrochloric acid 10M  Negative control = water  Application time: 24 hours | **Mean TER (1st run):**  Test item: 5.09 ± 0.42 kΩ  Positive control: 2.66 ± 0.23 kΩ  Negative control: 29.74 ± 6.74 kΩ  **Mean TER (2nd run):**  Test item: 17.10 ± 0.62 kΩ  Positive control: 3.14 ± 0.45 kΩ  Negative control: 23.51 ± 4.05 kΩ  **Conclusion:**  According to the OECD 430 guideline, based on the major deviation, no prediction can be made on skin corrosion potential of Gel avec Javel à 2.6%ca. | **Major deviation**   * Acceptability criteria of negative control (10-25 kΩ) are not met (run 1); * Acceptability criteria of positive controls (0.5-1 kΩ) are not met (run 1&2); * The properties and dimensions of the test apparatus are not reported; * No observation of the integrity of the skin disc is reported. | Richeux F. (2018)  Study Number:  TER-PH-18/0211 |
| *In vitro* Transcutaneous Electrical Resistance (TER) for Skin Corrosion  OECD 430    GLP  Reliability 3 | Eau de Javel à 4.8%ca Parfumée (product 1 of meta SPC 2.21)  150 µL onto 3 epidermal surfaces of skin disc | Positive control = hydrochloric acid 10M  Negative control = water  Application time: 24 hours | **Mean TER:**  Test item: 8.89 ± 1.24 kΩ  Positive control: 1.71 ± 0.09 kΩ  Negative control: 21.50 ± 1.49 kΩ  **Conclusion:**  According to the OECD 430 guideline, based on the major deviation, no prediction can be made on skin corrosion potential of Gel avec Javel à 4.8%ca. | **Major deviation:**   * Acceptability criteria of positive control (0.5-1 kΩ) are not met; * The properties and dimensions of the test apparatus are not reported; * No observation of the integrity of the skin disc is reported.   **Minor deviation:**  Positive control = hydrochloric acid 10M 36% instead of hydrochloric acid 10M 32% | Richeux F. (2018)  Study Number:  TER-PH-18/0209 |
| *In vitro* Transcutaneous Electrical Resistance (TER) for Skin Corrosion  OECD 430    GLP  Reliability 3 | Spray avec Javel à 1.5%ca (product 1 of meta SPC 5)  150 µL onto 3 epidermal surfaces of skin disc | Positive control = hydrochloric acid 10M  Negative control = water  Application time: 24 hours | **Mean TER (1st run):**  Test item: 5.08 ± 0.35 kΩ  Positive control: 2.66 ± 0.23 kΩ  Negative control: 29.74 ± 6.74 kΩ  **Mean TER (2nd run):**  Test item: 9.89 ± 3.79 kΩ  Positive control: 3.14 ± 0.45 kΩ  Negative control: 23.51 ± 4.05 kΩ  **Conclusion:**  According to the OECD 430 guideline, based on the major deviation, no prediction can be made on skin corrosion potential of Gel avec Javel à 2.6%ca. | **Major deviation**   * Acceptability criteria of negative control (10-25 kΩ) are not met (run 1); * Acceptability criteria of positive controls (0.5-1 kΩ) are not met (run 1&2); * The properties and dimensions of the test apparatus are not reported; * No observation of the integrity of the skin disc is reported. | Richeux F. (2018)  Study Number:  TER-PH-18/0210 |

**Conclusion on skin corrosion studies**

Major deviations are observed in the *in vitro* skin corrosion studies submitted by applicant.

The criteria for acceptability are not met especially for the positive control where the TER values recorded for Hypochloric acid are never in the range set by the guidance [0.5 – 1.0 kΩ]. This can lead to a lake of sensitivity of the tests and therefore the results of these data can not be deemed acceptable.

However, for the test on Eau de Javel à 2.6%ca Parfumée (product 1 of meta SPC 2.1), the TER value measure being close to 5 kΩ a dye binding method has been performed in order to confirm the results (as recommended in the OECD guideline). The mean dye binding results are accepted since the concurrent control values fall within the acceptable ranges for the method (positive control: 40-100 µg/disc and negative control: 15-35 µg/disc).

Taking into account the results of the dying method, it can be concluded that the product Eau de Javel à 2.6%ca Parfumée (product 1 of meta SPC 2.1) is corrosive to skin.

**Meta SPC 2.1-7.2-8-10.1**

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| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Corrosive to the skin. |
| Justification for the value/conclusion | Results obtained with the TER study performed with the product Eau de Javel 2.6% parfumée (product 1 of Meta SPC 3) have been deemed extrapolable to products from Meta SPC 2.1-7.2-8-10.1.  See confidential annex for more details. |
| Classification of the product according to CLP | Skin Corr. 1 (H314) |

**Meta SPC 1.1-1.2-2.21-2.22-3-4-5-6.1-6.21-6.22-7.11-7.12-9-10.2-11-12-13-14**

pH of products pertaining to Meta SPC 1.1-1.2-2.21-2.22-3-4-5-6.1-6.21-6.22-7.11-7.12-9-10.2-11-12-13-14 are all >11.5. Therefore, in accordance with CLP regulation, a classification skin corrosive is required for these products.

See confidential annex for more details.

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| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | The products of Meta SPC 1.1-1.2-2.21-2.22-3-4-5-6.1-6.21-6.22-7.11-7.12-9-10.2-11-12-13-14 are considered corrosive to the skin. |
| Justification for the value/conclusion | No study on skin corrosion/irritation was performed for Meta SPC 1.1-1.2-2.21-2.22-3-4-5-6.1-6.21-6.22-7.11-7.12-9-10.2-11-12-13-14.  Results of TER studies performed with product 1 of Meta SPC 4-8 and product 3 of Meta SPC 3 are not acceptable due to major deviations.  No read-across is possible with the TER study performed with the product Eau de Javel 2.6% parfumée.  pH of products pertaining to Meta SPC 1.1-1.2-2.21-2.22-3-4-5-6.1-6.21-6.22-7.11-7.12-9-10.2-11-12-13-14 are all >11.5.  Therefore, in accordance with CLP regulation, a classification Skin Corr. 1 H314 is required for these products. |
| Classification of the product according to CLP | Skin Corr. 1 (H314) |

***Eye irritation***

| **Summary table of *in vitro* studies on serious eye damage and eye irritation** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline,**  **GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks** *(e.g. major deviations)* | **Reference** |
| Isolated Chicken Eye Test Method  OECD 438  GLP  Reliability 1 | Eau de Javel à 2.6% c.a Parfumée (product 1 of meta SPC 2.1)  30 µL to 3 enucleated chicken eyes | Positive control = benzalkonium chloride (5%)  Negative control = physiological saline  Application time: 10 seconds  Rinse with 20 mL of physiological saline  Damages assessed by determination of corneal swelling, corneal opacity and fluorescein retention at 30, 75, 120, 180 and 240 minutes post-dose. | Mean score:  **Test item:**  Corneal opacity: 1.3  Fluorescein retention: 3.0  Corneal swelling: 25%   * Combination = 1 × IV, 1 × III, 1 × II   **Positive control:**  Corneal opacity: 3.0  Fluorescein retention: 3.0  Corneal swelling: 42%  Combination = 3 × IV  **Negative control:**  Corneal opacity: 0.0  Fluorescein retention: 0.0  Corneal swelling: 0%    Combination = 3 × I  **Conclusion:**  According to the OECD 438 guideline, with  this combination (1 × IV, 1 × III, 1 × II ), no prediction can be made for “Eau de Javel à 4.8% c.a Parfumée” eye irritation potential. | None. | Barré T. (2018)  Study Number: ICE-PH-18/0208 |
| Isolated Chicken Eye Test Method  OECD 438  GLP  Reliability 1 | Eau de Javel à 4.8% c.a Parfumée (product 1 of meta SPC 2.21)  30 µL to 3 enucleated chicken eyes | Positive control = benzalkonium chloride (5%)  Negative control = physiological saline  Application time: 10 seconds  Rinse with 20 mL of physiological saline  Damages assessed by determination of corneal swelling, corneal opacity and fluorescein retention at 30, 75, 120, 180 and 240 minutes post-dose. | Mean score:  **Test item:**  Corneal opacity: 2.0  Fluorescein retention: 3.0  Corneal swelling: 13%   * Combination = 1 × IV, 1 × III, 1 × II   **Positive control:**  Corneal opacity: 3.0  Fluorescein retention: 3.0  Corneal swelling: 42%  Combination = 3 × IV  **Negative control:**  Corneal opacity: 0.0  Fluorescein retention: 0.0  Corneal swelling: 0%    Combination = 3 × I  **Conclusion:**  According to the OECD 438 guideline, with  this combination (1 × IV, 1 × III, 1 × II ), no prediction can be made for “Eau de Javel à 4.8% c.a Parfumée” eye irritation potential. | None. | Barré T. (2018)  Study Number: ICE-PH-18/0209 |
| Isolated Chicken Eye Test Method  OECD 438  GLP  Reliability 1 | Spray avec Javel à 1.5%c.a (product 1 of meta SPC 5)  30 µL to 3 enucleated chicken eyes | Positive control = benzalkonium chloride (5%)  Negative control = physiological saline  Application time: 10 seconds  Rinse with 20 mL of physiological saline  Damages assessed by determination of corneal swelling, corneal opacity and fluorescein retention at 30, 75, 120, 180 and 240 minutes post-dose. | Mean score:  **Test item:**  Corneal opacity: 2.0  Fluorescein retention: 3.0  Corneal swelling: 7%   * Combination = 1 × IV, 1 × III, 1 × II   **Positive control:**  Corneal opacity: 3.0  Fluorescein retention: 3.0  Corneal swelling: 42%  Combination = 3 × IV  **Negative control:**  Corneal opacity: 0.0  Fluorescein retention: 0.0  Corneal swelling: 0%    Combination = 3 × I  **Conclusion:**  According to the OECD 438 guideline, with  this combination (1 × IV, 1 × III, 1 × II ), no prediction can be made for “Spray avec Javel à 1.5%c.a” eye irritation potential. | None. | Barré T. (2018)  Study Number: ICE-PH-18/0210 |

**Conclusion on in vitro eye irritation studies**

The results of the *in vitro* eye irritation studies are considered acceptable but do not allow to conclude on the potential of eye irritation of the tested products.

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| --- | --- | --- | --- | --- | --- |
| **Summary table of animal studies on serious eye damage and eye irritation** | | | | | |
| **Method, Guideline,**  **GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance,Dose levels, Duration of exposure** | **Results**  *Average score (24, 48, 72h)/*  *observations and time point of onset, reversibility* | **Remarks** *(e.g. major deviations)* | **Reference** |
| Acute Eye Irritation/Corrosion  OECD 405  GLP  Reliability 1 | Rabbit  (New Zealand White)  Female : 1  Males: 2 | Eau de Javel à 2.6%c.a Eucalyptus (product 1 of meta SPC 2.1)  0.1 mL into the conjunctival sac  Ocular examinations 1h, 24h, 48h, 72 h following treatment  Observation period up to 21 days | Mean value for cornea opacity score: 0.0/0.3/0.3  Mean value for iris lesion: 0.0/0.0/0.0  Mean value for conjunctivae redness: 1.3/1.3/1.0  Mean value for conjunctivae chemosis: 0.0/1.0/0.3    Slight to moderate ocular reactions (totally reversible):  Conjunctival effects:  Moderate redness 1 hour after instillation in all animals totally reversible between days 3 and 14.  Moderate chemosis 1 hour after instillation in all animals and totally reversible between days 1 and 14.  Corneal effects:  Slight opacity 1 or 24 hours after instillation in two animals and totally reversible on day 2.  **Conclusion:**  According to the CLP criteria, no signs of eye irritation are observable. Therefore, “Eau de Javel à 2.6%c.a Eucalyptus” is not an eye irritant.is not an eye irritant. | None. | Richeux. F (2018)  Study Number:  IO-OCDE-PH-18/0472 |
| Acute Eye Irritation/Corrosion  OECD 405  GLP  Reliability 1 | Rabbit  (New Zealand White)  Males  Female: 1  Males: 2 | Eau de Javel à 4.8% c.a Parfumée (product 1 of meta SPC 2.22)  0.1 mL into the conjunctival sac  Ocular examinations 1h, 24h, 48h, 72 h following treatment  Observation period up to 21 days | Mean value for cornea opacity score: 2.0/0.7/2.0  Mean value for iris lesion: 0.7/0.3/2.0  Mean value for conjunctivae redness: 1.7/1.3/2.3  Mean value for conjunctivae chemosis: 1.3/1.0/3.0    Slight to moderate ocular reactions, only partially reversible within 21 days:  **Corneal effects:**  Slight to moderate opacity 24 hours after instillation, totally reversible on day 3 or 21 in two animals and **remaining on day 21 in the third animal with slight intensity**.    **Conjunctival effects**: Moderate redness 1 hour after instillation totally reversible between days 7 and 14.  Moderate to important chemosis 1 hour after instillation totally reversible between days 3 and 14.  **Iris effects:**  Injection 1 or 24 hours after instillation in two animals and totally reversible between days 2 and 3. Haemorrhage noted 24 hours after instillation in the third animal, totally reversible on day 7.  White secretions on day 1 (required physiological saline rinse).  **Conclusion:**  Although only eye irritation is observable considering average scores (corneal opacity ≥1 in 2 animals), persistent corneal opacity in one animal occurs until 21 days.  Therefore, according to the CLP Guidance, “Eau de Javel à 4.8% c.a Parfumée” causes serious eye damage. | **Minor deviations:**  1)  Temperature higher than 23°C for 3 days. Maximum value: 29°C.  Relative humidity higher than 70% for 5 days. Maximum value: 75%  2) One animal administered with 0.40 mL of buprenorphine instead of 0.34 mL for 3 days.   * No effect on animals’ health | Richeux. F (2018)  Study Number:  IO-OCDE-PH-18/0209 |
| Acute Eye Irritation/Corrosion  OECD 405  GLP  Reliability 1 | Rabbit  (New Zealand White)  Males  3 | Eau de Javel à 4.8% c.a (product of meta SPC 7.12)  0.1 mL into the conjunctival sac  Ocular examinations 1h, 24h, 48h, 72 h following treatment  Observation period up to 21 days | Mean value for cornea opacity score: 0.7/1.0/1.0  Mean value for iris lesion: 0.0/0.0/0.0  Mean value for conjunctivae redness: 2.0/1.7/2.3  Mean value for conjunctivae chemosis: 1.3/1.0/2.3    Slight to important ocular reactions, only partially reversible within 21 days:  **Corneal effects:**  Slight to moderate opacity 24 hours after instillation in all animals, totally reversible between days 2 and 7 in two animals but remaining on day 21 in the third animal with slight intensity.  **Conjunctival effects**: Moderate redness 1 hour after instillation in all animals, totally reversible between days 7 and 14.  Moderate to important chemosis 1 hour or 24 hours after instillation in all animals, totally reversible between days 2 and 7.  Corneal neovascularization in one animal between days 7 and 21.  **Conclusion:**  Although only eye irritation is observable considering average scores (corneal opacity ≥1 in 2 animals, conjunctival redness ≥2 in 2 animals), persistent corneal opacity in one animal occurs until 21 days.  Therefore, according to the CLP Guidance, “Eau de Javel à 4.8% c.a” causes serious eye damage. | **Minor deviation:**  Relative humidity lower than 70% for 4 days. Minimum value: 26%   * No effect on animals’ health | Richeux. F (2018)  Study Number:  IO-OCDE-PH-18/0470 |
| Acute Eye Irritation/Corrosion  OECD 405  GLP  Reliability 1 | Rabbit  (New Zealand White)  Males  3 | Spray avec Javel à 1.5%c.a (product 1 of meta SPC 5)  0.1 mL into the conjunctival sac  Ocular examinations 1h, 24h, 48h, 72 h following treatment | Mean value for cornea opacity score: 0.0/0.0/0.0  Mean value for iris lesion: 0.0/0.0/0.0  Mean value for conjunctivae redness: 0.0/0.3/0.3  Mean value for conjunctivae chemosis: 0.0/0.0/0.0    Slight to moderate ocular reactions (totally reversible):  Conjunctival effects:  Slight to moderate redness 1 hour after instillation in all animals totally reversible between days 1 and 2.  Slight chemosis 1 hour after instillation in all animals and totally reversible on day 1.  **Conclusion:**  According to the CLP criteria, no signs of eye irritation are observable. Therefore, “Spray avec Javel à 1.5%c.a” is not an eye irritant. | **Minor deviations:**  Temperature higher than 23°C registred one day. Maximum value measured : 29°C  Relative humidity higher than 70% registred one day. Maximum value: 73%  no effects noted on animals’ health | Richeux. F (2018)  Study Number:  IO-OCDE-PH-18/0210 |

**Conclusion on *in vivo* eye irritation studies**

Based on the results of the *in vivo* eye irritation studies submitted:

* No classification is required for the product “Eau de Javel 2.6%c.a parfumée” (product 1 of meta SPC 2.1);
* Serious eye damage classification is required for “Eau de Javel à 4.8%c.a Parfumée” (product 1 of meta SPC 2.21);
* Serious eye damage classification is required for “Eau de Javel à 4.8%c.a” (product of 1 meta SPC 7.12);
* No classification is required for the product “Spray avec Javel à 1.5%c.a” (product 1 of meta SPC 5).

**Meta SPC 2.21-2.22-3-4-10.2-12**

Compositions of products pertaining to Meta SPC 2.21-2.22-3-4-10.2-12have been considered similar to the composition of the product Eau de Javel à 4.8% c.a Parfumée (product 1 of meta SPC 2.21) tested in the *in vitro* and *in vivo* eye irritation studies. The results of these studies are deemed extrapolable to Meta SPC 2.21-2.22-3-4-10.2-12, a classification for serious eye damage is therefore required.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Cause serious eye damage. |
| Justification for the value/conclusion | Results obtained with the *in vivo* study performed with the product Eau de Javel 4.8%ca parfumée (product 1 of meta SPC 2.21) extrapolable to products from meta SPC 2.21-2.22-3-4-10.2-12. Classification for Eye Dam.1 – H318 is required. |
| Classification of the product according to CLP | Eye Dam.1 – H318 |

**Meta SPC 2.1-5-7.2-8**

Compositions to products pertaining to Meta SPC 5-8 have been considered similar to the composition of the product Spray avec Javel à 1.5%c.a (product 1 of meta SPC 8) tested in the *in vitro* and *in vivo* eye irritation studies. The results of these studies are deemed extrapolable to Meta SPC 5-8, no classification for eye irritation is therefore required.

FR CA is aware that the absence of classification for eye irritation is in total contradiction with the classification skin corrosive of Spray avec Javel à 1.5%c.a (product 1 of meta SPC 5) determined with the pH value. Indeed, according to the CLP regulation, any product corrosive to the skin (H314) is considered to be classified for serious eye damage (H318). Therefore, the difference of classification in not scientifically explainable.

The *in vivo* eye irritation study is a valid study without deviation and therefore can not be ruled out. However, for a conservative assessment and without any other avialble information, Eau de Javel 2.6%c.a parfumée and therefore products of Meta SPC 5-8 are considered to be classified for skin corrosion (H314) and by extension Eye Dam.1 – H318.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Cause serious eye damage. |
| Justification for the value/conclusion | Results obtained with the *in vivo* study performed with the product Eau de Javel 2.6% parfumée (product 1 of meta SPC 2.1) extrapolable to products of meta SPC 2.1-7.2. No classification is required.  Results obtained with the *in vivo* study performed with the product Spray avec Javel à 1.5%c.a (product 1 of meta SPC 5) extrapolable to products of meta SPC 5-8. No classification is required.  However, products pertaining from Meta SPC 2.1-5-7.2 & 8 are deemed to be classified Eye Dam.1 – H318 based on the results of the skin corrosion (see above). |
| Classification of the product according to CLP | Eye Dam.1 – H318 |

**Meta SPC 7.11-7.12-10.1**

Compositions to products pertaining to Meta SPC 7.11-7.12-10.1 have been considered similar to the composition of the product Eau de Javel à 4.8%ca (product 1 of meta SPC 7.12) tested in the *in vivo* eye irritation study. The results of this study are deemed extrapolable to Meta SPC 7.11-7.12-10.1, a classification for serious eye damage is therefore required.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Cause serious eye damage. |
| Justification for the value/conclusion | Results obtained with the *in vivo* study performed with the product Eau de Javel à 4.8% c.a Parfumée (product 1 of meta SPC 2.22) are extrapolable to products of meta SPC 2.21-2.22-3-4-10.2-12.  Results obtained with the *in vivo* study performed with the product Eau de Javel à 4.8%ca (product of meta SPC 7.12) are extrapolable to products of meta SPC 7.11-7.12-10.1. |
| Classification of the product according to CLP | Eye Dam.1 (H318) |

**Meta SPC 1.1-1.2-6.1-6.21-6.22-9-11-13-14**

pH of products pertaining to meta SPC 1.1-1.2-6.1-6.21-6.22-9-11-13-14are all >11.5. Therefore, in accordance with Regulation EC/1272/2008, a classification serious eye dammage is required for these products.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Cause serious eye damage. |
| Justification for the value/conclusion | No study on eye irritation was performed for products from meta SPC 1.1-1.2-6.1-6.21-6.22-9-11-13-14.  No read-across is possible with the results of the *in vivo* studies performed with the products Eau de Javel 2.6% parfumée, Eau de Javel à 4.8% c.a Parfumée, Spray avec Javel à 1.5%c.a and Eau de Javel à 4.8%ca.  pH values of products pertaining to meta SPC 1.1-1.2-6.1-6.21-6.22-9-11-13-14 are >11.5.  Therefore, in accordance with Regulation EC/1272/2008, a classification Eye Dam. 1 H318 is needed for these products. |
| Classification of the product according to CLP | Eye Dam.1 (H318) |

***Respiratory tract irritation***

**All meta SPC**

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Respiratory tract irritation** | |
| Value/conclusion | Not irritating to the respiratory tract |
| Justification for the value/conclusion | None co-formulants are classified for respiratory tract irritation (H335). Therefore, no classification is required for irritation to the respiratory tract.  However, products from Meta SPC 1.1-1.2-5-6.21-6.22-7.11-7.12-7.2-10.1-10.2-11-12 are classified for skin corrosion (H314).  No data on acute inhalation toxicity is available and inhalation exposure during use of these products can be expected.  Therefore, according to the CLP regulation, a supplementary hazard statement EUH 071 “Corrosive to the respiratory tract” is required for these Meta SPC.  See confidential annex for more details. |
| Classification of the product according to CLP | Not classified but the supplementary hazard statement EUH 071: Corrosive to the respiratory tract is 1.1-1.2-5-6.21-6.22-7.11-7.12-7.2-10.1-10.2-11-12 |

***Skin sensitization***

**All meta SPC**

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitising to the skin |
| Justification for the value/conclusion | No study on skin sensitisation was performed. Therefore, the classification is determined according to the CLP Regulation (see excel file for classification).  Some ingredients are classified for skin sensitization (Skin Sens. 1/1B/1A - H317). However, they are present at a concentration largely inferior to the skin sensitization threshold of 1% (for Skin Sens. 1/1B) or 0.1% (for Skin Sens. 1A).  These ingredients are also present at a concentration inferior to the elicitation threshold of 0.1% (for Skin Sens. 1/1B) or 0.01% (for Skin Sens. 1A).  Therefore, no classification for skin sensitization or EUH208 labelling is required. |
| Classification of the product according to CLP | Not classified |

***Respiratory sensitization (ADS)***

**All meta SPC**

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not sensitizing to the respiratory tract |
| Justification for the value/conclusion | No co-formulants is classified for respiratory sensitisation (H334).  Therefore, no classification is required. |
| Classification of the product according to CLP | Not classified. |

***Acute toxicity***

*Acute toxicity by oral route*

**Meta SPC 1.1-1.2-6.1-6.21-6.22-9-14**

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not acutely toxic via oral route. |
| Justification for the selected value | The classification has been determined using the calculation method. Sodium chlorate is classified for acute oral toxicity Category 3 and present at a concentration above the generic cut-off value of 1% to be taken into account in the classification by calculation.  ATEmix is > 2000 mg/kg. Therefore, no classification for acute oral toxicity is required.  For more details, please see confidential annex. |
| Classification of the product according to CLP | Not classified |

**Meta SPC 11**

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not acutely toxic via oral route. |
| Justification for the selected value | The classification has been determined using the calculation method. One ingredient of co-formulant and sodium chlorate are classified for acute oral toxicity and present at a relevant concentration to be taken into account in the classification by calculation.  ATEmix is > 2000 mg/kg. Therefore, no classification for acute oral toxicity is required.  For more details, please see confidential annex. |
| Classification of the product according to CLP | Not classified |

**Meta SPC 2.1-2.21-2.22-3-4-5-7.11-7.12-7.2-8-9-10.1-10.2-12-13**

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not acutely toxic via oral route. |
| Justification for the selected value | The classification has been determined using the calculation method. Some ingredients of co-formulants and sodium chlorate are classified for acute oral toxicity but present at a concentration below the generic cut-off value of 1% to be taken into account in the calculation.  For more details, please see confidential annex. |
| Classification of the product according to CLP | Not classified |

*Acute toxicity by inhalation*

**All meta SPC**

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not acutely toxic via inhalation route. |
| Justification for the selected value | None of the co-formulants/ingredients is classified for acute inhalation toxicity. |
| Classification of the product according to CLP | Not classified |

*Acute toxicity by dermal route*

**All meta SPC**

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not acutely toxic via dermal route. |
| Justification for the selected value | None of the co-formulants/ingredients is classified for acute dermal toxicity. |
| Classification of the product according to CLP | Not classified |

***Information on dermal absorption***

**Active chlorine**(released by sodium hypochlorite)

Dermal absorption is considered as not relevant chlorine-related toxicity being only based on local effects (with secondary systemic effects at high doses).

In the absence of systemic effects, the BPC TOX working group (WGIII-2016) concluded that dermal absorption values are not deemed necessary.

***Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)***

**Meta SPC 2.21-2.22-3-4-5-10.2-11-12-13**

Sodium hydroxide (CAS 1310-73-2) is present in the TK of the active substance but also as a co-formulant in the products pertaining to Meta SPC 2.21-2.22-3-4-5-10.2-11-13. Considering that sodium hydroxide is a strong base, it is expected to contribute to the pH of the products.

Therefore, according to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, sodium hydroxide is considered as a SoC.

***Available toxicological data relating to a mixture***

Not relevant

***Other***

Not relevant

#### Exposure assessment and Risk characterization for Human Health

The biocidal family DAAP 19 is a water-based family containing sodium hypochlorite (NaOCl), which releases the active substance active chlorine (av.Cl).

The biocidal family contains 22 meta SPC.

Products pertaining to 22 Meta SPC are intended to be used by professionals and/or non-professionals. The 27 uses claimed by the applicant have been gathered in 7 groups as follows:

***Group 1:*** *Swimming pool disinfection*

* **Disinfection of private swimming pools** **(Use #1)** 🡪 NON-PROFESSIONALS
* **Shock disinfection of private swimming pools** **(Use #2)** 🡪 NON-PROFESSIONALS
* **Disinfection of footbaths in private swimming pools** **(Use #3)** 🡪 NON-PROFESSIONALS
* **Disinfection of public and private swimming pools** **(Use #4)** 🡪 PROFESSIONALS
* **Shock disinfection of public and private swimming pools** **(Use #5)** 🡪 PROFESSIONALS
* **Disinfection of footbaths in public and private swimming pools (Use #6)** 🡪 PROFESSIONALS

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Use #1** | **Use #2** | **Use #3** | **Use #4** | **Use #5** | **Use #6** | |
| **User** | NON-PRO | NON-PRO | NON-PRO | PRO | PRO | PRO |
| **Meta-SPC 1.1** | **×** | **×** | **×** |  |  |  |
| **Meta-SPC 1.2** |  |  |  | **×** | **×** | **×** |

***Group 2:*** *Hard surface disinfection (floors)*

* **Disinfection of surfaces (floors) by wiping with mop and bucket** **(Use #7)** 🡪 NON-PROFESSIONALS
* **Disinfection of surfaces in medical area (Use #10)** 🡪 PROFESSIONALS
* **Disinfection of surfaces in contact with food (Use #11)** 🡪 PROFESSIONALS
* **Disinfection of surfaces in institutions/industry (Use #12)** 🡪 PROFESSIONALS
* **Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings buildings** (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) **(Use #14)** 🡪 PROFESSIONALS
* **Disinfection of non-porous hard surfaces in livestock transportation vehicles (Use #15)** 🡪 PROFESSIONALS

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Use #7** | **Use #10** | **Use #11** | **Use #12** | **Use #14** | **Use #15** |
| **User** | NON-PRO | PRO | PRO | PRO | PRO | PRO |
| **Meta-SPC 2.1** | **×** |  |  |  |  |  |
| **Meta-SPC 2.21** | **×** |  |  |  |  |  |
| **Meta-SPC 2.22** | **×** |  |  |  |  |  |
| **Meta-SPC 6.1** | **×** |  |  |  |  |  |
| **Meta-SPC 6.21** |  | **×** | **×** | **×** | **×** | **×** |
| **Meta-SPC 6.22** |  | **×** | **×** | **×** | **×** | **×** |
| **Meta-SPC 7.11** |  | **×** | **×** | **×** | **×** | **×** |
| **Meta-SPC 7.12** |  | **×** | **×** | **×** | **×** | **×** |
| **Meta-SPC 7.2** |  | **×** | **×** | **×** | **×** | **×** |
| **Meta-SPC 8** | **×** |  |  |  |  |  |
| **Meta-SPC 9** |  |  |  |  |  |  |
| **Meta-SPC 10.1** |  | **×** | **×** | **×** | **×** | **×** |
| **Meta-SPC 10.2** |  | **×** | **×** | **×** | **×** | **×** |
| **Meta-SPC 11** |  | **×** | **×** | **×** | **×** | **×** |

***Group 3:*** *Hard surface disinfection (other than floors)*

* **Disinfection of surfaces (floors) by wiping with mop and bucket** **(Use #7)** 🡪 NON-PROFESSIONALS
* **Disinfection of surfaces (other than floors) by wiping with cloth and bucket** **(Use #8)** 🡪 PROFESSIONALS + NON-PROFESSIONALS
* **Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket** **(Use #9)** 🡪 NON-PROFESSIONALS
* **Disinfection of surfaces in medical area (Use #10)** 🡪 PROFESSIONALS
* **Disinfection of surfaces in contact with food (Use #11)** 🡪 PROFESSIONALS
* **Disinfection of surfaces in institutions/industry (Use #12)** 🡪 PROFESSIONALS
* **Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings buildings** (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.) **(Use #14)** 🡪 PROFESSIONALS
* **Disinfection of non-porous hard surfaces in livestock transportation vehicles (Use #15)** 🡪 PROFESSIONALS
* **Disinfection of companion animal housing and associated equipment** **(Use #16)** 🡪 NON-PROFESSIONALS
* **Disinfection of surfaces by spraying with trigger spray (Use #17)** 🡪 NON-PROFESSIONALS + PROFESSIONALS
* **Disinfection of hard surfaces by spraying (Use #18)** 🡪 PROFESSIONALS
* **Algaecide and fungicide for outdoor surfaces (Use #19)** 🡪 NON-PROFESSIONALS
* **Algaecide and fungicide for outdoor surfaces by spraying (Use #20)** 🡪 NON-PROFESSIONALS + PROFESSIONALS

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Use #7** | **Use #8** | | **Use #9** | **Use #10** | **Use #11** | **Use #12** | **Use #13** | **Use #14** | **Use #15** | **Use #16** | **Use #17** | | **Use #18** | **Use #19** | **Use #20** | |
| **User** | NP | NP | P | NP | P | P | P | P | P | P | NP | P | NP | P | NP | P | NP |
| **Meta-SPC 2.1** | **×** | **×** |  | **×** |  |  |  |  |  |  | **×** |  |  |  |  |  |  |
| **Meta-SPC 2.21** | **×** | **×** |  | **×** |  |  |  |  |  |  | **×** |  |  |  |  |  |  |
| **Meta-SPC 2.22** | **×** | **×** |  | **×** |  |  |  |  |  |  | **×** | **×** | **×** |  |  |  |  |
| **Meta-SPC 3** |  | **×** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Meta-SPC 4** |  | **×** | **×** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Meta-SPC 6.1** | **×** | **×** |  | **×** |  |  |  |  |  |  | **×** |  |  |  |  |  |  |
| **Meta-SPC 6.21** |  |  |  |  | **×** | **×** | **×** | **×** | **×** | **×** |  |  |  |  |  |  |  |
| **Meta-SPC 6.22** |  |  |  |  | **×** | **×** | **×** | **×** | **×** | **×** |  |  |  |  |  |  |  |
| **Meta-SPC 7.11** |  |  |  |  | **×** | **×** | **×** | **×** | **×** | **×** |  |  |  |  |  |  |  |
| **Meta-SPC 7.12** |  |  |  |  | **×** | **×** | **×** | **×** | **×** | **×** |  |  |  |  |  |  |  |
| **Meta-SPC 7.2** |  |  |  |  | **×** | **×** | **×** | **×** | **×** | **×** |  |  |  |  |  |  |  |
| **Meta-SPC 8** | **×** | **×** |  | **×** |  |  |  |  |  |  | **×** |  |  |  |  |  |  |
| **Meta-SPC 9** |  |  |  |  |  |  |  |  |  |  |  |  |  |  | **×** |  |  |
| **Meta-SPC 10.1** |  |  |  |  | **×** | **×** | **×** | **×** | **×** | **×** |  |  |  |  |  |  |  |
| **Meta-SPC 10.2** |  |  |  |  | **×** | **×** | **×** | **×** | **×** | **×** |  |  |  |  |  |  |  |
| **Meta-SPC 11** |  |  |  |  | **×** | **×** | **×** | **×** | **×** | **×** |  |  |  |  |  |  |  |
| **Meta-SPC 12** |  |  |  |  |  |  |  |  |  |  |  |  |  | **×** |  |  |  |
| **Meta-SPC 14** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | **×** | **×** |

***Group 4:*** *Inner surfaces disinfection*

* **Disinfection of surfaces by CIP (Use#13) 🡪** PROFESSIONALS
* **Disinfection of inner surfaces in human drinking water systems (Use #21)** 🡪 PROFESSIONALS
* **Disinfection of inner surfaces in veterinary water systems (Use #22)** 🡪 PROFESSIONALS

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Use#13** | **Use #21** | **Use #22** |
| **User** | PRO | PRO | PRO |
| **Meta-SPC 6.21** | **x** | **×** | **×** |
| **Meta-SPC 6.22** | **x** | **×** | **×** |
| **Meta-SPC 7.11** | **x** | **×** | **×** |
| **Meta-SPC 7.12** | **x** | **×** | **×** |
| **Meta-SPC 7.2** | **x** | **×** | **×** |

***Group 5:*** *Water disinfection*

* **Disinfection of water intended for human consumption (Use #23)** 🡪 PROFESSIONALS

|  |  |
| --- | --- |
|  | **Use #23** |
| **User** | PRO |
| **Meta-SPC 6.21** | **×** |
| **Meta-SPC 6.22** | **×** |
| **Meta-SPC 7.11** | **×** |
| **Meta-SPC 7.12** | **×** |
| **Meta-SPC 7.2** | **×** |

***Group 6:*** *Toilet bowls disinfection*

* **Disinfection of toilet bowls** **(Use #24)** 🡪 PROFESSIONALS + NON-PROFESSIONALS
* **Disinfection of toilet bowls in medical area (Use #25)** 🡪 PROFESSIONALS
* **Disinfection of toilet bowls in institutions/industry (Use #26)** 🡪 PROFESSIONALS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Use #24** | | **Use #25** | **Use #26** |
| **User** | PRO | NON-PRO | PRO | PRO |
| **Meta-SPC 2.1** |  | **×** |  |  |
| **Meta-SPC 2.21** |  | **×** |  |  |
| **Meta-SPC 2.22** |  | **×** |  |  |
| **Meta-SPC 3** | **×** | **×** |  |  |
| **Meta-SPC 4** |  | **×** |  |  |
| **Meta-SPC 8** |  | **×** |  |  |
| **Meta-SPC 13** |  |  | **×** | **×** |

***Group 7:*** *Laundry disinfection*

* **Laundry disinfection with hand soaking** **(Use #27)** 🡪 PROFESSIONALS + NON-PROFESSIONALS

|  |  |  |
| --- | --- | --- |
|  | **Use #27** | |
| **User** | PRO | NON-PRO |
| **Meta-SPC 2.1** |  | **×** |
| **Meta-SPC 2.21** |  | **×** |
| **Meta-SPC 2.22** |  | **×** |
| **Meta-SPC 6.1** |  | **×** |
| **Meta-SPC 6.21** | **×** |  |
| **Meta-SPC 6.22** | **×** |  |
| **Meta-SPC 7.11** | **×** |  |
| **Meta-SPC 7.12** | **×** |  |
| **Meta-SPC 7.2** | **×** |  |
| **Meta-SPC 8** |  | **×** |
| **Meta-SPC 10.2** | **×** |  |
| **Meta-SPC 11** | **×** |  |

*Calculation of active chlorine concentrations*

The concentration of active chlorine (avCl) released from sodium hypochlorite (NaOCl) in the products has been calculated based on the specification of the technical active substance presented in the CAR and the content of technical active substance in the product.

To obtain the maximum concentration of active chlorine released from sodium hypochlorite for the different meta-SPC, the content of sodium hypochlorite has been divided by the conversion factor of 1.05. The results as are as follows:

|  |  |  |
| --- | --- | --- |
|  | **NaOCl concentration** | **Calculated avCl concentration** |
| **Meta-SPC 1.1** | 10.08% | 9.6% |
| **Meta-SPC 1.2** | 13.123% | 12.5% |
| **Meta-SPC 2.1** | 2.73% | 2.6% |
| **Meta-SPC 2.21** | 5.04% | 4.8% |
| **Meta-SPC 2.22** | 3.78% | 3.6% |
| **Meta-SPC 3** | 2.73% | 2.6% |
| **Meta-SPC 4** | 1.575% | 1.5% |
| **Meta-SPC 5** | 1.575% | 1.5% |
| **Meta-SPC 6.1** | 10.08% | 9.6% |
| **Meta-SPC 6.21** | 10.08% | 9.6% |
| **Meta-SPC 6.22** | 14.175% | 13.5% |
| **Meta-SPC 7.11** | 3.78% | 3.6% |
| **Meta-SPC 7.12** | 5.04% | 4.8% |
| **Meta-SPC 7.2** | 2.73% | 2.6% |
| **Meta-SPC 8** | 1.68% | 1.6% |
| **Meta-SPC 9** | 10.08% | 9.6% |
| **Meta-SPC 10.1** | 2.73% | 2.6% |
| **Meta-SPC 10.2** | 50.04% | 4.8% |
| **Meta-SPC 11** | 6.30% | 6.0% |
| **Meta-SPC 12** | 5.04% | 4.8% |
| **Meta-SPC 13** | 4.725% | 4.5% |
| **Meta-SPC 14** | 10.08% | 9.6% |

*Mode of action and routes of exposure*

The active substance releaser sodium hypochlorite is characterised by primarily local effects (i.e corrosion or irritation due to direct chemical reactivity). According to the Assessment Report (2017) any systemic effects observed in toxicity studies were considered as secondary effects. Consequently, only a local risk assessment is performed for the active substance containing in the products of BPF.

Exposure assessment is performed for NaOCl as available chlorine (avCl) according to the assessment report of the active substance Sodium hypochlorite.

In water, sodium hypochlorite (NaOCl) hydrolyzes to hypochlorous acid (HClO). Furthermore, hypochlorous acid participates in the following equilibrium with chlorine (Cl2)

HClO + H3O+ + Cl─ ↔ Cl2 + 2H2O

The ratio of Cl2/HClO/ClO─ is pH and temperature dependent. At pH values > 10, the hypochlorite anion (ClO-) is the predominant species and only exposure to aerosols of NaOCl (as avCl) is considered relevant. The minor fraction of volatile hypochlorous acid (HClO) is considered negligible.

At pH values of about 4-6, hypochlorous acid (HClO) is the predominant species and exposure to vapours of HClO (as avCl) is considered relevant.

Considering this:

* A quantitative local risk assessment is performed for inhalation exposure to NaOCl(as avCl) aerosols and vapours (HClO) when relevant considering pH values;
* A qualitative local risk assessment is performed for dermal exposure due to the classification of the concentrated and diluted products.

Secondary exposure to NaOCl upon dermal contact with dry treated surfaces is considered to be non-relevant, as described in the CAR (2017): due to the high reactivity of chlorine species such as NaOCl, residues on surfaces degrade very rapidly. Decomposition to physiological sodium and chloride ions takes place which are not expected to arise any health risk.

Secondary exposure to NaOCl upon dermal contact with wet treated surfaces during contact time is considered relevant for assessment for bystanders and general public. Inhalation exposure to aerosols during application of NaOCl is also considered relevant for the assessment of secondary exposure.

Considerations on volatility of the active substance(s)



At pH values >10, the hypochlorite anion (ClO-) is the predominant species.

ClO- has a vapourpressure significantly less than 10-5 Pa. Therefore, it is not considered as a volatile chlorine species.

At pH values of about 4-6, hypochlorous acid (HClO) is the predominant species (considered as 100%). Vapourpressure of HClOdepends on temperature and ranges from 196 Pa at 20°C up to 725 Pa at 40°C. Therefore, it is considered as highly volatile.

At pH values between 6-8, hypochlorous acid (HClO) is in equilibrium with other chlorine species which are not volatile. Therefore, HClO is considered to be present at 50%.

The pH value of products pertaining to meta SPC has been provided by the applicant.

However, no information has been provided concerning the pH value of the product after dilution following the intended uses.

Therefore, the pH value of the diluted products has been calculated considering the worst-case dilution factor claimed by the applicant for each use as below:

* For meta SPCs containing NaOH as co-formulant, *i.e* Meta SPC 2.21-2.22-3-4-5-10.2-11-12-13, the following formula considering the presence of a strong base has been used:

**pH = 14 + log [OH-]**.

* For other Meta SPC, not containing NaOH as co-formulant, the following formula considering a weak base has been used:

**pH = 7 + ½ × pKa + ½ × log C NaOCl**.

The results are as follows:

|  |  |  |
| --- | --- | --- |
| **Meta SPC** | **pH values of concentrated products**  (submitted by applicant) | **pH values of diluted products**  (calculated from the formulation as explained above) |
| **Meta-SPC 1.1** | 12.2 | n.a (no dilution claimed) |
| **Meta-SPC 1.2** | 12.1 | n.a (no dilution claimed) |
| **Meta-SPC 2.1** | 12.1 | 9.91 ≤ pH ≤ 10.08 |
| **Meta-SPC 2.21** | 12.2 | 12.33 |
| **Meta-SPC 2.22** | 12.3 | 11.37 ≤ pH ≤ 11.79 |
| **Meta-SPC 3** | 12.6 | n.a (no dilution claimed) |
| **Meta-SPC 4** | 12.6 | n.a (no dilution claimed) |
| **Meta-SPC 5** | 12.8 | n.a (no dilution claimed) |
| **Meta-SPC 6.1** | 12.2 | 10.16 ≤ pH ≤ 10.32 |
| **Meta-SPC 6.21** | 12.2 | 10.15 ≤ pH ≤ 10.41 |
| **Meta-SPC 6.22** | 12.1 | 10.17 ≤ pH ≤ 10.46 |
| **Meta-SPC 7.11** | 12.1 | 10.02 ≤ pH ≤ 10.37 |
| **Meta-SPC 7.12** | 12.1 | 10.08 ≤ pH ≤ 10.35 |
| **Meta-SPC 7.2** | 12.1 | 9.95 ≤ pH ≤ 10.36 |
| **Meta-SPC 8** | 12.1 | 10.10 ≤ pH ≤ 10.32 |
| **Meta-SPC 9** | 12.2 | 10.51 |
| **Meta-SPC 10.1** | 12.3 | 10.11 ≤ pH ≤ 10.36 |
| **Meta-SPC 10.2** | 12.2 | 11.44 ≤ pH ≤ 11.96 |
| **Meta-SPC 11** | 12.8 | 13.53 ≤ pH ≤ 13.71 |
| **Meta-SPC 12** | 12.2 | n.a (no dilution claimed) |
| **Meta-SPC 13** | 12.7 | n.a (no dilution claimed) |
| **Meta-SPC 14** | 12.2 | 10.80 |

For details please refer to the Excel data sheet “pH dilutions” in Confidential Annex.

Calculated pH values for the diluted products are ≥ 10 for almost all Meta SPCs.

pH values below 10 are calculated for product pertaining to Meta SPC 2.1 and 7.2, with 9.91 and 9.95 respectively. These values are very close to 10 and, taking into account the incertitude due to the calculation and the poor relevance of two digits after the comma for a pH value, they have been rounded to 10.

Based on this, pH values of the diluted products being ≥ 10, no inhalation exposure to HClO vapours is considered during application of products.

Strategy for the assessment of substance(s) of concern (SoC)

Sodium hydroxide is identified as a SoC in meta SPC 2.21-2.22-3-4-5-10.2-11-12-13 due to its contribution to the extreme pH value(> 11.5). Therefore, according to the Guidance on BPR: Volume III Part B+C, sodium hydroxide is a band B substance of concern and a qualitative risk assessment has to be performed.

Strategy for disinfectant by-products assessment

No disinfectant by-products (DBP) guidance is available for TP2-3-4-5 uses, excepted for swimming pool. Therefore, the DBP assessment has not been performed.

Disinfectant-by-products are expected to be formed after the use of products containing NaOCl for the disinfection of surfaces, swimming pool and drinking waters.

For the disinfection of swimming pool and drinking waters, the Guidance on the BPR Volume V, Guidance on Disinfection by-Products (Version 1.0, January 2017) has been applied. For details, please refer to Annex I.

Concerning the surfaces disinfection, no information is available on the identity and the quantity of DBPs formed during the use of the products. Without these information and without any available guidance, no risk assessment can be performed.

**Reference values to be used in risk characterisation**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF** | **Correction for oral absorption** | **Value** |
| AEC inhalation (chlorine) | monkey 52-wks subchronic repeated dose inhalation study  human volunteer single dose inhalation study  (4-8 h)  human volunteer repeated dose inhalation study (3 d, 6 h/d) | NOAEC 1.5 mg/m3 | 3.2 (intra-species toxicodynamic factor) | - | 0.5 mg avCl/m³ |
| AEC inhalation  (HClO) | No repeated dose inhalation toxicity study on HClO is available since HClO does not exist as such but is only formed in aqueous solutions of chlorine. In the absence of data, the BPC TOX-WGIII-2016 agreed to derive an AECinhalation based on chlorine data (please see above) |  |  |  | 0.5 mg avCl/m³ |

**Identification of the main paths of human exposure towards active substance(s) and substance(s) of concern from use in the BPF**

**Summary table: main paths of human exposure**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table: main paths of human exposure** | | | | |  |
| **Exposure path** | **Primary (direct) exposure** | | **Secondary (indirect) exposure** | |  |
| **Professional users** (including industrial users and trained professional users) | **Non-**  **professional users** | **Professional users**  (including industrial users and trained professional users) | **Non-**  **professional bystanders/ General public** | **Via food** |
| Oral | No | No | No | Yes |  |
| Dermal | Yes | Yes | Yes | Yes |  |
| Inhalation | Yes | Yes | Yes | Yes |  |

|  |
| --- |
| **Hard surface Disinfection** |

In this section, the uses belonging to group 2&3 identified above have been assessed; *i.e* hard surfaces disinfection including floors and surfaces other than floors.

The assessment has been split in two parts:

* First part: exposure assessment for Professional users followed by a risk characterization;
* Second part: exposure assessment for Non-Professional users followed by a risk characterization.

**PROFESSIONALS USERS**

**Summary table: List of exposure scenarios**

Hard surface disinfection (floors and other than floors)

|  |  |  |
| --- | --- | --- |
| **Summary table: exposure scenarios** | | |
| **Scenario and task number** | **Description of scenario and tasks** | **Exposed group** |
| **Use #1**  **Use#8**  **Use#10**  **Use#11**  **Use#12**  **Use#14**  **Use#15**  **Use#17**  **Use#18** | **Algaecide and fungicide for outdoor surfaces by spraying**  **Disinfection of surfaces (other than floors) by wiping with cloth and bucket**  **Disinfection of surfaces in medical area**  **Disinfection of surfaces in contact with food**  **Disinfection of surfaces in institutions/industry**  **Disinfection of non-porous hard surfaces in veterinary healthcare facilities, animal housings buildings (such as kennels, hutches, cages, bee hives, stables, etc.), livestock (poultry, bovine, etc.)**  **Disinfection of non-porous hard surfaces in livestock transport vehicles**  **Disinfection of surfaces by spraying with trigger spray**  **Disinfection of hard surfaces by spraying** |  |
| **Primary exposure** | | |
| **Scenario [1]** | ***Disinfection of hard surfaces by wiping*** *(use #8-10-11-12-14-15)* | |
| Task [1.1] | *Mixing and loading (manual or semi-automated)* | Professionals |
| Task [1.2] | *Application and rinsing of treated surfaces* | Professionals |
| **Scenario 2** | ***Disinfection of hard surfaces by flooding*** *(use #10-11-12-14-15)* | |
| Task [2.1] | *Mixing and loading (manual or semi-automated)* | Professionals |
| Task [2.2] | *Application and rinsing of treated surfaces* | Professionals |
| **Scenario [3]** | ***Disinfection of hard surfaces by spraying indoors*** *(use #10-11-12-14-15-17-18)* | |
| Task [3.1] | *Mixing and loading (manual or semi-automated)* | Professionals |
| Task [3.2a] | *Application with a trigger spray and rinsing of treated surfaces* | Professionals |
| Task [3.2.b] | *Application with a coarse spray and rinsing of treated surfaces* | Professionals |
| Task [3.3] | *Cleaning of spray equipment* | Professionals |
| **Scenario [4]** | ***Disinfection of hard surfaces by spraying outdoors*** *(use #1)* | |
| Task [4.1] | *Mixing and loading (manual)* | Professionals |
| Task [4.2.a | *Application with a low-pressure sprayer and rinsing of treated surfaces* | Professionals |
| Task [4.2.b] | *Application with a high-pressure sprayer and rinsing of treated surfaces* | Professionals |
| Task [4.3] | *Cleaning of spray equipment* | Professionals |
| **Scenario [5]** | ***Disinfection of floors by mopping*** |  |
| Task [5.1] | *Mixing and loading (manual or semi-automated)* | Professionals |
| Task [5.2] | *Application and rinsing of treated surfaces* | Professionals |
| **Secondary exposure** | | |
| **Scenario [6]** | ***Inhalation exposure of bystander during application*** *(use #1-10-11-12-14-15-17-18)* | General public |
| **Scenario [7]** | ***Dermal contact with wet treated surface*** *(use #1-8-10-11-12-14-15-17-18)* | General public |

***Primary exposure***

**Scenario [1] – Disinfection of hard surfaces by wiping (use #8-10-11-12-14-15)**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Meta SPC 4** | **Meta SPC 6.21** | **Meta SPC 6.22** | **Meta SPC 7.11** | **Meta SPC 7.12** | **Meta SPC 7.2** | **Meta SPC 10.1** | **Meta SPC 10.2** | **Meta SPC 11** |
| **Concentrated product** | | | | | | | | | |
| Av.Cl concentration | 1.50% | 9.60% | 13.50% | 3.60% | 4.80% | 2.60% | 2.60% | 4.80% | 6.00% |
| Product classification | H314-H318 | | | | | | | | |
| pH values | 12.6 | 12.2 | 12.1 | 12.1 | 12.1 | 12.1 | 12.3 | 12.2 | 12.8 |
| **Diluted product** | | | | | | | | | |
| Claimed application dose (worst-case) | RTU | 1350 mL in 10L diluted solution | 1120 mL in 10 diluted solution | 340 mL in 1L diluted solution | 230 mL in 1L diluted solution | 450 mL in 1L diluted solution | 450 mL in 1L diluted solution | 230 mL in 1L diluted solution | 180 mL in 1L diluted solution |
| Dilution factor | 0.135 | 0.110 | 0.34 | 0.23 | 0.45 | 0.45 | 0.23 | 0.18 |
| Av.Cl concentration | 1.30% | 1.49% | 1.22% | 1.10% | 1.17% | 1.17% | 1.10% | 1.08% |
| Product classification | H315-H319 | | | | | | | H314-H318 |
| pH values (extrapolated by calculation) | >10 but < 11.5 | | | | | | | > 11.5 |

Products from Meta-SPC 4-6.21-6.22-7.11-7.12-7.2-10.1-10.2-11 can be used for the disinfection of hard surfaces by wiping.

Products pertaining to Meta SPC 7 are RTU whereas products from other Meta SPCs have to be diluted before application.

The range of concentration of active chlorine in the concentrated products is 1.5-13.5% and 1.08-1.49% in the in-use dilution.

The classifications of the in-use diluted products have been set according to the calculation rules laid down in the CLP regulation 1272/2008. For details please refer to the Excel data sheet “Classification\_In-use dilution\_PRO” in the confidential PAR.

Packaging sizes are as follows:

* between 120 mL and 20L for meta SPC 4-7.11-7.12-7.2-10.1-10.2;
* between 250 mL and 1000L for meta SPC 6.21-6.22-11.

The products are applied at an application rate of 100 mL/m2.

For this exposure scenario, 2 tasks have been considered:

* Task [1.1]: Mixing and loading phase (manual or semi-automated depending on the packaging size and Meta SPCs);
* Task [1.2]: Application phase by wiping and rinsing of treated surfaces.

**Task [1.1]: Mixing and loading**

|  |
| --- |
| **Description of Task [1.1] – Mixing and Loading** |
| Products from meta-SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2-11 have to be diluted in water before application by wiping on hard surfaces. This can be done manually or in a (semi)-automatically way depending on the packaging size and Meta SPCs.  No dilution is performed for product pertaining to Meta SPC 4 (RTU).  *Inhalation route*  The available pH value of the concentrated products is > 10, exposure by inhalation to vapors of HClO is therefore considered negligible.  Exposure during M&L is included in the exposure model used for the application (see task [1.2] below).  *Dermal route*  The concentrated products being classified H314-H318, a qualitative risk assessment is performed. |

***Calculations for Task [1.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.1] | 1/ No PPE | negligible | - |

**Task [1.2]: Application by wiping and rinsing of treated surfaces**

|  |
| --- |
| **Description of Task [1.2] – Application by wiping and rinsing of treated surfaces** |
| After dilution, products are applied on hard surfaces by wiping using a cloth. After the claimed contact time, the treated surfaces are rinsed off.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible.  The pH value extrapolated by calculation for the diluted products and the pH of Meta SPC 4 products (RTU) are > 10.  Exposure to aerosols should be assessed using the ***Surface Disinfection Model 1*** from BHHEM, with an exposure value of 22.2 mg/m3.  However, according to HEEG Opinion 8 “Defaults and appropriate models to assess human exposure for dipping processes (PT 8)”, the Dipping model 1 (p.26 of User guidance and p.308 of BHHEM) is appropriate to assess exposure during manual dipping.  In this model, no inhalation exposure is expected during the task consisting in the dipping of wooden articles in open tanks.  It is assumed that the inhalation exposure during the dipping of wooden articles is similar to the exposure during the dipping of a cloth in a bucket.  Therefore, exposure to aerosols during wiping activities (including the dipping of a cloth into a bucket) is considered negligible.  After application on surfaces, the active substance is expected to quickly react with the organic matter during the claimed contact time.  Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order.  Considering this, exposure through inhalation to vapours (HClO) during this task is considered negligible.  *Dermal route*  Products from meta SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2-being classified H315-H319 and the products from meta SPC 4 and 11 being classified H314-H318, a qualitative risk assessment is performed.  Exposure during the rinsing step is considered similar than exposure during application. |

***Calculations for Task [2.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [2.1] | 1/ No PPE | negligible | - |

**Combined exposure**

Combined exposure is not relevant based on the absence of systemic effects after exposure to sodium hypochlorite. The primary mode of action of NaOCl is characterised by local irritation/corrosion and oxidation at the site of first contact; thus effects triggered by NaOCl are rather concentration than time-dependent.

For this reason, only the highest exposure level (concentration as % active chlorine or mg active chlorine/m3) is relevant for risk characterisation.

The addition of exposure levels and the calculation of combined exposure during the different tasks (e.g. mixing and loading, application and post-application) is not relevant.

**Risk characterisation for primary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| **Scenario 1: Disinfection of hard surfaces by wiping** | | | | | |
| Task [1.1] | Negligible | | | nr | Yes |
| Task [1.2] | Negligible | | | nr | Yes |

For all tasks of scenario [1] for Meta-SPC 4-6.21-6.22-7.11-7.12-7.2-10.1-10.2-11, the estimated inhalation concentration is considered negligible. .

Outcome of qualitative local risk assessment (dermal)

The products from Meta SPC 4-6.21-6.22-7.11-7.12-7.2-10.1-10.2-11are classified Skin corrosive category 1 (H314) and Severe eye damage (H318).

Diluted products are classified Skin irritant (H315) and Eye irritant (H319) except for products from Meta SPC 4 (RTU) and 11.

All the products are intended to be applied by professionals.

Please refer to the tables below:

**Outcome of qualitative local risk assessment –** Handling of concentrated product classified H314 and H318 – Professional users

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant PPE** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Meta SPC 4 (RTU) and 11** | | | | | | | | | | |
| **Very high** | **H314** | **2**  **3**  **4** | **Application by wiping/rinsing**  **(Task 2)** | **Skin and eye** | **Frequency:** 1/day to 1/week  **Duration :**  Task 2: no data but potentially high exposure duration expected | Task 2 : Direct dermal contact and potential splashes or spills during dipping of a cloth into a bucket  Hand-to-eye transfer | Use of appropriate personal protective equipment:  Hand protection: gloves  Eye protection: goggles  Body protection: Protective clothing  RPE: Substance/task appropriate respirator | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) High hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency  (**↑**) Task 2: potentially high exposure duration |
| **EUH 071** | **inhalation** |
| **Meta SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2-11** | | | | | | | | | | |
| **Very high** | **H314** | **2**  **3**  **4** | Manual or semi-automatic mixing and loading  (Task 1) | **Skin and eye** | **Frequency:** 1/day to 1/week  **Duration :**  Task 1: no data but approximatively 10 min | Task 1 : Direct dermal contact and potential splashes or spills .  Hand-to-eye transfer | Use of appropriate personal protective equipment:  Hand protection: gloves  Eye protection: goggles  Body protection: Protective clothing  RPE: Substance/task appropriate respirator | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) High hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency  (**↓**) Task 1: Low exposure duration (few minutes per day) |
| **EUH 071** | **inhalation** |

**Outcome of qualitative local risk assessment –** Handling of diluted product classified H315 and H319 – Professional users

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant PPE** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Meta SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2** | | | | | | | | | | |
| **Low** | **H315** | **2**  **3**  **4** | Application by wiping**/rinsing** | **Skin** | **Frequency:** 1/day to 1/week  **Duration :**  Task 2: no data but potentially high exposure duration expected | Task 1 : Direct dermal contact and potential splashes or spills .  Hand-to-eye transfer | Use of appropriate personal protective equipment:  Hand protection: gloves  Eye protection: goggles  Body protection: Protective clothing | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) Potentially high exposure duration  (**↓**) Low hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency |
| **H319** | **eye** |

**Disinfection for hard surfaces by wiping – Primary exposure – Uses #8-10-11-12-14-15**

**Meta SPC 4:**

During application by wiping, the risk is considered acceptable considering the wear of PPE (gloves, protection coverall and goggles).

Due to local effects, pour the product directly on surfaces and wipe.

Considering that no exposure to aerosols nor vapour is expected (pH > 10), no respiratory protection is necessary.

**Meta SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2 and 11**

During M&L (corresponding to the dilution task) and application by wiping, the risk is considered acceptable considering the wear of PPE (gloves, protection coverall and goggles).

Considering that no exposure to aerosols nor vapour (pH > 10) is expected, no respiratory protection is necessary.

**Scenario [2] – Disinfection of hard surfaces by flooding(use #10-11-12-14-15)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Meta SPC 10.1** | **Meta SPC 10.2** | **Meta SPC 11** |
| **Concentrate product** | | | |
| Av.Cl concentration | 2.60% | 4.80% | 6.00% |
| Product classification | H314 - H318 | | |
| pH | 12.3 | 12.2 | 12.8 |
| **Diluted product** | | | |
| Claimed application dose (worst-case) | 450 mL in 1L diluted solution | 230 mL in 1L diluted solution | 240 mL in 1L diluted solution |
| Dilution factor | 0.45 | 0.23 | 0.24 |
| Av.Cl concentration | 1.17% | 1.10% | 1.44% |
| Diluted product classification | H315-H319 | | H314-H318 |
| pH | >10 but < 11.5 | | > 11.5 |

Products from Meta-SPC 10.1-10.2-11 are intended to be used for disinfection of hard surfaces by flooding. Products from these meta SPC are diluted before application.

The range of concentration of active chlorine in the concentrate products is 2.6-6% and 1.1-1.44% in the in-use dilution.

The classifications of the in-use diluted products have been set according to the calculation rules laid down in the CLP regulation 1272/2008. For details please refer to the Excel data sheet “Classification\_In-use dilution\_PRO” in the confidential PAR.

Packaging sizes are as follows:

* 5L for Meta SPC 10.1-102;
* between 5L and 1000L for Meta SPC 11.

The products are applied at an application rate of 100 mL/m2.

For this exposure scenario, 2 tasks of primary exposure are considered:

* Task [2.1]: Mixing and loading (manual or semi-automated depending on packaging size and Meta SPCs)
* Task [2.2]: Application by flooding and rinsing of treated surfaces

**Task [2.1]: Mixing and loading**

|  |
| --- |
| **Description of Task [2.1] – Mixing and Loading** |
| Products from meta-SPC 10.1-10.2-11 are diluted in water before application by flooding on hard surfaces. This is done manually or (semi)-automatically depending on the packaging size and Meta SPCs.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible since pH of the concentrated product is > 10 for all meta-SPCs.  Exposure to aerosols is also considered negligible for manual loading due to the small quantities manipulated.  During semi-automatic loading, no exposure is expected.  *Dermal route*  The concentrated products being classified H314-H318, a qualitative risk assessment is performed. |

***Calculations for Task [2.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [2.1] | 1/ No PPE | negligible | - |

**Task [2.2]: Application by flooding and rinsing of treated surfaces**

|  |
| --- |
| **Description of Task [2.2] – Application by flooding and rinsing of treated surfaces** |
| After dilution, products are applied on hard surfaces by flooding.  After the claimed contact time, the treated surfaces are rinsed off.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible.  The pH value extrapolated by calculation for the diluted products is > 10.  Considering the type of application, inhalation exposure to aerosols is also not expected.  After application on surfaces, the active substance is expected to quickly react with the organic matter during the claimed contact time.  Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order.  Considering this, exposure through inhalation to vapours during this task is considered negligible.  *Dermal route*  A qualitative risk assessment is performed for diluted products from meta SPC 10.1 and 10.2 classified H315-H319, and for diluted products from Meat SPC 11 classified H314-H318.  Exposure during the rinsing step is considered similar than exposure during application. |

***Calculations for Task [2.2]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [2.2] | 1/ No PPE | negligible | - |

**Combined exposure**

Not relevant.

**Risk characterisation for primary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| **Scenario 2: Disinfection of hard surfaces by flooding** | | | | | |
| Task [2.1] | Negligible | | | nr | Yes |
| Task [2.2] | Negligible | | | nr | Yes |

For all tasks of scenario [2], the estimated inhalation concentration is considered negligible.

Outcome of qualitative local risk assessment (dermal)

Products of Meta SPC 10.1-10.2-11are classified Skin corrosive category 1 (H314) and Severe eye damage (H318).

Diluted products are classified Skin irritant (H315) and Eye irritant (H319) except for Meta SPC 11.

All the products are intended to be applied by professionals.

Please refer to the tables below:

**Outcome of qualitative local risk assessment –** Handling of concentrated product classified H314 and H318 – Professional users

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant PPE** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Meta SPC 10.1 - 10.2 - 11** | | | | | | | | | | |
| **Very high** | **H314** | **2**  **3**  **4** | Manual M&L  (Task 1) | **Skin and eye** | **Frequency:** 1/day  **Duration :** no data but 10 min expected | Direct dermal contact and potential splashes or spills  Hand-to-eye transfer | Use of appropriate personal protective equipment:  Hand protection: gloves  Eye protection: goggles  Body protection: Protective clothing  RPE: Substance/task appropriate respirator | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) High hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency and exposure duration (few minutes per day) |
| **EUH 071** | **inhalation** |

**Outcome of qualitative local risk assessment –** Handling of diluted – Professional users

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant PPE** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Meta SPC 11** | | | | | | | | | | |
| **Very high** | **H314** | **2**  **3**  **4** | Application by flooding/rinsing  (Task 2) | **Skin and eye** | **Frequency:** 1/day  **Duration** : no data but potentially high exposure duration expected | Direct dermal contact and potential splashes or spills during flooding application  Hand-to-eye transfer | Use of appropriate personal protective equipment:  Hand protection: gloves  Eye protection: goggles  Body protection: Protective clothing  RPE: Substance/task appropriate respirator | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) High hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency  (**↑**) High exposure duration |
| **EUH 071** | **inhalation** |
| **Meta SPC 10.1 – 10.2** | | | | | | | | | | |
| **Low** | **H315** | **2**  **3**  **4** | Application by flooding/rinsing  (Task 2) | **Skin** | **Frequency:** 1/day to 1/week  **Duration :**  Task 2: no data but potentially high exposure duration expected | Direct dermal contact and potential splashes or spills during flooding application  Hand-to-eye transfer | Use of appropriate personal protective equipment:  Hand protection: gloves  Eye protection: goggles  Body protection: Protective clothing | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) Potentially high exposure duration  (**↓**) Low hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency |
| **H319** | **eye** |

**Disinfection for hard surfaces by flooding – Primary exposure - Uses #10-11-12-14-15**

**Meta SPC 10.1 and 10.2**

During M&L (corresponding to the dilution task) and application by flooding, the risk is considered acceptable considering the wear of PPE (gloves, protection coverall and googles).

**Meta SPC 11**

During M&L (corresponding to the dilution task) and application by flooding, the risk is considered acceptable considering the wear of PPE (gloves, protection coverall and googles).

Considering that no exposure to aerosols nor vapour (pH > 10) is expected, no respiratory equipment is necessary.

**Scenario [3] – Disinfection of hard surfaces by spraying indoors (use #10-11-12-14-15-17-18)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Meta SPC 5** | **Meta SPC 11** | **Meta SPC 12** |
| **Concentrate product** | | | |
| Av.Cl concentration | 1.50% | 6.00% | 4.80% |
| Product classification | H314 - H318 | | |
| pH | 12.8 | 12.8 | 12.2 |
| **Diluted product** | | | |
| Claimed application dose (worst-case) | RTU | 240 mL in 1L diluted solution | RTU |
| Dilution factor | 0.24 |
| Av.Cl concentration | 1.44% |
| Diluted product classification | H314-H318 |
| pH extrapolated by calculation | >11.5 |

Products from Meta-SPC 5-11-12 can be used for the disinfection of hard surfaces by spraying indoors.

Products from meta SPC 5 and 12 are RTU and products from Meta SPC 11 are diluted before application.

The range of concentration of active chlorine in the concentrate products is 1.5-6% and 1.44-4.8% in the in-use dilution.

The classifications of the in-use diluted products have been set according to the calculation rules laid down in the CLP regulation 1272/2008. For details please refer to the Excel data sheet “Classification\_In-use dilution\_PRO” in the confidential PAR.

Packaging sizes are as follows:

* between 500 mL and 750mL for meta SPC 5-12.
* between 20L and 1000L for meta SPC 11

The products are applied on hard surfaces (other than floors) by spraying indoors with a trigger spray (for meta SPC 5 and 12) or with a coarse spray (only for meta SPC 11) at an application rate of 100 mL/m2.

The use of a trigger spray is not clearly indicated for products pertaining to Meta SPC 11.

However, considering an indoor application, an application with a trigger (including a M&L task) has been considered as a worst-case approach.

For this exposure scenario, 4 tasks of primary exposure are considered:

* **Task [3.1]:** Mixing and loading (manual or semi-automated;
* **Task [3.2a]** Application by spraying with a trigger spray and rinsing of treated surfaces;
* **Task [3.2b]:** Application by spraying with a coarse spray and rinsing of treated surfaces;
* **Task [3.3]:** Cleaning of the coarse spray.

**Task [3.1]: Mixing and loading**

|  |
| --- |
| **Description of Task [3.1] – Mixing and Loading** |
| Products from meta-SPC 12 has to be diluted in water before application by spraying with a trigger spray on hard surfaces. This can be done manually or (semi)-automatically depending on the packaging size.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible since pH of the concentrated product is > 10 for products of the meta-SPC.  Exposure to aerosols is also considered negligible for manual loading due to small quantities handled.  For (semi)-automated loading no exposure is expected.  *Dermal route*  The concentrated products being classified H314-H318, a qualitative risk assessment ise performed. |

***Calculations for Task [3.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [3.1] | 1/ No PPE | negligible | - |

**Task [3.2.a]: Application by spraying indoors with a trigger spray and rinsing of treated surfaces**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Description of Scenario [3.2.a]** | | | | |
| Products are applied on hard surfaces by spraying using a trigger spray.  After the claimed contact time, the treated surfaces are rinsed off.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible.  The pH extrapolated by calculation for the diluted products from Meta SPC 11 and the pH of Meta SPC 5 and 12 products (RTU) are > 10.  To assess inhalation exposure to aerosols generated by the trigger spray, the ***Consumer product spraying and dusting model 2 – (Hand-held trigger spray)*** from BHHEM, 2015 (p.344) is used.  The exposure value from the model is:   * 10.5 mg/m3 (inhalation)   Density of the diluted products from Meta SPC 11 has been considered to be close to 1 g/cm3 because of the water provided by the dilution. Density of Meta SPC 5 and 12 has been considered in the exposure calculation as they are RTU products.  After application on surfaces, the active substance is expected to quickly react with the organic matter during the claimed contact time.  Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order.  Considering this, exposure through inhalation to vapours during this task is considered negligible.  *Dermal route*  RTU products from meta SPC 5 and 12 and diluted products from meta SPC 11 being classified H314-H318, a qualitative risk assessment is performed.  Exposure during the rinsing step is considered similar than exposure during application. | | | | |
| *Inhalation exposure (****aerosols****)* | | | | |
| **Tier** | **Parameters** | | **Value** | **Reference and**  **justification** |
| Tier 1 | Concentration of active chlorine (% w/w) | Meta SPC 5  Meta SPC 11  Meta SPC 12 | 1.50%  1.44%  4.8% | Applicant’s data |
| Density (g/cm3) | Meta SPC 5  Meta SPC 11  Meta SPC 12 | 1.0282  1  1.07 | Applicant’s data |
| Inhalation exposure (**aerosols**) – (mg/m3) | | 10.5 | Consumer product spraying and dusting model 2 – Handheld trigger spray (BHHEM, 2015) |
| Tier 2 | RPE | | APF 4 | BHHEM, 2015 (p154) |

***Calculations for Task [3.2a]***

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [3.2.a] | 1/ No PPE | **Meta SPC 5:** 0.16  **Meta SPC 11:** 0.15  **Meta SPC 12:** 0.54 |
| 2/ RPE APF 4 | **Meta SPC 12:** 0.13 |

**Task [3.2.b]: Application by spraying indoors with a coarse spray and rinsing of treated surfaces**

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [3.2.b]** | | | |
| Products from Meta SPC 11 can be applied on hard surfaces by spraying using a coarse spray.  After the claimed contact time, the treated surfaces are rinsed off.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible.  the pH extrapolated by calculation for the diluted products from Meta SPC 11 is >10.  To assess inhalation exposure to aerosols generated by the coarse spray, the ***Spraying Model* *2*** from BHHEM, 2015 (p.284) is used considering the large surface to treat.  The exposure value from the model is:   * 76 mg/m3 (inhalation)   Density of the diluted products from Meta SPC 11 has been considered to be close to 1 g/cm3 because of the water provided by the dilution.  After application on surfaces, the active substance is expected to quickly react with the organic matter during the claimed contact time.  Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order.  Considering this, exposure through inhalation to vapours during this task is considered negligible.  *Dermal route*  Products from meta SPC 11 are classified H314-H318, a qualitative risk assessment is performed.  Exposure during the rinsing step is considered similar than exposure during application. | | | |
| *Inhalation exposure (****aerosols****)* | | | |
| **Tier** | **Parameters** | **Value** | **Reference and**  **justification** |
| Tier 1 | Concentration of active chlorine  (% w/w) in meta SPC 11 | 1.44% | Applicant’s data |
| Inhalation exposure (**aerosols**) – (mg/m3) | 76 | Spraying Model 2 (BHHEM, 2015) |
| Tier 2 | RPE | APF 4 | BHHEM, 2015 (p154) |

***Calculations for Task [3.2.b]***

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [3.2.b] | 1/ No PPE | **Meta SPC 12:** 1.09 |
| 2/ Mask APF 4 | **Meta SPC 12:** 0.27 |

**Task [3.3]: Manual cleaning of the spray equipment (coarse spray application)**

|  |
| --- |
| **Description of Task [3.3] – Manual cleaning of the spray equipment** |
| After application, the spray equipment used is assumed to be cleaned.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible.  Considering the type of manipulation performed, no inhalation exposure to aerosols is expected.  *Dermal route*  The use of water to clean the spray equipment leads to an additional dilution of the product. Therefore, the diluted solution after cleaning is expected to be no longer corrosive but as a worst-case approach irritant (H315-H319). Therefore, a qualitative risk assessment is performed. |

**Combined exposure**

Not relevant.

**Risk characterisation for primary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| **Scenario [3]: Disinfection of hard surfaces by spraying indoors** | | | | | |
| Task [3.1] | Negligible | | | nr | Yes |
| Task [3.2.a]  (trigger spray appli.) | Tier 1/no PPE | 0.5 | **Meta SPC 5:** 0.16  **Meta SPC 11:** 0.15  **Meta SPC 12:** 0.54 | 32  30  108 | Yes  Yes  **No** |
| Tier 2/mask APF 4 | **Meta SPC 12:** 0.13 | 27 | Yes |
| Task [3.2.b]  (coarse spray appli.) | Tier 1/no PPE | 0.5 | **Meta SPC 11:** 1.09 | 219 | **No** |
| Tier 2 /mask APF 4 | **Meta SPC 11:** 0.27 | 55 | Yes |
| Task [3.3] | Negligible | | | nr | Yes |

RPE with APF 4 (at minima) is necessary for the application task of products pertaining to Meta SPC 11 (coarse spray application) and 12 (trigger spray application).

Outcome of qualitative local risk assessment (dermal)

The products from Meta SPC 5-11-12 are classified Skin corrosive category 1 (H314) and Severe eye damage (H318).

Diluted products from Meta SPC 11 are classified H314-H318.

All the products are intended to be applied by professionals.

Please refer to the tables below:

**Outcome of qualitative local risk assessment –** Handling of products classified H314 and H318 – Professional users

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant PPE** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Meta SPC 11** | | | | | | | | | | |
| **Very high** | **H314** | **2**  **3**  **4** | M&L (manual or (semi)-automated)  (Task 1) | **Skin and eye** | **Frequency:** 1/day  **Duration :** no data but 10 min expected | Direct dermal contact and potential splashes or spills  Hand-to-eye transfer | Use of appropriate personal protective equipment:  Hand protection: gloves  Eye protection: goggles  Body protection: Protective clothing  RPE: Substance/task appropriate respirator | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) High hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency and exposure duration (few minutes per day) |
| **EUH 071** | **inhalation** |
| **Meta SPC 5 and 12** | | | | | | | | | | |
| **Very high** | **H314** | **2**  **3**  **4** | Spray application using a trigger spray/spray | **Skin and eye** | **Frequency:** 1/day  **Duration** : no data but potentially high exposure duration expected (30 min) | Direct dermal contact and exposure to generated aerosols (eye and inhalation)  Hand-to-eye transfer | Use of appropriate personal protective equipment:  Hand protection: gloves  Eye protection: goggles  Body protection: Protective clothing  RPE APF 4 (at minima) for Meta SPC 12  Substance/task appropriate respirator for Meta SPC 5 | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals  Application to be performed downward in order to avoid facial exposure. | **Acceptable** | (**↑**) High hazard category  (**↑**) Potentially high exposure duration but sequenced exposure  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency |
| **EUH 071** | **inhalation** |
| **Meta SPC 11** | | | | | | | | | | |
| **Very high** | **H314** | **2**  **3**  **4** | Spray application using a coarse spray/spray | **Skin and eye** | **Frequency:** 1/day  **Duration** : no data but potentially high exposure duration expected (220 min) | Direct dermal contact and exposure to generated aerosols (eye and inhalation) | Use of appropriate personal protective equipment:  Hand protection: gloves  Eye protection: goggles  Body protection: Protective clothing  RPE APF 4 | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals  Application to be performed downward in order to avoid facial exposure | **Unacceptable** | (**↑**) High hazard category  (**↑**) Potentially high exposure duration and continuous exposure (without break) during the task  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency |
| **EUH 071** | **inhalation** |

**Outcome of qualitative local risk assessment –** Handling of diluted products– Professional users

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant PPE** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Meta SPC 11** | | | | | | | | | | |
| **Low** | **H315** | **2**  **3**  **4** | Cleaning of the spray equipment (coarse spray application) | **Skin** | **Frequency:** 1/day to 1/week  **Duration :**  no data but expected to be 30 min | Direct dermal contact and potential splashes or spills during cleaning task  Hand-to-eye transfer | Use of appropriate personal protective equipment:  Hand protection: gloves  Eye protection: goggles  Body protection: Protective clothing | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) Potentially high exposure duration  (**↓**) Low hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency |
| **H319** | **eye** |

**Disinfection for indoor hard surfaces by spraying – Primary exposure - Uses #10-11-12-14-15-17-18**

**Meta SPC 5**

During spray application, the risk is considered acceptable considering the wear of PPE (gloves, protection coverall, googles and respiratory equipment).

The spray application must be performed downward in order to avoid exposure.

**Meta SPC 11**

During M&L (corresponding to the dilution task) and application by spraying, the risk is considered acceptable considering the wear of PPE (gloves, protection coverall, googles and RPE with APF 4 at minima). However, considering that the exposure duration is expected to be high and in a continuous way (when the task is started it has to be finished, no break in the application is expected), the risk is considered unacceptable due to local effect (H314).

During the cleaning of the equipment, gloves, coverall and goggles are required.

**Meta SPC 12**

During application by spraying, the risk is considered acceptable considering the wear of PPE (gloves, protection coverall, googles and RPE with APF 4 at minima).

The spray application must be performed downward in order to avoid exposure.

**Scenario [4] – Disinfection of hard surfaces by spraying outdoors (use #1)**

|  |  |
| --- | --- |
|  | **Meta SPC 14** |
| **Concentrate product** | |
| Av.Cl concentration | 9.60% |
| Product classification | H314 - H318 |
| pH | 12.2 |
| **Diluted product** | |
| Claimed application dose (worst-case) | RTU but M&L required (mixing of 4L gel SETS and 1 L of the biocidal product) |
| Dilution factor | n.a |
| Av.Cl concentration | 1.92% |
| Diluted product classification | H315-H319 |
| pH | >10 |

Products from Meta-SPC 14 can be used for the disinfection of outdoor surfaces by spraying. Products are RTU, no dilution in water is intended to be performed. However, before use, the biocidal product containing the active substance has to be mixed up within 4L of gel SETS containing co-formulants only.

Packaging size of the biocidal products containing the a.s is 1L.

The concentration of active chlorine in the concentrated products is 9.6% and 1.92% in the in-use dilution.

The classifications of the in-use diluted products have been set according to the calculation rules laid down in the CLP regulation 1272/2008. For details please refer to the Excel data sheet “Classification\_In-use dilution\_PRO” in the confidential PAR.

The products are applied at an application rate of 100 mL/m2.

For this exposure scenario, 4 tasks of primary exposure are considered:

* **Task [4.1]:** Manual mixing and loading;
* **Task [4.2a]:** Application by spraying with a low-pressure sprayer (1 -3 bar) and rinsing of treated surfaces;
* **Task [4.2b]:** Application by spraying with a medium-pressure sprayer (4-7 bar) and rinsing of treated surfaces;
* **Task [4.3]:** Cleaning of the spray equipment.

**Task [4.1]: Manual mixing and loading**

|  |
| --- |
| **Description of Task [4.1] – Manual mixing and Loading** |
| Products from meta-SPC 14 are mixed up within 4L of gel SETS before application by spraying on outdoor surfaces.  Considering the claimed packaging size of 1L, this is assumed to be performed manually.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible since pH for the concentrated product is > 10.  Exposure to aerosols is also considered negligible for manual loading due to the small quantities handled.  *Dermal route*  The concentrated products being classified H314-H318, a qualitative risk assessment is performed. |

***Calculations for Task [4.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [4.1] | 1/ No PPE | negligible | - |

**Task [4.2.a]: Application by spraying outdoors with a low-pressure sprayer and rinsing of treated surfaces**

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [4.2.a]** | | | |
| After mixing up, products can be applied on outdoor surfaces by using a low-pressure sprayer (1-3 bar).  After the claimed contact time, the treated surfaces are rinsed off.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible.  The pH value extrapolated by calculation for the products after mixing up is > 10.  To assess inhalation exposure to aerosols generated by the low-pressure sprayer (1-3 bar), the **Spraying Model 1** from BHHEM, 2015 (p.281) is used.  The exposure value from the model is:   * 104 mg/m3 (inhalation).   After application on surfaces, the active substance is expected to quickly react with the organic matter during the claimed contact time.  Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order.  Considering this, exposure through inhalation to vapours during this task is considered negligible.  *Dermal route*  During application, as products from meta SPC 14 are classified H315-H319, a qualitative risk assessment is performed.  Exposure during the rinsing step is considered similar than exposure during application. | | | |
| **Input parameters for Scenario [4.2.a]** | | | |
| **Tier** | **Parameters** | **Value** | **Reference and**  **justification** |
| Tier 1 | Concentration of active chlorine  (% w/w) in meta SPC 14 | 1.92% | Applicant’s data |
| Inhalation exposure (**aerosols**) – (mg/m3) | 104 | Spraying Model 1 – (BHHEM, 2015) |

***Calculations for Task [4.2.a]***

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [4.2.a] | 1/ No PPE | 2 |
| 2/RPE APF 4 | **0.5** |
| 2/ RPE APF 10 | 0.2 |

**Task [4.2.b]: Application by spraying outdoors with a medium-pressure sprayer and rinsing of treated surfaces**

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [4.2.b** | | | |
| After mixing up, products from meta SPC 14 can be applie on outdoor surfaces by spraying using a medium-pressure sprayer (4-7 bar).  After the claimed contact time, the treated surfaces are rinsed off.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible.  The pH value extrapolated by calculation for the products after mixing up is > 10.  To assess inhalation exposure to aerosols generated by a medium-pressure sprayer (4-7 bar), considering the high surface to treat, the **Spraying Model 2** from BHHEM, 2015 (p.284) is used.  The exposure value from the model is:   * 76 mg/m3 (inhalation)   After application on surfaces, the active substance is expected to quickly react with the organic matter during the claimed contact time.  Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order.  Considering this, exposure through inhalation to vapours during this task is considered negligible.  *Dermal route*  During application, as products from meta SPC 14 are classified H315-H319, a qualitative risk assessment is performed.  Exposure during the rinsing step is considered similar than exposure during application. | | | |
| **Input parameters for Scenario [4.2.b]** | | | |
| **Tier** | **Parameters** | **Value** | **Reference and**  **justification** |
| Tier 1 | Concentration of active chlorine  (% w/w) in meta SPC 14 | 1.92% | Applicant’s data |
| Inhalation exposure (**aerosols**) – (mg/m3) | 76 | Spraying Model 2 (BHHEM, 2015) |

***Calculations for Task [*4.2.b*]***

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [**4.2.b**] | 1/ No PPE | 1.5 |
| 2/ RPE APF 4 | 0.4 |

**Task [4.3]: Manual cleaning of the spray equipment**

|  |
| --- |
| **Description of Task [4.3] – Manual cleaning of spray equipment** |
| After application, the spray equipment used is assumed to be cleaned.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible.  Considering the type of manipulation performed, no inhalation exposure to aerosols is expected.  *Dermal route*  The use of water to clean the spray equipment leads to an additional dilution of the product. Therefore, the generated diluted solution after cleaning is expected to be not classified and a qualitative risk assessment is not required. |

**Combined exposure**

Not relevant.

**Risk characterisation for primary exposure**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| **Scenario 4: Disinfection of hard surfaces by spraying outdoors** | | | | | |
| Task [4.1] | Negligible | | | nr | Yes |
| Task [4.2.a]  Low-pressure sprayer (1-3 bar) | Tier 1/no PPE | 0.5 | 2 | 399 | **No** |
| Tier 2/RPE APF 4 | 05 | 100 | yes |
| Tier 2/RPE APF 10 | 0.2 | 40 | Yes |
| Task [4.2.b]  (medium-pressure sprayer (4-7 bar) | Tier 1/no PPE | 0.5 | 1.5 | 292 | **No** |
| Tier 2/RPE APF 4 | 0.4 | 73 | Yes |
| Task [4.3] | Negligible | | | nr | Yes |

RPE with APF 4 (at minima) is necessary for the spray application with a low or a medium-pressure sprayer. However, due to the outdoor application, inhlataione xposure is expected to be of very low extent, and no RPE is deemed necessary.

Outcome of qualitative local risk assessment (dermal)

The products from Meta SPC 14 are classified Skin corrosive category 1 (H314) and Severe eye damage (H318). After mixing up, products are classified H315-H319.

All the products are intended to be applied by professionals.

Please refer to the tables below:

**Outcome of qualitative local risk assessment –** Products from meta SPC **14** used by professionals

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant PPE** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Handling products classified H314-H318** | | | | | | | | | | |
| **Very high** | **H314** | **2** | Manual M&L | **Skin and eye** | **Frequency:** Max 1 every 3 months  **Duration :** no data but 10 min expected | Direct dermal contact and potential splashes or spills  Hand-to-eye transfer | Use of appropriate personal protective equipment:  Hand protection: gloves  Eye protection: goggles  Body protection: Protective clothing  RPE: Substance/task appropriate respirator | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) High hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency and exposure duration |
| **EUH 071** | **inhalation** |
| **Handling product classified H315-H319** | | | | | | | | | | |
| **Low** | **H315** | **2** | Spray application with a low or medium-pressure sprayer/rinsing | **Skin** | **Frequency:** Max 1 every 3 months  **Duration :** no data but high exposure duration expected | Direct dermal contact and potential deposit of aerosols on skin and eye  Hand-to-eye transfer | Use of appropriate personal protective equipment:  Hand protection: gloves  Eye protection: goggles  Body protection: Protective clothing | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals  Application to be performed downward in order to avoid facial exposure. | **Acceptable** | (**↑**) Potentially high exposure duration  (**↓**) Low hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency |
| **H319** | **eye** |

**Disinfection for outdoor hard surfaces by spraying – Primary exposure - Uses #1**

**Meta SPC 14**

During M&L (corresponding to the mixing up with 4L of GEL SETS), the risk is considered acceptable considering the wear of PPE (gloves, protection coverall and googles).

Considering that no exposure to aerosols nor vapour (pH > 10) is expected, no respiratory equipment is necessary.

During spray application (using a low-(1-3 bar) or medium (4-7 bar) -pressure sprayer), the risk is considered acceptable considering the wear of PPE (gloves, protection coverall and googles).

The spray application must be performed downward in order to avoid exposure.

**Scenario [5] – Disinfection of floors by mopping (use #10-11-12-14-15)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Meta SPC 6.21** | **Meta SPC 6.22** | **Meta SPC 7.11** | **Meta SPC 7.12** | **Meta SPC 7.2** | **Meta SPC 10.1** | **Meta SPC 10.2** | **Meta SPC 11** |
| **Concentrate product** | | | | | | | | |
| Av.Cl concentration | 9.60% | 13.50% | 3.60% | 4.80% | 2.60% | 2.60% | 4.80% | 6.00% |
| Product classification | H314 - H318 | | | | | | | |
| pH | 12.2 | 12.1 | 12.1 | 12.1 | 12.1 | 12.3 | 12.2 | 12.8 |
| **Diluted product** | | | | | | | | |
| Claimed application dose (worst-case) | 1350 mL in 10L diluted solution | 1120 mL in 10 diluted solution | 340 mL in 1L diluted solution | 230 mL in 1L diluted solution | 450 mL in 1L diluted solution | 450 mL in 1L diluted solution | 230 mL in 1L diluted solution | 240 mL in 1L diluted solution |
| Dilution factor | 0.135 | 0.11 | 0.34 | 0.23 | 0.45 | 0.45 | 0.23 | 0.24 |
| Av.Cl concentration | 1.30% | 1.49% | 1.22% | 1.10% | 1.17% | 1.17% | 1.10% | 1.44% |
| Diluted product classification | H315-H319 | | | | | | | H314-H318 |
| pH | >10 but < 11.5 | | | | | | | > 11.5 |

Products from Meta-SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2-11 can be used for the disinfection of floors by mopping. All products are diluted before application.

The range of concentration of active chlorine in the concentrated products is 2.6-13.5% and 1.1-1.49% in the in-use dilution.

The classifications of the in-use diluted products have been set according to the calculation rules laid down in the CLP regulation 1272/2008. For details please refer to the Excel data sheet “Classification\_In-use dilution\_PRO” in the confidential PAR.

Packaging sizes are as follows:

* between 250 mL and 1000L for Meta SPC 6.21-6.22-11
* between 120 mL and 20L for Meta SPC 7.11-7.12-7.2-10.1-10.2

The products are applied at an application rate of 100 mL/m2.

For This exposure scenario, 2 tasks of primary exposure have been considered:

* Task [5.1]:Mixing and loading (manual or semi-automated, depending on packaging size and on Meta SPC)
* Task [5.2]: Application by mopping and rinsing of treated floors

**Task [5.1]: Mixing and loading**

|  |
| --- |
| **Description of Task [5.1] – Mixing and Loading** |
| Products from all meta-SPC have to be diluted in water before application by mopping on floors.  This can be done manually or (semi)-automatically depending on the packaging size and on Meta SPC.  *Inhalation route*  The available pH value of the concentrated products is > 10, exposure by inhalation to vapors of HClO is therefore considered negligible.  *Dermal route*  The concentrated products are classified H314-H318, a qualitative risk assessment is performed. |

***Calculations for Task [5.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [5.1] | 1/ No PPE | negligible | - |

**Task [5.2]: Application by mopping and rinsing of treated surfaces**

|  |
| --- |
| **Description of Task [5.2] – Application by moping and rinsing of treated surfaces** |
| After dilution, products are applied on floors using a mop and a bucket. After the claimed contact time, the treated surfaces are rinsed off.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible.  The pH value extrapolated by calculation for the diluted products are > 10.  Exposure to aerosols should be assessed using the ***Surface Disinfection Model 1*** from BHHEM, with an exposure value of 22.2 mg/m3.  However, according to HEEG Opinion 8 “Defaults and appropriate models to assess human exposure for dipping processes (PT 8)”, the Dipping model 1 (p.26 of User guidance and p.308 of BHHEM) is appropriate to assess exposure during manual dipping.  In this model, no inhalation exposure is expected during the task consisting in the dipping of wooden articles in open tanks.  It is assumed that the inhalation exposure during the dipping of wooden articles is similar to the exposure during the dipping of a mop in a bucket.  Therefore, exposure to aerosols during mopping activities (including the dipping of a mop into a bucket) is considered negligible.  After application on surfaces, the active substance is expected to quickly react with the organic matter during the claimed contact time.  Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order.  Considering this, exposure through inhalation to vapours (HClO) during this task is considered negligible.  *Dermal route*  Products from meta SPC 10 to 14 and 17-18 being classified H315-H319 after dilution, except product from Meta SPC 11 classified H314-H318, a qualitative risk assessment is performed.  Exposure during the rinsing step is considered similar than exposure during application. |

***Calculations for Task [5.2]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [5.2] | 1/ No PPE | negligible | - |

**Combined exposure**

Not relevant.

**Risk characterisation for primary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| **Scenario 1: Disinfection of hard surfaces by mopping** | | | | | |
| Task [5.1] | Negligible | | | nr | yes |
| Task [5.2] | Negligible | | | nr | yes |

For all tasks, the estimated inhalation concentration is considered negligible.

Outcome of qualitative local risk assessment (dermal)

Products from Meta SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2-11are classified Skin corrosive category 1 (H314) and Severe eye damage (H318).

After dilution, products from all Meta SPC are classified Skin irritant (H315) and Eye irritant (H319) except for products from Meta SPC 11 that are classified H314-H318.

All the products are intended to be applied by professionals.

Please refer to the tables below

**Outcome of qualitative local risk assessment –** Handling of concentrated product classified H314 and H318 – Professional users

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant PPE** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Meta SPC 11** | | | | | | | | | | |
| **Very high** | **H314** | **2**  **3**  **4** | Application by mopping  (Task 2)/rinsing | **Skin and eye** | **Frequency:** 1/day to 1/week  **Duration :**  Task 2: no data but potentially high exposure duration expected | Task 2 : Direct dermal contact and potential splashes or spills during dipping of a mop into a bucket  Hand-to-eye transfer | Use of appropriate personal protective equipment:  Hand protection: gloves  Eye protection: goggles  Body protection: Protective clothing  RPE: Substance/task appropriate respirator | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) High hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency  (**↑**) Task 2: potentially high exposure duration |
| **EUH 071** | **inhalation** |
| **Meta SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2-11** | | | | | | | | | | |
| **Very high** | **H314** | **2**  **3**  **4** | Manual or semi-automatic mixing and loading  (Task 1) | **Skin and eye** | **Frequency:** 1/day to 1/week  **Duration :**  Task 1: no data but approximatively 10 min | Task 1 : Direct dermal contact and potential splashes or spills .  Hand-to-eye transfer | Use of appropriate personal protective equipment:  Hand protection: gloves  Eye protection: goggles  Body protection: Protective clothing  RPE: Substance/task appropriate respirator | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) High hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency and exposure duration (few minutes per day) |
| **EUH 071** | **inhalation** |

**Outcome of qualitative local risk assessment –** Handling of diluted product classified H315 and H319 – Professional users

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant PPE** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Meta SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2** | | | | | | | | | | |
| **Low** | **H315** | **2**  **3**  **4** | Application by mopping/rinsing | **Skin** | **Frequency:** 1/day to 1/week  **Duration :**  Task 2: no data but potentially high exposure duration expected | Task 1 : Direct dermal contact and potential splashes or spills during dipping of a mop into a bucket.  Hand-to-eye transfer | Use of appropriate personal protective equipment:  Hand protection: gloves  Eye protection: goggles  Body protection: Protective clothing | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals | **Acceptable** | (**↓**) Low hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low exposure duration  (**↑**) Potentially high exposure frequency |
| **H319** | **eye** |

**Disinfection for hard surfaces by mopping – Primary exposure – Uses #10-11-12-14-15**

**Meta SPC 11:**

During application by mopping (including M&L corresponding to the dilution task), the risk is considered acceptable considering the wear of PPE (gloves, protection coverall and googles).

Due to local effects, pour the product directly on surfaces and mop with a cloth and a handle.

Considering that no exposure to aerosols nor vapour is expected, no respiratory protection is necessary.

**Meta SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2**

During M&L (corresponding to the dilution task) and application by mopping, the risk is considered acceptable considering the wear of PPE (gloves, protection coverall and googles).

Considering that no exposure to aerosols nor vapour (pH > 10) is expected, no respiratory protection is necessary.

***Secondary exposure***

**Scenario [6]: Inhalation exposure of bystanders during spray application indoor and outdoor (use #1-10-11-12-14-15-17-18)**

|  |
| --- |
| **Description of Scenario [6]** |
| Bystanders present during the application by spraying (indoors) can be exposed to aerosols generated by the spray equipment.  Inhalation exposure during M&L phases has been considered negligible (see above).  It is assumed that inhalation exposure of bystanders is equal or of less extend than the exposure of the professional performing the task.  For outdoor application, inhalation exposure of the bystander is considered negligible. |

**Scenario [7]: Dermal contact with wet treated surface (use # 1-8-10-11-12-14-15-17-18)**

|  |
| --- |
| **Description of Scenario [7]** |
| Bystanders re-entering a room freshly treated can touch the treated surfaces.  As a worst-case approach, a direct contact with a treated surface before the rinsing step is assumed.  A qualitative risk assessment has to be performed. |

**Risk characterisation for secondary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

As a worst-case approach, inhalation exposure of bystanders during indoor spray application is considered to be the same than inhalation exposure of the professional performing the task.

In this context, an additional RMM is required for products pertaining to Meta SPC5, 11 and 12 where a RPE is required for professional users.

The following RMM is proposed: “Do not enter the room during the disinfection process”.

Outcome of qualitative local risk assessment (dermal)

After application by wiping, flooding, spraying (indoors or outdoors) and mopping, a direct contact with products remaining on the freshly treated surface is assumed.

* Product from Meta SPC 4-5-12 (RTU products), Meta SPC 11 (diluted products) being classified **H314-H318,** an additional RMM is required in order to avoid any exposure: “Do not enter the room before the treated surfaces are completely dried.”
* Products from Meta SPC 6.21-6.22-7.11-7.12-7.2-9-10.1-10.2-14 (diluted products) being classified **H315-H319,** an additional RMM is required in order to avoid any exposure: “Do not enter the room before the treated surfaces are completely died.” For outdoor spray application, the RMM is as follows: “Do not touch treated surfaces before they are completely dried”.

**Overall conclusion regarding the disinfection of hard surfaces (floors and other than floors) by professional users**

|  |  |  |  |
| --- | --- | --- | --- |
| **Meta SPC** | **Uses (application by)** | **Conclusion** | **PPE and RMM if required** |
| **4** | Wiping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product.  RMM:   * Do not enter the treated area before the treated surfaces are completely dried; * Pour directly the product on surfaces and wipe with a cloth. |
| **5** | Spraying (indoor) | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall, goggles and respiratory equipment during the application of the product.  RMM:   * Do not be present in the treatment area during the disinfection process. If necessary to be present, wear the same PPE/RPE than the applicator of the products. * Do not enter the treated area before the treated surfaces are completely dried |
| **6.21** | Wiping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried. |
| Mopping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling of the product (M&L corresponding to the dilution phase and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried. |
| **6.22** | Wiping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried. |
| Mopping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling of the product (M&L corresponding to the dilution phase and application).  RMM:  - Do not enter the room before the treated surfaces are completely dried. |
| **7.11** | Wiping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried. |
| Mopping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling of the product (M&L corresponding to the dilution phase and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried.  - |
| **7.12** | Wiping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried. |
| Mopping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling of the product (M&L corresponding to the dilution phase and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried. |
| **7.2** | Wiping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried. |
| Mopping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling of the product (M&L corresponding to the dilution phase and application).  RMM:  - Do not enter the room before the treated surfaces are completely dried. |
| **10.1** | Wiping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried. |
| Flooding | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried. |
| Mopping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling of the product (M&L corresponding to the dilution phase and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried. |
| **10.2** | Wiping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried. |
| Flooding | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried. |
| Mopping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling of the product (M&L corresponding to the dilution phase and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried. |
| **11** | Wiping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried. |
| Flooding | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling phase of the product (M&L and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried.  - Pour the product directly on surfaces and wipe with a cloth. |
| Spraying (indoor) | **Unacceptable** | None |
| Mopping | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the handling of the product (M&L corresponding to the dilution phase and application).  RMM:  - Do not enter the treated area before the treated surfaces are completely dried.  - Pour the product directly on surfaces and mop using a cloth and a handle. |
| **12** | Spraying (indoor) | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall, goggles and RPE with APF at minima 4 during the application of the product.  RMM:   * The spray application must be performed downward in order to avoid exposure. * Do not be present in the treatment area during the disinfection process. If necessary to be present, wear the same PPE/RPE than the applicator of the products. * Do not enter the treated area before the treated surfaces are completely dried |
| **14** | Spraying (outdoor) | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information during), a protective coverall and goggles during the mixing and loading phase (corresponding to the dilution phase) and the application of the product.  RMM:   * The spray application must be performed downward in order to avoid exposure. * Do not touch the treated surfaces before they are completely dried. * Do not be present in the treatment area during the disinfection process. If necessary to be present, wear the same PPE/RPE than the applicator of the product. |

**NON-PROFESSIONALS USERS**

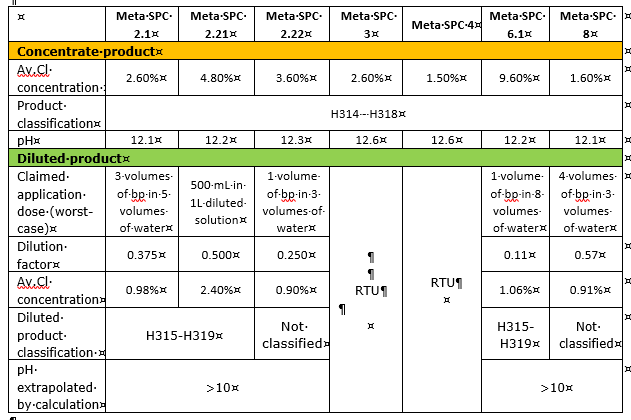
**Summary table: List of exposure scenarios**

Hard surface disinfection (floors and other than floors)

|  |  |  |
| --- | --- | --- |
| **Summary table: exposure scenarios** | | |
| **Scenario and task number** | **Description of scenario and tasks** | **Exposed group** |
| **Use#8**  **Use#9**  **Use#16**  **Use#17**  **Use#19**  **Use#20** | **Disinfection of surfaces (other than floors) by wiping with cloth and bucket**  **Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket**  **Disinfection of companion animal housing and associated equipment**  **Disinfection of surfaces by spraying with trigger spray**  **Algaecide and fungicide for outdoor surfaces**  **Algaecide and fungicide for outdoor surfaces by spraying** |  |
| **Primary exposure** | | |
| **Scenario [1]** | ***Disinfection of hard surfaces by wiping*** *(use #8-9-16)* | |
| Task [1.1] | *Manual mixing and loading* | Non-professionals |
| Task [1.2] | *Application and rinsing of treated surfaces* | Non-professionals |
| **Scenario [2]** | ***Disinfection of hard surfaces with a trigger spray*** *(use #17)* | |
| Task [2.2] | *Application with a trigger spray and rinsing of treated surfaces* | Non-professionals |
| **Scenario [3]** | ***Disinfection of hard surfaces by spraying outdoors*** *(use #19-20)* | |
| Task [3.1] | *Manual mixing and loading* | Non-professionals |
| Task [3.2] | *Application a pre-pressurised aerosol spray can and rinsing of treated surfaces* | Non-professionals |
| Task [3.4] | *Cleaning of spray equipment* | Non-professionals |
| **Scenario [4]** | ***Disinfection by mopping*** *(use #7)* | |
| Task [1.1] | *Mixing and loading (manual)* | Non-professionals |
| Task [1.2] | *Application and rinsing of treated surfaces* | Non-professionals |
| **Secondary exposure** | | |
| **Scenario 5** | ***Inhalation exposure of bystander during application*** *(use #17-19-20)* | General public |
| **Scenario 6** | ***Dermal contact with wet treated surface*** *(use #8-9-16-17-19-20)* | General public |

***Primary exposure***

**Scenario [1] – Disinfection of hard surfaces by wiping (use # 8-9-16)**



Products from Meta-SPC 2.1-2.21-2.22-3-4-6.1-8 can be used for the disinfection of hard surfaces by wiping.

Products from Meta SPC 3 and 4 are RTU products whereas products from other Meta SPCs have to be diluted before application.

The range of concentration of active chlorine in the concentrated products is 1.5-4.8% and 0.9-2.4% in the in-use dilution.

The classifications of the in-use diluted products have been set according to the calculation rules laid down in the CLP regulation 1272/2008. For details please refer to the Excel data sheet “Classification\_In-use dilution\_PRO” in the confidential PAR.

Packaging sizes are between 120 mL and 20L.

The products are applied on hard surfaces (other than floors) by wiping at an application rate of 100 mL/m2.

For this exposure scenario; 2 tasks of primary exposure have been considered:

* **Task [1.1]:** Manual mixing and loading;
* **Task [1.2]:** Application by wiping and rinsing of treated surfaces.

**Task [1.1]: Manual mixing and loading**

|  |
| --- |
| **Description of Task [1.1] – Manual mixing and loading** |
| Products from meta-SPC 2.1-2.21-2.22-6.1-8 have to be diluted in water before application by wiping on hard surfaces.  Considering the packaging sizes, mixing and loading is assumed to be performed manually.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible, thepH value for the concentrated products being > 10 for all the meta-SPC.  Exposure during M&L is included in the exposure model used for the application (see task [1.2] below).  *Dermal route*  The concentrated products being classified H314-H318, a qualitative risk assessment is performed. |

***Calculations for Task [1.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from non-professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.1] | 1/ No PPE | negligible | - |

**Task [1.2]: Application by wiping and rinsing of treated surfaces**

|  |
| --- |
| **Description of Task [1.2] – Application by wiping and rinsing of treated surfaces** |
| After dilution (except for Meta SPC 3 & 4 = RTU), products can be applied on hard surfaces by wiping using a cloth. After the claimed contact time, the treated surfaces are rinsed off.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible.  The pH value extrapolated by calculation for the diluted products and the pH of products from Meta SPC 3&4 (RTU) are > 10.  Exposure to aerosols should be assessed using the ***Surface Disinfection Model 1*** from BHHEM, with an exposure value of 22.2 mg/m3.  However, according to HEEG Opinion 8 “Defaults and appropriate models to assess human exposure for dipping processes (PT 8)”, the Dipping model 1 (p.26 of User guidance and p.308 of BHHEM) is appropriate to assess exposure during manual dipping.  In this model, no inhalation exposure is expected during the task consisting in the dipping of wooden articles in open tanks.  It is assumed that the inhalation exposure during the dipping of wooden articles is similar to the exposure during the dipping of a mop or a cloth in a bucket.  Therefore, exposure to aerosols during wiping activities (including the dipping of a mop into a bucket) is considered negligible.  After application on surfaces, the active substance is expected to quickly react with the organic matter during the claimed contact time.  Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order.  Considering this, exposure through inhalation to vapours (HClO) during this task is considered negligible.  *Dermal route*  Products from meta SPC 2.1-2.21--6.1 being classified H315-H319 and the RTU products from Meta SPC 3&4 being classified H314-H318, a qualitative risk assessment is performed.  Diluted products from Meta SPC 2.22 and 8 are not classified.  Exposure during the rinsing step is considered similar than exposure during application. |

***Calculations for Task [2.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from non-professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [2.1] | 1/ No PPE | negligible | - |

**Combined exposure**

Not relevant.

**Risk characterisation for primary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| **Scenario 1: Disinfection of hard surfaces by wiping** | | | | | |
| Task [1.1] | Negligible | | | nr | yes |
| Task [1.2] | Negligible | | | nr | yes |

The estimated inhalation concentration is considered negligible.

Outcome of qualitative local risk assessment (dermal)

The products from Meta SPC 2.1-2.21-2.22-3-4-6.1-8are classified Skin corrosive category 1 (H314) and Severe eye damage (H318).

Diluted products from Meta SPC 2.1-2.21-6.1 are classified Skin irritant (H315) and Eye irritant (H319). Diluted products from Meta SPC 2.22 and 8 are not classified.

All the products are intended to be applied by non-professionals.

Please refer to the tables below:

**Outcome of qualitative local risk assessment –** Handling of concentrated product classified H314 and H318 – Non Professional users

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Meta SPC 2.1 – 2.21 – 2.22 – 6.1 - 8** | | | | | | | | | |
| **Very high** | **H314** | **2**  **3**  **4** | Manual mixing and loading  (Task 1) | **Skin and eye** | **Frequency:** 2/day to 2/week  **Duration :**  no data but approximatively 10 min | Direct dermal contact and potential splashes or spills  Hand-to-eye transfer | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals | **Unacceptable** | (**↓**) Potentially low exposure duration    (**↑**) High frequency  (**↑**) High hazard category  (**↑**) Absence of a protection offered by a cap with directional nozzle on the bottle to pour the product  (**↑**) No child-proof closure |
| **EUH 071** | **inhalation** |
| **Meta SPC 3 & 4 (RTU)** | | | | | | | | | |
| **Very high** | **H314** | **2**  **3**  **4** | Application by wiping (task 2)/rinsing | **Skin and eye** | **Frequency:** 1/week (Meta SPC 6)  1/day (Meta SPC 7)  **Duration :**  no data but high duration expected | Direct dermal contact and potential splashes or spills during dipping of a cloth into a bucket.  Hand-to-eye transfer | Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  Instructions for use minimizing exposure for professionals | **Unacceptable** | (**↑**) High hazard category  (**↑**) High frequency for Meta SPC 7    (**↑**) Potentially high exposure duration for task 2  (**↑**) Absence of a protection offered by a cap with directional nozzle on the bottle to pour the product  (**↑**) No child-proof closure |

**Outcome of qualitative local risk assessment –** Handling of diluted product classified H315 and H319 – Non Professional users

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Meta SPC 2.1 – 2.21 – 6.1** | | | | | | | | | |
| **Low** | **H315** | **2**  **3**  **4** | Application by wiping (task 2)/rinsing | **Skin** | **Frequency:** 2/day to 2/week  **Duration :**  no data but high duration expected | Direct dermal contact and potential splashes or spills during dipping of a cloth into a bucket.  Hand-to-eye transfer | Wash hands after application  Avoid contact with eyes | **Acceptable** | (**↓**) Low hazard category  (**↓**) RMM to avoid dermal and ocular long term exposure  (**↑**) Potentially high exposure duration and frequency |
| **H319** | **eye** |

**Disinfection for hard surfaces by wiping – Primary exposure – Uses # 8-9-16**

**Meta SPC 2.1 – 2.21 – 2.22 –5 – 6.1 - 8**

Products are classified corrosive to skin (H314) and severe eye damage (H318).

They have to be diluted in water before use.

No specific device (specific packaging, closure…) being available in order to drastically reduce exposure during the dilution task, the risk is considered unacceptable for non-professional users.

**Meta SPC 3 – 4**

Products from Meta SPC 3&4 are RTU product classified H314 and H318.

No dilution is necessary, however, the application task requires direct dermal contact with the product through the cloth used for wiping. The risk is therefore considered unacceptable for non-professional users.

**Scenario [2] – Disinfection of hard surfaces with a trigger spray (use #17)**

|  |  |
| --- | --- |
|  | **Meta SPC 5** |
| **RTU** | |
| Av.Cl concentration | 1.50% |
| Product classification | H314 - H318 |
| pH | 12.8 |

RTU products from Meta-SPC 5 can be used for the disinfection of hard surfaces by spraying indoors using a trigger spray.

The concentration of active chlorine in the products is 1.5%.

Packaging size is between 500 mL and 750 mL.

The products are applied at an application rate of 100 mL/m2.

For this exposure scenario, 1 task of primary exposure has been considered:

* Task [2.1]: Application by spraying with a trigger spray and rinsing of treated surfaces.

**Task [2.1]: Application with a trigger spray and rinsing of treated surfaces**

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [2.1]** | | | |
| RTU products from meta SPC 5 can be applied on hard surfaces by spraying using a trigger spray.  After the claimed contact time, the treated surfaces are rinsed off.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible since the pH of the RTU products is > 10.  To assess inhalation exposure to aerosols generated by the trigger spray, the ***Consumer product spraying and dusting model 2 – (Hand-held trigger spray)*** from BHHEM, 2015 (p.344) is used.  The exposure value from the model is:   * 10.5 mg/m3 (inhalation)   Density products from Meta SPC 5 has been considered in the exposure calculation.  After application on surfaces, the active substance is expected to quickly react with the organic matter during the claimed contact time.  Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order.  Considering this, exposure through inhalation to vapours during this task is considered negligible.  *Dermal route*  Products pertaining to meta SPC 5 being classified H314-H318, a qualitative risk assessment is performed.  Exposure during the rinsing step is considered similar than exposure during application. | | | |
| **Input parameters for Scenario [2.1]** | | | |
| **Tier** | **Parameters** | **Value** | **Reference and**  **justification** |
| Tier 1 | Concentration of active chlorine  (% w/w) in meta SPC 5 | 1.5% | Applicant’s data |
| Inhalation exposure (**aerosols**) – (mg/m3) | 10.5 | Consumer product spraying and dusting model 2 – Handheld trigger spray (BHHEM, 2015) |
| Density (g/cm3) | 1.028 | Applicant’s data |

***Calculations for Task [2.1]***

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure concentration from non-professional uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [2.1] | 1/ No PPE | 0.16 |

**Combined exposure**

Not relevant.

**Risk characterisation for primary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| **Scenario 2 – Disinfection of hard surfaces with a trigger spray** | | | | | |
| Task [2.1] | 1 | 0.5 | 0.16 | 32 | yes |

Outcome of qualitative local risk assessment (dermal)

The RTU products from Meta SPC 5are classified Skin corrosive category 1 (H314) and Severe eye damage (H318). All the products are intended to be applied by non-professionals.

Please refer to the tables below:

**Outcome of qualitative local risk assessment –** RTU products from meta SPC **5** classified H314/H318 used by non-professionals

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Meta SPC 5** | | | | | | | | | |
| **Very high** | **H314** | **2** | Application with trigger spray/rinsing | **Skin and eye** | **Frequency:** up to 1/day  **Duration :**  no data but high duration expected | Direct dermal contact with treated surfaces  Deposit of aerosols on skin and eye  Hand-to-eye transfer | none | **Unacceptable** | (**↑**) High hazard category  (**↑**) Potentially high exposure duration and high frequency  (**↑**) No child-proof closure  (**↑**) Spray application |
| **EUH 071** | **inhalation** |

**Disinfection for indoor hard surfaces by spraying – Primary exposure - Uses #17**

**Meta SPC 5**

Products from Meta SPC 5 are RTU product classified H314 and H318.

No dilution is necessary, however, exposure to skin, eye and respiratory through aerosols formation is expected. The risk is therefore considered unacceptable for non-professional users.

**Scenario [3] – Disinfection of hard surfaces by spraying outdoors (use #19-20)**

|  |  |
| --- | --- |
|  | **Meta SPC 14** |
| **Concentrate product** | |
| Av.Cl concentration | 9.60% |
| Product classification | H314 - H318 |
| pH | 12.8 |
| **Diluted product** | |
| Claimed application dose (worst-case) | Mixing of 4L gel and 1 L of bp |
| Dilution factor | n.a |
| Av.Cl concentration | 1.96% |
| Diluted product classification | H315-H319 |
| pH | >10 |

Products from Meta-SPC 14 can be used for the disinfection of outdoor surfaces by spraying. The biocidal product containing the active substance has to be mixed up within 4L of gel SETS containing co-formulants only.

Packaging size is 1L for products of Meta SPC 14.

The concentration of active chlorine in the concentrated products is 9.6% and 1.96 in the in-use dilution.

The classifications of the in-use diluted products have been set according to the calculation rules laid down in the CLP regulation 1272/2008. For details please refer to the Excel data sheet “Classification\_In-use dilution\_PRO” in the confidential PAR.

The products are applied at an application rate of 5L/100 m2.

For this exposure scenario, 2 tasksof primary exposure have been considered:

* **Task [3.1]:** Mixing and loading (manual);
* **Task [3.2]:** Application by spraying with a pre-pressurised aerosol spray can: dermal and inhalation exposure to aerosols is expected.

**Task [3.1]: Mixing and loading**

|  |
| --- |
| **Description of Task [3.1] – Mixing and Loading** |
| Products from 14 are mixed up with a 4L gel of SETS.  Considering the packaging size, this task is assumed to be done manually.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible since pH for the concentrated products is > 10 for all meta-SPC.  Exposure to aerosols is also considered negligible for manual loading due to the small quantities manipulated.  *Dermal route*  Products are classified H314-H318, a qualitative risk assessment is performed. |

***Calculations for Task [3.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from non-professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [3.1] | 1/ No PPE | negligible | - |

**Task [3.2]: Application a pre-pressurised aerosol spray can and rinsing of treated surfaces**

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [3.2]** | | | |
| After dilution or mixing up, products can be applied on outdoor surfaces by spraying using a pre-pressurised aerosol spray can.  After the claimed contact time, the treated surfaces are rinsed off.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible.  The pH value extrapolated by calculation for the in-use products is > 10.  To assess inhalation exposure to aerosols, the **Consumer product spraying and dusting model 2 – (pre-pressurised aerosol spray can)** from BHHEM, 2015 (p.344) is used..  The exposure value from the model is:   * 35.9 mg/m3 (inhalation)   Density of the diluted products has been considered to be close to 1 g/cm3 because of the water provided by the dilution mixing with SETS (Meta SPC 14).  After application on surfaces, the active substance is expected to quickly react with the organic matter during the claimed contact time.  Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order.  Considering this, exposure through inhalation to vapours during this task is considered negligible.  *Dermal route*  Products of meta SPC 14 are classified H315-H319, a qualitative risk assessment is performed.  Exposure during the rinsing step is considered similar than exposure during application. | | | |
| **Input parameters for Scenario [3.2]** | | | |
| **Tier** | **Parameters** | **Value** | **Reference and**  **justification** |
| Tier 1 | Concentration of active chlorine  (% w/w) in meta SPC 14 | 1.96-2.4% | Applicant’s data |
| Inhalation exposure (**aerosols**) – (mg/m3) | 35.9 | Consumer product spraying and dusting model 2 – (pre-pressurised aerosol spray can) – (BHHEM, 2015) |

***Calculations for Task [3.2]***

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure concentration from non-professional uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [3.2] | 1/ No PPE | **Meta SPC 14:** 0.86 |

**Task [3.3]: Manual cleaning of the spray equipment**

|  |
| --- |
| **Description of Task [3.3] – Manual cleaning of spray equipment** |
| After application, the spray equipment is assumed to be cleaned with water.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible.  Considering the type of manipulation performed, no inhalation exposure to aerosols is expected.  *Dermal route*  For dermal route, the use of water to clean the spray equipment leads to an additional dilution of the product. Therefore, the generated diluted solution after cleaning is expected to be not classified and a qualitative risk assessment is not required. |

**Combined exposure**

Not relevant.

**Risk characterisation for primary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| **Scenario 3: Disinfection of hard surfaces by spraying outdoors** | | | | | |
| Task [3.1] | Negligible | | | nr | Yes |
| Task [3.2] | **Meta SPC 14:** 0.86 | | | 172 | No |
| Task [3.3] | Negligible | | | nr | Yes |

Outcome of qualitative local risk assessment (dermal)

The products from 14are classified Skin corrosive category 1 (H314) and Severe eye damage (H318).

In-use products are classified Skin irritant (H315) and Eye irritant (H319).

All the products are intended to be applied by non-professionals.

Please refer to the table below:

**Outcome of qualitative local risk assessment -** Products from meta SPC **14** used by non-professionals

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Handling products classified H314-H318** | | | | | | | | | |
| **Very high** | **H314** | **2** | Manual M&L | **Skin and eye** | **Frequency:** Max 1 every 3 months  **Duration :** no data but 10 min expected | Direct dermal contact and potential splashes or spills  Hand-to-eye transfer | Labelling:  - Labelling according to CLP | **Unacceptable** | (**↑**) High hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency and exposure duration |
| **EUH 071** | **inhalation** |
| **Handling product classified H315-H319** | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Low** | **H315** | **2** | Application by spraying outdoors with a pre-pressurised aerosol spray can | **Skin** | **Frequency:** Max 1 every 3 months  **Duration :** no data but high exposure duration expected | Direct dermal contact and potential deposit of aerosols on skin and eye  Hand-to-eye transfer | Labelling:  - Labelling according to CLP | **Unacceptable** | (**↑**) Potentially high exposure duration  (**↓**) Low hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency |
| **H319** | **eye** |

**Disinfection for outdoor hard surfaces by spraying – Primary exposure - Uses #19 - 20**

**Meta SPC 14**

Products from Meta SPC 14 classified H314 and H318 have to be mixed up in water or gel before use.

No specific device (specific packaging, closure…) being available in order to drastically reduce exposure during the dilution task, the risk is considered unacceptable for non-professional users.

**Scenario [4] – Disinfection of floors by mopping (Use #7)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Meta SPC 2.1** | **Meta SPC 2.21** | **Meta SPC 2.22** | **Meta SPC 6.1** | **Meta SPC 8** |
| **Concentrate product** | | | | | |
| Av.Cl concentration | 2.60% | 4.80% | 3.60% | 9.60% | 1.60% |
| Product classification | H314 - H318 | | | | |
| pH | 12.1 | 12.2 | 12.3 | 12.2 | 12.1 |
| **Diluted product** | | | | | |
| Claimed application dose (worst-case) | 3 volumes of bp into 7 volumes of water | 50/50 dilution | 2 volumes of bp into 7 volumes of water | 1 volumes of bp into 11 volumes of water | 1 volume of bp into 1 volumes of water |
| Dilution factor | 0.3 | 0.5 | 0.22 | 0.09 | 0.5 |
| Av.Cl concentration | 0.78% | 2.40% | 0.79% | 0.86% | 0.80% |
| Diluted product classification | Not classified | H315-H319 | Not classified | | |
| pH | >10 | | | | |

Products from Meta-SPC 2.1-2.21-2.22-6.1-8 can be applied for the disinfection of floors by mopping. All products are diluted before application.

The range of concentration of active chlorine in the concentrate products is 1.6-9.6% and 0.78-2.4% in the in-use dilution.

The classifications of the in-use diluted products have been set according to the calculation rules laid down in the CLP regulation 1272/2008. For details please refer to the Excel data sheet “Classification\_In-use dilution\_PRO” in the confidential PAR.

Packaging size is between 120 mL and 20L.

The products are applied at an application rate of 100 mL/m2.

For this exposure scenario, 2 tasks of primary exposure are considered:

* Task [4.1]: Manual mixing and loading
* Task [4.2]: Application by mopping and rinsing of treated surfaces

**Task [1.1]: Manual mixing and loading**

|  |
| --- |
| **Description of Task [1.1] – Manual mixing and Loading** |
| Products from all meta-SPC have to be diluted in water before application by mopping on floors. Considering the packaging size, this task is assumed to be done manually.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible since pH for the concentrated products is > 10 for all the meta-SPC.  Exposure to aerosols is also considered negligible for manual loading due to the small quantities manipulated.  *Dermal route*  Products are classified H314-H318, a qualitative risk assessment is performed. |

***Calculations for Task [1.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from non-professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.1] | 1/ No PPE | negligible | - |

**Task [1.2]: Application by mopping and rinsing of treated surfaces**

|  |
| --- |
| **Description of Task [1.2] – Application by mopping and rinsing of treated surfaces** |
| After dilution, products are applied on floors using a mop and a bucket.  After the claimed contact time, the treated surfaces are rinsed off.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible.  The pH value extrapolated by calculation for the diluted products is > 10.  Exposure to aerosols should be assessed using the Surface Disinfection Model 1 from BHHEM, with an exposure value of 22.2 mg/m3.  However, according to HEEG Opinion 8 “Defaults and appropriate models to assess human exposure for dipping processes (PT 8)”, the Dipping model 1 (p.26 of User guidance and p.308 of BHHEM) is appropriate to assess exposure during manual dipping.  In this model, no inhalation exposure is expected during the task consisting in the dipping of wooden articles in open tanks.  It is assumed that the inhalation exposure during the dipping of wooden articles is similar to the exposure during the dipping of a mop in a bucket.  Therefore, exposure to aerosols during mopping activities (including the dipping of a mop into a bucket) is considered negligible.  After application on surfaces, the active substance is expected to quickly react with the organic matter during the claimed contact time.  Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order.  Considering this, exposure through inhalation to vapours (HClO) during this task is considered negligible.  *Dermal route*  Products from meta SPC 2.1-2.21-2.22-6.1-8 are classified H315-H319, a qualitative risk assessment is performed.  Exposure during the rinsing step is considered similar than exposure during application. |

***Calculations for Task [2.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from non-professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [2.1] | 1/ No PPE | negligible | - |

**Combined exposure**

Not relevant.

**Risk characterisation for primary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| **Scenario 1: Disinfection of hard surfaces by mopping** | | | | | |
| Task [1.1] | Negligible | | | nr | yes |
| Task [1.2] | Negligible | | | nr | yes |

Outcome of qualitative local risk assessment (dermal)

The products from Meta SPC 2.1-2.21-2.22-6.1-8 are classified Skin corrosive category 1 (H314) and Severe eye damage (H318).

After dilution, no classification is required for products pertaining to all Meta SPC except for Meta SPC 2.21 where classification Skin irritant (H315) and Eye irritant (H319) is required.

All the products are intended to be applied by non-professionals.

Please refer to the table below:

**Outcome of qualitative local risk assessment –** Handling of concentrated product classified H314 and H318 – Professional users

|  |  |  |
| --- | --- | --- |
| **Hazard** | **Exposure information** | **Risk** |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |

|  |
| --- |
| **Meta SPC 2.1-2.21-2.22-6.1-8** |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Very high** | **H314** | **2**  **3**  **4** | Manual mixing and loading  (Task 1) | **Skin and eye** | **Frequency:** 2/day to 1/week  **Duration :**  Task 1: no data but approximatively 10 min | Direct dermal contact and potential splashes or spills .  Hand-to-eye transfer | Labelling:  - Labelling according to CLP | **Unacceptable** | (**↑**) High hazard category  (**↑**) High  frequency (up to 2/day)  (**↑**) Absence of a protection offered by a cap with directional nozzle on the bottle to pour the product  (**↑**) No child-proof closure (excepted for meta SPC 9)  (**↓**) Low exposure duration (few minutes per day) |
| **EUH 071** | **inhalation** |

**Outcome of qualitative local risk assessment –** Handling of diluted product classified H315 and H319 – Professional users

|  |  |  |
| --- | --- | --- |
| **Hazard** | **Exposure information** | **Risk** |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |

|  |
| --- |
| **Meta SPC 2.21** |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Low** | **H315** | **2** | Application by mopping  (task 2)/rinsing | **Skin** | **Frequency:** 1/week up to 2/day  **Duration :**  Task 2: no data but potentially high exposure duration expected | Direct dermal contact and potential splashes or spills during dipping of a mop into a bucket.  Hand-to-eye transfer | Labelling:  - Labelling according to CLP | **Acceptable** | (**↓**) Low hazard  (**↑**) High frequency and potentially high exposure duration |
| **H319** | **eye** |

**Disinfection for hard surfaces by mopping – Primary exposure – Uses #7**

**Meta SPC 2.1-2.21-2.22-6.1-8**

Products from all Meta SPC classified H314 and H318 have to be diluted in water before use.

No specific device (specific packaging, closure…) being available in order to drastically reduce exposure during the dilution task, the risk is considered unacceptable for non-professional users.

***Secondary exposure***

**Scenario [5]: Inhalation exposure of bystanders during spray application (use #17-19-20)**

|  |
| --- |
| **Description of Scenario [5]** |
| Bystander present during the application by spraying indoors can be exposed to aerosols generated by the spray equipment.  It is assumed that inhalation exposure of bystanders is equal or of less extend than the exposure of the professional performing the task.  For spraying outdoors, inhalation exposure of the professional bystander is considered negligible. |

**Scenario [6]: Dermal contact with wet treated surface (use #8-9-16-17-19-20)**

|  |
| --- |
| **Description of Scenario [6]** |
| Bystanders re-entering a room freshly treated can touch the treated surfaces.  As a worst-case approach, a direct contact with a treated surface before the rinsing step is assumed.  A qualitative risk assessment has to be performed. |

**Risk characterisation for secondary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

As a worst-case approach, inhalation exposure of bystanders during indoor spray application is considered to be the same than inhalation exposure of the professional performing the task. An additional RMM is therefore necessary for product from Meta SPC 5: “Do not enter the room during the disinfection process”.

However, no acceptable risk has been identified for non-professional users, therefore no secondary exposure is expected.

Outcome of qualitative local risk assessment (dermal)

After application by wiping, spraying (indoors or outdoors) and mopping, a direct contact with products remaining on the freshly treated surfaces is assumed.

* For products from Meta SPC 2.21-14 (diluted products) being classified **H315-H319** and products from Meta SPC 3-4-5 being classified **H314-H318,** an additional RMM is required in order to avoid any exposure: “Do not enter the room before the treated surfaces are completely dried”. For outdoor spray application, the RMM is as follows: “Do not touch treated surfaces before they are completely dried”.
* For products from Meta SPC 2.1-2.22-6.1-8 (diluted products) being not classified, no additional RMM is required.

However, no acceptable risk has been identified for non-professional users, therefore no secondary exposure is expected.

**Overall conclusion regarding the disinfection of hard surfaces (floors and other than floors) by non-professional users**

|  |  |  |  |
| --- | --- | --- | --- |
| **Meta SPC** | **Uses (application by)** | **Acceptability of the use** | **RMM if required** |
| **2.1** | Wiping | **Unacceptable** | None |
| Mopping | **Unacceptable** | None |
| **2.21** | Wiping | **Unacceptable** | Do not enter the room before the treated surfaces are completely dried. |
| Mopping | **Unacceptable** | Do not enter the room before the treated surfaces are completely dried. |
| **2.22** | Wiping | **Unacceptable** | None |
| Mopping | **Unacceptable** | None |
| **3** | Wiping | **Unacceptable** | Do not enter the room before the treated surfaces are completely dried. |
| **4** | Wiping | **Unacceptable** | Do not enter the room before the treated surfaces are completely dried. |
| **5** | Spraying indoor | **Unacceptable** | Do not enter the room during the disinfection process |
| **6.1** | Wiping | **Unacceptable** | None |
| Mopping | **Unacceptable** | None |
| **8** | Wiping | **Unacceptable** | None |
| Mopping | **Unacceptable** | None |
| **14** | Spraying outdoor | **Unacceptable** | Do not touch treated surfaces before they are completely dried |

|  |
| --- |
| **Swimming Pool Disinfection** |

In this section, the uses belonging to group 1 identified above have been assessed; *i.e* swimming pool/footbaths disinfection.

The assessment has been split in three parts:

* First part: exposure assessment for Professional users followed by a risk characterization;
* Second part: exposure assessment for Non-Professional users followed by a risk characterization;
* Third part: exposure assessment for general public followed by a risk characterization

**PROFESSIONALS USERS**

**Summary table: List of exposure scenarios**

|  |  |  |
| --- | --- | --- |
| **Summary table: exposure scenarios** | | |
| **Scenario and task number** | **Description of scenario and tasks** | **Exposed group** |

|  |  |  |
| --- | --- | --- |
| **Use#4**  **Use#5**  **Use#6** | **Disinfection of public and private swimming pools**  **Shock disinfection of public and private swimming pools**  **Disinfection of footbaths in public and private swimming pools** |  |

|  |  |  |
| --- | --- | --- |
| **Primary exposure** | | |
| **Scenario [1]** | ***Disinfection of swimming pool/footbaths by direct pouring on water or by automated dosing system*** | |
| Task [1.1] | *Pouring in the tank connected with the automated dosing system* | Professionals |
| Task [1.2] | *Application* | Professionals |
| Task [1.3] | *Post-application – Maintenance/cleaning of dosing system* | Professionals |
| **Secondary exposure** | | |
| **Scenario [2]** | ***Inhalation exposure of the swimming instructor*** | General public (swimming instructor) |
| **Scenario [3]** | ***Secondary exposure of children and adults during swimming*** | General public (adults, children) |
| **Scenario [4]** | ***Secondary exposure of infants during swimming*** | General public (infants) |

***Primary exposure***

**Scenario [1] – Disinfection of swimming pool/footbaths by direct pouring on water or by automated dosing system (use #4-5-6)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Meta SPC 1.2** | | |
| **Concentrated product** | | | |
| av.Cl concentration | 12.5% | | |
| Product classification | H314-H318 | | |
| pH | 12.1 | | |
| **Diluted product** | | | |
| Claimed application dose | **Shock disinfection of public and private swimming pool (use #5)** | **Continuous flow disinfection in public and private swimming pool (use #4)** | **Footbaths in public and private swimming pools (use #6)** |
| 50 mg av.Cl/L | 3 mg av.Cl/L | 5 mg av.Cl/L |
| Dilution factor | 0.004 | 0.00024 | 0.0004 |
| av.Cl concentration | 0.05% | 0.003% | 0.005% |
| Product classification | Not classified | | |
| Expected pH | 7.2-7.6 | | |

Products from Meta-SPC 1.2 can be used for the disinfection of swimming pool/footbaths by direct pouring in the swimming water or by automated dosing system.

These products are diluted to reach an in-use concentration of 0.003-0.05% active chlorine in swimming water, the application rate depending on the type of disinfection, *i.*e shock or continuous; and the type of water to be treated (swimming water or footbaths).

The concentration of active chlorine in the concentrated products is 12.5% and maximum 0.05% in the in-use dilution.

The classifications of the in-use diluted products have been set according to the calculation rules laid down in the CLP regulation 1272/2008. For details please refer to the Excel data sheet “Classification\_In-use dilution\_PRO” in the confidential PAR.

Packaging sizes are as follows:

* between 10 L and 20L

For this exposure scenario, 3 tasks have been considered:

* **Task [1.1]:** Pouring in the tank connected with the automated dosing system;
* **Task [1.2]:** Automated application or direct application on water by pouring;
* **Task [1.3]:** Post-Application: Maintenance/cleaning of dosing system.

**Task [1.1]: Pouring in the tank connected with the automated dosing system**

|  |
| --- |
| **Description of Task [1.1] – Pouring in the tank connected with the automated dosing system** |
| In case of automated application, products from meta-SPC 1.2 are manually poured by professional users in the tank connected with the automated dosing system.  *Inhalation route*  The available pH value of the concentrated products is > 10, exposure by inhalation to vapors of HClO is therefore considered negligible.  Inhalation exposure to generated aerosols is also considered negligible due to the small quantities manipulated.  *Dermal route*  Products being classified H314-H318, a qualitative risk assessment is performed. |

***Calculations for Task [1.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.1] | 1/ No PPE | negligible | - |

**Task [1.2]: Application**

|  |
| --- |
| **Description of Task [1.2] – Application** |
| The disinfection process (application) is an automated process taking place in a closed system or is done manually by direct pouring on water.  During automated process, exposure is considered negligible.  During manual process (direct pouring into water), potential exposure is considered similar to the exposure assessment performed for the scenario “pouring in the tank connected with the automated dosing system” (see task [1.1]):   * Inhalation exposure is considered negligible; * Dermal exposure is assessed with a qualitative RA. |

***Calculations for Task [1.2]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.2 ] | 1/ No PPE | negligible | - |

**Task [1.3]: Post-application – Maintenance/cleaning of dosing system**

|  |
| --- |
| **Description of Task [1.3] – Post-application – Maintenance/cleaning of dosing system** |
| Professionals exposure to the concentrated product may occur during maintenance/cleaning of dosing pumps.  *Inhalation route*  The available pH value of the concentrated products is > 10, exposure by inhalation to vapors of HClO is therefore considered negligible.  Aerosols may be generated through the pressure present in the dosing pumps; inhalation exposure to aerosols is therefore expected. This potential inhalation exposure is assessed usingh the **Mixing and loading model 7 (manual liquid)** from BHHEM (p.277).  The exposure value from the model is as follows:  - 0.94 mg/m3 (inhalation)  *Dermal route*  Products being classified H314-H318, a qualitative risk assessment is performed. |

***Calculations for Task [1.3]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.3] | 1/ No PPE | 0.12 | - |

**Combined exposure**

Not relevant.

**Risk characterisation for primary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| **Scenario 1: Disinfection of swimming pool/footbaths by direct pouring on water or by automated dosing system** | | | | | |
| Task [1.1] | Negligible | | | nr | Yes |
| Task [1.2] | Negligible | | | nr | Yes |
| Task [1.3] | 1/no PPE | 0.5 | 0.12 | 24 | Yes |

Outcome of qualitative local risk assessment (dermal)

Products pertaining to Meta SPC 1.2are classified Skin corrosive category 1 (H314) and Severe eye damage (H318). Diluted products (corresponding to the treated swimming water) are not classified.

All the products are intended to be applied by professionals.

Please refer to the tables below:

**Outcome of qualitative local risk assessment – Concentrated** products of meta SPC **1.2** classified H314/H318 used by professionals

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant PPE** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Very high** | **H314** | **2** | Task 1:  Direct pouring of the rpoduct (in teh dosing system or water)  Task 2:  Post application – Maintenance/cleaning of dosing pumps | **Skin and eye** | **Frequency:**  Task 1-2: Rarely for shock application (use #5)  No data for continuous disinfection in swimming pools and footbaths (use #4-6)  **Duration :**  Task 1: no data but 10 min expected  Task 2: no data but potentially high duration | Direct dermal contact and potential splashes or spills  Hand-to-eye transfer | Gloves  Skin coverage  Eye protection  Optional face shield  RPE: Substance/task appropriate respirator | * Labelling:   Labelling according to CLP   * Professionals:   Professional workers  Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) High hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↑**) Potentially high frequency for continuous disinfection  (**↑**) Potentially high exposure duration for task 2 (more than few minutes per day) |
| **EUH071** | **Inhalation** | Exposure to aerosols generated by the pressure remaning in the dispensing pumps |

**Disinfection of swimming pools – Primary exposure – Uses #4-5-6**

**Meta SPC 1.2:**

During pouring application, the risk is considered acceptable considering the wear of PPE (gloves, protection coverall and goggles).

***Secondary Exposure***

Secondary dermal and inhalation exposure of general public (adults, children and babies) may occur after swimming pools treatment with chlorine by professionals or non-professionals. The following scenarios have been envisaged:

* **Scenario [2]:** Inhalation exposure of the swimming instructor;
* **Scenario [3]:** Dermal and inhalation exposure of children and adults during swimming;
* **Scenario [4]**: Dermal and inhalation exposure of babies during swimming.

The exposure in public swimming pools is considered covered by exposure in private swimming pools. Indeed, private swimming pool are smaller than public swimming pool and most of the private swimming pool are outdoor, where inhalation exposure is considered negligible.

As the presence of swimmers and instructor is not expected after shock disinfection, the maximum in-use concentration of 0.003% av.Cl in the swimming water during continuous disinfection is considered.

**Scenario [2]: Inhalation exposure of the swimming instructor**

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [2] – Inhalation exposure of the swimming instructor** | | | |
| According to the information provided by the applicant, the targeted pH value of swimming pool water is 7.2-7.6.  At this pH value, exposure by inhalation to vapors of HClO is considered relevant for any person present in the close environment of the swimming pool.  Therefore, a swim instructor might be exposed to vapors of HClO during a working day (estimated at 8 hours). This scenario is only relevant for indoor public swimming pools as inhalation exposure is considered negligible in outdoor public swimming pools.  Inhalation exposure is estimated with **ConsExpo - Evaporation model (constant surface**), using the “Disinfectant Products Fact Sheet” (Appendix: Exposure in public swimming pools p.87). | | | |
|  | **Parameters** | **Value** | **References** |
| Tier 1 | Product amount | 5.6×108 g | Default value from ConsExpo |
| Maximum concentration of active chlorine  (% w/w) in treated swimming water | 0.003% | Applicants data |
| Molecular weight HClO | 52.5 g/mol | - |
| Vapour pressure HClO | 337 Pa | - |
| Exposure duration | 480 minutes | Considering a 8h working day |
| Room volume | 188 m3 | Default value from ConsExpo |
| Ventilation rate | 2/hr | Default value from ConsExpo |
| Inhalation rate | 1.25 m3/h | HEAd Hoc Recommendation 17 |
| Release area | 375 m2 | Default value from ConsExpo |
| Emission duration | 480 minutes | Considering a 8h working day |
| Molecular weight matrix (water) | 18 g/mol | - |
| Mass transfer coefficient | 5.2×103 m/min | Default value from ConsExpo |
| Temperature | 28°C | Default value from ConsExpo |

***Calculations for Scenario [2]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Scenario 2 | 1/ No PPE | 0.072 | - |

**Combined exposure**

Not relevant.

**Scenario [3]: Dermal and inhalation exposure of children and adults during swimming (use #1-2-3-4-5-6)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [3] – Secondary exposure of children and adults during swimming** | | | |
| *Inhalation route*  The targeted pH of public and private swimming pools is 7.2-7.6. At this pH value, exposure by inhalation to vapors of HClO is considered relevant for anyone swimming.  Therefore, adults and children are exposed via the inhalation route to chlorine species evaporating from the swimming pool surface during swimming.  Inhalation exposure is estimated with ConsExpo - Evaporation model (constant surface), using the “Disinfectant Products Fact Sheet” (Appendix: Exposure in public swimming pools p.87).  6-12 years old child is considered to be the worst-case population for this scenario due to the highest inhalation rate compared to adults (1.26 m3/hr for child 6-12 years vs 1.25 m3/hr for an adult).  *Dermal route*  For dermal route, as public and private swimming pool treated water is not classified, a qualitative risk assessment is not required. | | | |
|  | **Parameters** | **Value** | **References** |
| Tier 1 | Product amount | 5.6×108 g | Default value from ConsExpo |
| Maximum concentration of active chlorine  (% w/w) in swimming water | 0.003% | Applicant’s data |
| Molecular weight HClO | 52.5 g/mol | - |
| Vapour pressure HClO | 337 Pa | - |
| Exposure duration | 120 minutes | Default value from ConsExpo |
| Room volume | 188 m3 | Default value from ConsExpo |
| Ventilation rate | 2/hr | Default value from ConsExpo |
| Inhalation rate (for a 6-12 years-old child) | 1.26 m3/h | HEAd Hoc Recommendation 17 |
| Release area | 375 m2 | Default value from ConsExpo |
| Emission duration | 120 minutes | Default value from ConsExpo |
| Molecular weight matrix (water) | 18 g/mol | - |
| Mass transfer coefficient | 5.2×103 m/min | Default value from ConsExpo |
| Temperature | 28°C | Default value from ConsExpo |

***Calculations for Scenario [3]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration for general public** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Scenario [3] | 1/ No PPE | 0.072 | - |

**Scenario [4]: Dermal and inhalation exposure of babies during swimming (use #1-2-3-4-5-6)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [4] – Secondary exposure of babies during swimming** | | | |
| *Inhalation route*  Babies are also exposed via the inhalation route to chlorine species evaporating from the swimming pool surface during swimming.  The inhalation exposure of babies during swimming is considered to be not covered by inhalation exposure of adults/children due to different swimming parameters and swimming pool size, particularly the room volume and the temperature of the swimming pool water (32°C for babies vs 28°C for adults/children). As the temperature of the swimming pool water is higher for babies’ than for adults/children, the vapour pressure of HClO is also higher (438 Pa vs 377 Pa).  Inhalation exposure is estimated with ConsExpo - Evaporation model (constant surface), using the “Disinfectant Products Fact Sheet” (Appendix: Exposure in public swimming pools p.87).  *Dermal route*  For dermal route, as public and private swimming pool treated water is not classified, a qualitative risk assessment is not required. | | | |
|  | **Parameters** | **Value** | **References** |
| Tier 1 | Product amount | 5.6×108 g | Default value from ConsExpo |
| Maximum concentration of active chlorine  (% w/w) in swimming water (after shock disinfection) | 0.003% | Applicant’s data |
| Molecular weight HClO | 52.5 g/mol | - |
| Vapour pressure HClO | 438 Pa | - |
| Exposure duration | 30 minutes | Default value from ConsExpo |
| Room volume | 50 m3 | Default value from ConsExpo |
| Ventilation rate | 2/hr | Default value from ConsExpo |
| Inhalation rate | 1.25 m3/h | HEAd Hoc Recommendation 17 |
| Release area | 100 m2 | Default value from ConsExpo |
| Emission duration | 30 minutes | Default value from ConsExpo |
| Molecular weight matrix (water) | 18 g/mol | - |
| Mass transfer coefficient | 5.2×103 m/min | Default value from ConsExpo |
| Temperature | 32°C | Default value from ConsExpo |

***Calculations for Scenario [4]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration for general public** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Scenario [4] | 1/ No PPE | 0.269 | - |

**Combined exposure**

Not relevant.

**Risk characterisation for secondary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| Scenario [2] | 1/no PPE | 0.5 | 0.072 | 14 | Yes |
| Scenario [3] | 0.072 | 14 | Yes |
| Scenario [4] | 0.269 | 54 | Yes |

Outcome of qualitative local risk assessment (dermal)

Diluted products from Meta SPC 1.2in swimming water are not classified.

Therefore, no qualitative risk assessment is required.

**Overall conclusion regarding the Disinfection of swimming pools by porfessionnal users**

|  |  |  |  |
| --- | --- | --- | --- |
| **Meta SPC** | **Uses (application by)** | **Conclusion** | **PPE and RMM if required** |
| **1.2** | Pouring into automated system or directly in water | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall, goggles and a respiratory protection during the application of the product and the maintenance of the system. |

**NON-PROFESSIONALS**

|  |  |  |
| --- | --- | --- |
| **Summary table: exposure scenarios** | | |
| **Scenario and task number** | **Description of scenario and tasks** | **Exposed group** |
| **Use#4**  **Use#5**  **Use#6** | **Disinfection of public and private swimming pools**  **Shock disinfection of public and private swimming pools**  **Disinfection of footbaths in public and private swimming pools** |  |
| **Primary exposure** | | |
| **Scenario [1]** | ***Disinfection of private swimming pool/footbaths by automated dosing system*** | |
| Task [1.1] | *Pouring in the tank connected with the automated dosing system* | Non-professionals |
| Task [1.2] | *Automated application* | Non-professionals |
| Task (1.3] | *Post-application – Maintenance/cleaning of dosing system* | Non-professionals |
| **Secondary exposure** | | |
| **Scenario [3]** | ***Secondary exposure of children and adults during swimming*** | General public (adults, children) |
| **Scenario [4]** | ***Secondary exposure of infants during swimming*** | General public (infants) |

***Primary exposure***

**Scenario [1] – Disinfection of private swimming pool/footbaths by automated dosing system (use #1-2-3)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Meta SPC 1 | | |
| Concentrated product | | | |
| av.Cl concentration | 9.6% | | |
| Product classification | H314-H318 | | |
| pH | 12.2 | | |
| Diluted product | | | |
| Claimed application dose | Shock disinfection of private swimming pool (use #2) | Continuous flow disinfection in private swimming pool (use #1) | Footbaths in private swimming pools (use #3) |
| 50 mg av.Cl/L | 3 mg av.Cl/L | mg av.Cl/L |
| Dilution factor | 0.0052 | 0.0003 | 0.00052 |
| av.Cl concentration | 0.05% | 0.003% | 0.005% |
| Product classification | Not classified | | |
| Expected pH | 7.2-7.6 | | |

Products from Meta-SPC 1 can be used for the disinfection of private swimming pool/footbaths by automated dosing system.

These products are diluted to reach a concentration of 0.003-0.05% of active chlorine in swimming water, the application rate depending of the type of disinfection, *i.*e shock or continuous; and the type of water to treat (swimming water or footbaths).

The concentration of active chlorine in the concentrated products is 9.6% and maximum 0.05% in the in-use dilution.

Packaging sizes are as follows:

* between 5 L and 20L

For this exposure scenario, 3 tasks have been considered:

* **Task [1.1]:** Pouring in the tank connected with the automated dosing system;
* **Task [1.2]:** Automated application;
* **Task [1.3]:** Post-Application: Maintenance/cleaning of dosing system.

**Task [1.1]: Connection of the can with the automated dosing system**

|  |
| --- |
| **Description of Task [1.1] – Pouring in the tank connected with the automated dosing system** |
| Products from meta-SPC 1.1 are available in can/tin of 5, 10 and 20L.  According to the information provided by the applicant, non-professional users connected the can with the automated dosing system by removing the cap and dip a hose into the bottle/jerrycan to collect the product.  *Inhalation route*  The available pH value of the concentrated products is > 10, exposure by inhalation to vapours of HClO is therefore considered negligible.  Inhalation exposure to aerosols is also considered negligible due to the small quantities manipulated.  *Dermal route*  Dermal exposure is considered negligible durin the diping of the hose into the bottle. |

***Calculations for Task [1.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from non-professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.1] | 1/ No PPE | negligible | - |

**Task [1.2]: Automated application**

|  |
| --- |
| **Description of Task [1.2] – Automated application** |
| The disinfection process (application) is an automated process taking place in a closed system.  Exposure is therefore considered. |

***Calculations for Task [1.2]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.2 ] | 1/ No PPE | negligible | - |

**Task [1.3]: Post-application – Maintenance/cleaning of dosing system**

|  |
| --- |
| **Description of Task [1.3] – Post-application – Maintenance/cleaning of dosing system** |
| Non-professional exposure to the concentrated product may occur during the maintenance/cleaning of dosing pumps and the removing of the hose.  *Inhalation route*  The available pH value of the concentrated products is > 10, exposure by inhalation to vapors of HClO is therefore considered negligible.  Aerosols may be generated through the pressure present in the dosing pumps; inhalation exposure to aerosols of active chlorine is expected. No model being available to determine the inhalation exposure for non-professionals during this task, the same model than for professional users, *i.e* **Mixing and loading model 7 (manual liquid)** from BHHEM (p.277), has been used as a worst-case approach.  The exposure value from the model is as follows:  - 0.94 mg/m3 (inhalation)  *Dermal route*  Products are classified H314-H318, a qualitative risk assessment is performed.  Dermal exposure could occur during the removing of the hose from the bottle. |

***Calculations for Task [1.3]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.3] | 1/ No PPE | 0.09 | - |

**Combined exposure**

Not relevant.

**Risk characterisation for primary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| **Scenario 1: Disinfection of private swimming pool/footbaths by automated dosing system** | | | | | |
| Task [1.1] | Negligible | | | nr | Yes |
| Task [1.2] | Negligible | | | nr | Yes |
| Task [1.3] | 1/no PPE | 0.5 | 0.09 | 18 | Yes |

Outcome of qualitative local risk assessment (dermal)

Products pertaining to Meta SPC 1.1are classified Skin corrosive category 1 (H314) and Severe eye damage (H318). Diluted products are not classified.

All the products are intended to be applied by non-professionals.

Please refer to the tables below:

**Outcome of qualitative local risk assessment – Concentrated** products of meta SPC **1.1** classified H314/H318 used by non-professionals

|  |  |  |
| --- | --- | --- |
| **Hazard** | **Exposure information** | **Risk** |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Very high** | **H314** | **2** | Task 2:  Post application – Maintenance/Cleaning of dosing pumps and removing of the hose | **Skin and eye** | **Frequency:**  Task 2:  No data, rarely expected )  **Duration :**  Task 2: no data but 10 min expected | Direct dermal contact and potential splashes or spills  Hand-to-eye transfer | * Labelling:   Labelling according to CLP | **Unacceptable** | (**↑**) High hazard category  (**↑**) Potentially high exposure duration for task 2 (more than few minutes per day)  (**↓**) Potentially low frequency (less than once per week)  (**↓**) Child-proof closure  (**↑**) Absence of a protection during the removing of the hose |

**Disinfection of private swimming pool - primary exposure - Use #1-2-3**

**Meta SPC 1.1**

Products pertaining to Meta SPC 1.1 are classified H314 and H318.

During the use of the products, exposure to skin and eye can be expected and no specific packaging or devices to avoid exposure is available.

The risk is therefore considered unacceptable for non-professional users.

***Secondary exposure***

Please refer to scenario [3] and [4] above.

**Risk characterisation for secondary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| Scenario [3] | Tier 1 | 0.5 | 0.072 | 14 | Yes |
| Scenario [4] | 0.269 | 54 | Yes |

Outcome of qualitative local risk assessment (dermal)

Diluted products from Meta SPC 1.1in swimming water are not classified.

Therefore, no qualitative risk assessment is required.

**Overall conclusion regarding the Disinfection of swimming pools by non-professional users**

|  |  |  |  |
| --- | --- | --- | --- |
| Meta SPC | Uses (application by) | Conclusion | RMM if required |
| 1.1 | Pouring into automated system or directly in water | Unacceptable | none |

|  |
| --- |
| **Inner surfaces disinfection (CIP)** |

In this section, the uses belonging to group 4 identified above have been assessed; *i.e* inner surfaces disinfection or surface disinfection by CIP. Products are indented to be used by professionals only.

**PROFESSIONALS USERS**

**Summary table: List of exposure scenarios**

|  |  |  |
| --- | --- | --- |
| **Summary table: exposure scenarios** | | |
| **Scenario and task number** | **Description of scenario and tasks** | **Exposed group** |

|  |  |  |
| --- | --- | --- |
| **Use#13**  **Use#21**  **Use#22** | **Disinfection of surfaces by CIP**  **Disinfection of inner surfaces in human drinking water systems**  **Disinfection of inner surfaces in veterinary water** |  |

|  |  |  |
| --- | --- | --- |
| **Primary exposure** | | |
| **Scenario [1]** | ***Disinfection of surfaces by CIP (inner surfaces)*** | |
| Task [1.1] | *Mixing and loading* | Professionals |
| Task [1.2] | *Application* | Professionals |
| Task [1.3] | *Post-application – Cleaning/maintenance of dosing pumps* | Professionals |
| Task [1.4] | *Post-application – Maintenance of circuit system* | Professionals |
| **Secondary exposure** | | |
| **Scenario [2]** | ***Inhalation exposure of bystander*** | Bystander |

***Primary exposure***

**Scenario [1] – Disinfection of surfaces by CIP (use #13-21-22)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Meta SPC 6.21 | Meta SPC 6.22 | Meta SPC 7.11 | Meta SPC 7.12 | Meta SPC 7.2 | Meta SPC 10.1 | Meta SPC 10.2 | Meta SPC 11 |

|  |
| --- |
| Concentrated product |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| av.Cl concentration | 9.6% | 13.5% | 3.6% | 4.8% | 2.6% | 2.6% | 4.8% | 6.0% |
| Product classification | H314-H318 | | | | | | | |
| pH | 12.2 | 12.1 | 12.1 | 12.1 | 12.1 | 12.1 | 12.2 | 12.3 |

|  |
| --- |
| Diluted product |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Claimed application dose (worst-case) | 1350 mL in 10L of diluted solution | 940 mL in 10L of diluted solution | 340 mL in 1L of diluted solution | 230 mL in 1L of diluted solution | 450 mL in 1L of diluted solution | 450 mL in 1L of diluted solution | 230 mL in 1L of diluted solution | 240 mL in 1L of diluted solution |
| Dilution factor | 0.135 | 0.094 | 0.34 | 0.23 | 0.45 | 0.45 | 0.23 | 0.24 |
| av.Cl concentration | 1.30 | 1.27 | 1.22 | 1.10 | 1.17 | 1.17 | 1.10 | 1.44 |
| Product classification | H315-H319 | | | | | | | H314-H318 |
| pH (extrapolated by calculation) | >10 but < 11.5 | | | | | | | > 11.5 |

Products from Meta-SPC 6.21-.622-7.11-7.12-7.2-10.1-10.2-11 can be used for the disinfection of surfaces by CIP.

The concentration of active chlorine in the concentrated products is 2.6-13.5% and 1.1-1.44% in the in-use dilution.

The classifications of the in-use diluted products have been set according to the calculation rules laid down in the CLP regulation 1272/2008. For details please refer to the Excel data sheet “Classification\_In-use dilution\_PRO” in the confidential PAR.

Packaging sizes are as follows:

* between 250 mL and 1000L for Meta SPC 6.21-6.22-11;
* between 120 mL and 20L for Meta SPC 7.11-7.12-7.2-10.1-10.2.

For this exposure scenario, 4 tasks of primary exposure have been considered:

* Task [1.1]: Mixing and loading;
* Task [1.2]: Application;
* Task [1.3]: Post-Application: Cleaning/maintenance of dosing pumps.

**Task [1.1]: Mixing and loading**

|  |
| --- |
| **Description of Task [1.1]: Mixing and loading** |
| Products pertaining to Meta SPC 6.21-.622-7.11-7.12-7.2-10.1-10.2-11 have to be diluted in water before loading in a container connected with the automatic dosing system. This can be done manually or (semi)-automatically depending on the packaging size and Meta SPC.  *Inhalation route*  The available pH value of the concentrated products is > 10, exposure by inhalation to vapors of HClO is therefore considered negligible.  Exposure to aerosols of NaOCl is also considered negligible for manual loading due to the small quantities handled. For (semi) automated loading, no exposure is expected.  *Dermal route*  Products are classified H314-H318, a qualitative risk assessment is performed. |

***Calculations for Task [1.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.1] | 1/ No PPE | negligible | - |

**Task [1.2]: Application**

|  |
| --- |
| **Description of Task [1.2]** |
| The disinfection process (application) is an automated process taking place in a closed system.  Therefore, exposure is considered negligible. |

**Task [1.3]: Post-application - Cleaning/maintenance of dosing pumps and circuit system**

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Task [1.3]** | | | |
| Exposure to the diluted product may occur during maintenance process or cleaning of dosing pumps.  *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible, the pH value extrapolated by calculation for the diluted products being > 10.  Inhalation exposure to aerosols is expected due to the pressure present in the dosing pumps. The **Mixing and loading model 7 (manual liquid)** from BHHEM (p.277), has been used.  The exposure value from the model is as follows:  - 0.94 mg/m3 (inhalation)  *Dermal route*  The in-use dilution from products pertaining to Meta SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2 are classified H315-H319.  The in-use dilution from products pertaining to Meta SPC 11 are classified H314-H318; a qualitative risk assessment will be performed. | | | |
| **Input parameters for Task [1.3]** | | | |
| **Tier** | **Parameters** | **Value** | **Reference and**  **justification** |
| Tier 1 (no PPE) | Maximum concentration of active chlorine  (% w/w) in concentrated products of meta SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2-11 | 13.5% | Applicant’s data |
| Inhalation exposure value (mg/m3) | 0.94 mg/m3 | HEEG Opinion 1 (2008) |

***Calculations for Task [1.3]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.3] | 1/ No PPE | 0.13 | - |

**Combined exposure**

Not relevant.

**Risk characterisation for primary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | | **Acceptable (Yes/no)** | |
| **Scenario 1 – Disinfection of surfaces by CIP** | | | | | | |  | |
| Task [1.1] | negligible | | | | nr | | yes | |
| Task [1.2] | negligible | | | | nr | | yes | |
| Task [1.3] | 1/ no PPE | 0.5 | 0.13 | 25% | | yes | |

Outcome of qualitative local risk assessment (dermal)

Concentrated products pertaining to Meta SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2-11are classified Skin corrosive category 1 (H314) and Severe eye damage (H318).

The in-use dilution of products from Meta SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2 are classified H315-H319; only in-use dilutions from Meta SPC 11 are classified H314-H318.

All the products are intended to be applied by professionals.

Please refer to the tables below:

**Outcome of qualitative local risk assessment –** Products from meta SPC **11** classified H314/H318 used by professionals

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant PPE** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Very high** | **H314** | 2  3  4 | Task 1: Mixing and loading  Task 2: Maintenance/Cleaning of dosing pumps | **Skin and eye** | **Frequency:** up to 1/day  **Duration :**  Task 1:  no data but 10 min expected  Task 2:  no data but potentially high duration | Direct dermal contact with treated surfaces  Deposit of aerosols on skin and eye  Hand-to-eye transfer | Gloves  Skin coverage  Eye protection  Chemical goggles  RPE : Substance task appropriate reposiraor | Labelling:   * Labelling according to CLP   Professionals:   * Professional workers   Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) High hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency  (**↑**) Potentially high exposure duration for task 2 (more than few minutes per day) |
| **EUH 071** | **inhalation** |

**Outcome of qualitative local risk assessment –** Products from meta SPC **6.21-6.22-7.11-7.12-7.2-10.1-10.2** classified H314/H318 (concentrated products) and H315/H319 (in-use dilution) used by professionals

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant PPE** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Concentrated products** | | | | | | | | | | |
| **Very high** | **H314** | 2  3  4 | Task 1: Mixing and loading | **Skin and eye** | **Frequency:** up to 1/day  **Duration :**  Task 1:  no data but 10 min expected | Direct dermal contact with treated surfaces  Deposit of aerosols on skin and eye  Hand-to-eye transfer | Gloves  Skin coverage  Eye protection  Chemical goggles  RPE : Substance task appropriate reposiraor | Labelling:   * Labelling according to CLP   Professionals:   * Professional workers   Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) High hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency  (**↑**) Potentially high exposure duration for task 2 (more than few minutes per day) |
| **EUH 071** | **inhalation** |
| **in-use dilutions** | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Low** | **H315** | **2**  **3**  **4** | **Post application** Task 2: Maintenance/Cleaning of dosing pumps | **Skin** | **Frequency:** 1/week up to 1/day  **Duration :**  Task 2:  no data but potentially high duration | Direct dermal contact with treated surfaces  Deposit of aerosols on skin and eye  Hand-to-eye transfer | Gloves  Skin coverage  Eye protection  Chemical goggles | Labelling:   * Labelling according to CLP   Professionals:   * Professional workers   Instructions for use minimizing exposure for professionals | **Acceptable** | (**↓**) Low hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency  (**↑**) Potentially high exposure duration (few hours) |
| **H319** | **eye** |

**Surface disinfection by CIP (inner surfaces) – Primary exposure – Uses #13-21-22**

**Meta SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2**

During M&L (corresponding to the dilution task) and post-application task, the risk is deemed acceptable considering the wear of PPE (gloves, protection coverall and googles).

**Meta SPC 11**

During M&L (corresponding to the dilution task) and post-application tasks, the risk is deemed acceptable considering the wear of PPE (gloves, protection coverall and googles).

Exposure to aerosols is expected during maintenance of the system, a respiratory protection is therefore necessary for this task.

***Secondary exposure***

**Scenario [2]: Inhalation exposure of bystanders**

|  |
| --- |
| **Description of Scenario [2]** |
| Bystander present during the mixing and loading, application or post-application tasks may be exposed by inhalation.  Exposure is not expected to be of greater extent than professional exposure (see primary exposure). |

**Combined exposure**

Not relevant.

**Risk characterisation for secondary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

Inhalation exposure of the bystander is expected to be the same than inhalation exposure of the professional user (see primary exposure, task 1.3).

Therefore, the estimated inhalation concentration is below the AEC of sodium hypochlorite for bystander.

**Overall conclusion regarding the disinfection of inner surface (by CIP) by professional users**

|  |  |  |  |
| --- | --- | --- | --- |
| **Meta SPC** | **Uses (application by)** | **Conclusion** | **PPE and RMM if required** |
| **6.21** | Disinfection of inner surfaces (by CIP) | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system). |
| **6.22** |
| **7.11** |
| **7.12** |
| **7.2** |
| **10.1** |
| **10.2** |
| **11** | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (M&L) and post-application tasks (maintenance of the system).  Wear a respiratory protection during the post-application tasks (maintenance of the system). |

|  |
| --- |
| **Toilet bowl Disinfection** |

In this section, the uses belonging to group 6 identified above have been assessed; *i.e* toilet bowl disinfection.

The assessment has been split in two parts:

* First part: exposure assessment for Professional users followed by a risk characterization;
* Second part: exposure assessment for Non-Professional users followed by a risk characterization.

**PROFESSIONALS USERS**

**Summary table: List of exposure scenarios**

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: exposure scenarios** | | | |
| **Scenario and task number** | **Description of scenario and tasks** | **Exposed group** | |
| **Use#24**  **Use#25**  **Use#26** | **Disinfection of toilet bowls**  **Disinfection of toilet bowls in medical area**  **Disinfection of toilet bowls in institutions/industry** |  | |
| **Primary exposure** | | | | |
| **Scenario [1]** | ***Toilet bowl disinfection*** | | | |
| Task [1.1] | *Application by pouring* | | Professionals | |
| Task [1.2] | *Rinsing with flush* | | Professionals | |

***Primary exposure***

**Scenario [1] – Disinfection of toilet bowls (use #24-25-26)**

|  |  |  |
| --- | --- | --- |
|  | **Meta SPC 3** | **Meta SPC 13** |
| **RTU** | | |
| av.Cl concentration | 2.6% | 4.5% |
| Product classification | H314 - H318 | |
| pH | 12.6 | 12.7 |

RTU products from Meta-SPC 3-13 can be used for the disinfection of toilet bowls.

These gel products are packed in bottles of 750 mL with or without gooseneck.

The concentration of active chlorine in the concentrated products is 2.6-4.5%.

For this exposure scenario, 2 tasks have been considered:

* Task [1.1]: Application by pouring (pressing on packaging);
* Task [1.2]: Rinsing by flushing.

**Task [1.1]: Application by pouring**

|  |
| --- |
| **Description of Task [1.1] – Application by pouring** |
| RTU products from Meta SPC 3-13 are intended to be directly poured in toilet bowls by pressing on packaging.    *Inhalation route*  The available pH value of the RTU products is > 10. Therefore, inhalation exposure to vapors of HClO is considered negligible.  Considering the type of formulation and the applciation, inhalation exposure to aerosols is not expected.  *Dermal route*  Products are classified H314-H318, a qualitative risk assessment is performed. |

***Calculations for Task [1.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.1] | 1/ No PPE | negligible | - |

**Task [1.2]: Rinsing by flushing**

|  |
| --- |
| **Description of Task [1.2] – Rinsing with flush** |
| After the claimed contact time, the toilet flush is intended to be activated to eliminate the product on the toilet bowl surface.  Inhalation and dermal exposure are considered negligible during this atsk. |

**Combined exposure**

Not relevant.

**Risk characterisation for primary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| **Scenario 1: Disinfection of toilet bowls** | | | | | |
| Task [1.1] | Negligible | | | nr | Yes |
| Task [1.2] | Negligible | | | nr | Yes |

Outcome of qualitative local risk assessment (dermal)

RTU products from Meta SPC 3-13are classified Skin corrosive category 1 (H314) and Severe eye damage (H318).

All the products are intended to be applied by professionals.

Please refer to the table below:

**Outcome of qualitative local risk assessment –** RTUproducts of meta SPC 3-13classified H314/H318 used by professionals

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant PPE** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| High | **Skin Corr.**  **1**  **H314** | 2 | Application by pouring | Dermal | **Frequency**: 2/week up to 1/day  **Duration :** no data but 10 min expected | Direct dermal contact | Gloves  Skin coverage  Eye protection  Optional face shield | Labelling:   * Labelling according to CLP   Professionals:   * Professional workers   Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) High hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency and exposure duration (few minutes per day)  (**↓**) Gel formulation |
| **Eye Dam.1, H318** | Ocular | Eye exposure through potential splashes or hand to eye transfer | Chemical goggles |

**Disinfection of toilet bowls by pouring – Primary exposure – Uses # 24-25-26**

**Meta SPC 6-13**

During application by pouring, the risk is deemed acceptable considering the wear of PPE (gloves, protection coverall and googles).

***Secondary exposure***

Not relevant.

**Overall conclusion regarding the disinfection of toilet bowls by professional users**

|  |  |  |  |
| --- | --- | --- | --- |
| **Meta SPC** | **Uses (application by)** | **Conclusion** | **PPE and RMM if required** |
| **3** | Pouring | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product. |
| **13** |

**NON-PROFESSIONALS**

**Summary table: List of exposure scenarios**

|  |  |  |
| --- | --- | --- |
| **Summary table: exposure scenarios** | | |
| **Scenario and task number** | **Description of scenario and tasks** | **Exposed group** |

|  |  |  |
| --- | --- | --- |
| **Use#24** | **Disinfection of toilet bowls** |  |

|  |  |  |
| --- | --- | --- |
| **Primary exposure** | | |
| **Scenario 1** | ***Toilet bowl disinfection*** | |
| Task 1.1 | *Manual mixing and loading* | Non-professionals |
| Task 1.2 | *Application by pouring* | Non-professionals |
| Task 1.3 | *Rinsing with flush* | Non-professionals |

***Primary exposure***

**Scenario 1 – Disinfection of toilet bowls (use #27)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Meta SPC 2.1** | **Meta SPC 2.21** | **Meta SPC 2.22** | **Meta SPC 3** | **Meta SPC 4** | **Meta SPC 8** |
| **Concentrate product** | | | | | |  |
| av.Cl concentration | 2.6% | 4.8% | 3.6% | 2.6% | 1.5% | 1.6% |
| Product classification | H314 - H318 | | | | | |
| pH | 12.1 | 12.2 | 12.3 | 12.6 | 12.6 | 12.1 |
| **Diluted product** | | | | | |  |
| Claimed application dose (worst-case) | 3 volumes in 7 volumes of water | 1 volume in 1 volume of water | 2 volumes in 7 volumes of water | RTU | RTU | 1 volume in 1 volume of water |
| Dilution factor | 0.3 | 0.5 | 0.22 | 0.5 |
| av.Cl concentration | 0.78% | 2.4% | 0.792% | 0.8% |
| Diluted product classification | Not classified | H315 - H319 | Not classified | Not classified |
| pH (extrapolated by calculation) | >10 | | | >10 |

Products from Meta-SPC 2.1-2.21-2.22-3-4-8 are intended to be used for the disinfection of toilet bowls.

Products from Meta SPC 2.1-2.21-2.22-8 has to diluted in water before application. No dilution is required for RTU products from Meta SPC 3-4 (gel formulation).

The concentration of active chlorine in the concentrated products is 1.5-4.8% and 0.78-2.4% in the in-use dilution.

The classifications of the in-use diluted products have been set according to the calculation rules laid down in the CLP regulation 1272/2008. For details please refer to the Excel data sheet “Classification\_In-use dilution\_NPRO” in the confidential PAR.

Packaging sizes are between 120 mL and 10Lwith the following specifications:

* Meta SPC 2.1-2.22-8: HDPE bottle or container;
* Meta SPC 2.21: PVC flexible pack with spout (berlingot);
* Meta SPC 3-4: bottle with or without gooseneck.

For this exposure scenario, 3 tasks have been considered:

* Task [1.1]: Manual mixing and loading (only for Meta SPC 2.1-2.21-2.22-8);
* Task [1.2]: Application by pouring (pressing on packaging);
* Task [1.3]: Rinsing by flushing

**Task [1.1]: Manual mixing and loading**

|  |
| --- |
| **Description of Task [1.1] – Manual mixing and loading** |
| Products from meta-SPC 2.1-2.21-2.22-8 has to be diluted in water before application. Considering the information available (packaging size,…), it is assumed to be done manually..  *Inhalation route*  The available pH value of the concentrated products is > 10, exposure by inhalation to vapors of HClO is therefore considered negligible.  Due to the small quantities manipulated, inhalation exposure to aerosols is also considered negligible.  *Dermal route*  Products are classified H314-H318, a qualitative risk assessment is performed. |

***Calculations for Task [1.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from non-professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.1] | 1/ No PPE | negligible | - |

**Task [1.2]: Application by pouring**

|  |
| --- |
| **Description of Task [1.2] – Application by pouring** |
| RTU products from Meta SPC 3-4 and in-use dilution of products from Meta SPC 2.1-2.21-2.22-8 are intended to be poured in toilet bowls.    *Inhalation route*  Exposure by inhalation to vapors of HClO is considered negligible, the pH values extrapolated by calculation for the in-use dilutions being > 10.  pH values of RTU products (Meta SPC 3-4) are > 10. Inhalation exposure to vapors of HClO is considered negligible.  Considering the formulation and the application’s type, aerosols generation is not expected.  *Dermal route*  RTU products being classified H314-H318 and in-use dilutions from of Meta SPC 2.21 being classified H315-H319, a qualitative risk assessment is performed.  The other in-use dilutions being not classified, no further assessment is required. |

***Calculations for Task [1.2]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from non-professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.2] | 1/ No PPE | negligible | - |

**Task [1.2]: Rinsing by flushing**

|  |
| --- |
| **Description of Task [1.2] – Rinsing by flushing** |
| After the claimed contact time, the toilet’s flush is intended to be activated to eliminate the product.  Inhalation and dermal exposure are considered negligible during this task. |

**Combined exposure**

Not relevant.

**Risk characterisation for primary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| **Scenario 1: Disinfection of toilet bowls** | | | | | |
| Task [1.1] | Negligible | | | nr | Yes |
| Task [1.2] | Negligible | | | nr | Yes |
| Task [1.3] | Negligible | | | nr | Yes |

Outcome of qualitative local risk assessment (dermal)

Products from Meta SPC 2.1--2.22-3(RTU)-4(RTU)-8 are classified Skin corrosive category 1 (H314) and Severe eye damage (H318).

In-use dilutions are not classified, excepted dilutions of products from Meta SPC 2.21 classified H315-H319.

All the products are intended to be applied by non-professionals.

Please refer to the tables below:

**Outcome of qualitative local risk assessment – RTU products** of meta SPC **3-4** classified H314/H318 used by non-professionals

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | | **Exposure information** | | | | | | **Risk** | |
| **Hazard category** | **Effects in**  **terms of C&L** | **Additional relevant hazard information** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| High | **Skin Corr.**  **1**  **H314** | - | 2 | Application by pouring | Dermal | **Frequency:** up to 2/week  **Duration** : no data but 10 min expected | Direct dermal contact | none | **Acceptable** | (**↑**) High hazard category  (**↑**) Moderate frequency (more than once per week)  e  (**↓**) Potentially low exposure duration (few minutes per day)  (**↓**) Cap with directional nozzle on the bottle to pour the product (gooseneck bottle)  (**↓**) Gel formulation |
| **Eye Dam.1, H318** | Ocular | Eye exposure through potential splashes or hand to eye transfer |

**Outcome of qualitative local risk assessment –** Products of meta SPC **2.1-2.21-2.22-8** which are classified H314/H318 used by non-professionals

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** |  |  | **Exposure information** | | |  |  |  | **Risk** |  |
| **Hazard category** | **Effects in**  **terms of C&L** | **Additional relevant hazard information** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Concentrated products (Meta SPC 2.1-2.22-8)** | | | | | | | | | | |
| High | **Skin Corr.**  **1**  **H314** | - | 2 | Manual mixing and loading | Dermal | **Frequency:** up to 2/week  **Duration :** no data | Potential splashes and spills | none | **Unacceptable** | (**↑**) High hazard category  (**↑**) Liquid formulation  (**↑**) Berlingot (Meta SPC 4)  (**↑**) Moderate frequency (more than once per week)  (**↑**) Absence of cap with directional nozzle on the bottle to pour the product  (**↓**) Potentially low exposure duration (few minutes per day) |
| **Eye Dam.1, H318** | Ocular | Eye exposure through potential splashes or hand to eye transfer | none |
| **In-use dilutions (Meta SPC 2.21)** | | | | | | | | | | |
| Low | **Skin Irrit. 2 H315** | - | 2 | Application by pouring | Dermal | Frequency: up to 2/week  Duration : no data but 10 min expected | Dermal contact | “Wash hands after application” | **Acceptable** | (**↓**) Low hazard category  (**↑**) Moderate frequency (more than once per week)  (**↓**) RMM to avoid dermal long term exposure  (**↓**) Low exposure duration (less than one hour per day) |
| **Eye Irrit. 2 H319** |  | Ocular | Eye exposure through potential splashes or hand to eye transfer |

**Disinfection of toilet bowls by pouring – Primary exposure – Uses # 27**

**Meta SPC 3-4**

Products from Meta SPC 3-4 are RTU products classified H314 and H318.

Considering the packaging of bottle with gooseneck claimed by the applicant that can prevent dermal and ocular exposure, the risk is deemed acceptable for non-professional users. For other claimed packaging (bottle without gooseneck) the risk is deemed unacceptable.

**Meta SPC 2.1-2.22-8**

Products from Meta SPC 2.1-2.22-8 classified H314 and H318 has to be diluted before pouring in the toilet bowls.

Considering the packaging of HDPE bottle or container claimed by the applicant, the risk is deemed unacceptable for non-professional users. With these types of packaging, exposure cannot be prevent during the dilution step (M&L).

**Meta SPC 2.21**

Products from Meta SPC 2.21 classified H314 and H318 has to be diluted before pouring in the toilet bowls.

Considering the packaging of PVC flexible pack with spout (berlingot) claimed by the applicant, the risk is deemed unacceptable for non-professional users. With these types of packaging, exposure cannot be prevent during the dilution step (M&L).

***Secondary exposure***

Not relevant.

**Overall conclusion regarding the disinfection of toilet bowls by non-professional users**

|  |  |  |  |
| --- | --- | --- | --- |
| **Meta SPC** | **Uses (application by)** | **Conclusion** | **RMM if required** |
| **2.1** | Pouring | **Unacceptable** | None |
| **2.21** |
| **2.22** |
| **3** | Acceptable | Packaging such as bottle with gooseneck are required to prevent exposure. |
| **4** |
| **8** | **Unacceptable** | None |

|  |
| --- |
| **Laundry Disinfection** |

In this section, the uses belonging to group 7 identified above have been assessed; *i.e* laundry disinfectionwith hand soaking.

The assessment has been split in two parts:

* First part: exposure assessment for Professional users followed by a risk characterization;
* Second part: exposure assessment for Non-Professional users followed by a risk characterization.

**PROFESSIONALS USERS**

**Summary table: List of exposure scenarios**

|  |  |  |
| --- | --- | --- |
| **Summary table: exposure scenarios** | | |
| **Scenario and task number** | **Description of scenario and tasks** | **Exposed group** |

|  |  |  |
| --- | --- | --- |
| **Use#27** | **Laundry disinfection with hand soaking** |  |

|  |  |  |
| --- | --- | --- |
| **Primary exposure** | | |
| **Scenario [1]** | ***Laundry disinfection by hand soaking*** | |
| Task 1.1 | *Mixing and Loading* | Professionals |
| Task 1.2 | *Application by hand soaking, rinsing and hang out of laundry to dry* | Professionals |

|  |
| --- |
| **Secondary exposure** |

|  |  |  |
| --- | --- | --- |
| **Scenario [2]** | ***Post application: migration from fabric*** | Adults and children |

***Primary exposure***

**Scenario [1] – Laundry disinfection with hand soaking (use #27)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Meta SPC 6.21** | **Meta SPC 6.22** | **Meta SPC 7.11** | **Meta SPC 7.12** | **Meta SPC 7.22** | **Meta SPC 10.1** | **Meta SPC 10.2** |
| **Concentrate product** | | | | | | | |
| av.Cl concentration | 9.6% | 13.5% | 3.6% | 4.8% | 2.6% | 2.6% | 4.8% |
| Product classification | H314 - H318 | | | | | | |
| pH | 12.2 | 12.1 | 12.1 | 12.1 | 12.1 | 12.3 | 12.2 |
| **Diluted product** | | | | | | | |
| Claimed application dose (worst-case) | 400 mL in 10L diluted solution | 280 mL in 10 diluted solution | 110 mL in 1L diluted solution | 70 mL in 1L diluted solution | 140 mL in 1L diluted solution | 140 mL in 1L diluted solution | 70 mL in 1L diluted solution |
| Dilution factor | 0.04 | 0.028 | 0.11 | 0.07 | 0.14 | 0.14 | 0.07 |
| av.Cl concentration | 0.384% | 0.378% | 0.396% | 0.336% | 0.364% | 0.364% | 0.336% |
| Diluted product classification | Not classified | | | | | | |
| pH (extrapolated by calculation and expected considering the use) | >10 but < 11.5 | | | | | | |

Products from Meta-SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2 can be used for the disinfection of laundry by hand soaking.

Products have to be diluted in water before application.

The concentration of active chlorine in the concentrated products is 2.6-13.5% and 0.336-0.396% in the in-use dilution.

Packaging sizes are as follows:

* between 250 mL and 1000L for Meta SPC 6.21-6.22;
* between 120 mL and 20L for Meta SPC 7.11-7.12-7.2-10.1-10.2.

For this exposure scenario, 2 tasks of primary exposure have been considered:

* **Task [1.1]:** Mixing and Loading;
* **Task [1.2]:** Application by hand soaking, rinsing and hang out of laundry.

**Task [1.1]: Mixing and loading**

|  |
| --- |
| **Description of Task [1.1] – Mixing and loading** |
| Products from meta-SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2 have to be loaded in a container and diluted in warm water (40°C) before laundry disinfection by hand soaking. This can be done manually or in a (semi)-automatically way depending on the packaging size and the Meta SPC c.  *Inhalation route*  The available pH value of the concentrated products is > 10, exposure by inhalation to vapors of HClO is therefore considered negligible.  During manual M&L, inhalation exposure to aerosols is considered negligible due to the small quantities manipulated.  For semi-automatic loading, no exposure is expected.  *Dermal route*  Products are classified H314-H318, a qualitative risk assessment is performed. |

***Calculations for Task [1.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.1] | 1/ No PPE | negligible | - |

**Task [1.2]: Application by hand soaking, rinsing and hang out of laundry to dry**

|  |
| --- |
| **Description of Task [1.2] – Application by hand soaking, rinsing and hang out of laundry** |
| After dilution, laundry is disinfected by hand soaking within the diluted solution.  After the claimed contact time, the laundry is rinsed with water and hanged out to dry.  *Inhalation route*  The pH values extrapolated by calculation for the in-use dilutions being > 10, exposure by inhalation to vapors of HClO during hand soaking is considered negligible.  Considering the type of application, inhalation exposure to aerosols is not expected.  After hand soaking, the active substance is expected to quickly react with the organic matter during the claimed contact time. Besides, the decrease of the pH induced by rinsing is assumed to be of low order. Taking together, these elements show that inhalation to vapours during rinsing is also negligible.  *Dermal route*  No classification is required for the in-use dilutions of products, no qualitative risk assessment is performed. |

***Calculations for Task [1.2]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.2 ] | 1/ No PPE | negligible | - |

**Combined exposure**

Not relevant.

**Risk characterisation for primary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| **Scenario 1: Laundry disinfection with hand soaking** | | | | | |
| Task [1.1] | Negligible | | | nr | Yes |
| Task [1.2] | Negligible | | | nr | Yes |

Outcome of qualitative local risk assessment (dermal)

Products from Meta SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2are classified Skin corrosive category 1 (H314) and Severe eye damage (H318).

In use-dilutions of products are not classified.

All the products are intended to be applied by professionals.

Please refer to the table below:

**Outcome of qualitative local risk assessment – Concentrated** products from meta SPC 6.21-6.22-7.11-7.12-7.22-10.1-10.2 classified H314/H318 used by professionals

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure information** | | | | | **Risk** | | | |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant PPE** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| Very High | **Skin Corr.**  **1**  **H314** | 2 | Mixing and loading | Dermal | **Frequency:** 1/week up to 1/day  **Duration :** no data but 10 min expected | Potential splashes and spills | Gloves  Skin coverage  Eye protection  Optional face shield | Labelling:   * Labelling according to CLP   Professionals:   * Professional workers   Instructions for use minimizing exposure for professionals | **Acceptable** | (**↑**) High hazard category  (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low frequency and exposure duration (few minutes per day) |
| **Eye Dam.1, H318** | Ocular | Eye exposure through potential splashes and spills or hand-to-eye transfer | Chemical goggles |

**Laundry disinfection by transfer – Primary exposure – Use #27**

**Meta SPC 6.21-6.22-7.11-7.12-7.22-10.1-10.2**

During M&L (corresponding to the dilution task), the risk is deemed acceptable considering the wear of PPE (gloves, protection coverall and googles).

***Secondary exposure***

**Scenario [2] – Post-application: migration from fabric**

|  |
| --- |
| **Description of Scenario [2]** |
| General public (adults and children) may be exposed to residues of active chlorine when wearing disinfected clothes.  However, considering the quick degradation and reactivity of the active substance as well as the rinsing phase performing after hand soaking (and the claimed contact time) it is assumed that the amount of active substance remaining in the fabric is negligible.  No inhalation or dermal exposure is expected during wearing disinfected fabric. |

**Combined exposure**

Not relevant.

**Risk characterisation for secondary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| Scenario 2 | 1/no PPE | negligible | | | |

Outcome of qualitative local risk assessment (dermal)

Not relevant.

**Overall conclusion regarding laundry disinfection by professionals users**

|  |  |  |  |
| --- | --- | --- | --- |
| **Meta SPC** | **Uses (application by)** | **Conclusion** | **PPE and RMM if required** |
| **6.21** | Laundry disinfection | Acceptable | Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a protective coverall and goggles during the application of the product (mixing and loading task). |
| **6.22** |
| **7.11** |
| **7.12** |
| **7.22** |
| **10.1** |
| **10.2** |

**NON-PROFESSIONALS**

**Summary table: List of exposure scenarios**

|  |  |  |
| --- | --- | --- |
| **Summary table: exposure scenarios** | | |
| **Scenario and task number** | **Description of scenario and tasks** | **Exposed group** |

|  |  |  |
| --- | --- | --- |
| **Use#27** | **Laundry disinfection with hand soaking** |  |

|  |  |  |
| --- | --- | --- |
| **Primary exposure** | | |
| **Scenario [1]** | ***Laundry disinfection by hand soaking*** | |
| Task [1.1] | *Manual mixing and loading* | Non-professionals |
| Task (1.2] | *Application by hand soaking, rinsing and hang out of laundry* *to dry* | Non-professionals |
| **Secondary exposure** | | |
| **Scenario [2}** | ***Post application: migration from fabric*** | Adults and children |

***Primary exposure***

**Scenario [1] – Laundry disinfection with hand soaking (use #27)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Meta SPC 2.1** | **Meta SPC 2.21** | **Meta SPC 2.22** | **Meta SPC 6.1** | **Meta SPC 8** |
| **Concentrate product** | | | | | |
| av.Cl concentration | 2.6% | 4.8% | 3.6% | 9.6% | 1.6% |
| Product classification | H314 - H318 | | | | |
| pH | 12.1 | 12.2 | 12.3 | 12.2 | 12.1 |
| **Diluted product** | | | | | |
| Claimed application dose (worst-case) | 1 volume in 5 volumes of water | First 50/50 dilution then  1 volume in 5 volume of water | 1 volume in 8 volumes of water | 1 volume in 23 volumes of water | 2 volumes in 7 volumes of water |
| Dilution factor | 0.17 | 0.17 | 0.11 | 0.042 | 0.22 |
| av.Cl concentration | 0.442% | 0.41% | 0.396% | 0.403% | 0.352% |
| Diluted product classification | Not classified | | | | |
| pH (extrapolated by calculation and expected considering the use) | >10 but < 11.5 | | | | |

Products from Meta-SPC 2.1-2.21-2.22-6.1-8 can be used for the disinfection of laundry by hand soaking.

These products have to be diluted in water before application.

The concentration of active chlorine in the concentrated products is 1.6-9.6% and 0.352-2.4% in the in-use dilution.

Packaging sizes are as follows:

* between 120 mL and 20L

For this exposure scenario, 2 tasks of primary exposure have been considered:

* **Task [1.1]:** Manual mixing and Loading;
* **Task [1.2]:** Application by hand soaking, rinsing and hang out of laundry.

**Task [1.1]: Manual mixing and loading**

|  |
| --- |
| **Description of Task [1.1] – Manual mixing and loading** |
| Products from meta-SPC 2.1-2.21-2.22-6.1-8 are intended to be loaded in a container and diluted in warm water (40°C) before laundry disinfection by hand soaking.  Considering the packaging size, it is assumed to be done manually.  *Inhalation route*  The available pH value of the concentrated products is > 10, exposure by inhalation to vapors of HClO is therefore considered negligible.  Due to the small quantities manipulated, no inhalation exposure to aerosols is expected.  *Dermal route*  Products are classified H314-H318, a qualitative risk assessment is performed. |

***Calculations for Task [1.1]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from non-professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.1] | 1/ No PPE | negligible | - |

**Task [1.2]: Application by hand soaking, rinsing and hang out of laundry****to dry**

|  |
| --- |
| **Description of Task [1.2] – Application by hand soaking, rinsing and hang out of laundry** |
| After dilution is prepared, laundry is disinfected by by hand soaking. After the claimed contact time, the treated laundry is rinsed with water and hanged out to dry.  *Inhalation route*  For in-use dilutions of products, the pH values extrapolated by calculation being > 10, inhalation exposure to vapors of HClO is considered negligible .  After hand soaking, the active substance is expected to quickly react with the organic matter during the claimed contact time. Besides, the decrease of the pH induced by rinsing is assumed to be of low order. Taken together, these elements show that inhalation to vapours during rinsing is considered negligible.  *Dermal route*  The in-use dilutions of products being not classified, no qualitative risk assessment is required. |

***Calculations for Task [1.2]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from non-professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% av.Cl)** |
| Task [1.2 ] | 1/ No PPE | negligible | - |

**Combined exposure**

Not relevant.

**Risk characterisation for primary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| **Scenario 1: Laundry disinfection with hand soaking** | | | | | |
| Task [1.1] | Negligible | | | nr | Yes |
| Task [1.2] | Negligible | | | nr | Yes |

Outcome of qualitative local risk assessment (dermal)

Products from Meta SPC 2.1-2.21-2.22-6.1-8 are classified Skin corrosive category 1 (H314) and Severe eye damage (H318).The in-use dilutions of products are not classified..

All the products are intended to be applied by non-professionals.

Please refer to the tables below:

**Outcome of qualitative local risk assessment –** Products from meta SPC **2.1-2.21-2.22-6.1-8** classified H314/H318 used by non-professionals

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** |  |  | **Exposure information** | | |  |  |  | **Risk** |  |
| **Hazard category** | **Effects in**  **terms of C&L** | **Additional relevant hazard information** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant**  **RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| Very High | **Skin Corr.**  **1**  **H314** | - | 2 | Manual mixing and loading | Dermal | **Frequency:** 1/day  **Duration:** no data but approximately 10 min | Potential splashes and spills | none | **Unacceptable** | (**↑**) High hazard category  (**↑**) PVC flexible pack with spout (Berlingot) (Meta SPC 2.21)  (**↑**) Absence of a protection offered by a cap with directional nozzle on the bottle to pour the product (Meta SPC 2.1-2.21-2.22-6.1-8)  (**↑**) No child-proof closure (excepted for Meta SCP 6.1)  (**↑**) High frequency (more than once per week)  (**↓**) Potentially low exposure duration (few minutes per day) |
| **Eye Dam.1, H318** | Ocular | Potential splashes and spills or hand-to-eye transfer | none |

**Laundry disinfection by transfer – Primary exposure – Use #27**

**Meta SPC 2.1-2.22-6.1-8**

Products from Meta SPC 2.1-2.22-6.1-8 classified H314 and H318 have to be diluted before using for laundry hand soaking.

Considering the packaging of HDPE bottle or container claimed by the applicant, the risk is deemed unacceptable for non-professional users. With these types of packaging, exposure cannot be prevent during the dilution step (M&L).

**Meta SPC 2.21**

Products from Meta SPC 2.21 classified H314 and H318 have to be diluted before usinf for laundry hand soaking.

Considering the packaging of PVC flexible pack with spout (berlingot) claimed by the applicant, the risk is deemed unacceptable for non-professional users. With these types of packaging, exposure cannot be prevent during the dilution step (M&L).

***Secondary exposure***

**Scenario [2] – Post-application: migration from fabric**

|  |
| --- |
| **Description of Scenario [2]** |
| General public (adults and children) may be exposed to residues of active chlorine when wearing disinfected clothes.  However, considering the quick degradation and reactivity of the active substance as well as the rinsing phase performing after hand soaking (and the claimed contact time) it is assumed that the amount of active substance remaining in the fabric is negligible.  No inhalation or dermal exposure is expected during wearing disinfected fabric. |

**Combined exposure**

Not relevant.

**Risk characterisation for secondary exposure**

Outcome of (semi-)quantitative local exposure and risk characterisation (inhalation)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** | **Acceptable (Yes/No)** |
| Scenario 2 | 1/no PPE | negligible | | | |

Outcome of qualitative local risk assessment (dermal)

Not relevant.

**Overall conclusion regarding Laundry disinfection by non-professionals**

|  |  |  |  |
| --- | --- | --- | --- |
| **Meta SPC** | **Uses (application by)** | **Conclusion** | **RMM if required** |
| **2.1** | Laundry disinfection | **Unacceptable** | None |
| **2.21** |
| **2.22** |
| **6.1** |
| **8** |

***Dietary exposure***

By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore, residues in food or feed are not expected.

**Sodium hypochlorite** is widely used for disinfection of surfaces and equipment in food and feed processing areas, in veterinary area as well as for disinfection of drinking water, and thus, chlorate residues can be carried-over into food and feed during cleaning, washing and processing steps. Hence a dietary exposure assessment is presented below.

Residue definitions

Due to the high reactivity of chlorine species, residues on surfaces degrade very rapidly (decomposition to physiological sodium and chloride). Hence, residue formation is assumed to be negligible for aqueous solutions of Na(OCl). Finally, no systemic assessment is required for substances such as Na(OCl) which act by a local mode of action only.

The BPC TOX-WG-IV-2016 concluded that chlorate residues may still be relevant as chlorate is considered a stable metabolite. Sodium chlorate is a by-product of the manufacturing process and can be formed during storage. Thus, chlorate may represent a worst-case for Na(OCl).

Furthermore, at EU level (WG TOX III-2016) it was finally discussed that only **chlorates** (ClO3-) is relevant for the dietary risk assessment. This relevant residue can be present in the BP as impurity and can be generated as Disinfection By Products (DBP) or degradation of the active ingredient in the biocidal product upon storage. Consequently, chlorates is a relevant compound to assess for food, feed and drinking water.

*List of scenarios*

*Please note that the applicant has developed an approach to estimate the risk for consumer via drinking water consumption. This approach have been considered as not relevant by eCA. This assessment is presented in Annex Residue §3.4 as informative data.*

| **Summary table: scenarios** | | | | |
| --- | --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Use** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| DRA-1 | Professional PT 3 uses -  Indirect exposure via food and food of animal origin | - Disinfection of non-porous hard surfaces in veterinary area  - Disinfection of non-porous hard surfaces in livestock transportation vehicles | Secondary  Exposure to food of animal origin from livestock in contact with treated hard surfaces/equipment | General public |
| DRA-2 | Non Professional PT 3 use -  Indirect exposure via food of animal origin | - Disinfection of animal housing (such as kennels, hutches, cages) and associated equipment | Secondary  Exposure to food of animal origin from livestock in contact with treated hard surfaces/equipment | General public |
| DRA-3 | Professional PT 4 uses -  Indirect exposure via food and food of animal origin | -Disinfection of hard surfaces in contact with food  - Disinfection of hard surfaces by CIP  - Disinfection of inner surfaces in human drinking water systems  - Disinfection of inner surfaces in veterinary water systems | Secondary  Exposure to food in contact with treated hard surfaces/equipment | General public |
| DRA-4 | Non Professional PT 4 use -Indirect exposure via food | - Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket | Secondary  Exposure to food in contact with treated hard surfaces | General public |
| DRA-5 (a) | Professional PT 5 use – Exposure via drinking water | - Disinfection of water intended for human consumption | Secondary  Exposure to drinking water | General public |

(a) For PT 5 intended use, no application rate is detailed for this use. **Therefore, no exposure assessment can be performed for this use.**

*Information of non-biocidal use of the active substance*

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use** | **Intended use** | **Reference value(s)** |
| 1. | Plant protection products | Disinfectant – in irrigation water applied by watering tree – indoor use for mushroom crop.  Not approved as a PPP active substance. | ADI: 0.15 mg/kg bw/d  ARfD: not applicable  Default MRL of 0.01 mg/kg according to Art 18(1)(b) Reg 396/2005. |

*Estimating Livestock Exposure to Active Substances used in Biocidal Products*

**Scenario DRA-1 and 2:**

Disinfection of animal housing (such as kennels, hutches, cages) and associated equipment for non professional and disinfection of non-porous hard surfaces in livestock transportation vehicles (animal husbandry, veterinary healthcare) for professional are intended by the applicant.

As only PT 3 scenario for professional uses are available in existing guidance document[[4]](#footnote-5) (ECHA, 2017), eCA proposed to apply the following scenario (ECHA 2017) to both professional and non professional users as follows:

* Disinfection of areas in which animals are housed. This scenario is applied to intended non professional use “Disinfection of animal housing and associated equipment”
* Disinfection of animals transport vehicles. This scenario is applied to professional intended use “disinfection of non-porous hard surfaces in livestock transportation vehicles”

To be noted that the applicant also intends the use of DAAP19 as PT3 for disinfection of non-porous hard surfaces in veterinary area (animal husbandry, veterinary healthcare).

For these uses, no European exposure scenario are available. Nevertheless, theses uses can be considered as minor contributor to livestock exposure. Therefore, for this intended use, livestock exposure is considered negligible and no exposure calculation is performed.

Livestock exposure was calculated according to ECHA guidance document[[5]](#footnote-6) (ECHA, 2017) by using the “BfR Livestock Exposure Calculator” (2012;<https://www.bfr.bund.de/en/exposure_estimation_for_biocides-239939.html>). The assessment includes a screening step as well as a realistic worst-case scenario. The subsequent dietary exposure assessment has been performed according to the EMA “Guideline on risk characterization and assessment of maximum residue limits (MRL) for biocides” (2015) taking into account the standard EMA food basket.

Two calculation steps were performed, i.e. a worst-case screening scenario and – in case the screening led to exposure higher than the trigger value of 0.004 mg/kg bw – a realistic scenario.

A rinsing step was considered, and livestock exposure was performed for two tiers:

* Tier-I (without rinsing of treated surfaces);
* Tier-II (with rinsing of the treated surfaces).

In the absence of measured residue data, the assumption was made that 10% (Tier-IIa) or 1% (Tier-IIb) of chlorate residues remain on the treated surface after rinsing, while 90% or 99%, respectively, of chlorate residues are flushed. This is considered realistic, as chlorate is highly soluble in water: for sodium chlorate, a solubility of 960-1000 g/L is described (EFSA CONTAM Panel, 2015. Scientific Opinion on risks for public health related to the presence of chlorate in food. EFSA Journal 2015; 13:4135).

It is noticed that chlorate residue formation may depend on the formulation of the products as well as on the storage conditions of the product.

Table below summarizes final chlorate concentration in diluted biocidal product among all intended meta SPC for PT3 use disinfection of animal housing or livestock transport vehicle for professional or non professional uses.

**Table : final chlorate concentration in diluted biocidal product among all intended meta SPC for PT3 use “disinfection of animal housing or livestock transport vehicle” for professional or non professional use**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **PT 3** | **Meta SPC** | | | | | | | | | | | | |
|  | **2.1** | **2.21** | **2.22** | **6.1** | **6.21** | **6.22** | **7.11** | **7.12** | **7.2** | **8** | **10.1** | **10.2** | **11** |
| **Users** | **Non professional** | | | | **Professional** | | | | | **Non professional** | **Professional** | | |
| Available chlorine eq Cl2 (%w/w) | 2.6 | 4.8 | 3.6 | 9.6 | 9.6 | 13.5 | 3.6 | 4.8 | 2.6 | 1.6 | 2.6 | 4.8 | 6 |
| Chlorate (%w/w) after storage | 0.09 | 0.31 | 0.17 | 1.74 | 1.74 | 2.87 | 0.17 | 0.31 | 0.09 | 0.09 | 0.09 | 0.31 | 1.26 |
| Chlorate (mg/L) after storage | 900 | 3100 | 1700 | 17400 | 17400 | 28700 | 1700 | 3100 | 900 | 900 | 900 | 3100 | 12600 |
| Dilution of biocidal product | 0.375 | 0.5 | 0.29 | 0.11 | 0.105 | 0.093 | 0.263 | 0.18 | 0.35 | 0.6 | 0.35 | 0.18 | 0.18 |
| Density | 1.0397 | 1.0755 | 1.0559 | 1.151 | 1.151 | 1.226 | 1.052 | 1.07 | 1.07 | 1.0262 | 1.04 | 1.072 | 1.192 |
| Chlorate final concentration (mg/L) | 350.9 | 1667.0 | 520.6 | **2203.0** | 2102.9 | **3272.3** | 470.3 | 597.1 | 337.1 | 527.8 | 327.6 | 598.2 | 2703.5 |

The highest chlorate concentration measured for respectively professional and non professional users is used for livestock exposure calculation respectively for professional and non professional uses (see table below).

**Table : amount of chlorate remaining on treated surface after rinsing or not**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Units** | **Tier I** | **Tier IIA** | **Tier IIB** |
| **Professional** | | | | |
| **In-use concentration chlorate** | **g/L** | 3.27 | 3.27 | 3.27 |
| **Application rate product** | **L/m2** | 0.1 | 0.1 | 0.1 |
| **Amount chlorate applied** | **g/m2** | 0.327 | 0.327 | 0.327 |
| **Remaining chlorate after rinsing** | **%** | 100 | 10 | 1 |
| **Amount of chlorate after rinsing (“application rate of a.s”)** | **mg/m2** | 327 | 32.7 | 3.27 |
| **Non professional** | | | | |
| **In-use concentration chlorate** | **g/L** | 2.20 | 2.20 | 2.20 |
| **Application rate product** | **L/m2** | 0.1 | 0.1 | 0.1 |
| **Amount chlorate applied** | **g/m2** | 0.220 | 0.220 | 0.220 |
| **Remaining chlorate after rinsing** | **%** | 100 | 10 | 1 |
| **Amount of chlorate after rinsing (“application rate of a.s”)** | **mg/m2** | 220 | 22.0 | 2.20 |

In the screening scenarios performed for livestock housing and vehicle transport disinfection, the trigger value of 0.004 mg/kg bw was exceeded at least for some animal species. Thus, a realistic exposure scenario was calculated taking into account that animals are not present in the stables/transport vehicles during disinfection and feed is removed from troughs in the stables.

The following three scenarios were considered relevant and assessed for livestock housing use:

* oral – animals licking surfaces and direct treatment of feeding trough surface
* dermal – rubbing against surfaces
* Inhalation with saturated vapour concentration model SVC

The following three scenarios were considered relevant and assessed for transport vehicle use:

* oral – animals licking surfaces
* dermal – rubbing against surfaces
* Inhalation with saturated vapour concentration model SVC

Parameters, default values and results for these two scenarios are presented in the tables below.

Scenario [DRA-1] - Transport vehicles disinfection

| **Description of Scenario [DRA-1]** | | |
| --- | --- | --- |
| Disinfection of non-porous hard surfaces in livestock transportation vehicles. Application rate is 100 mL/m2. Surfaces to be treated: Floor and wall without partitions | | |
|  | Parameters | Value |
| **Tier 1** | Application rate of chlorate | 327 mg/m2 |
| Vapour Pressure (at 25°C) | 3.50 x10-07 Pa |
| Molecular weight | 83.5 g/mol |
| Body weight of animals, number of animal per stable  Gas constant  Temperature | See guidancea |
| **Tier IIa** | Rinsing (default value) | 10% |
| **Tier IIb** | Rinsing (default value) | 1% |

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Scenario [DRA - 2] – Animal housing disinfection

| **Description of Scenario [DRA-2]** | | |
| --- | --- | --- |
| Disinfection of animal housing (such as kennels, hutches, cages) and associated equipment Application rate is 100 mL/m2. Surfaces to be treated: Floor and wall without partitions | | |
|  | Parameters | Value |
| **Tier 1** | Application rate of chlorate | 220 mg/m2 |
| Vapour Pressure (at 25°C) | 3.50 x10-07 Pa |
| Molecular weight | 83.5 g/mol |
| Body weight of animals, number of animal per stable  Gas constant  Temperature | See guidancea |
| **Tier IIa** | Rinsing (default value) | 10% |
| **Tier IIb** | Rinsing (default value) | 1% |

a Guidance on the Biocidal Products Regulation -Volume III Human Health - Assessment & Evaluation (Parts B+C) -6. Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products

As stated in the guidance document, not all scenarios apply to all animal species.

Consequently, exposure in the three chosen scenarios was calculated for relevant animal species only. Total exposure via all three scenarios was then calculated by summing up the values obtained for the three individual scenarios.

As the trigger value of 0.004 mg/kg bw was exceeded in Tier-1 (i.e. without rinsing),

Tier-IIa (90% of chlorate residues remaining after rinsing) and Tier-IIb (99% of chlorate residues remaining after rinsing), a worst case consumer exposure estimate (WCCE) was performed for the realistic scenarios (Tier-I, Tier-IIa and Tier-IIb). For this purpose, the standard EMA food basket (according to the EMA Guideline on MRLs, 2015) was taken into account.

**Table : Worst case consumer exposure (WCCE) estimation – with livestock exposure values for Tier-I - Transport vehicles disinfection**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Livestock exposure results from realistic scenario** | | **Sum of  all routes of exposure (mg chlorate/kg bw/d)** | **Standard Food basket (amount of food eaten) (kg/day) (a)** | | | **Dietary exposure by (mg chlorate/pers/day)** | | |
| **Animal Species** |  | **Meat (muscle. kidney. liver. fat)** | **Milk** | **Eggs** | **Meat** | **Milk** | **Eggs** |
| Beef cattle |  | 5.23 X10-01 | 0.5 | nr | nr | 2.62 X10-01 | nr | nr |
| Dairy cattle |  | 4.63 X10-01 | nr | 1.50 | nr | nr | 6.94 X10-01 | nr |
| Calf |  | 8.42 X10-01 | 0.5 | nr | nr | 4.21 X10-01 | nr | nr |
| Fattening pig |  | 9.97 X10-01 | 0.5 | nr | nr | 4.99 X10-01 | nr | nr |
| Breeding pig |  | 6.29 X10-01 | nr | nr | nr | nr | nr | nr |
| Breeding pig | individual housing | - | nr | nr | nr | nr | nr | nr |
| Breeding pig | group housing | - | nr | nr | nr | nr | nr | nr |
| Sheep |  | 3.49 X10-01 | 0.5 | nr | nr | 1.74 X10-01 | nr | nr |
| Lamb |  | 6.54 X10-01 | 0.5 | nr | nr | 3.27 X10-01 | nr | nr |
| Slaughter goat (= goat kids) |  | 3.90 | 0.5 | nr | nr | 1.95 | nr | nr |
| Lactating goat |  | 1.42 | nr | 1.50 | nr |  | 2.14 | nr |
| Broilers |  | 1.39 X10-06 | 0.5 | nr | nr | 6.93 X10-07 | nr | nr |
| Broilers | free range. litter floor | - | nr | nr | nr | nr | nr | nr |
| Broilers | parent broilers. free range (grating floor) | - | nr | nr | nr | nr | nr | nr |
| Broilers | parent broilers in rearing. free range (grating floor) | - | nr | nr | nr | nr | nr | nr |
| Laying hen |  | 1.24 X10-06 | nr | nr | 0.1 | nr | nr | 1.24 X10-07 |
| Laying hen | battery | - | nr | nr | 0.1 | nr | nr | nr |
| Laying hen | free range (litter floor) | - | nr | nr | 0.1 | nr | nr | nr |
| Laying hen | free range (grating floor) | - | nr | nr | 0.1 | nr | nr | nr |
| Turkey |  | 1.01 X10-06 | 0.5 | nr | nr | 5.05 X10-07 | nr | nr |
| Horse |  | 6.62 X10-01 | 0.5 | nr | nr | 3.31 X10-01 | nr | nr |
| Rabbit |  | 4.24 X10-06 | 0.5 | nr | nr | 2.12 X10-06 | nr | nr |
| Maximum |  |  |  |  |  | 1.95 | 2.14 | 1.24 X10-07 |

(a) The **standard food basket** proposed in the EMA guidance on MRL setting (2010) contains: muscle 300 g, liver 100 g, fat 50 g, kidney 50 g, milk 1500 g, eggs 100 g, honey 20 g. For calculations, amounts of muscle, liver, kidney and fat were added, resulting in 500 g of animal tissue eaten.

**Table : Worst case consumer exposure (WCCE) estimation – with livestock exposure values for Tier-IIa - Transport vehicles disinfection .**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Livestock exposure results from realistic scenario** | | **Sum of  all routes of exposure (mg chlorate/kg bw/d)** | **Standard Food basket (amount of food eaten) (kg/day) (a)** | | | **Dietary exposure by (mg chlorate/pers/day)** | | |
| **Animal Species** |  | **Meat (muscle. kidney. liver. fat)** | **Milk** | **Eggs** | **Meat** | **Milk** | **Eggs** |
| Beef cattle |  | 5.23 X10-02 | 0.5 | nr | nr | 2.62 X10-02 | nr | nr |
| Dairy cattle |  | 4.63 X10-02 | nr | 1.50 | nr | nr | 6.94 X10-02 | nr |
| Calf |  | 8.42 X10-02 | 0.5 | nr | nr | 4.21 X10-02 | nr | nr |
| Fattening pig |  | 9.97 X10-02 | 0.5 | nr | nr | 4.99 X10-02 | nr | nr |
| Breeding pig\* |  | 6.29 X10-02 | nr | nr | nr | nr | nr | nr |
| Breeding pig | individual housing | - | nr | nr | nr | nr | nr | nr |
| Breeding pig | group housing | - | nr | nr | nr | nr | nr | nr |
| Sheep |  | 3.49 X10-02 | 0.5 | nr | nr | 1.74 X10-02 | nr | nr |
| Lamb |  | 6.54 X10-02 | 0.5 | nr | nr | 3.27 X10-02 | nr | nr |
| Slaughter goat (= goat kids) |  | 3.90 X10-01 | 0.5 | nr | nr | 1.95 X10-01 | nr | nr |
| Lactating goat |  | 1.42 X10-01 | nr | 1.50 | nr | nr | 2.14 X10-01 | nr |
| Broilers |  | 1.39 X10-06 | 0.5 | nr | nr | 6.93 X10-07 | nr | nr |
| Broilers | free range. litter floor | - | nr | nr | nr | nr | nr | nr |
| Broilers | parent broilers. free range (grating floor) | - | nr | nr | nr | nr | nr | nr |
| Broilers | parent broilers in rearing. free range (grating floor) | - | nr | nr | nr | nr | nr | nr |
| Laying hen |  | 1.24 X10-06 | nr | nr | 0.1 | nr | nr | 1.24 X10-07 |
| Laying hen | battery | - | nr | nr | 0.1 | nr | nr | nr |
| Laying hen | free range (litter floor) | - | nr | nr | 0.1 | nr | nr | nr |
| Laying hen | free range (grating floor) | - | nr | nr | 0.1 | nr | nr | nr |
| Turkey |  | 1.01 X10-06 | 0.5 | nr | nr | 5.05 X10-07 | nr | nr |
| Horse |  | 6.62 X10-02 | 0.5 | nr | nr | 3.31 X10-02 | nr | nr |
| Rabbit |  | 4.24 X10-06 | 0.5 | nr | nr | 2.12 X10-06 | nr | nr |
| Maximum |  |  |  |  |  | 1.95 X10-01 | 2.14 X10-01 | 1.24 X10-07 |

(a) The **standard food basket** proposed in the EMA guidance on MRL setting (2010) contains: muscle 300 g, liver 100 g, fat 50 g, kidney 50 g, milk 1500 g, eggs 100 g, honey 20 g. For calculations, amounts of muscle, liver, kidney and fat were added, resulting in 500 g of animal tissue eaten.

**Table : Worst case consumer exposure (WCCE) estimation – with livestock exposure values for Tier-IIb - Transport vehicles disinfection.**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Livestock exposure results from realistic scenario** | | **Sum of  all routes of exposure (mg chlorate/kg bw/d)** | **Standard Food basket (amount of food eaten) (kg/day) (a)** | | | **Dietary exposure by (mg chlorate/pers/day)** | | |
| **Animal Species** |  | **Meat (muscle. kidney. liver. fat)** | **Milk** | **Eggs** | **Meat** | **Milk** | **Eggs** |
| Beef cattle |  | 5.23 X10-03 | 0.5 | nr | nr | 2.62 X10-03 | nr | nr |
| Dairy cattle |  | 4.63 X10-03 | nr | 1.50 | nr | nr | 6.94 X10-03 | nr |
| Calf |  | 8.42 X10-03 | 0.5 | nr | nr | 4.21 X10-03 | nr | nr |
| Fattening pig |  | 9.98 X10-03 | 0.5 | nr | nr | 4.99 X10-03 | nr | nr |
| Breeding pig |  | 6.29 X10-03 | nr | nr | nr | nr | nr | nr |
| Breeding pig | individual housing | 0.00 X10+00 | nr | nr | nr | nr | nr | nr |
| Breeding pig | group housing | 0.00 X10+00 | nr | nr | nr | nr | nr | nr |
| Sheep |  | 3.49 X10-03 | 0.5 | nr | nr | 1.74 X10-03 | nr | nr |
| Lamb |  | 6.54 X10-03 | 0.5 | nr | nr | 3.27 X10-03 | nr | nr |
| Slaughter goat (= goat kids) |  | 3.90 X10-02 | 0.5 | nr | nr | 1.95 X10-02 | nr | nr |
| Lactating goat |  | 1.42 X10-02 | nr | 1.50 | nr | nr | 2.14 X10-02 | nr |
| Broilers |  | 1.39 X10-06 | 0.5 | nr | nr | 6.93 X10-07 | nr | nr |
| Broilers | free range. litter floor | - | nr | nr | nr | nr | nr | nr |
| Broilers | parent broilers. free range (grating floor) | - | nr | nr | nr | nr | nr | nr |
| Broilers | parent broilers in rearing. free range (grating floor) | - | nr | nr | nr | nr | nr | nr |
| Laying hen |  | 1.24 X10-06 | nr | nr | 0.1 | nr | nr | 1.24 X10-07 |
| Laying hen | battery | - | nr | nr | 0.1 | nr | nr | nr |
| Laying hen | free range (litter floor) | - | nr | nr | 0.1 | nr | nr | nr |
| Laying hen | free range (grating floor) | - | nr | nr | 0.1 | nr | nr | nr |
| Turkey |  | 1.01 X10-06 | 0.5 | nr | nr | 5.05 X10-07 | nr | nr |
| Horse |  | 6.62 X10-03 | 0.5 | nr | nr | 3.31 X10-03 | nr | nr |
| Rabbit |  | 4.24 X10-06 | 0.5 | nr | nr | 2.12 X10-06 | nr | nr |
| Maximum |  |  |  |  |  | 1.95 X10-02 | 2.14 X10-02 | 1.24 X10-07 |

(a) The **standard food basket** proposed in the EMA guidance on MRL setting (2010) contains: muscle 300 g, liver 100 g, fat 50 g, kidney 50 g, milk 1500 g, eggs 100 g, honey 20 g. For calculations, amounts of muscle, liver, kidney and fat were added, resulting in 500 g of animal tissue eaten.

**Table : Worst case consumer exposure (WCCE) estimation – with livestock exposure values for Tier-I – animal housing disinfection**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Livestock exposure results from realistic scenario** | | **Sum of  all routes of exposure (mg chlorate/kg bw/d)** | **Standard Food basket (amount of food eaten) (kg/day) (a)** | | | **Dietary exposure by (mg chlorate/pers/day)** | | |
| **Animal Species** |  | **Meat (muscle. kidney. liver. fat)** | **Milk** | **Eggs** | **Meat** | **Milk** | **Eggs** |
| Beef cattle |  | 1.50 | 0.5 | nr | nr | 7.48 X10-01 | nr | nr |
| Dairy cattle |  | 2.55 | nr | 1.50 | nr | nr | 3.82 | nr |
| Calf |  | 2.77 | 0.5 | nr | nr | 1.38 | nr | nr |
| Fattening pig |  | 3.31 | 0.5 | nr | nr | 1.66 | nr | nr |
| Breeding pig |  | 4.23 X10-01 | nr | nr | nr | nr | nr | nr |
| Breeding pig | individual housing | 5.28 | nr | nr | nr | nr | nr | nr |
| Breeding pig | group housing | 2.37 X10 | nr | nr | nr | nr | nr | nr |
| Sheep |  | 2.35 X10-01 | 0.5 | nr | nr | 1.17 X10-01 | nr | nr |
| Lamb |  | 4.40 X10-01 | 0.5 | nr | nr | 2.20 X10-01 | nr | nr |
| Slaughter goat (= goat kids) |  | 2.62 X10 | 0.5 | nr | nr | 1.31 | nr | nr |
| Lactating goat |  | 9.59 X10-01 | nr | 1.50 | nr | nr | 1.44 | nr |
| Broilers |  | 1.39 X10-06 | 0.5 | nr | nr | 6.93 X10-07 | nr | nr |
| Broilers | free range. litter floor | - | nr | nr | nr | nr | nr | nr |
| Broilers | parent broilers. free range (grating floor) | - | nr | nr | nr | nr | nr | nr |
| Broilers | parent broilers in rearing. free range (grating floor) | - | nr | nr | nr | nr | nr | nr |
| Laying hen |  | 1.24 X10-06 | nr | nr | 0.1 | nr | nr | 1.24 X10-07 |
| Laying hen | battery | 1.16 | nr | nr | 0.1 | nr | nr | 1.16 X10-01 |
| Laying hen | free range (litter floor) | - | nr | nr | 0.1 | nr | nr | nr |
| Laying hen | free range (grating floor) | - | nr | nr | 0.1 | nr | nr | nr |
| Turkey |  | 1.01 X10-06 | 0.5 | nr | nr | 5.05 X10-07 | nr | nr |
| Horse |  | 4.46 X10-01 | 0.5 | nr | nr | 2.23 X10-01 | nr | nr |
| Rabbit |  | 4.24 X10-06 | 0.5 | nr | nr | 2.12 X10-06 | nr | nr |
| Maximum |  |  |  |  |  | 1.66 | 3.82 | 1.16 X10-01 |

(a) The **standard food basket** proposed in the EMA guidance on MRL setting (2010) contains: muscle 300 g, liver 100 g, fat 50 g, kidney 50 g, milk 1500 g, eggs 100 g, honey 20 g. For calculations, amounts of muscle, liver, kidney and fat were added, resulting in 500 g of animal tissue eaten.

**Table : Worst case consumer exposure (WCCE) estimation – with livestock exposure values for Tier-IIa - animal housing disinfection**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Livestock exposure results from realistic scenario** | | **Sum of  all routes of exposure (mg chlorate/kg bw/d)** | **Standard Food basket (amount of food eaten) (kg/day) (a)** | | | **Dietary exposure by (mg chlorate/pers/day)** | | |
| **Animal Species** |  | **Meat (muscle. kidney. liver. fat)** | **Milk** | **Eggs** | **Meat** | **Milk** | **Eggs** |
| Beef cattle |  | 1.50 X10-01 | 0.5 | nr | nr | 7.48 X10-02 | nr | nr |
| Dairy cattle |  | 2.55 X10-01 | nr | 1.50 | nr | nr | 3.82 X10-01 | nr |
| Calf |  | 2.77 X10-01 | 0.5 | nr | nr | 1.38 X10-01 | nr | nr |
| Fattening pig |  | 3.31 X10-01 | 0.5 | nr | nr | 1.66 X10-01 | nr | nr |
| Breeding pig |  | 4.23 X10-02 | nr | nr | nr | nr | nr | nr |
| Breeding pig | individual housing | 5.28 X10-01 | nr | nr | nr | nr | nr | nr |
| Breeding pig | group housing | 2.37 X10-01 | nr | nr | nr | nr | nr | nr |
| Sheep |  | 2.35 X10-02 | 0.5 | nr | nr | 1.17 X10-02 | nr | nr |
| Lamb |  | 4.40 X10-02 | 0.5 | nr | nr | 2.20 X10-02 | nr | nr |
| Slaughter goat (= goat kids) |  | 2.62 X10-01 | 0.5 | nr | nr | 1.31 X10-01 | nr | nr |
| Lactating goat |  | 9.59 X10-02 | nr | 1.50 | nr | nr | 1.44 X10-01 | nr |
| Broilers |  | 1.39 X10-06 | 0.5 | nr | nr | 6.93 X10-07 | nr | nr |
| Broilers | free range. litter floor | - | nr | nr | nr | nr | nr | nr |
| Broilers | parent broilers. free range (grating floor) | - | nr | nr | nr | nr | nr | nr |
| Broilers | parent broilers in rearing. free range (grating floor) | - | nr | nr | nr | nr | nr | nr |
| Laying hen |  | 1.24 X10-06 | nr | nr | 0.1 | nr | nr | 1.24 X10-07 |
| Laying hen | battery | 1.16 X10-01 | nr | nr | 0.1 | nr | nr | 1.16 X10-02 |
| Laying hen | free range (litter floor) | - | nr | nr | 0.1 | nr | nr | nr |
| Laying hen | free range (grating floor) | - | nr | nr | 0.1 | nr | nr | nr |
| Turkey |  | 1.01 X10-06 | 0.5 | nr | nr | 5.05 X10-07 | nr | nr |
| Horse |  | 4.46 X10-02 | 0.5 | nr | nr | 2.23 X10-02 | nr | nr |
| Rabbit |  | 4.24 X10-06 | 0.5 | nr | nr | 2.12 X10-06 | nr | nr |
| Maximum |  |  |  |  |  | 1.66 X10-01 | 3.82 X10-01 | 1.16 X10-02 |

(a) The **standard food basket** proposed in the EMA guidance on MRL setting (2010) contains: muscle 300 g, liver 100 g, fat 50 g, kidney 50 g, milk 1500 g, eggs 100 g, honey 20 g. For calculations, amounts of muscle, liver, kidney and fat were added, resulting in 500 g of animal tissue eaten.

**Table : Worst case consumer exposure (WCCE) estimation – with livestock exposure values for Tier-IIb - animal housing disinfection**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Livestock exposure results from realistic scenario** | | **Sum of  all routes of exposure (mg chlorate/kg bw/d)** | **Standard Food basket (amount of food eaten) (kg/day) (a)** | | | **Dietary exposure by (mg chlorate/pers/day)** | | |
| **Animal Species** |  | **Meat (muscle. kidney. liver. fat)** | **Milk** | **Eggs** | **Meat** | **Milk** | **Eggs** |
| Beef cattle |  | 1.50 X10-02 | 0.5 | nr | nr | 7.48 X10-03 | nr | nr |
| Dairy cattle |  | 2.55 X10-02 | nr | 1.50 | nr | nr | 3.82 X10-02 | nr |
| Calf |  | 2.77 X10-02 | 0.5 | nr | nr | 1.38 X10-02 | nr | nr |
| Fattening pig |  | 3.31 X10-02 | 0.5 | nr | nr | 1.66 X10-02 | nr | nr |
| Breeding pig |  | 4.23 X10-03 | nr | nr | nr | nr | nr | nr |
| Breeding pig | individual housing | 5.28 X10-02 | nr | nr | nr | nr | nr | nr |
| Breeding pig | group housing | 2.37 X10-02 | nr | nr | nr | nr | nr | nr |
| Sheep |  | 2.35 X10-03 | 0.5 | nr | nr | 1.17 X10-03 | nr | nr |
| Lamb |  | 4.40 X10-03 | 0.5 | nr | nr | 2.20 X10-03 | nr | nr |
| Slaughter goat (= goat kids) |  | 2.62 X10-02 | 0.5 | nr | nr | 1.31 X10-02 | nr | nr |
| Lactating goat |  | 9.59 X10-03 | nr | 1.50 | nr | nr | 1.44 X10-02 | nr |
| Broilers |  | 1.39 X10-06 | 0.5 | nr | nr | 6.93 X10-07 | nr | nr |
| Broilers | free range. litter floor | - | nr | nr | nr | nr | nr | nr |
| Broilers | parent broilers. free range (grating floor) | - | nr | nr | nr | nr | nr | nr |
| Broilers | parent broilers in rearing. free range (grating floor) | - | nr | nr | nr | nr | nr | nr |
| Laying hen |  | 1.24 X10-06 | nr | nr | 0.1 | nr | nr | 1.24 X10-07 |
| Laying hen | battery | 1.16 X10-02 | nr | nr | 0.1 | nr | nr | 1.16 X10-03 |
| Laying hen | free range (litter floor) | - | nr | nr | 0.1 | nr | nr | nr |
| Laying hen | free range (grating floor) | - | nr | nr | 0.1 | nr | nr | nr |
| Turkey |  | 1.01 X10-06 | 0.5 | nr | nr | 5.05 X10-07 | nr | nr |
| Horse |  | 4.46 X10-03 | 0.5 | nr | nr | 2.23 X10-03 | nr | nr |
| Rabbit |  | 4.24 X10-06 | 0.5 | nr | nr | 2.12 X10-06 | nr | nr |
| Maximum |  |  |  |  |  | 1.66 X10-02 | 3.82 X10-02 | 1.16 X10-03 |

(a) The **standard food basket** proposed in the EMA guidance on MRL setting (2010) contains: muscle 300 g, liver 100 g, fat 50 g, kidney 50 g, milk 1500 g, eggs 100 g, honey 20 g. For calculations, amounts of muscle, liver, kidney and fat were added, resulting in 500 g of animal tissue eaten.

*Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)*

**Scenario DRA-3:**

With regards to professional intended PT 4 use, dietary exposure to available chlorine and chlorate in food was assessed and considered acceptable in the CAR[[6]](#footnote-7). This refers to the EFSA Scientific Opinion of the EFSA CONTAM Panel on “*Risks for public health related to the presence of chlorate in food*” (EFSA Journal 2015;13(6):4135) which includes a comprehensive dietary exposure and risk assessment for chlorate residues in food and drinking water based on occurrence data. The conclusion of this assessment remains valid for intended professional PT 4 uses:

*“Potential chlorate residues from the application of chlorine and hypochlorite in PTs 4 and 5 are considered to be included in the measured chlorate residue values, and the conclusions drawn by the EFSA CONTAM Panel on chlorate residues cover thus also the dietary risk arising from PT4 and PT5 uses of chlorine and hypochlorite. Since the EFSA Scientific Opinion on chlorate residues provides actual measured data for chlorate residues in food and an exhaustive exposure and risk assessment based on consumption data, the conclusions drawn in the EFSA Scientific Opinion are superior to any dietary risk assessment based on exposure models.”*

**Consequently, no dietary risk assessment is deemed necessary for the intended PT 4 professional uses.**

**Scenario DRA-5:**

For PT 5 intended use, no application rate is detailed for this use. **Therefore, no exposure assessment can be performed for this use.**

*Estimating transfer of biocidal active substances into foods as a result of non-professional use*

**Scenario DRA-4:**

After non professional PT 4 use, general public may be exposed to chlorate residue by consumption of food that could have been in contact with hard surfaces treated.

Dietary exposure assessment has been performed according to ECHA guidance document[[7]](#footnote-8) for adults only. Indeed, as detailed in ECHA guidance document[[8]](#footnote-9), default value of 0.2 m2 for parameter “area in contact with food” is “*derived for adults; flexibility can be applied in regard to the value to be used for toddlers to allow for different or lower food consumption*”. Therefore, detailed scenario exposure is not representative of toddler food intake.

A rinsing step was considered, and indirect exposure via food was performed for two tiers:

* Tier-I (without rinsing of treated surfaces);
* Tier-II (with rinsing of the treated surfaces).

In the absence of measured residue data, the assumption was made that 10% (Tier-IIa) or 1% (Tier-IIb) of chlorate residues remain on the treated surface after rinsing, while 90% or 99%, respectively, of chlorate residues are flushed. This is considered realistic, as chlorate is highly soluble in water: for sodium chlorate, a solubility of 960-1000 g/L is described (EFSA CONTAM Panel, 2015. Scientific Opinion on risks for public health related to the presence of chlorate in food. EFSA Journal 2015; 13:4135).

It is noticed that chlorate residue formation may depend on the formulation of the products as well as on the storage conditions of the product.

Table below summarizes final chlorate concentration in diluted biocidal product among all intended meta SPC for PT4 use disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket for non professional use.

**Table: final chlorate concentration in diluted biocidal product among all intended meta SPC for PT4 use disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket for non professional use**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket** | **Meta SPC** | | | | |
|  | **2.1** | **2.21** | **2.22** | **6.1** | **8** |
| **Users** | **Non professional** | | | | |
| Available chlorine eq Cl2 (%w/w) | 2.6 | 4.8 | 3.6 | 9.6 | 1.6 |
| Chlorate (%w/w) after storage | 0.09 | 0.31 | 0.17 | 1.74 | 0.09 |
| Chlorate (mg/L) after storage | 900 | 3100 | 1700 | 17400 | 900 |
| Dilution of biocidal product | 0.3 | 0.5 | 0.22 | 0.09 | 0.5 |
| Density | 1.0397 | 1.0755 | 1.0559 | 1.151 | 1.0262 |
| Chlorate final concentration (mg/L) | 280.7 | 1667.0 | 398.9 | **1820.7** | 461.8 |

The highest chlorate concentration is used for indirect exposure via food calculation presented below.

**Table: Parameters and input values for scenario DRA-4**

| **Description of Scenario [DRA-4]** | | | |
| --- | --- | --- | --- |
|  | **Parameters** | **Value** | **Reference/remarks** |
| Tier I | In-use concentration chlorate (C) | 1820.7 mg/L | DAAP19 intended uses |
| Water film thickness on treated surfaces | 0.002 cm | Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017) (1) |
| Volume expected considering the water film thickness on treated surfaces (V) | 0.02 L/m² |  |
| Biocide residues on surface (mg a.s./m2) (Rsurface) | 36.41 mg/m² | Rsurface = CxV |
| Area in contact with food (A food contact) | 0.2 m2 | Guidance on the BPR : volume III P art B+C, Version 4.0 December 2017 - Default value for surface treatment, acute/ chronic exposure |
| Dietary Intake Fraction:  Acute/chronic exposure (D) | 1 / 0.5 | Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017 |
| Default Body weight (kg) adults (bw) | 60 kg | Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017 |
| Mass transfer efficiency (TF) | 1 | Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017 - Default value (worst case) |
|  | Remaining residues on treated surfaces after a rinsing step Tier I (RF) | 100% | Default rinsing factor |
| Tier IIa/IIb | Remaining residues on treated surfaces after a rinsing step Tier IIa/ Tier IIb (RF) | 10% / 1% | Default rinsing factor |

1. Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses -Version 4.0 December 2017

**Calculations for Scenario [DRA-4]**

Following equation has been used to estimate adult, chronic/acute consumer exposure in both Tier I and Tier IIa/Tier IIb:

Expcons = Rsurface x Afood contact x TF x D x RF ÷ bw

**Table: Estimation of consumer exposure via food for scenario DRA-4**

|  |  |  |  |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier** | **Exposure** | **Adult** |
| Scenario [DRA-3] | Tier I | Estimation of consumer exposure via food (acute exposure) (mg/kg bw) | 0.1214 |
| Estimation of consumer exposure via food (chronic exposure) (mg/kg bw) | 0.0607 |
| Tier IIa | Estimation of consumer exposure via food (acute exposure) (mg/kg bw) | 0.0121 |
| Estimation of consumer exposure via food (chronic exposure) (mg/kg bw) | 0.0061 |
| Tier IIb | Estimation of consumer exposure via food (acute exposure) (mg/kg bw) | 0.0012 |
| Estimation of consumer exposure via food (chronic exposure) (mg/kg bw) | 0.0006 |

**Conclusion**

For non-professional PT 4 uses, dietary exposure assessment has been performed according ECHA guidance document[[9]](#footnote-10) for adults only.

***Exposure associated with production, formulation and disposal of the biocidal product***

Not relevant

***Aggregated exposure***

Not relevant

#### Risk characterisation for human health (Dietary RA)

Reference values to be used in Risk Characterisation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| ARfD | based on human 12-wks repeated dose oral (drinking water) clinical study according to EFSA CONTAM Panel (EFSA Journal 2015;13(6):4135 | Not applicable | Not applicable | Not applicable | 36 µg chlorate/kg bw |
| ADI | based on the TDI for perchlorate (derived from human observations) according to EFSA CONTAM Panel (EFSA Journal 2015;13(6):4135) | Not applicable | Not applicable | Not applicable | 3 µg chlorate/kg bw |

1 Please explain background and reason for assessment factor.

*[Please insert rows for additional reference values if necessary, e.g. for local effects.]*

**Maximum residue limits or equivalent**

|  |  |  |  |
| --- | --- | --- | --- |
| **MRLs or other relevant reference values** | **Reference** | **Relevant commodities** | **Value** |
| Drinking water limit – chlorate | WHO, 2005 WHO/SDE/WSH/05.08/86[[10]](#footnote-11)  Water Directive  Proposed limit (EC 2020[[11]](#footnote-12)) | Drinking water  Drinking water with disinfection method | 0.7 mg/L |
| Drinking water limit – chlorate | Water Directive  Proposed limit (EC 2020[[12]](#footnote-13)) | Drinking water except for disinfection method | 0.25 mg/L |
| MRL chlorate - Reg. (EU) 2020/749 | MRL fixed based on monitoring data and target sampling on Food commodities | Raw food commodities  plant matrices | From 0.05 to 0.7 mg/kg |
| MRL fixed based on monitoring data and target sampling on Food commodities | Raw food commodities  animal matrices | Muscle: 0.05 mg/kg  Fat: 0.1\* mg/kg  Liver: 0.05 mg/kg  Kidney:0.05 mg/kg  Edible offals: 0.05 mg/kg  Milk: 0.1 mg/kg  Eggs: 0.05 mg/kg |

MRL compliance can only be performed for intended PT 3 professional use. For animal transport vehicle disinfection, based on calculations performed above and taking into account a rinsing step (Tier IIb), it can be concluded that MRLs for chlorate in food of animal origin will not be exceeded (see table below).

**Table: estimated chlorate residues in food of animal origin and MRL compliance**

|  |  |  |  |
| --- | --- | --- | --- |
| **Food commodities** | **Estimated chlorate residues (mg/kg)** | **In force MRLs (mg/kg)** | **MRL exceedance (Yes/No) ?** |
| Meat \* | 0.039 | 0.05 | No |
| Milk \*\* | 0.014 | 0.1 | No |
| Eggs \*\* | 0.00000124 | 0.05 | No |

\* Highest value among beef cattle, calf, fattening pig, sheep, lamb, slaughter goat, broilers, turkey, horse and rabbit

\*\* Highest value among dairy cattle and lactating goat

\*\*\* Value for laying hen

***Risk for consumers via residues in food***

**Scenario DRA 1 and 2:**

For intended PT 3 professional and non professional uses, dietary risk assessment has been performed and results are detailed below:

**Table: risk calculation for intended PT3 use “disinfection of livestock transport vehicle” for professional**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Tier** | **Product consumed** | **chlorated taken up via diet (kg)** | **Body weight (kg)** | **Systemic exposure to chlorate (mg/kg bw)** | **% ADI (0.003 mg/kg bw/d)** |
| **Tier I** | meat | 1.95 | 60 | 0.032 | 1083% |
| milk | 2.14 | 60 | 0.036 | 1187% |
| eggs | 1.24 X10-07 | 60 | 2.07 X10-09 | 0% |
| meat+milk+eggs | 4.09 | 60 | 0.068 | 2270% |
| **Tier IIa** | meat | 0.19 | 60 | 3.25 X10-03 | 108% |
| milk | 0.21 | 60 | 3.56 X10-03 | 119% |
| eggs | 1.24 X10-07 | 60 | 2.07 X10-09 | 0% |
| meat+milk+eggs | 0.41 | 60 | 6.81 X10-03 | 227% |
| **Tier IIb** | meat | 0.019 | 60 | 3.25 X10-04 | 10.8% |
| milk | 0.021 | 60 | 3.56 X10-04 | 11.9% |
| eggs | 1.24 X10-07 | 60 | 2.07 X10-09 | 0% |
| meat+milk+eggs | 0.041 | 60 | 6.81 X10-04 | 22.7% |

**Table: risk calculation for intended PT3 use “disinfection of animal housing ” for non professional use**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Tier** | **Product consumed** | **chlorated taken up via diet (kg)** | **Body weight (kg)** | **Systemic exposure to chlorate (mg/kg bw)** | **% ADI (0.003 mg/kg bw/d)** |
| **Tier I** | meat | 1.66 | 60 | 0.028 | 920% |
| milk | 3.82 | 60 | 0.064 | 2121% |
| eggs | 0.12 | 60 | 0.002 | 64% |
| meat+milk+eggs | 5.59 | 60 | 0.093 | 3105% |
| **Tier IIa** | meat | 0.17 | 60 | 2.76 X10-03 | 92% |
| milk | 0.38 | 60 | 6.36 X10-03 | 212% |
| eggs | 0.01 | 60 | 1.93 X10-04 | 6% |
| meat+milk+eggs | 0.56 | 60 | 9.32 X10-03 | 311% |
| **Tier IIb** | meat | 0.017 | 60 | 2.76 X10-04 | 9.2% |
| milk | 0.038 | 60 | 6.36 X10-04 | 21.2% |
| eggs | 0.001 | 60 | 1.93 X10-05 | 0.6% |
| meat+milk+eggs | 0.056 | 60 | 9.32 X10-04 | 31.1% |

Consumption of eggs, milk and meat from livestock potentially in contact with chlorate residues resulting from the use of sodium hypochlorite disinfection products exceeds ADIchlorate or ARfDchlorate for Tier-I and Tier IIa assessment for both uses. For Tier-IIb ADI and ARfD are not exceeded for both intended uses.

**Scenario DRA-3:**

See above paragraph “dietary exposure”.

For the intended PT 4 professional uses, no dietary risk assessment is deemed necessary.

**Scenario DRA-4**

For intended PT 4 non professional use, dietary risk assessment has been performed according ECHA guidance document[[13]](#footnote-14) for adults only and results are detailed below:

**Table: risk calculation for intended PT4 use “Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket” for non professional use**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | ***Risk for consumers via residues in food*** | | | | | |
|  | **Scenario DRA 4: Non professional PT 4 use** | | | | | |
|  | **Dietary exposure** (mg/kg bw/d) | | | **Dietary Risk** % of ADI (0.003 mg/kg b.w./d) or ARfD (0.036 mg/kg b.w.) | | |
|  | **Tier I** | **Tier IIa** | **Tier IIb** | **Tier I** | **Tier IIa** | **Tier IIb** |
| Adult (chronic) | 0.0607 | 0.0061 | 0.0006 | 2023.0 | 202.3 | 20.2 |
| Adult (acute) | 0.1214 | 0.0121 | 0.0012 | 337.2 | 33.7 | 3.4 |

**Conclusion**

For non-professional PT 4 uses:

* in Tier I: Indirect exposure via food is above toxicological reference values
* in Tier IIa: Indirect exposure via food is above ARfD
* in Tier IIb: Indirect exposure via food is below toxicological reference values

As a conclusion, no concern for general public from indirect exposure to either available chlorine or chlorate in food is observed when a rinsing of treated surfaces occurs.

### Risk assessment for animal health

**Disinfection of swimming pools/footbaths**

**Meta SPC 1.1 & 1.2**

Pets may be exposed to treated water in private swimming pools.

Inhalation and dermal exposure of pets to active chlorine is considered covered by the assessment performed for the general public (especially for infants).

In this context, the risk is deemed acceptable for pets.

**Disinfection of hard surfaces (floors and other than floors)**

**Meta SPC 2.1-2.21-2.22-6.1-8**

Animals may be exposed to treated surfaces when re-entering the housing or be in contact with treated equipment.

Inhalation and dermal exposure of animals to active chlorine is considered covered by the assessment performed for the bystanders (secondary exposure).

Similar RMMs set for human secondary exposure are therefore required to avoid animal exposure:

* Do not let animals enter the treated area during the disinfection process;
* Do not let animals enter the treated area before the surfaces/equipment are completely dried.

However, no acceptable risk has been identified for non-professional users, therefore no animal exposure is expected.

**Meta SPC 6.21-6.22-7.11-7.12-7.2-10.1-10.2-11**

Animals may be exposed to treated surfaces when re-entering the housing or the transport vehicles.

Inhalation and dermal exposure of animals to active chlorine is considered covered by the assessment performed for the bystanders (secondary exposure).

Similar RMMs set for human secondary exposure are therefore required to avoid animal exposure:

* Do not let animals enter the treated area (animal housing or transport vehicles) during the disinfection process;
* Do not let animals enter the treated area before the surfaces are completely dried.

**Water disinfection**

**Meta SPC 6.21-6.22-7.11-7.12-7.2**

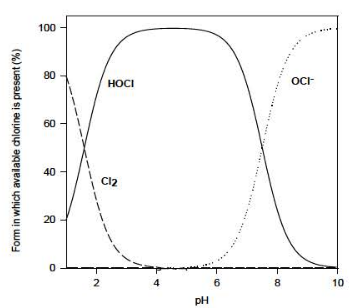
Animals may be exposed to treated water during showering.

The exposure is considered covered by the assessment performed for general public for this scenario.

Therefore, the risk is considered acceptable for products from meta SPC 6.21-6.22-7.11-7.12-7.2.

### Risk assessment for the environment

The active substance released from sodium hypochlorite, calcium chlorite or chlorine in water, is active chlorine. Hypochlorous acid (HClO) is in equilibrium with the hypochlorite ion (ClO-) and chlorine (Cl2). The equilibrium depends on the pH value: chlorine is available below pH 4, in the neutral pH range hypochlorous acid is predominant, and at pH values higher than 10, the only species present is the hypochlorite ion, see figure below.

The sum of these species [hypochlorite ion + hypochlorous acid + chlorine] is defined as active chlorine or available chlorine. For the chemical reactivity in aqueous solution with the same active chlorine concentrations and the same pH conditions, it is irrelevant whether active chlorine is generated from either chlorine gas, calcium hypochlorite or sodium hypochlorite. Therefore, all studies investigating hypochlorite aqueous solutions can be used for evaluation and assessment of active chlorine released from any of the three substances.

TRC (total residual chlorine) is a measurement of both free and combined chlorine (such as chloramines). It is difficult to separate the contribution to toxicity of the FAC (free available chlorine) such as HClO/ClO- from that of the combined chlorine species. For studies where the percentage of FAC (free available chlorine) in TRC (total residual chlorine) was measured, the toxicity endpoints were expressed as FAC/L as well

Available chlorine (or free chlorine) is expressed as equivalent content of Cl2 (AR, 2017). The active chlorine equivalent content is:

* 1 g of sodium hypochlorite is equivalent to 0.953 g active chlorine (MWCl2 / MWNaOCl = 71/74.5)
* Or 1 g active chlorine equivalent to 1.05 g sodium hypochlorite (MWNaOCl / MWCl2 = 74.5 / 71).

There are no substances of concern (refer to confidential PAR for details).

Chlorate formation during storage

The maximal sodium chlorate content after storage exceeds the reference specification. Consequently, a risk assessment for chlorate formed during storage is needed.

No harmonized endpoints are actually available for chlorate. As agreed during the WG-I-2020-Part B meeting, considering that chlorate (EC50 = 10 mg/L) is less toxic than the active substance (EC50 = 0.023 mg free available chlorine/L), it can be assessed qualitatively for all the environmental compartments including groundwater.

Chlorate is a substance of concern in relation to human health. Then, a semi qualitative assessment of chlorate in groundwater and surface water intended for the abstraction of drinking water have been performed (worst case assessment based on the maximal chlorate concentration, *i.e.* at the end of the storage period, as proposed for the HH assessment).

Disinfection by-products (DBPs)

An argumutation for the environmental risk assessment of DBPs has been provided by the applicant and is given in Annex 3.7. The risk assessment is still under development and will be amended as agreement on PNEC values and exposure concentration of DBPs are agreed at Working Group level. Indeed, a harmonization of the environmental risk assessment for DBPs is currently under investigation at EU level. Consequently, and according to the WG-I-2020 Part B meeting agreements, any conclusion on the risk of DBPs for the environment cannot be drawn for the time being.

#### Effects assessment on the environment

Short and long term toxicity data from literature are available for fish, invertebrates, algae and micro-organisms, resulting from flow-through or static tests. Most tests with a static test design result in a factor of 100-500 higher end-points (NOEC, LC50) than studies performed according to a flow-through design. Due to very fast hypochlorite decay, a static test system is continuously exposed to the same hypochlorite concentration. When data from literature were considered not valid or incomplete for the risk assessment, new toxicity laboratory studies were performed and included in the CAR.

No studies have been conducted on the product. Effects are based on data on the active substance. The applied endpoints are taken from the assessment report and summarised below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PNEC A.C.** | **Lowest endpoint** | **AF** | **PNEC** | **Test/species** |
| **Free available chlorine (FAC)** | | | | |
| STP | NOEC: 41.1 mg/L\* | 10 | 4.11 mg FAC/L | Respiration inhibition test |
| fresh water | NOEC: 2.1 µg/L | 50 | 0.042 FAC µg/L | Algae |
| sediment | - | - | 0.045 μg FAC/kg wwt | Equilibrium partioning from aquatic data using a theoretical Koc of 13.22 L/kg. Calculated according to the Guidance part B, vol. IV. |
| soil | - | - | 0.015 μg FAC/kg wwt |
| groundwater | Reference value for groundwater = 0.1 μg/L | | | |
| atmosphere | At environmental pH (6.5-8.5) half of the active chlorine is available as the unvolatile hypochlorite ion; half as hypochlorous acid with a Henry’s law constant as 0.11 Pa m³/mol. Hence, the concentration in air will be very low and the air is not an environmental compartment of concern. | | | |
| birds | No data available for birds and mammals as primary and secondary poisoning is not considered relevant (see paragraph 2.8.2.2) | | | |
| mammals |

FAC: Free available chorine, Wwt wet weight; bw body weight; a endpoint is converted to standard soil

***Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required***

|  |  |  |
| --- | --- | --- |
| META SPC | Classification | Remarks |
| 1.1 | H400 – H411 (H410 label) |  |
| 1.2 | H400 – H411 (H410 label) |  |
| 2.1 | H400 – H410 (H410 label) |  |
| 2.21 | H400 – H411 (H410 label) |  |
| 2.22 | H400 – H411 (H410 label) |  |
| 3 | H400 – H411 (H410 label) |  |
| 4 | H412 |  |
| 5 | H412 |  |
| 6.1 | H400 – H411 (H410 label) |  |
| 6.21 | H400 – H411 (H410 label) |  |
| 6.22 | H400 – H411 (H410 label) |  |
| 7.11 | H400 – H411 (H410 label) |  |
| 7.12 | H400 – H411 (H410 label) |  |
| 7.2 | H400 – H410 (H410 label) |  |
| 8 | H412 |  |
| 9 | H400 – H411 (H410 label) |  |
| 10.1 | H400 – H411 (H410 label) |  |
| 10.2 | H400 – H411 (H410 label) |  |
| 11 | H400 – H411 (H410 label) |  |
| 12 | H400 – H411 (H410 label) |  |
| 13 | H400 – H411 (H410 label) |  |
| 14 | H400 – H411 (H410 label) |  |

***Further Ecotoxicological studies***

| **Summary table of in vitro studies on short-term toxicity to aquatic invertebrates** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline,**  **GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks** *(e.g. major deviations)* | **Reference** |
| OECD 202 | Eau de javel 2.6% | In an OECD 202 test with the product Eau de Javel 2.6%: based on the number of immobilized daphnids, the EC50 after a 24-hour exposure period was calculated to be 3.29 mg/L, and the EC50 after a 48-hour exposure period was calculated to be 3.25 mg/L | | | RRCo-000269\_02 |

| **Summary table of in vitro studies on growth inhibition study on algae** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline,**  **GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks** *(e.g. major deviations)* | **Reference** |
| OECD 201 | Eau de javel 2.6% | The effects of EAU DE JAVEL 2.6 % added by water-accommodated fractions to OECD 201 test medium at the definitive loading rates of 0.1, 0.32, 1, 3.2 and 10 mg test item.L-1 to Pseudokirchneriella subcapitata were investigated under laboratory conditions: ECgrowth rate 50-72h is 0.33 mg/L | | | RRCo-000268\_02 |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Further ecotoxicological studies** | |
| Value/conclusion | Products in meta-SPC 2.1, 7.2, 8 (identical or lower SA and co-formulants concentrations than the tested product): Classification H400 required |
| Justification for the value/conclusion |

The product EAU DE JAVEL 2.6% has been tested with an OECD 202 study on daphnids and lead to a EC50 = 3.25 mg/L. Since the deviations from target concentrations were more than 20% in the study, analysis of the results were based on the mean between measured concentrations at initial time and those measured after renewal at 24h. However, endpoints were only calculated from the initial concentration which is incorrect. However, taken into account of final measured concentration would lead to EC50 > 1mg/L and no modification of classification.

The product EAU DE JAVEL 2.6% has also been tested on algae with an OECD 201. The conclusion of the applicant is that the ECgrowth rate 50-72h is 0.33 mg/L/. However at 0.32 mg/L (nominal) growth rate inhibition is >70%. Therefore EC50 is considered to be <0.32 mg/L which lead to a classification of H400 – H410 according to the CLP guidance, e.g. the same labelling than without this study.

***Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)***

No new data is available for DAAP19 family.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Not relevant |
| Justification | No additional test on other target organisms is needed on the basis of intended uses, data available on the active substance or risk assessment. |

***Supervised trials to assess risks to non-target organisms under field conditions***

No new data is available for DAAP19 family.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Not relevant |
| Justification | No product of the DAAP19 family is in the form of bait or granules |

***Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk***

No new data is available for DAAP19 family.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Not relevant |
| Justification | No product of the DAAP19 family is in the form of bait or granules |

***Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)***

No new data is available for DAAP19 family.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Not relevant |
| Justification | No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment. |

***Foreseeable routes of entry into the environment on the basis of the use envisaged***

See Fate and distribution in exposed environmental compartments.

***Further studies on fate and behaviour in the environment (ADS)***

No new data is available for DAAP19 product family

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Not relevant |
| Justification | No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment. |

***Leaching behaviour (ADS)***

The performance of a study on leaching (e.g. from treated surfaces) is neither applicable nor relevant for the intended uses within PT1-5.

***Testing for distribution and dissipation in soil (ADS)***

No new data is available for DAAP19 product family.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Not relevant |
| Justification | No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment. |

***Testing for distribution and dissipation in water and sediment (ADS)***

No new data is available for DAAP19 product family.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Not relevant |
| Justification | No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment. |

***Testing for distribution and dissipation in air (ADS)***

No new data is available for DAAP19 product family.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Not relevant |
| Justification | No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment. |

***If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)***

No new data is available for DAAP19 product family.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Not relevant |
| Justification | The product is not intended to be sprayed near to surface waters. |

#### Exposure assessment

General information

|  |  |
| --- | --- |
| Assessed PT | PT 2 |
| Assessed scenarios | **PT2 – Scenario 1:** Disinfection of private (permanent) swimming pools   * Shock disinfection * Chronic disinfection   **PT2 – Scenario 2**: Disinfection of public swimming pools   * Shock disinfection * Chronic disinfection   **PT2 – Scenario 3a**: Sanitary purposes (general disinfection)  **PT2 – Scenario 3b**: Sanitary purposes (Toilet bowl)  **PT2 – Scenario 4**: Laundry disinfection in closed washing machine, covering hand-washing for non-professional  **PT2 – Scenario 5**: Disinfectants used in the professional sector for laundry disinfection (covering industrial and medical uses)  **PT2 – Scenario 6**: Industrial area – Large and small scale applications  **PT2 – Scenario 7**: Medical sector, room, furniture and object  **PT2 – Scenario 8**: Anti-lichen and anti-algae treatment of hard surfaces |
| ESD(s) used | * Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), P. van der Poel, 2001. * ESD for PT 2: Emission Scenarios for private and public health area disinfectants and other biocidal products (RIVM, 2001). * Technical Agreements for Biocides v2.1, December 2019 - TAB entry (2019) - ENV 51 (public swimming pools). * Technical Agreements for Biocides v2.1, December 2019 - TAB entry (2019) – ENV 44 (private swimming pools). * Emission scenario document for biocides used as masonry preservatives (product type 10). |
| Approach | PT2 – Scenario 1: Average consumption  PT2 – Scenario 2: Average consumption  PT2 – Scenario 3a and 3b : Average consumption and tonnage approach  PT2 – Scenario 4: Average consumption  PT2 – Scenario 5: Average consumption  PT2 – Scenario 6 : Average consumption and tonnage approach  PT2 – Scenario 7: Average consumption  PT2 – Scenario 8: Average consumption |
| Distribution in the environment | Calculated based on Guidance for BPR IV Part B+C (2017).  Technical Agreements for Biocides v2.1, December 2019. |
| Groundwater simulation | Yes |
| Confidential Annexes | Yes |
| Life cycle steps assessed | All scenarios:  Production: No  Formulation : No  Use: Yes  Service life: No |
| Remarks | - |

|  |  |
| --- | --- |
| Assessed PT | PT 3 |
| Assessed scenarios | **PT3 – Scenario 1:** Disinfection of animal housing  **PT3 – Scenario 2:** Disinfectants used for vehicles used for animal transport  **PT3 – Scenario 3:** Drinking water pipe disinfection by injection |
| ESD(s) used | * Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, 2011. * Adaptation of ESD for PT 4: Emission scenarios for Disinfectants used in food and feed areas (JRC Scientific and Technical Reports, 2011). |
| Approach | Average consumption |
| Distribution in the environment | Calculated based on Guidance for BPR IV Part B+C (2017).  Technical Agreements for Biocides v2.1, December 2019. |
| Groundwater simulation | Yes |
| Confidential Annexes | No |
| Life cycle steps assessed | All scenarios:  Production: No  Formulation : No  Use: Yes  Service life: No |
| Remarks | - |

|  |  |
| --- | --- |
| Assessed PT | PT 4 |
| Assessed scenarios | **PT4 – Scenario 1:** Disinfection of large scale kitchens/canteens and slaughterhouses  **PT4 – Scenario 2:** Disinfectants used in food and feed areas (entire plants scenarios)  **PT4 – Scenario 3:** Disinfectants used in milking parlour systems  **PT4 – Scenario 4:** Disinfectants used in entire plants |
| ESD(s) used | * ESD for PT 4: Emission scenarios for Disinfectants used in food and feed areas (JRC Scientific and Technical Reports, 2011). |
| Approach | Average consumption |
| Distribution in the environment | Calculated based on Guidance for BPR IV Part B+C (2017).  Technical Agreements for Biocides v2.1, December 2019. |
| Groundwater simulation | Yes |
| Confidential Annexes | No |
| Life cycle steps assessed | All scenarios:  Production: No  Formulation : No  Use: Yes  Service life: No |
| Remarks | - |

***Emission estimation***

The tonnage scenarios proposed in the confidential PAR (only for information) are not the worst case as they report only the active substance and not chlorates and substances of concern.

**PT2 scenarios**

##### PT2 – Scenario 1: Disinfection of private (permanent) swimming pools (META-SPC 1.1 and META-SPC 1.2), maintenance and shock doses

For this scenario, only active chlorine and chlorates formed during storage are relevant. No substance of concern is identified for these Meta-SPC.

Disinfection of swimming pools is carried out with an in-use concentration in free available chlorine (ac) in the swimming pools of up to 50 mg/L for shock dosing and at maximum 5 mg/L as maintenance level. The maintenance level of 5 mg/L is a worst case as it is intended for the disinfection of footbaths only. The maintenance dose for the swimming pools is in fact 3 mg/L. Shock dosing is performed in case of increased contamination to enable a further usage of the pool water. The shock dosing concentration is assessed, as a worst-case, even though no emission to the environment is expected with such a high concentration. Releases to the environment can either be due to a chronic emission or due to a peak emission of disinfected pool water.

According to the label instructions, disinfected pool water may only be discharged via the drain and direct discharge into the environment is prohibited. Thus, the only relevant emission pathway is via STP.

The document “PT2 - Private pool scenarios - Permanent installed pools (2015)” is embedded under item ENV44 in the TAB (v. 2.1, 2019) and provides emission scenarios for the disinfection of private pools that are permanently installed. There are scenarios available for chronic and peak emission, respectively. Both scenarios are addressed below. Additionally, the scenarios differentiate between southern and northern countries, with southern countries representing the worst case. Only this worst case is assessed in the calculations below.

Following the disinfection, the pool water is emitted to a local STP via the facility drain. During transport from the sewer system to the STP, active chlorine is expected to degrade within the first minutes due to the high level of organic matter. The degradation of the active substance in the sewer system was taken into account for the estimation of local emission using the following input parameters (according to the assessment report):

* Half-life of hypochlorite in the sewer system, DT50 = 56 sec at 12°C
* Residence time in the sewer system: 1h (default value in the ESD, based upon an average distance of 4.5 km from the point of release to the STP and an estimated flow rate of 1.5 km in 20 minutes in the municipal canal sewer system).

The input parameters relevant for the emission estimation are listed in table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Variable/Parameters** | **Unit** | **Symbol** | **S/D/O/P** | **Value** | **Remark** |
| Private pool volume | m3 | Vpool | D | 48 | - |
| Number of private pools per STP:  Chronic  Southern countries  Acute  Southern countries | - | Npool | D | 550  10 | TAB ENV 44 |
| Fraction chronically released to STP | d-1 | Facute\_rel  Fchronic\_rel | D | 0.33  0.0143 | - |
| Application rate of **active substance** in the pool water | g avCl/L | Qappl\_shock  Qappl\_continuous | S | 0.05  0.005 | - |
| Market share | - | Fmarket | D | 1 | - |
| Fraction of active substance released to wastewater | - | Fwater | D | 1 | - |
| Output:  Elocalwater\_acute\_southern= Emission to waste water, acute emission, southern countries [kg/d]  Elocalwater\_chronic\_southern= Emission to waste water, chronic emission, southern countries [kg/d] | | | | | |
| Shock dose | | | | | |
| Elocalwater\_acute\_southern= Vpool\*Npool\*Fmarket\*Facut\_rel\*Qappl\_shock | | | | | 7.92 kg/d |
| Elocalwater\_chronic\_southern= Vpool\*Npool\*Fmarket\*Fchro\_rel\*Qappl\_shock | | | | | 1.89E+01 kg/d |
| Continuous dose | | | | | |
| Elocalwater\_acute\_southern= Vpool\*Npool\*Fmarket\*Facut\_rel\*Qappl\_continuous | | | | | 0.79 kg/d |
| Elocalwater\_chronic\_southern= Vpool\*Npool\*Fmarket\*Fchro\_rel\*Qappl\_continuous | | | | | 1.89 kg/d |

Degradation of hypochlorite in the sewer system was considered:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1  = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k= rate constant (k = 44.6 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | **Elocal at the STP [kg/d]:**  **Shock dose:**  Elocalwater\_acute\_southern= 3.52E-19  Elocalwater\_chronic\_southern= 8.39E-19  **Continuous dose:**  Elocalwater\_acute\_southern= 3.52E-20  Elocalwater\_chronic\_southern= 8.39E-20 |

Considering the very low emission rates to the STP due to the hypochlorite degradation in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

Note that acute emissions after a shock treatment are unrealistic worst case since the pools are not emptied just after a shock treatment. Furthermore, the chronic emissions following a shock treatment correspond to an unrealistic number of pools connected per STP.

It has to be noticed that the maximal sodium chlorate content after storage exceeds the reference specification. Consequently, a risk assessment for chlorates formed during storage is needed. As previously, only the southern countries are presented. We assumed that the concentration of chlorate will be proportionnal to the active chlorine. Therefore, for a concentration of 50 mg ac/L from the representative product of meta SPC 1.2 (the worst case) containing 12.5% of active chlorine (as claimed by the applicant) and 2.87% chlorates, the concentration of chlorates is assumed to be 1.15E-02 g/L for the shock disinfection and 1.15E-03 g/L for continuous disinfection.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Variable/Parameters** | **Unit** | **Symbol** | **S/D/O/P** | **Value** | **Remark** |
| Private pool volume | m3 | Vpool | D | 48 | - |
| Number of private pools per STP:  Chronic  Southern countries  Acute  Southern countries | - | Npool | D | 550  10 | TAB ENV 44 |
| Fraction chronically released to STP | d-1 | Facute\_rel  Fchronic\_rel | D | 0.33  0.0143 | - |
| Application rate of **chlorate** in the pool water | g avCl/L | Qappl\_shock  Qappl\_continuous | S | 1.15E-02  1.15E-03 | - |
| Market share | - | Fmarket | D | 1 | - |
| Fraction of chlorate released to wastewater | - | Fwater | D | 1 | - |
| Output:  Elocalwater\_acute\_southern= Emission to waste water, acute emission, southern countries [kg/d]  Elocalwater\_chronic\_southern= Emission to waste water, chronic emission, southern countries [kg/d] | | | | | |
| Shock dose | | | | | |
| Elocalwater\_acute\_southern= Vpool\*Npool\*Fmarket\*Facut\_rel\*Qappl\_shock | | | | | 1.82 kg/d |
| Elocalwater\_chronic\_southern= Vpool\*Npool\*Fmarket\*Fchro\_rel\*Qappl\_shock | | | | | 4.34 kg/d |
| Continuous dose | | | | | |
| Elocalwater\_acute\_southern= Vpool\*Npool\*Fmarket\*Facut\_rel\*Qappl\_continuous | | | | | 1.82E-01 kg/d |
| Elocalwater\_chronic\_southern= Vpool\*Npool\*Fmarket\*Fchro\_rel\*Qappl\_continuous | | | | | 4.34E-01 kg/d |

##### PT2 – Scenario 2: Disinfection of public swimming pools (META-SPC 1.2), maintenance and shock dose

Refer to scenario 1 above for the explanations. The same dose rates and assumptions are applied.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Variable/Parameters** | **Unit** | **Symbol** | **S/D/O/P** | **Value** | **Remark** |
| Number of visitor per day | - | Nvisit | D | 400 | TAB ENV 51 (v2.1, 2019) |
| Average depth of water | m | DEPTHswim | D | 1.8 | TAB ENV 51 (v2.1, 2019) |
| Water of surface | m² | AREAswim | D | 440 | TAB ENV 51 (v2.1, 2019) |
| Concentration of the **active substance** in swimming water | kg avCl/m3 | Cproc\_shock  Cproc\_continunous | S | 0.05  0.005 | Information provided by the applicant |
| Water replaced by visitor | m3 | Vrepl | D | 0.05 | TAB ENV 51 (v2.1, 2019) |
| Emission period | - | Epacute  Epchronic | D | 3  1 | TAB ENV 51 (v2.1, 2019) |
| Output:  Elocalwater acute = (DEPTHswim x AREAswim x Cproc)/Epacute  Elocalwater chronic = (Nvisit x Vrepl x Cproc)/ Epchronic | | | | | |
| Shock dose | | | | | |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater\_acute | O | 1.32E+01 | Too worst case situation considering that public swimming pool will not be shock treated before emptying |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater\_chronic | O | 1 |  |
| Continuous dose | | | | | |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater\_acute | O | 1.32 |  |
| Emission rate to wastewater (standard STP) | Kg/d | Elocalwater\_chronic | O | 1.00E-01 |  |

Degradation of hypochlorite in the sewer system was considered after the release from the swimming pool to the wastewater:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1  = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k= rate constant (k = 44.6 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | **Elocal at the STP [kg/d]:**  **Shock dose:**  Elocalwater\_acute = 5.87E-19  Elocalwater\_chronic = 4.44E-20  **Continuous dose:**  Elocalwater\_acute = 5.87E-20  Elocalwater\_chronic = 4.44E-21 |

Considering the very low emission rates to the STP due to the hypochlorite degradation in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

Note that acute emissions after a shock treatment are unrealistic worst case since the pools are not emptied just after a shock treatment. Furthermore, the chronic emissions following a shock treatment correspond to an unrealistic number of pools connected per STP.

It has to be noticed that the maximal sodium chlorate content after storage exceeds the reference specification. Consequently, a risk assessment for chlorate formed during storage is needed. We assumed that the concentration of chlorate will be proportionnal to the active chlorine. Therefore, for a concentration of 50 mg ac/L from the representative product of meta SPC 1.2 containing 12.5% of active chlorine (as claimed by the applicant) and 2.87% chlorates, the concentration of chlorates is assumed to be 1.15E-02 g/L for the shock disinfection and 1.15E-03 g/L for continuous disinfection.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Variable/Parameters** | **Unit** | **Symbol** | **S/D/O/P** | **Value** | **Remark** |
| Number of visitor per day | - | Nvisit | D | 400 | TAB ENV 51 (v2.1, 2019) |
| Average depth of water | m | DEPTHswim | D | 1.8 | TAB ENV 51 (v2.1, 2019) |
| Water of surface | m² | AREAswim | D | 440 | TAB ENV 51 (v2.1, 2019) |
| Concentration of **chlorate** in swimming water | kg avCl/m3 | Cproc\_shock  Cproc\_continunous | S | 1.15E-02  1.15E-03 | Information provided by the applicant |
| Water replaced by visitor | m3 | Vrepl | D | 0.05 | TAB ENV 51 (v2.1, 2019) |
| Emission period | - | Epacute  Epchronic | D | 3  1 | TAB ENV 51 (v2.1, 2019) |
| Output:  Elocalwater acute = (DEPTHswim x AREAswim x Cproc)/Epacute  Elocalwater chronic = (Nvisit x Vrepl x Cproc)/ Epchronic | | | | | |
| Shock dose | | | | | |
| Emission rate to wastewater (standard STP) | Kg/d | Elocalwater\_acute | O | 3.04 | Too worst case situation considering that public swimming pool will not be shock treated before emptying |
| Emission rate to wastewater (standard STP) | Kg/d | Elocalwater\_chronic | O | 2.30E-01 |  |
| Continuous dose | | | | | |
| Emission rate to wastewater (standard STP) | Kg/d | Elocalwater\_acute | O | 3.04E-01 |  |
| Emission rate to wastewater (standard STP) | Kg/d | Elocalwater\_chronic | O | 2.30E-02 |  |

##### PT2 – Scenario 3a: Sanitary purposes - general disinfection (META-SPC 2.1; 2.21; 2.22; 3; 4; 5; 6.1; 6.21; 6.22; 7.11; 7.12; 8; 10.1; 10.2; 11 and 12)

The use of disinfection for sanitary purpose is intended for META-SPC 2.1; 2.21; 2.22; 3; 4; 5; 6.1; 6.21; 6.22; 7.11; 7.12; 7.2; 8; 10.1; 10.2; 11; 12 covering the following uses in private houses and institutional areas:

* Disinfection of surfaces (floors) by wipping with mop and bucket
* Disinfection of surfaces (other than floors) by wipping with cloth and bucket
* Disinfection of companion animal housing and associated equipment (as it is only indoor)
* Disinfection of surfaces by spraying with trigger spray
* Disinfection of surfaces in institutions/industry
* Disinfection of hard surfaces in industries/institutions
* Disinfection of hard surfaces by spraying

In order to cover the use Disinfection of companion animal housing and associated equipment (as it is only indoor) which is a PT03, the worst case concentrations between PT02 and PT03 (for this specific use) have been considered.

Emissions to wastewater were calculated according to the ESD for PT2 Disinfection in institutional areas (RIVM, 2011) for the active substance and chlorates.

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the worst case in-use concentrations has been done in the table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Substance | Concentration of substance (%) | Dilution factor (worst case) | Density | Concentration in working solution (g/L) |
| Meta SPC 2.1 | Active chlorine | 2.6 | 0.375 | 1.0397 | 10.14 |
| Meta SPC 2.21 | Active chlorine | 4.8 | 0.5 | 1.0755 | 25.81 |
| Chlorate | 0.31 | 0.5 | 1.0755 | 1.67 |
| Meta SPC 2.22 | Active chlorine | 3.6 | 0.29 | 1.0559 | 10.86 |
| Chlorate | 0.17 | 0.29 | 1.0559 | 0.51 |
| Meta SPC 3 | Active chlorine | 2.6 | RTU | 1.0461 | 27.2 |
|  |  |  |  |  |
| Meta SPC 4 | Active chlorine | 1.5 | RTU | 1.025 | 15.38 |
| Chlorate | 0.09 | RTU | 1.025 | 0.92 |
| Meta SPC 5 | Active chlorine | 1.5 | RTU | 1.0282 | 15.42 |
| Meta SPC 6.1 | Active chlorine | 9.6 | 0.11 | 1.151 | 12.277 |
| Chlorate | 1.74 | 0.11 | 1.151 | 2.23 |
| Meta SPC 6.21 | Active chlorine | 9.6 | 0.135 | 1.151 | 14.92 |
| Chlorate | 1.74 | 0.135 | 1.151 | 2.7 |
| Meta SPC 6.22 | Active chlorine | 13.5 | 0.112 | 1.226 | 18.54 |
| Chlorate | 2.87 | 0.112 | 1.226 | **3.94** |
| Meta SPC 7.1 | Active chlorine | 3.6 | 0.34 | 1.052 | 12.876 |
| Chlorate | 0.17 | 0.34 | 1.052 | 0.608 |
| Meta SPC 7.12 | Active chlorine | 4.8 | 0.23 | 1.07 | 11.81 |
| Chlorate | 0.31 | 0.23 | 1.07 | 0.76 |
| Meta SPC 7.2 | Active chlorine | 2.6 | 0.45 | 1.07 | 12.52 |
| Meta SPC 8 | Active chlorine | 1.6 | 0.6 | 1.0262 | 9.38 |
| Meta SPC 10.1 | Active chlorine | 2.6 | 0.45 | 1.04 | 12.17 |
| Meta SPC 10.2 | Active chlorine | 4.8 | 0.23 | 1.072 | 11.83 |
| Chlorate | 0.31 | 0.23 | 1.072 | 0.76 |
| Meta SPC 11 | Active chlorine | 6 | 0.24 | 1.192 | 17.16 |
| Chlorate | 1.26 | 0.24 | 1.192 | 3.6 |
|  |  |  |  |  |
| Meta SPC 12 | Active chlorine | 4.8 | RTU | 1.072 | **51.46** |
| Chlorate | 0.31 | RTU | 1.072 | 3.32 |

The worst case Meta-SPC and in-use concentrations are the following:

- META-SPC 12 for active chlorine (51.46 g/L),

- META-SPC 6.22 for chlorates (3.94 g/L),

The average consumption is presented below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Input parameters for calculating the local emission | | | | |
| Input | Unit | Symbol | Value | Remarks |
| Number of inhabitants feeding one STP | cap | Nlocal | 10000 | Default value |
| Consumption per capita | L/cap/d | Qproduct | 0.005 | Average daily consumption for general purpose according to ESD PT02 (2011) |
| Concentration of active substance in the product | g/L | Cproduct | 51.46 |  |
| Concentration of ClO3- from storage in the product | g/L | Cproduct | 3.94 |  |
| Penetration factor of disinfectant | - | Fpenetr | 0.5 | Default value ESD PT2 (2011) |
| Fraction of the product released to waste-water | - | Fwater | 1 | Worst case |
| OUTPUT | | | | |
| Calculation:  Elocalwater = Nlocal • Vform • Cform • Fpenetr • Fwater • 10-3 | | | | |
| Emission rate to wastewater (standard STP) for general purposes | kg/d | Elocalwater | 1.29 | As Active chlorine eq. Cl2 |
| kg/d | Elocalwater | 9.85E-02 | As Chlorate |
|  |  |  |  |
|  |  |  |  |

Degradation of hypochlorite in the sewer system was considered. Based on the assessment report of active chlorine released from sodium hypochlorite, the DT50 is 56 seconds at 12°C for hypochlorite in the sewer system. This value is used for the emission estimation. No degradation was considered for chlorates.

A sewer residence time of 1h is proposed a default value in the ESD, based upon an average distance of 4.5 km from the point of release to the STP and an estimated flow rate of 1.5 km in 20 minutes in the municipal canal sewer system.

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.6 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 5.72E-20 kg av Cl/d |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

##### PT2 – Scenario 3b: Sanitary purposes - toilet bowl (META-SPC 2.1; 2.21; 2.22; 3; 4; 8 and 13)

The use of disinfection for sanitary purpose in toilet bowl is intended for META-SPC 2.1; 2.21; 2.22; 3; 4; 8 and 13 covering the following uses:

* Disinfection of toilet bowls
* Disinfection of toilet bowls in medical areas
* Disinfection of toilet bowls in institutions/industry

Emissions to wastewater were calculated according to the ESD for PT2 Disinfection in institutional areas (RIVM, 2011.) for the active substance and chlorates.

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different worst case in-use concentrations has been done in the table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Substance | Concentration of substance (%) | Dilution factor (worst case) | Density | Concentration in working solution (g/L) |
| Meta SPC 2.1 | Active chlorine | 2.6 | 0.3 | 1.0397 | 8.11 |
| Meta SPC 2.21 | Active chlorine | 4.8 | 0.5 | 1.0755 | 25.81 |
| Chlorate | 0.31 | 0.5 | 1.0755 | 1.67 |
| Meta SPC 2.22 | Active chlorine | 3.6 | 0.22 | 1.0559 | 8.45 |
| Chlorate | 0.17 | 0.22 | 1.0559 | 0.4 |
| Meta SPC 3 | Active chlorine | 2.6 | RTU | 1.0461 | 27.2 |
|  |  |  |  |  |
| Meta SPC 4 | Active chlorine | 1.5 | RTU | 1.025 | 15.38 |
| Chlorate | 0.09 | RTU | 1.025 | 0.92 |
| Meta SPC 8 | Active chlorine | 1.6 | 0.5 | 1.0262 | 8.21 |
| Meta SPC 13 | Active chlorine | 4.5 | RTU | 1.07 | **48.15** |
| Chlorate | 0.27 | RTU | 1.07 | **2.89** |
|  |  |  |  |  |

The worst case Meta-SPC and in-use concentrations are the following:

- META-SPC 13 for active chlorine (48.15 g/L),

- META-SPC 13 for chlorates (2.89 g/L),

The average consumption is presented below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Input parameters for calculating the local emission | | | | |
| Input | Unit | Symbol | Value | Remarks |
| Number of inhabitants feeding one STP | cap | Nlocal | 10000 | Default value |
| Consumption per capita | L/cap/d | Qproduct | 0.002 | Average daily consumption for lavatory according to ESD PT02 (2011) |
| Concentration of active substance in the product | g/L | Cproduct | 48.15 |  |
| Concentration of ClO3- from storage in the product | g/L | Cproduct | 2.89 |  |
| Penetration factor of disinfectant | - | Fpenetr | 0.5 | Default value ESD PT2 (2011) |
| Fraction of the product released to waste-water | - | Fwater | 1 | Worst case |
| OUTPUT | | | | |
| Calculation:  Elocalwater = Nlocal • Vform • Cform • Fpenetr • Fwater • 10-3 | | | | |
| Emission rate to wastewater (standard STP) for general purposes | kg/d | Elocalwater | 4.82E-01 | As Active chlorine eq. Cl2 |
| kg/d | Elocalwater | 2.89E-02 | As Chlorate |
|  |  |  |  |

Degradation of hypochlorite in the sewer system was considered. Based on the assessment report of active chlorine released from sodium hypochlorite, the DT50 is 56 seconds at 12°C for hypochlorite in the sewer system. This value is used for the emission estimation. No degradation was considered for chlorates.

A sewer residence time of 1h is proposed a default value in the ESD, based upon an average distance of 4.5 km from the point of release to the STP and an estimated flow rate of 1.5 km in 20 minutes in the municipal canal sewer system.

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.6 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 2.14E-20kg av Cl/d |

##### PT2 – Scenario 4: Laundry disinfection in closed washing machine, covering hand-washing for non-professional (META-SPC 2.1; 2.21; 2.22; 6.1 and 8)

The emission estimation of the consumption-based scenario for the laundry disinfection in closed washing machine, covering hand-washing for non-professional has been performed using the ESD for PT06, with some adaptations to properly cover the use laundry disinfection with hand soaking for META-SPC 2.1; 2.21; 2.22; 6.1; 6.21; 6.22; 7.11; 7.12; 7.2; 8; 10.1 and 10.2.

The laundry disinfection in washing machines can be regarded as worst case in Europe, as ca 87% of laundry is performed using washing machines and only 5% is performed by hand wash (Laitala et al., 2017)[[14]](#footnote-15). Therefore, the emission estimation for the use of the products in washing machines covers the use for soaking/hand-washing.

The Emission Scenario for calculating the release of preservatives used in non-professional detergents for fabric washing is based on the model:

Elocalwater = Nhouse \* Nwash \* Fwater \* Cproduct \* (Fdisinfectant \* DOSEliquid] \* Fpenetr

Where:

DOSEactive substance: the proposed quantity of diluted product used per wash (5 L considering this use is only for hand wash)

Fdisinfectant: the fraction of washes performed with the disinfectant product. A value of 0.1 coming from the TAB v.2.1 ENV-70 was chosen. The TAB entry for household kitchen disinfection states this value is derived from the ESD for PT 2, page 15, taking into account conservatively the values provided for the daily application of detergents and cleaning agent applications, i.e. 8%, rounded up to 10%. This approach represents a more realistic estimation of the frequency of application than 100% of people using a laundry disinfectant.

Default values from the ESD PT06 has been used for the other variables.

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different worst case in-use concentrations has been done in the table below with the worst case product of each META-SPC:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Substance | Concentration of substance (%) | Dilution factor (worst case) | Density | Concentration in working solution (g/L) |
| Meta SPC 2.1 | Active chlorine | 2.6 | 0.16 | 1.0397 | 4.33 |
| Meta SPC 2.21 | Active chlorine | 4.8 | 0.5 | 1.0755 | **25.81** |
| Chlorate | 0.31 | 0.5 | 1.0755 | **1.67** |
| Meta SPC 2.22 | Active chlorine | 3.6 | 0.11 | 1.0559 | 4.22 |
| Chlorate | 0.17 | 0.11 | 1.0559 | 0.20 |
| Meta SPC 6.1 | Active chlorine | 9.6 | 0.042 | 1.151 | 4.60 |
| Chlorate | 1.74 | 0.042 | 1.151 | 0.83 |
| Meta SPC 8 | Active chlorine | 1.6 | 0.22 | 1.0262 | 3.65 |

For the active chlorine and chlorate, the product of the META-SPC 2.21 is considered as the worst-case and will be used for the calculations.

The input for scenario 5 are presented in the table below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Input parameters for calculating the local emission | | | | |
| Input | Unit | Symbol | Value | Remarks |
| Number of houses feeding one STP | [-] | Nhouse | 4000 | Default value |
| Number of laundry washes per household per day | d | Nwash | 0.61 | Default value |
| Fraction released to waste water | [-] | Fwater | 1 | Default value |
| Fraction of washes performed with liquid laundry detergents | [-] | Fdisinfectant | 0.1 | Extrapolation from TAB v.2.1 ENV-70 |
| Dosage of liquid laundry disinfectant/wash | [L] | DOSEliquid | 5 | Default |
| Concentration of active substance in the product | g/L | Cproduct | 25.81 |  |
| Concentration of ClO3- from storage in the product | g/L | Cproduct | 1.67 |  |
| Market penetration factor | [-] | Fpenetr | 0.5 | Default value |
| OUTPUT | | | | |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | 1.57E+01 | As Active chlorine eq. Cl2 |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | 1.02 | As Chlorate |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.6 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 7.00E-19kg av Cl/d |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

##### PT2 – Scenario 5: Disinfectants used in the professional sector for laundry disinfection (covering industrial and medical uses) (META-SPC 6.21; 6.22; 7.11; 7.12; 7.2; 10.1 and 10.2)

This scenario covers the professional use laundry disinfection by hand soaking in healthcare and industry of the META-SPC 6.21; 6.22; 7.11; 7.12; 7.2; 10.1 and 10.2.

**It has to be noticed that this scenario considers a capacity of washing tube of 8000 kg/d, this is a very worst case assumption as this scenario covers the use laundry disinfection with hand soaking only (and not in washing machine).**

In order to make a worst-case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Substance | Concentration of substance (%) | Dilution factor (worst case) | Density | Concentration in working solution (g/L) |
| Meta SPC 6.21 | Active chlorine | 9.6 | 0.04 | 1.151 | 4.42 |
| Chlorate | 1.74 | 0.04 | 1.151 | 0.8 |
| Meta SPC 6.22 | Active chlorine | 13.5 | 0.036 | 1.226 | **5.96** |
| Chlorate | 2.87 | 0.036 | 1.226 | **1.27** |
| Meta SPC 7.11 | Active chlorine | 3.6 | 0.11 | 1.052 | 4.166 |
| Chlorate | 0.17 | 0.11 | 1.052 | 0.197 |
| Meta SPC 7.12 | Active chlorine | 4.8 | 0.07 | 1.07 | 3.6 |
| Chlorate | 0.31 | 0.07 | 1.07 | 0.23 |
| Meta SPC 7.2 | Active chlorine | 2.6 | 0.14 | 1.07 | 3.89 |
| Meta SPC 10.1 | Active chlorine | 2.6 | 0.14 | 1.04 | 3.79 |
| Meta SPC 10.2 | Active chlorine | 4.8 | 0.07 | 1.072 | 3.60 |
| Chlorate | 0.31 | 0.07 | 1.072 | 0.23 |

The Meta-SPC 6.22 is considered as the worst-case and will be used for the calculations for the active substance and for the active chlorine and chlorates.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Input parameters for calculating the local emission | | | | |
| Input | Unit | Symbol | Value | Remarks |
| Number of washing tubes (with disinfectant) | [-] | Nm | 3 | Default value |
| Capacity of washing tube (laundry) | Kg/d | Cap | 8000 | Default value |
| Amount of disinfectant for laundry | l/kg | Vproduct | 1 | S |
| Concentration of active substance in disinfectant solution | Kg/l | Cdisinf | 5.96E-03 | S |
| Concentration of chlorate in disinfectant solution | Kg/l | Cdisinf | 1.27E-03 | S |
| Concentration reduction in washing process | [-] | Fred | 0 | D |
| OUTPUT | | | | |
| Maximum emission rate at the day of a replacement | kg/d | Elocalwater | 1.43E+02 | As Active chlorine eq. Cl2 |
| Maximum emission rate at the day of a replacement | kg/d | Elocalwater | 3.05E+01 | As Chlorate |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.6 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 6.36E-18kg av Cl/d |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

##### PT2 – Scenario 6: Industrial areas – Large scale and small scall applications (META-SPC 4; 5; 6.21; 6.22; 7.11; 7.12; 7.2; 10.1; 10.2; 11; 12 and 13)

The use of disinfection in industrial areas is intended for META-SPC 4, 5, 6.21, 6.22, 7.11, 7.12, 7.2, 10.1, 10.2, 11, 12 and 13 covering the following uses:

* Disinfection of surfaces by spraying with trigger spray
* Disinfection of surfaces in institutions/industry
* Disinfection of hard surfaces in industries/institutions
* Disinfection of hard surfaces by spraying
* Disinfection of surfaces (other than floors) by wiping with cloth and bucket
* Disinfection of surfaces (floors) by wipping with mop and bucket
* PT03: Disinfection of non-porous hard surfaces in veterinary area

Local emission due to disinfection of industrial areas were calculated using ESD for PT2 Disinfection in industrial premises (RIVM, 2011). This scenario applies to disinfection of a wide range of surfaces: small surfaces such as furniture and bigger surfaces syr as rooms, walls or floors. Industrial premises are considered as local emission sourecs which release their wastewater to a local STP.

The scenario is based on the concentration of the active substance and volume applied on a surface: an application rate 0.1 L/m² was considered for the assessment as claimed by the applicant. Surface areas of 1000 m² and 25 m2 was assessed for large and small scale applications respectively. Small sacle applications are for RTU products only.

In order to make a worst-case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Substance | Concentration of substance (%) | Dilution factor (worst case) | Density | Concentration in working solution (g/L) |
| Meta SPC 4 | Active chlorine | 1.5 | RTU | 1.025 | 15.38 |
| Chlorate | 0.09 | RTU | 1.025 | 0.92 |
| Meta SPC 5 | Active chlorine | 1.5 | RTU | 1.0282 | 15.42 |
| Meta SPC 6.21 | Active chlorine | 9.6 | 0.135 | 1.151 | 14.92 |
| Chlorate | 1.74 | 0.135 | 1.151 | 2.70 |
| Meta SPC 6.22 | Active chlorine | 13.5 | 0.112 | 1.226 | **18.54\*** |
| Chlorate | 2.87 | 0.112 | 1.226 | **3.94\*** |
| Meta SPC 7.11 | Active chlorine | 3.6 | 0.34 | 1.052 | 12.88 |
| Chlorate | 0.17 | 0.34 | 1.052 | 0.61 |
| Meta SPC 7.12 | Active chlorine | 4.8 | 0.23 | 1.07 | 11.81 |
| Chlorate | 0.31 | 0.23 | 1.07 | 0.76 |
| Meta SPC 7.2 | Active chlorine | 2.6 | 0.45 | 1.07 | 12.52 |
| Meta SPC 10.1 | Active chlorine | 2.6 | 0.45 | 1.04 | 12.17 |
| Meta SPC 10.2 | Active chlorine | 4.8 | 0.23 | 1.072 | 11.83 |
| Chlorate | 0.31 | 0.23 | 1.072 | 0.76 |
| Meta SPC 11 | Active chlorine | 6 | 0.24 | 1.192 | 17.16 |
| Chlorate | 1.26 | 0.24 | 1.192 | 3.6 |
|  |  |  |  |  |
| Meta SPC 12 | Active chlorine | 4.8 | RTU | 1.072 | **51.46\*\*** |
| Chlorate | 0.31 | RTU | 1.072 | **3.32\*\*** |

\* worst case for large sclae

\*\* worst case for small scale

The worst case Meta-SPC and in-use concentrations are the following for large scale applications:

- META-SPC 6.22 for active chlorine (18.54 g/L),

- META-SPC 6.22 for chlorates (3.94 g/L),

The worst case Meta-SPC and in-use concentrations are the following for small scale applications (RTU products):

- META-SPC 12 for active chlorine (51.46 g/L),

- META-SPC 12 for chlorates (3.32 g/L),

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Input parameters for calculating the local emission | | | | |
| Input | Unit | Symbol | Value | Remarks |
| Application rate of active chlorine | L/m² | Vform | 0.1 |  |
| Concentration of active chlorine in the product | g/L | Cform | 1.85E+01  5.15E+01 | Large scale  Small scale |
| Concentration of chlorate in the product | g/L | Cform | 3.94  3.32 | Large scale  Small scale |
| Surface area/Volume to be disinfected | m² | AREA | 1000  25 | Large scale  Small scale |
| Number f application per day | d-1 | Nappl | 1 |  |
| Fraction of substance disintegrated during or after application | [-] | Fdis | 0 |  |
| Fraction released to wastewater | [-] | Fwater | 1 |  |
| Fraction realesed to air | [-] | Fair | 0 |  |
| OUTPUT | | | | |
| Calculation:  Elocalwater = Vform \* Cform \* AREAsurface \* Nappl \* (1-Fdis) \* Fwater / 100 | | | | |
| Emission rate to wastewater (standard STP) for industrial applications (large scale) | kg/d | Elocalwater | 1.85 | As Active chlorine eq. Cl2 |
| kg/d | Elocalwater | 3.94E-01 | As Chlorate |
|  |  |  |  |
|  |  |  |  |
| Emission rate to wastewater (standard STP) for industrial applications (small scale) | kg/d | Elocalwater | 1.29E-01 | As Active chlorine eq. Cl2 |
| kg/d | Elocalwater | 8.31E-03 | As Chlorate |
|  |  |  |  |
|  |  |  |  |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.6 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 8.24E-20kg av Cl/d (large scale) and 5.72E-21 (small scale) |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

##### PT2 – Scenario 7: Medical sector, room, furniture and object (META-SPC 5; 6.21; 6.22; 7.11; 7.12; 10.1; 10.2; 11 and 12)

The use of disinfection in medical sector, room, furniture and object is intended for META-SPC 5, 6.21, 6.22, 7.11, 7.12, 7.2, 10.1, 10.2, 11, and 12 covering the following uses:

* Disinfection of surfaces by spraying with trigger spray
* Disinfection of surfaces in medical area
* Disinfection of hard surfaces in medical area
* Disinfection of hard surfaces by spraying

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Substance | Concentration of substance (%) | Dilution factor (worst case) | Density | Concentration in working solution (g/L) |
| Meta SPC 5 | Active chlorine | 1.5 | RTU | 1.0282 | 15.42 |
| Meta SPC 6.21 | Active chlorine | 9.6 | 0.089 | 1.151 | 9.83 |
| Chlorate | 1.74 | 0.089 | 1.151 | 1.78 |
| Meta SPC 6.22 | Active chlorine | 13.5 | 0.079 | 1.226 | 13.08 |
| Chlorate | 2.87 | 0.079 | 1.226 | 2.78 |
| Meta SPC 7.11 | Active chlorine | 3.6 | 0.23 | 1.052 | 8.71 |
| Chlorate | 0.17 | 0.23 | 1.052 | 0.41 |
| Meta SPC 7.12 | Active chlorine | 4.8 | 0.15 | 1.07 | 7.7 |
| Chlorate | 0.31 | 0.15 | 1.07 | 0.5 |
| Meta SPC 7.2 | Active chlorine | 2.6 | 0.3 | 1.07 | 8.35 |
| Meta SPC 10.1 | Active chlorine | 2.6 | 0.3 | 1.04 | 8.11 |
| Meta SPC 10.2 | Active chlorine | 4.8 | 0.15 | 1.072 | 7.72 |
| Chlorate | 0.31 | 0.15 | 1.072 | 0.5 |
| Meta SPC 11 | Active chlorine | 6 | 0.16 | 1.192 | 11.44 |
| Chlorate | 1.26 | 0.16 | 1.192 | 2.4 |
|  |  |  |  |  |
| Meta SPC 12 | Active chlorine | 4.8 | RTU | 1.072 | **51.46** |
| Chlorate | 0.31 | RTU | 1.072 | **3.32** |

The worst case Meta-SPC and in-use concentrations are the following:

- META-SPC 12 for active chlorine (51.46 g/L),

- META-SPC 12 for chlorates (3.32 g/L),

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable/parameter** | **Unit** | **Symbol** | **Value** | **Remark** |
| Fractions released to waste water:  Sanitary purposes  Brushes | - | Fsan,water  Fobj,water | 0.55  0.95 |  |
|  |
| Concentration at which active substance is used:  Active chlorine:  Sanitary purposes  Brushes  Chlorate:  Sanitary purposes  Brushes | g/l | Csan  Cobj | 5.15E+01  5.15E+01  3.32E+00  3.32E+00 |  |
| Amount of water with active substance:  Sanitary purposes  Brushes | l.d-1 | Qwater\_san  Qwater\_obj | 25  25 |  |

Output:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Calculations:  Elocalwater = Qwater\_san\*Csan\*Fsan,water+Qwater\_obj\*Cobj\*Fobj,water (sanitary purposes + brush) | | | | |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | 1.93 | As Active chlorine eq Cl2 |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | 1.25E-01 | As Chlorate |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 8.58E-20 kg av Cl/d |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

##### PT2 – Scenario 8: Anti-lichen and anti-algae treatment of hard surfaces (META-SPC 9 and 14)

There is no existing Emission Scenario Documents (ESD) for PT2 covering use of an algaecide on construction materials; therefore, the assessment of environmental emissions for DAAP19 products has been conducted using several guidance documents. The assessment is based on models simulating spray application on hard surfaces likely to be treated by non-professionals from ESD for PT10 (Emission scenario document for biocides used as masonry preservatives, EUBEES 2002) and ESD for Product Type 8 (Revised Emission Scenario Document for Wood Preservatives, OECD 2013).

Estimation of environmental concentrations due to use and service life of DAAP19 was conducted considering two hard surface models:

* House (walls and roof) from ESD PT10
* Bridge over pond, from ESD PT8

Considering the physico-chemical properties of the active substance, a service life is not relevant as it will react very rapidly with the organic matter on the treated surfaces and thus this service-life phase is not assessed in this dossier. Moreover it was decided at WGI2020 that the only relevant pathway of a quantitative assessment was surface water in case of direct release. Therefore, active chlorine exposure and risk assessment will be proposed only for the bridge over pond scenario.

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Substance | Concentration of substance (%) | Dilution factor (worst case) | Density | Concentration in working solution (g/L) |
| Meta SPC 9 | Active chlorine | 9.6 | 0.25 | 1.151 | **27.62** |
| Chlorate | 9.6 | 0.25 | 1.151 | **5.01** |
| Meta SPC 14 | Active chlorine | 9.6 | 0.2 | 1.15 | 22.08 |
| Chlorate | 9.6 | 0.2 | 1.15 | 4.002 |

The worst case Meta-SPC and in-use concentrations are the following:

- META-SPC 9 for active chlorine (27.62 g/L),

- META-SPC 9 for chlorates (5.01 g/L),

**House scenario**

According to ESD for PT10, assessment of emissions has been performed for two types of houses: house in rural area for which all loses of product during application go to local soil and house in a city for which all loses go to rain water.

Based on the ESD and the supplementing document “The assessment of direct emission to surface water in urban areas”, products applied on facades or roofs are subject to leaching during rain events. However as a worst-case, we considered that 100% of the product applied is released directly to the STP/separate sewer system, or the adjacent soil.

|  |  |
| --- | --- |
| **Scenario** | **Receiving compartments** |
| House in a city | Surface water, Soil, Sediment |
| House in the countryside | Soil adjacent to application area |

Calculations were done for an area of 270 m² (145 m² roof + 125 m² walls) according to the model house proposed in OECD (2002) (used in ESD PT10).

Concerning the soil distant to a treated horizontal surface, the risk can be considered to be covered by the assessment of vertical surfaces as the spray drift will be lower. Regarding soil adjacent to a treated horizontal surface, run-off is more likely and cannot be mitigated.

For vertical surfaces both facade and roof were considered for the risk assessment. Compared to a horizontal surface with a smaller treated area releasing product to the adjacent soil compartment, this assessment can be considered as a worst case situation

**Emissions during application (considering a total release of the whole applied product):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Unit** | **Value** | **Source** |
| Fraction of substance in the product:  Active chlorine  Chlorate | Fform | (-) | 2.76E-02  5.00E-03 | S – considering a product density of 1.13 |
| Volume of product applied on area | V form | l.m-2 | 0.1 | D |
| Application interval of the product | Applic\_interval | years | 1 | S – intended |
| Number of houses in a city | Nhouse | (-) | 4000 | D |
| Fraction of houses on which an algaecide/disinfectant is applied (considering a market share = 1.0) | fhouse | (-) | 0.5 | D (AHEE-4) |
| Number of houses treated per day in the city scenario | nhouse\_applic\_city | d-1 | 6 | O (TAB v2.0 ENV119) |
| Number of houses treated in the countryside scenario | nhouse\_applic\_countryside | (-) | 1 | D |
| Treated area of a façade | AREAfaçade | m2 | 125 | D |
| Treated area of a roof | AREAroof | m2 | 145 | D |
| Density of the product | RHOform | kg/m3 | 1000 | D |
| Fraction of product lost during application (covering post-application releases | Fspray | (-) | 1 | S (as a worst-case) |

Model calculation for spray application (considering a release of the total applied quantity as a worst case) for the rural area:

Local emission of active substance during application considering that all the product is lost during application (Fspray = 1):

*Elocal spray= (AREAfaçade + AREAroof) x V form x C form x Fspray x E-3*

**House in the countryside – Emissions to local soil due to direct emissions**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Usage scenario** | **Symbol** | **Receiving Compartment** | **Emissions to local soil (kg.d-1)** | |
|  | | | **Active chlorine** | **Chlorate** |
| ESD PT10 House in the countryside | Elocal spray | Soil adjacent to treated surface | 7.46E-01 | 1.35E-01 |

Model calculation for spray application (considering a release of the total applied quantity as a worst case) for the urban area:

Local emission of active substance during application considering that all the product is lost during application (separate sewer systems)

*Elocal water = nhouses\_applic\_city\*Elocalspray*

**House in the urban area – Emissions to STP or separate sewer systems**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Usage scenario** | **Symbol** | **Receiving Compartment** | **Emission rate to rain water (kg.d-1)** | |
|  |  |  | Active chlorine | Chlorate |
| ESD PT10 House in a city | Elocal water | Rain water or STP | 4.48 | 8.10E-01 |

It was decided at WGI2020 that the only relevant pathway justifying a quantitative assessment of active chlorine was surface water in case of direct release. Therefore, active chlorine exposure and risk assessment for direct release to soil are not presented.

Chlorate is a substance of concern in relation to human health. Then, a semi qualitative assessment of chlorate in groundwater and surface water intended for the abstraction of drinking water have been performed (worst case assessment based on the maximal chlorate concentration, *i.e.* at the end of the storage period, as proposed for the HH assessment).

PEC groundwater for chlorates (rural area):

Concerning the direct release to soil in the countryside, the PECgw for chlorate has been calculated from the PECsoil considering 1 hectare as follow:

PECsoil/ha = Elocalsoil\*nhouse/Vsoil = 2.54E-01 mg/kg wwt

* nhouse = 16 houses per hectare (TAB v2.0 ENV 98)
* The soil volume of 1 hectare is : Vsoil= 10000\*0.5\*1700 = 8.5E+06 kg soil/ha

With: RHOsoil = 1700kg/m3

Depth: 0.5 m

We can thus deduce a PECgw/ha:

PECgw/ha = PECsoil \* RHOsoil/(Ksoilwater) = **3.76E+02 µg/L**

**The intended application frequency proposed by the applicant was 4 times per year. Nevertheless, considering that 2 applications would lead to a concentration of chlorates in groundwater higher than 700 µg/L, the maximal number of application must be restricted to 1 per year.**

Emission to STP/separate sewer system (urban area):

Emission rate to STP/separate sewer sysems is used to calculate the PEC in the relevant compartments based on the dicument [Assessment of direct emission to surface water in urban areas (UBA, 2014)](https://echa.europa.eu/documents/10162/16908203/pt_6_7_8_9_10_assessment_of_direct_emission_surface_water_urban_areas_en.pdf/56073606-24c6-4b77-89ea-bfeec98d5943).

Calculation after degradation of active chlorine in the sewer system:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 1.99E-19 kg av Cl/d |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

**Bridge over pond scenario (direct releases to water)**

Calculations were done considering two guidance documents. Characteristics of the bridge are from ESD PT8 and models and parameters governing spray application (losses of product, etc.) are from ESD PT10.

For this scenario, in order to not to be in a too worst case situation, only application is considered.

**Emission scenario for calculating the releases from a bridge treated by sprayer (ESD PT10 and ESD PT8) – Application only**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Unit** | **Value** | **Source** | **Guidance document** |
| Treated area per day | AREA | m².d-1 | 10 | D | ESD PT8 |
| Volume of product applied on area | V form | l.m-2 | 0.1 | D |  |
| Concentration ofsubstance  Active chlorine  Chlorate | C form | g.l-1 | 27.62  5.01 | S | For active chlorine, based on the density of the product of 1.13 |
| Fraction of product lost during application by spray drift | F drift | - | 0.1 | D | ESD PT10 |
| Fraction of product lost during application due to runoff | F runoff | - | 0.2 | D | ESD PT10 |
| Water volume under bridge | V water | m3 | 1000 | D | ESD PT8 |

Fraction of product lost during brush application initially described in ESD PT8 is replaced by fractions of product lost due to spray drift and runoff described in ESD PT10 (spray application on House).

Local emission of active substance during application due to spray drift

*Elocal drift = AREA x V form x C form x F drift x E-3*

Local emission of active substance during application due to runoff

*Elocal runoff = AREA x V form x C form x F runoff x E-3*

Emission to local water during day of emission

*Elocal water = Elocal drift + Elocal runoff*

Local concentration in water (pond) during day of emission

*Clocal water = Elocal water / V water*

**Emissions and concentrations local water and concentration in water during application**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Usage scenario** | **Symbol** | **Receiving Compartment** | **Output** | |
|  |  |  | Active chlorine | Chlorate |
| PT10: Spray application PT8: Pond under bridge | Elocal water | Pond under bridge | **Emission rate to water (kg.d-1):** | |
| 8.29E-03 | 1.50E-03 |
| Clocal water | Pond under bridge | **Concentration in water (mg.l-1):** | |
| 8.29E-03 | 1.50E-03 |

**PT3 scenarios**

##### PT3 – Scenario 1: Disinfection in animal housing (META-SPC 6.21; 6.22; 7.11; 7.12; 7.2; 10.1; 10.2 and 11)

The use of disinfection for animal housing is intended for META-SPC 6.21; 6.22; 7.11; 7.12; 7.2; 10.1; 10.2 and 11 covering the uses:

- Disinfection of non-porous hard surfaces in veterinary healthcare facilities,

- Animal housings (such as kennels, hutches, cages, bee hives, stables, etc.) – professional uses,

- Livestock (poultry, bovine, etc.) buildings.

It is worst noting that non-professionnals uses for animal housings (such as kennels, hutches, cages, bee hives, stables, etc.) of META-SPC 2.1, 2.21, 2.22, 6.1 and 8 are considered covered by the scenario PT2 – Scenario 3a: Sanitary purposes - general disinfection.

For the professional uses:

- Disinfection of non-porous hard surfaces in veterinary healthcare facilities,

- Animal housings (such as kennels, hutches, cages, bee hives, stables, etc,

Only releases to the STP are foreseen; no emission to manure/slurry is considered relevant.

All parameters (area of accommodations, number of animals…) considered are from ESDTP3, 2011 and ESDTP18 for stables and manure storage systems, 2006. For an easier reading of the PAR, only worst-case situations is presented: “For cattle: veal calves emissions”.

For the calculated PECs when main releases are via the STP, it corresponds to the “Turkey in free range – litter floor” scenario. Moreover for manure application, only results for grassland are detailed corresponding to the worst case approach compared to arable land.

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below, taking into account the same application rate for every Meta-SPC (250 mL/m2 as intended in the SPC):

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Substance | Concentration of substance (%) | Dilution factor (worst case) | Density | Concentration in working solution (g/L) |
| Meta SPC 6.21 | Active chlorine | 9.6 | 0.105 | 1.151 | 11.60 |
| Chlorate | 1.74 | 0.105 | 1.151 | 2.10 |
| Meta SPC 6.22 | Active chlorine | 13.5 | 0.093 | 1.226 | **15.39** |
| Chlorate | 2.87 | 0.093 | 1.226 | **3.27** |
| Meta SPC 7.11 | Active chlorine | 3.6 | 0.27 | 1.052 | 10.23 |
| Chlorate | 0.17 | 0.27 | 1.052 | 0.48 |
| Meta SPC 7.12 | Active chlorine | 4.8 | 0.18 | 1.07 | 9.24 |
| Chlorate | 0.31 | 0.18 | 1.07 | 0.6 |
| Meta SPC 7.2 | Active chlorine | 2.6 | 0.35 | 1.07 | 9.74 |
| Meta SPC 10.1 | Active chlorine | 2.6 | 0.35 | 1.04 | 9.46 |
| Meta SPC 10.2 | Active chlorine | 4.8 | 0.18 | 1.072 | 9.26 |
| Chlorate | 0.31 | 0.18 | 1.072 | 0.60 |
| Meta SPC 11 | Active chlorine | 6 | 0.19 | 1.192 | 13.59 |
| Chlorate | 1.26 | 0.19 | 1.192 | 2.85 |

The worst case Meta-SPC and in-use concentrations are the following:

- META-SPC 6.22 for active chlorine (15.39 g/L),

- META-SPC 6.22 for chlorates (3.27 g/L),

Only the worst case scenarios are presented: veal calf for the emission via slurry/amnure and turkey for emission via the STP. Moreover, it was considered that grassland also cover arable land and only grassland PEC are calculated.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | | | |
| **Parameter** | **Nomenclature** | | **Value** | | **Unit** | **Origin\*** |
| INPUTS | | | | | | |
| Type of housing/manure storage (for application of the notification) | cat-subcat (i1) | Turkey in free range – litter floor (releases to STP) | | Veal calves (release to slurry/manure) | [-] | D |
| Type of biocide | bioctype (i2) | Disinfectant | | | [-] | D |
| Type of application | App way (i3) | Spraying | | | [-] | D |
| Content of active ingredient in applied formulation (after dilution)  Active chlorine  Chlorate | F bioc | 15.39  3.27 | | | [g.L-1] | S |
| Amount of product prescribed to be used per m2 | V prod | 0.1 | | | [L.m-2] | S |
| Fraction of active ingredient released | F **slurry/manure** | 0.3 | | 0.5 | [-] | D |
| F **waste water** | 0.2 | | 0 | [-] | D |
| Area of the housing | AREA | 8 040 | | 650 | [m2] | D – Total area |
| Biocide application interval | Tbioc-int | 182 | | 91 | [d] | D/O |
| Number of disinfectant applications in one year | Napp-bioc | 2 | | 4 | [-] | D |
| Number of manure applications - grassland | Nlapp-grass | 4 | | 4 | [-] | D |
| Manure application time interval for grassland | Tgr-int | 53 | | 53 | [d] | D |
| Number of animals | Nanimal i1 | 10 000 | | 80 | [-] | D |
| Amount of nitrogen per animal | Qnitrog i1 | 0.00482 | | 0.02382 | [kg.d-1] | D |
| OUTPUTS | | | | | | |
| ***STP*** | | | | | | |
| Emission from one application to sewer | E local wastewater | | 2.47 | n.r. | [kg.d-1] | As active chlorine |
| 5.26E-01 | n.r. | Chlorate |
|  |  |  |
| ***Manure/slurry exposure*** | | | | | | |
| Amount of a.i. in manure after one application | Q ai manure/slurry | | 3.71 | 5.00E-01 | [kg] | As active chlorine |
| 7.89E-01 | 1.06E-01 | Chlorate |
|  |  |  |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 1.10E-19 kg av Cl/d |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

For manure/slurry exposure, by analogy with the degradation in the STP, we consider that active chlorine is expected to degrade within the first minutes due to the high level of organic matter which is a worst-case approach as the DT50 in manure/slurry would be fewer than the DT50 in the sewer. Therefore, the degradation of the active substance was taken into account for the estimation of local emission using the following input parameters (according to the assessment report):

* Half-life of hypochlorite in the sewer system, DT50 = 56 sec at 12°C
* Residence time in manure/slurry: 1h

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalmannure = 1.65E-19 kg av Cl/d (turkeys)  Elocalmannure = 2.22E-20 kg av Cl/d (veal claves) |

##### PT3 – Scenario 2: Disinfection of vehicles for animal transport (META-SPC 6.21; 6.22; 7.11; 7.12; 7.2; 8; 10.1; 10.2 and 11)

The use of disinfection of vehicles for animal transport is intended for META-SPC 6.21; 6.22; 7.11; 7.12; 7.2; 8; 10.1; 10.2 and 11 covering the following uses:

* Disinfection of non-porous hard surfaces in livestock transportation vehicles

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the worst case in-use concentrations has been done in the table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Substance | Concentration of substance (%) | Dilution factor (worst case) | Density | Concentration in working solution (g/L) |
| META SPC 6.21 | Active chlorine | 9.6 | 0.105 | 1.151 | 11.6 |
| Chlorate | 1.74 | 0.105 | 1.151 | 2.10 |
| META SPC 6.22 | Active chlorine | 13.5 | 0.093 | 1.226 | **15.39** |
| Chlorate | 2.87 | 0.093 | 1.226 | **3.27** |
| META SPC 7.11 | Active chlorine | 3.6 | 0.27 | 1.052 | 10.23 |
| Chlorate | 0.17 | 0.27 | 1.052 | 0.48 |
| META SPC 7.12 | Active chlorine | 4.8 | 0.18 | 1.07 | 9.24 |
| Chlorate | 0.31 | 0.18 | 1.07 | 0.6 |
| META SPC 7.2 | Active chlorine | 2.6 | 0.35 | 1.07 | 9.74 |
| META SPC 10.1 | Active chlorine | 2.6 | 0.35 | 1.04 | 9.46 |
| META SPC 10.2 | Active chlorine | 4.8 | 0.18 | 1.072 | 9.26 |
| Chlorate | 0.31 | 0.18 | 1.072 | 0.6 |
| META SPC 11 | Active chlorine | 6 | 0.18 | 1.192 | 12.87 |
| Chlorate | 1.26 | 0.18 | 1.192 | 2.7 |
|  |  |  |  |  |

The worst case Meta-SPC and in-use concentrations are the following:

- META-SPC 6.22 for active chlorine (15.39 g/L),

- META-SPC 6.22 for chlorates (3.27 g/L),

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emissions** | | | | |
| **Input** | **Symbol** | **Value** | **Unit** | **Remarks** |
| Application rate of working solution | [Vprod] | 0.1 | L/m² | Information provided by the applicant |
| Concentration of active substance in the working solution  Active chlorine  Chlorate | [Fbioc] | 15.39  3.27 | g/L | O |
| Area of trucks (mammal transports) | [AREAmam] | 4546 | m² | ESD guidance PT3 |
| Area of trucks (poultry transports) | [AREApoul] | 1120 | m² | ESD guidance PT3 |
| Area of containers (poultry transports) | [AREAcont] | 3355 | m² | ESD guidance PT3 |
| Fraction released to waste water | [Fstp] | 1 | - | ESD guidance PT3 (adapted) |
| Number of disinfectant applications in one year | [Napp-bioc] | 365 | - | ESD guidance PT3 |

Calculation for Scenario 2:

| **Resulting local emissions to relevant environmental compartments** | | | |
| --- | --- | --- | --- |
| **Compartment** | **Local emission (ElocalSTP) [kg/d]** | | |
|  | **Active chlorine** | **Chlorate** |  |
| STP - mammals | 7.00 | 1.49 |  |
| STP – poultry | 6.89 | 1.46 |  |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | STP – mammals:  Elocalwater = 3.11E-19 kg av Cl/d  STP – poultry:  Elocalwater = 3.06E-19 kg av Cl/d |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

##### PT3 – Scenario 3: Drinking water pipe disinfection by injection (META-SPC 6.21; 6.22; 7.11; 7.12 and 7.2)

The scenario disinfection for drinking water pipe by injection is intended for META-SPC 6.21; 6.22; 7.11; 7.12 and 7.2 covering the following use: Disinfection of inner surfaces in veterinary water systems.

For the disinfection of drinking water pipes, a worst case value of 200 L of solution is used in worst case (corresponding to 0.5 L of diluted solution for 1 m of pipe (with a radius of 1.3 cm) and a pipe length of 400 m at a maximum).

Only the worst case scenarios are developed below. For the calculated PECs when main releases are via manure/slurry application, it corresponds to the “Veal calves” scenario. For the calculated PECs via the STP, the calculation is independent of the type of housing/manure storage.

Moreover for manure application, only results for grassland are detailed corresponding to the worst case approach compared to arable land.

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below, taking into account the same application rate for every Meta-SPC:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Substance | Concentration of substance (%) | Dilution factor (worst case) | Density | Concentration in working solution (g/L) |
| META SPC 6.21 | Active chlorine | 9.6 | 0.105 | 1.151 | 11.6 |
| Chlorate | 1.74 | 0.105 | 1.151 | 2.10 |
| META SPC 6.22 | Active chlorine | 13.5 | 0.093 | 1.226 | **15.39** |
| Chlorate | 2.87 | 0.093 | 1.226 | **3.27** |
| META SPC 7.11 | Active chlorine | 3.6 | 0.26 | 1.052 | 9.96 |
| Chlorate | 0.17 | 0.26 | 1.052 | 0.47 |
| META SPC 7.12 | Active chlorine | 4.8 | 0.17 | 1.07 | 8.94 |
| Chlorate | 0.31 | 0.17 | 1.07 | 0.58 |
| META SPC 7.2 | Active chlorine | 2.6 | 0.35 | 1.07 | 9.63 |

The worst case Meta-SPC and in-use concentrations are the following:

- META-SPC 6.22 for active chlorine (15.39 g/L),

- META-SPC 6.22 for chlorates (3.27 g/L),

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | | |
| **Parameter** | **Nomenclature** | | **Value** | **Unit** | **Origin\*** |
| INPUTS | | | | | |
| Type of housing/manure storage (for application of the notification) | cat-subcat (i1) | Veal calves | | [-] | D |
| Type of biocide | bioctype (i2) | Disinfectant | | [-] | D |
| Type of application | App way (i3) | Drinking water pipe disinfection by injection | | [-] | D |
| Content of active ingredient in formulation  Active chlorine  Chlorate | F bioc | 15.39  3.27 | | [g.L-1] | S |
| Volume of solution diluted for the pipe | V pipe | 200 | | [L] | O |
| Dilution factor | F dil | 1 | | [-] | S |
| Fraction of active ingredient released | F slurry/manure | 1 | | [-] | D |
| F waste water | 1 | | [-] | D |
| Biocide application interval | Tbioc-int | 91 | | [d] | D/O |
| Number of disinfectant applications in one year | Napp-bioc | 4 | | [-] | D |
| Number of manure applications - grassland | Nlapp-grass | 4 | | [-] | D |
| Manure application time interval for grassland | Tgr-int | 53 | | [d] | D |
| Number of animals | Nanimal i1 | 80 | | [-] | D |
| Amount of nitrogen per animal | Qnitrog i1 | 0.02382 | | [kg.d-1] | D |
| OUTPUTS | | | | | |
| ***STP*** | | | | | |
| Emission from one application to sewer | E local wastewater | | 3.08 | [mg L-1] | As active chlorine |
| 6.54E-01 | As Chlorate |
| ***Soil exposure*** | | | | | |
| Amount of a.i. in manure after one application | Q ai manure/slurry | | 3.08 | [kg] | As active chlorine |
| 6.54E-01 | As Chlorate |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 1.37E-19 kg av Cl/d |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

For manure/slurry exposure, by analogy with the degradation in the STP, we consider that active chlorine is expected to degrade within the first minutes due to the high level of organic matter which is a worst-case approach as the DT50 in manure/slurry would be fewer than the DT50 in the sewer. Therefore, the degradation of the active substance was taken into account for the estimation of local emission using the following input parameters (according to the assessment report):

* Half-life of hypochlorite in the sewer system, DT50 = 56 sec at 12°C
* Residence time in manure/slurry: 1h

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalsoil\_mannure = 1.37E-19 kg av Cl/d |

**PT4 scenarios**

##### PT4 – Scenario 1: Disinfection of large scale kitchens /canteens and slaughterhouses (META-SPC 2.1; 2.21; 2.22; 6.1; 6.21; 6.22; 7.11; 7.12; 8; 10.1; 10,2 and 11)

The use of disinfection of large scale kitchens/canteens and slaughterhouses is intended for META-SPC 2.1; 2.21; 2.22; 6.1; 6.21; 6.22; 7.11; 7.12; 8; 10.1; 10.2 and 11 covering the following uses:

* Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket
* Disinfection of surfaces in contact with food
* Disinfection of hard surfaces in contact with food

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below with the worst case product of each META-SPC:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Substance | Concentration of substance (%) | Dilution factor (worst case) | Density | Concentration in working solution (g/L) |
| Meta SPC 2.1 | Active chlorine | 2.6 | 0.3 | 1.0397 | 8.11 |
| Meta SPC 2.21 | Active chlorine | 4.8 | 0.5 | 1.0755 | **25.81** |
| Chlorate | 0.31 | 0.5 | 1.0755 | 1.67 |
| Meta SPC 2.22 | Active chlorine | 3.6 | 0.22 | 1.0559 | 8.45 |
| Chlorate | 0.17 | 0.22 | 1.0559 | 0.40 |
| Meta SPC 6.1 | Active chlorine | 9.6 | 0.09 | 1.151 | 10.05 |
| Chlorate | 1.74 | 0.09 | 1.151 | 1.82 |
| Meta SPC 6.21 | Active chlorine | 9.6 | 0.135 | 1.151 | 14.92 |
| Chlorate | 1.74 | 0.135 | 1.151 | 2.70 |
| Meta SPC 6.22 | Active chlorine | 13.5 | 0.112 | 1.226 | 18.54 |
| Chlorate | 2.87 | 0.112 | 1.226 | **3.94** |
| Meta SPC 7.11 | Active chlorine | 3.6 | 0.34 | 1.052 | 12.88 |
| Chlorate | 0.17 | 0.34 | 1.052 | 0.61 |
| Meta SPC 7.12 | Active chlorine | 4.8 | 0.23 | 1.07 | 11.81 |
| Chlorate | 0.31 | 0.23 | 1.07 | 0.76 |
| Meta SPC 7.2 | Active chlorine | 2.6 | 0.45 | 1.07 | 12.52 |
| Meta SPC 8 | Active chlorine | 1.6 | 0.5 | 1.0262 | 8.21 |
| Meta SPC 10.1 | Active chlorine | 2.6 | 0.45 | 1.04 | 12.17 |
| Meta SPC 10.2 | Active chlorine | 4.8 | 0.31 | 1.072 | 11.83 |
| Chlorate | 0.31 | 0.31 | 1.072 | 0.76 |
| Meta SPC 11 | Active chlorine | 6 | 1.26 | 1.192 | 17.16 |
| Chlorate | 1.26 | 1.26 | 1.192 | 3.6 |
|  |  |  |  |  |

The worst case Meta-SPC and in-use concentrations are the following:

- META-SPC 2.21 for active chlorine (25.81 g/L),

- META-SPC 6.22 for chlorates (3.94 g/L),

An application rate of 0.1 L/m² (based on Technical Agreements for Biocides Environment (ENV) Version 2.1, December 2019), is considered based on the applicant.

Therefore, the concentration of active chlorine is 2.581 g/m² andthe concentration of chlorate is 0.394 g/m²

By default, one application per day is considered as a reasonable worst-case value.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Input parameters for calculating the local emission | | | | |
| Input | Unit | Symbol | Value | Remarks |
| Surface area to be disinfected for slaughterhouses | m² | AREAsurface | 10000 | Default value |
| Surfaces area to be disinfected for kitchens and canteens | m² | AREAsurface | 2000 | Default value |
| Concentration of active substance in the product | g/m² | Qa.i.appl | 2.581 |  |
| Concentration of ClO3- from storage in the product | g/m² | Qa.i.appl | 0.394 |  |
|  |  |  |  |  |
| Number of application per day | d-1 | Nappl | 1 | Default value |
| Fraction of substance disintegrated during or after application, before release to te sewer system | - | Fdis | 0 | Worst case |
| Fraction of the substance eliminated due to on-site pre-treatment of the plant waste water | - | Felim | 0 | Default value |
| Fraction released to wastewater | - | Fwater | 1 | Default value |
| OUTPUT | | | | |
| Calculations:  Elocalwater = Qa.i.appl • AREAsurface • Nappl • (1 - Fdis) • (1 – Felim) • Fwater / 1000 | | | | |
| **Slaughterhouses** | | | | |
| Emission rate to wastewater (standard STP) for general purposes | kg/d | Elocalwater | 2.58E+01 | As Active chlorine eq. Cl2 |
| kg/d | Elocalwater | 3.94 | As Chlorate |
| kg/d |  |  |  |
| **Catering kitchens** | | | | |
| Emission rate to wastewater (standard STP) for general purposes | kg/d | Elocalwater | 5.16 | As Active chlorine eq. Cl2 |
| kg/d | Elocalwater | 7.88E-01 | As Chlorate |
| kg/d |  |  |  |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.6 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Slaugtherhouses:  Elocalwater = 1.15E-18 kg av Cl/d  Catering kitchens:  Elocalwater = 2.29E-19 kg av Cl/d |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

##### PT4 – Scenario 2: Disinfectants used in food and feed areas (entire plant scenario) (META-SPC 6.21; 6.22; 7.11; 7.12; 7.2; 10.1; 10.2 and 11)

The use of disinfectants used in food and feed areas covering by the entire plants scenario is intended for META-SPC 6.21; 6.22; 7.11; 7.12; 7.2; 10.1; 10.2 and 11 covering the following uses:

* Disinfection of hard surfaces by CIP (also covering PT02 and 03)
* Disinfection of surfaces by CIP (also covering PT02 and 03)
* Disinfection of surfaces in contact with food
* Disinfection of hard surfaces in contact with food
* Disinfection of inner surfaces in human drinking water systems

This emission scenario is based on the consumption of disinfectant by a model plant. As no annual tonnage for a local plant was known for the products assessed, the default data for chlorine given in the ESD was used (228 kg/yr).

The default data for chlorine is adapted to the chlorate by comparing the percentage of active chlorine in META-SPC 6.22 (worst case) of 13.5% and the percentage of chlorate of 2.87% of the META-SPC 6.22 as a worst-case to estimate an annual tonnage: Qai\_chlorate = 2.87% \* 228 kg/yr / 13.5% = 48.47 kg/yr.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | |
| **Input** | **Symbol** | **Unit** | **Value** | **Remarks** |
| Amount of biocidal active substance used per year:   * Active chlorine * Chlorate | Qai | [kg chlorine/y] | 228  48.47 | Pick list value (Table 6; ESD for PT 4, 2011) |
| Number of emission days per year | Temission | [d/y] | 231 | Default according to ESD PT4 (2011). |
| Fraction released to waste water | Fwater | - | 1 | Default value ESD PT4 (2011) |
| Emission rate to wastewater (standard STP) – before degradation   * Active chlorine * Chlorate | Elocal waste water | [kg/d] | 9.87E-01  2.10E-01 | - |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.6 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 4.39E-20 kg/d |

##### PT4 – Scenario 3: Disinfectants used in milking parlour systems (META-SPC 6.21, 6.22, 7.11, 7.12, 7.2, 10.1, 10.2 and 11)

The use of disinfection in milking parlour system is intended for META-SPC 6.21, 6.22, 7.11, 7.12, 7.2, 10.1, 10.2 and 11 covering the following uses:

* Disinfection of surfaces in contact with food
* Disinfection of surfaces by CIP
* Disinfection of hard surfaces in contact with food
* Disinfection of hard surfaces by CIP

Local emission due to disinfection of milking parlour systems were calculated using the ESD for PT4 Disinfection of milking parlour systems (SCC, 2011). Disinfection is performed by CIP. Wastewater is then discarded to sewer system.

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Substance | Concentration of substance (%) | Dilution factor (worst case) | Density | Concentration in working solution (g/L) |
| Meta SPC 6.21 | Active chlorine | 9.6 | 0.135 | 1.151 | 14.92 |
| Chlorate | 1.74 | 0.135 | 1.151 | 2.7 |
| Meta SPC 6.22 | Active chlorine | 13.5 | 0.112 | 1.226 | **18.54** |
| Chlorate | 2.87 | 0.112 | 1.226 | **3.94** |
| Meta SPC 7.11 | Active chlorine | 3.6 | 0.34 | 1.052 | 12.88 |
| Chlorate | 0.17 | 0.34 | 1.052 | 0.61 |
| Meta SPC 7.12 | Active chlorine | 4.8 | 0.23 | 1.07 | 11.81 |
| Chlorate | 0.31 | 0.23 | 1.07 | 0.76 |
| Meta SPC 7.2 | Active chlorine | 2.6 | 0.45 | 1.07 | 12.52 |
| Meta SPC 10.1 | Active chlorine | 2.6 | 0.45 | 1.04 | 12.17 |
| Meta SPC 10.2 | Active chlorine | 4.8 | 0.23 | 1.072 | 11.83 |
| Chlorate | 0.31 | 0.23 | 1.072 | 0.76 |
| Meta SPC 11 | Active chlorine | 6 | 0.24 | 1.192 | 17.16 |
| Chlorate | 1.26 | 0.24 | 1.192 | 3.6 |
|  |  |  |  |  |

The worst case Meta-SPC and in-use concentrations are the following:

- META-SPC 6.22 for active chlorine (18.54 g/L),

- META-SPC 6.22 for chlorates (3.94 g/L),

Input parameters for the emission scenario - Disinfection of milking parlour systems:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Variable/parameter** | **Unit** | **Symbol** | **S/D/O/P** | **Value** | **Remark** |
| Concentration of:  Active chlorine  Chlorate | g/L | Cform | S | 18.54  3.94 |  |
| Amount of disinfectant used for cleaning of the milking installation | L/d | Vforminst | D | 130 | Based on ESD: 65L per application is used for cleaning of the milking installation. As milking installation are usually cleaned twice a day, an amount of 130L per day (65 x 2) was considered for the assessment. |
| Amount of disinfectant used for cleaning of the milk storage tank | L/d | Vformtank | D | 45 |  |
| Fraction of substance disintegrated during or after application (before release to the sewage system) | [-] | Fdis | D | 0 |  |
| Fraction of the emission to wastewater | [-] | Fwater | D | 1 |  |

Output:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Quantity of active ingredient used | g/d | Qai | 3.24E+03 | As Active chlorine eq Cl2 | Qai = Cform \* (Vforminst + Vformtank) |
| 6.9E+02 | As Chlorate |
|  |  |
| Local emission to wastewater | kg/d | Elocalwater | 3.24 | As Active chlorine eq Cl2 | Elocalwater = Qai \* (1-Fdis) \* Fwater /1000 |
| 6.90E-01 | As Chlorate |
|  |  |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | **Elocal,water= 1.44E-19 kg/d** |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

***Fate and distribution in exposed environmental compartments***

The fate and behaviour of active chlorine in the environment is described in detail in the CARs of sodium/calcium hypochlorite and active chlorine. Hypochlorite is a highly reactive compound, which reacts rapidly with organic matter in the sewer, STP, surface water and soil. Where organic and nitrogenous materials are present, hypochlorite acts as a highly reactive oxidizing agent. It reacts rapidly with organic matter in sewage or activated sludge and most (≈ 99%) of the available chlorine is converted to inorganic chloride. Oxidation is probably the predominant chemical reaction occurring in chlorine’s disinfection processes. Furthermore, circumstances influencing the reactivity of hypochlorite are time, temperature, pH and the availability of amount and type of organic matter. The content of organic matter in soil is lower than in sewage or activated sludge but it is high enough to ensure complete decomposition in a relatively short time.

The kinetic model of Vandepitte and Schowanek (sodium hypochlorite CAR) shows that hypochlorite is eliminated during transport in the sewer within the first minutes. The HClO/ClO- (expressed as FAC) concentration drops quickly in the sewer, parallel to a sharp increase of the chloramine concentration, which can be explained by the high availability of ammonia in the sewer. Chloramine further reacts as an oxidant during additional transport in the sewer, the STP and in the river. The extensive degradation of chloramine in the activated sludge can be explained by the presence of reduced organic material. At environmental pH values (6.5-8.5) half of the active chlorine is present in the undissociated form of hypochlorous acid and half is dissociated to the hypochlorite anion. Only the hypochlorous acid fraction is volatile, but the amount of hypochlorous acid that could volatilise from water into air is expected to be very low.

**Active chlorine**

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
|  | | STP | Freshwater including sediment | Soil | Groundwater | Air |
| PT 2 | | | | | | |
| PT2 – Scenario 1: private swimming pool | | Q | Q | Q | Q | n.r. |
| PT2 – Scenario 2: public swimming pool | | Q | Q | Q | Q | n.r. |
| PT2 – Scenario 3a: sanitary purpose (general disinfection) | | Q | Q | Q | Q | n.r. |
| PT2 – Scenario 3b: sanitary purpose (toilet bowls) | | Q | Q | Q | Q | n.r. |
| PT2 – Scenario 4: Laundry disinfection in closed washing machine, covering hand-washing | | Q | Q | Q | Q | n.r. |
| PT2 – Scenario 5: Disinfectants for laundry (professional) | | Q | Q | Q | Q | n.r. |
| PT2 – Scenario 6: Industrial areas | | Q | Q | Q | Q | n.r. |
| PT2 – Scenario 7: Medical sector, room, furniture and object | | Q | Q | Q | Q | n.r. |
| PT2 – Scenario 8: Anti-lichen and anti-algae treatment of hard surfaces | House release | Q | Q | Q | n.r. | n.r. |
| Bridge over pond (application only) | Q | SQ | Q | n.r. | n.r. |
| PT 3 | | | | | | |
| PT3 – Scenario 1: Disinfection of animal housing | | Q | Q | Q | Q | n.r. |
| PT3 – Scenario 2: Disinfection of vehicles for animal transport | | Q | Q | Q | Q | n.r. |
| PT3 – Scenario 3: Drinking water pipe disinfection by injection | | Q | Q | Q | Q | n.r. |
| PT 4 | | | | | | |
| PT4 – Scenario 1: Disinfection of large scale kitchens and canteens | | Q | Q | Q | Q | n.r. |
| PT4 – Scenario 2: Disinfection used in food and feed areas (Entire plants) | | Q | Q | Q | Q | n.r. |
| PT4 – Scenario 3: Disinfection in milking parlour systems | | Q | Q | Q | Q | n.r. |

Q: Qualiitative assessment

SQ: Semi-qualitative assessment

n.r. : Not relevant

**Chlorate**

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | STP | Freshwater incl. sediment | Marine | Groundwater | Air |
| PT 2 | | | | | |
| PT2 – Scenario 1: private swimming pool | a | SQ | a | SQ | a |
| PT2 – Scenario 2: public swimming pool | a | SQ | a | SQ | a |
| PT2 – Scenario 3a: sanitary purpose (general disinfection) | a | SQ | a | SQ | a |
| PT2 – Scenario 3b: sanitary purpose (toilet bowls) | a | SQ | a | SQ | a |
| PT2 – Scenario 4: Laundry disinfection in closed washing machine, covering hand-washing | a | SQ | a | SQ | a |
| PT2 – Scenario 5: Disinfectants for laundry (professional) | a | SQ | a | SQ | a |
| PT2 – Scenario 6: Industrial areas | a | SQ | a | SQ | a |
| PT2 – Scenario 7: Medical sector, room, furniture and object | a | SQ | a | SQ | a |
| PT2 – Scenario 8: Anti-lichen and anti-algae treatment of hard surfaces  House – Urban STP  House – Urban separate sewer system | a | SQ | a | SQ | a |
| PT2 – Scenario 8: Anti-lichen and anti-algae treatment of hard surfaces  House – Rural direct release to soil | a | SQ | a | SQ | a |
| PT2 – Scenario 8: Anti-lichen and anti-algae treatment of hard surfaces  Bridge over the pond | a | SQ | a | SQ | a |
| PT 3 | | | | | |
| PT3 – Scenario 1: Disinfection of animal housing | a | SQ | a | SQ | a |
| PT3 – Scenario 2: Disinfection of vehicles for animal transport | a | SQ | a | SQ | a |
| PT3 – Scenario 3: Drinking water pipe disinfection by injection | a | SQ | a | SQ | a |
| PT 4 | | | | | |
| PT4 – Scenario 1: Disinfection of large scale kitchens and canteens | a | SQ | a | SQ | a |
| PT4 – Scenario 2: Disinfection used in food and feed areas (Entire plants) | a | SQ | a | SQ | a |
| PT4 – Scenario 3: Disinfection in milking parlour systems | a | SQ | a | SQ | a |

a: covered by the active substance assessment

SQ: semi qualitative assessment

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment - Chlorate** | | | |
| Input | Value | Unit | Remarks |
| Molecular weight | 83.5 | g/mol | - |
| Vapour pressure (at 25°C) | 3.50E-07 | Pa | - |
| Water solubility (at 25°C) | 7.36E+05 | mg/l | At pH 4.49 to 8.70 |
| Organic carbon/water partition coefficient (Koc) | 31.62 | l/kg | QSAR (KOCWIN v2.00) |
| Henry’s Law Constant (at 25°C) | 5.20E-09 | Pa/m3/mol | Estimated |
| Biodegradability | Not applicable to inorganic substances | [-] | ot readily biodegradabl |
| DT50 for degradation in soil | 1E+06 | d (at 12°C) | Not readily biodegradable |
| Rate constant for soil biodegradation (application to arable land) | 6.93E-07 | d-1 (at 12°C) | - |

The distribution of chlorate within STP using the SimpleTreat 4.0 Model:

|  |  |  |
| --- | --- | --- |
| Compartment | Percentage (%) | Remarks |
| Air | 1E-08 | - |
| Water | 99.6 | - |
| Sludge | 0.394 | - |
| Degraded in STP | 0 | - |

***Calculated PEC values***

**Active chlorine**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values – Active Chlorine** | | | | | | |
|  | | **PECSTP** | **PECwater** | **PECsoil** | **PECGW1** | **PECair** |
| [mg/L] | [mg/l] | [mg/kg] | [μg/l] | [mg/m3] |
| PT 2 | | | | | | |
| PT2 – Scenario 1: private swimming pool | | Q | Q | Q | Q | Q |
| PT2 – Scenario 2: public swimming pool | | Q | Q | Q | Q | Q |
| PT2 – Scenario 3a: sanitary purpose (general disinfection) | | Q | Q | Q | Q | Q |
| PT2 – Scenario 3b: sanitary purpose (toilet bowls) | | Q | Q | Q | Q | Q |
| PT2 – Scenario 4: Laundry disinfection in closed washing machine, covering hand-washing | | Q | Q | Q | Q | Q |
| PT2 – Scenario 5: Disinfectants for laundry (professional) | | Q | Q | Q | Q | Q |
| PT2 – Scenario 6: Industrial areas | | Q | Q | Q | Q | Q |
| PT2 – Scenario 7: Medical sector, room, furniture and object | | Q | Q | Q | Q | Q |
| PT2 – Scenario 8: Anti-lichen and anti-algae treatment of hard surfaces | House release | Q | Q | Q | Q | Q |
| Bridge over pond (application only) | Q | 8.29E-03 | Q | Q | Q |
| PT 3 | | | | | | |
| PT3 – Scenario 1: Disinfection of animal housing | | Q | Q | Q | Q | Q |
| PT3 – Scenario 2: Disinfection of vehicles for animal transport | | Q | Q | Q | Q | Q |
| PT3 – Scenario 3: Drinking water pipe disinfection by injection | | Q | Q | Q | Q | Q |
| PT 4 | | | | | | |
| PT4 – Scenario 1: Disinfection of large scale kitchens and canteens | | Q | Q | Q | Q | Q |
| PT4 – Scenario 2: Disinfection used in food and feed areas (Entire plants) | | Q | Q | Q | Q | Q |
| PT4 – Scenario 3: Disinfection in milking parlour systems | | Q | Q | Q | Q | Q |

Q: Qualitative assessment considering negligible emissions

**Chlorate**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values – Chlorate** | | | | | | | | |
|  | | | | **PECSTP** | **PECwater** | **PECsoil** | **PECGW1** | **PECair** |
| [mg/L] | [mg/l] | [mg/kg] | [μg/l] | [mg/m3] |
| PT 2 | | | | | | | | |
| PT2 – Scenario 1: private swimming pool | Shock | | Acute | a | 9.07E-02 | n.r. | 1.98E+02 | n.r. |
| Chronic | a | 2.16E-01 | n.r. | 4.71E+02 | n.r. |
| Continuous | | Acute | a | 9.07E-03 | n.r. | 1.98E+01 | n.r. |
| Chronic | a | 2.16E-02 | n.r. | 4.71E+01 | n.r. |
| PT2 – Scenario 2: public swimming pool | Shock | | Acute | a | 1.51E-01 | n.r. | 3.29E+02 | n.r. |
| Chronic | a | 1.15E-02 | n.r. | 2.50E+01 | n.r. |
| Continuous | | Acute | a | 1.51E-02 | n.r. | 3.29E+01 | n.r. |
| Chronic | a | 1.15E-03 | n.r. | 2.50 | n.r. |
| PT2 – Scenario 3a: sanitary purpose (general disinfection) | | | | a | 4.91E-03 | a | 1.07E+01 | n.r. |
| PT2 – Scenario 3b: sanitary purpose (toilet bowls) | | | | a | 1.44E-03 | a | 3.14 | n.r. |
| PT2 – Scenario 4: Laundry disinfection in closed washing machine, covering hand-washing | | | | a | 5.08E-02 | a | 1.11E+02 | n.r. |
| PT2 – Scenario 5: Disinfectants for laundry (professional) | | | | a | 1.52 | a | 3.31E+03 | n.r. |
| PT2 – Scenario 6: Industrial areas (large scale) | | | | a | 1.96E-02 | a | 4.27E+01 | n.r. |
| PT2 – Scenario 6: Industrial areas (small scale) | | | |  | 4.14E-04 |  | 9.00E-01 |  |
| PT2 – Scenario 7: Medical sector, room, furniture and object | | | | a | 6.20E-03 | a | 1.35E+01 | n.r. |
| PT2 – Scenario 8: Anti-lichen and anti-algae treatment of hard surfaces - Total release considering application and service-life  House – Urban STP  House – Urban separate sewer system | | | | a  n.r. | 4.03E-02  1.35E-01 | a  n.r. | 8.79E+01  n.r. | n.r. |
| PT2 – Scenario 8: Anti-lichen and anti-algae treatment of hard surfaces - Total release considering application and service-life  House – Rural direct release to soil | | | | n.r. | n.r. | a | 3.76E+02 | n.r. |
| PT2 – Scenario 8: Anti-lichen and anti-algae treatment of hard surfaces  Bridge over the pond | | | | a | 1.50E-03 | a | a | n.r. |
| PT 3 | | | | | | | | |
| PT3 – Scenario 1: Disinfection of animal housing – Turkey in free range – litter floor (releases via the STP) | | | | a | 2.62E-02 | a | 5.71E+01 | n.r. |
| PT3 – Scenario 1: Disinfection of animal housing – Veal calves (releases via slurry/manure, grassland as worst case) | | | | a | 3.12E-01 | a | 3.12\* | n.r. |
| PT3 – Scenario 2: Disinfection of vehicles for animal transport (mammals as worst case) | | | | a | 7.40E-02 | a | 1.61E+02 | n.r. |
| PT3 – Scenario 3: Drinking water pipe disinfection by injection | | Via STP | | a | 3.26E-02 | a | 7.10E+01 | n.r. |
| Via manure/slurry | | n.r. | 1.92 | a | 1.92E+01 | n.r. |
| PT 4 | | | | | | | | |
| PT4 – Scenario 1: Disinfection of large scale kitchens and canteens | | | Slaughterhouses | a | 1.96E-01 | a | 4.27E+02 | n.r. |
| Catering kitchens | a | 3.92E-02 | a | 8.55E+01 | n.r. |
| PT4 – Scenario 2: Disinfection used in food and feed areas (Entire plants) | | | | a | 1.05E-02 | a | 2.28E+01 | n.r. |
| PT4 – Scenario 3: Disinfection in milking parlour systems | | | | a | 3.43E-02 | a | 7.48E+01 | n.r. |

a: covered by the active substance assessment

n.r.: not relevant

\* in mg/L

***Primary and secondary poisoning***

Active chlorine does not bio-accumulate and does not concentrate in the food chain. The low BCF indicates that the risk for birds and mammals is low regarding secondary poisoning. Hence the product meets the standards for the risk to birds and mammals. Primary poisoning is not expected for the intended uses.

No secondary poisoning is expected for chlorate and the two substances of concern as they do not bioaccumulate, as indicated their low Log(Kow) < 3.

#### Risk characterisation

Due to the high reactivity of the active substance with organic matter, indirect releases from all the intended uses lead to negligible environmental concentrations and risks are acceptable for all compartments.

A qualitative risk characterisation of chlorate is presented for all the environmental compartments as covered by the active substance, except for groundwater as chlorate is a substance of concern in relation to human health. Then, a semi-qualitative risk assessment is proposed for groundwater and surface water intended to drinking water.

***Active chlorine***

Risk characterisation of the active substance is summarized in the following table for each environmental compartment. Results are presented for the three emission scenarios, with degradation of the active substance in the sewer system as it represents the most realistic case in view of the active substance properties.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values – Active chlorine** | | | | | |
|  | **PEC/PNECSTP** | **PEC/PNECwater** | **PEC/PNECsoil** | **PEC/Limitgw** | **PEC air** |
| PT 2 | | | | | |
| PT2 – Scenario 1: private swimming pool | Negligible | Negligible | Negligible | Negligible | Negligible |
| PT2 – Scenario 2: public swimming pool | Negligible | Negligible | Negligible | Negligible | Negligible |
| PT2 – Scenario 3a: sanitary purpose (general disinfection) | Negligible | Negligible | Negligible | Negligible | Negligible |
| PT2 – Scenario 3b: sanitary purpose (toilet bowls) | Negligible | Negligible | Negligible | Negligible | Negligible |
| PT2 – Scenario 4: Laundry disinfection in closed washing machine, covering hand-washing | Negligible | Negligible | Negligible | Negligible | Negligible |
| PT2 – Scenario 5: Disinfectants for laundry (professional) | Negligible | Negligible | Negligible | Negligible | Negligible |
| PT2 – Scenario 6: Industrial areas | Negligible | Negligible | Negligible | Negligible | Negligible |
| PT2 – Scenario 7: Medical sector, room, furniture and object | Negligible | Negligible | Negligible | Negligible | Negligible |
| PT2 – Scenario 8: Anti-lichen and anti-algae treatment of hard surfaces  Bridge over the pond | Negligible | **1.97E+02** | Negligible | Negligible | Negligible |
| PT 3 | | | | | |
| PT3 – Scenario 1: Disinfection of animal housing | Negligible | Negligible | Negligible | Negligible | Negligible |
| PT3 – Scenario 2: Disinfection of vehicles for animal transport (mammals as worst case) | Negligible | Negligible | Negligible | Negligible | Negligible |
| PT3 – Scenario 3: Drinking water pipe disinfection by injection | Negligible | Negligible | Negligible | Negligible | Negligible |
| PT 4 | | | | | |
| PT4 – Scenario 1: Disinfection of large scale kitchens and canteens | Negligible | Negligible | Negligible | Negligible | Negligible |
| PT4 – Scenario 2: Disinfection used in food and feed areas (Entire plants) | Negligible | Negligible | Negligible | Negligible | Negligible |
| PT4 – Scenario 3: Disinfection in milking parlour systems | Negligible | Negligible | Negligible | Negligible | Negligible |

Conclusions:

As the risk assessment is based on a qualitative assessment, all the risks are acceptable for the chlore for all the compartment except for the scenario anti-lichen and anti-algea for the freshwater.

The following risk mitigation measure should be applied to limit the direct emissions of product to the aquatic compartment: **Do not apply where the product can reach surface water.**

***Chlorate***

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values – Chlorate** | | | | | | | | | | | |
|  | | | | | **PEC/PNECSTP** | | **PEC/ Limitgw\*** | | **PEC/PNECsoil** | **PEC/Limitgw\*** | **PEC air** |
| PT 2 | | | | | | | | | | | |
| PT2 – Scenario 1: private swimming pool | | Shock | | Acute | a | | 1.30E-01 | | a | 2.82E-01 | n.r. |
| Chronic | a | | 3.09E-01 | | a | 6.73E-01 | n.r. |
| Continuous | | Acute | a | | 1.30E-02 | | a | 2.82E-02 | n.r. |
| Chronic | a | | 3.09E-02 | | a | 6.73E-02 | n.r. |
| PT2 – Scenario 2: public swimming pool | | Shock | | Acute | a | | 2.16E-01 | | a | 4.70E-01 | n.r. |
| Chronic | a | | 1.64E-02 | | a | 3.56E-02 | n.r. |
| Continuous | | Acute | a | | 2.16E-02 | | a | 4.70E-02 | n.r. |
| Chronic | a | | 1.64E-03 | | a | 3.56E-03 | n.r. |
| PT2 – Scenario 3a: sanitary purpose (general disinfection) | | | | | a | | 7.01E-03 | | a | 1.53E-02 | n.r. |
| PT2 – Scenario 3b: sanitary purpose (toilet bowls) | | | | | a | | 2.06E-03 | | a | 4.48E-03 | n.r. |
| PT2 – Scenario 4: Laundry disinfection in closed washing machine, covering hand-washing | | | | | a | | 7.26E-02 | | a | 1.58E-01 | n.r. |
| PT2 – Scenario 5: Disinfectants for laundry (professional) | | | | | a | | **2.17** | | a | **4.73** | n.r. |
| PT2 – Scenario 6: Industrial areas (Large scale) | | | | | a | | 2.80E-02 | | a | 6.11E-02 | n.r. |
| PT2 – Scenario 6: Industrial areas (Small scale) | | | | | a | | 5.91E-04 | | a | 1.29E-03 | n.r |
| PT2 – Scenario 7: Medical sector, room, furniture and object | | | | | a | | 8.86E-03 | | a | 1.93E-02 | n.r. |
| PT2 – Scenario 8: Anti-lichen and anti-algae treatment of hard surfaces - Total release considering application and service-life  House – Urban STP  House – Urban separate sewer system | | | | | a | | 5.76E-02  1.93E-01 | | a | 1.26E-01n.r. | n.r. |
| PT2 – Scenario 8: Anti-lichen and anti-algae treatment of hard surfaces - Total release considering application and service-life  House – Rural direct release to soil | | | | | n.r. | | n.r. | | n.r. | 5.37E-01 | n.r. |
| PT2 – Scenario 8: Anti-lichen and anti-algae treatment of hard surfaces  Bridge over the pond | | | | | n.r. | | 2.14E-03 | | n.r. | n.r. | n.r. |
| PT 3 | | | | | | | | | | | |
| PT3 – Scenario 1: Disinfection of animal housing – Turkey in free range – litter floor  (release via STP) | | | | | | a | | 3.74E-02 | a | 8.15E-02 | n.r. |
| PT3 – Scenario 1: Disinfection of animal housing – Veal calves (release via manure/slurry) | | | | | a | | 4.45E-01 | | a | **4.44** | n.r. |
| PT3 – Scenario 2: Disinfection of vehicles for animal transport (mammals as worst case) | | | | | a | | 1.06E-01 | | a | 2.30E-01 | n.r. |
| PT3 – Scenario 3: Drinking water pipe disinfection by injection | | | Via STP | | a | | 4.66E-02 | | a | 1.01E-01 | n.r. |
| Via manure/slurry | | a | | **2.74** | | a | **2.74E+01** | n.r. |
| PT 4 | | | | | | | | | | | |
| PT4 – Scenario 1: Disinfection of large scale kitchens and canteens | Slaughterhouses | | | | a | | 2.80E-01 | | a | 6.11E-01 | n.r. |
| Catering kitchens | | | | a | | 5.61E-02 | | a | 1.22E-01 | n.r. |
| PT4 – Scenario 2: Disinfection used in food and feed areas (Entire plants) | | | | | a | | 1.49E-02 | | a | 3.25E-02 | n.r. |
| PT4 – Scenario 3: Disinfection in milking parlour systems | | | | | a | | 4.91E-02 | | a | 1.07E-01 | n.r. |

a: covered by the active substance assessment

\* compared to the drinking water limit value of 700 µg chlorate/L (WHO drinking water limit) for water disinfected by chloration.

n.r.: not relevant

A semi-qualitative risk assessment has been performed for chlorates leading to theoretical unacceptable risks for freshwater intended for the abstraction of drinking water and/or groundwater for

- PT2 – Scenario 8: Anti-lichen and anti-algae treatment of hard surfaces (for more than one application per year),

- PT3 – Scenario 1: Disinfection of animal housing – Veal calves (release via manure/slurry),

- PT3 – Scenario 3: Drinking water pipe disinfection by injection (release via manure/slurry).

However, during the WG-I-2020, it was concluded that a qualitative assessment for chlorate was sufficient as there are no harmonized endpoint values at the moment and therefore a refinement was not possible without harmonized endpoints. In conclusion, the risks for chlorate cannot be finalized and they cannot be used for decision making.

For Scenario PT2 – Scenario 5: Disinfectants for laundry (professional), the risks are unacceptable for the groundwater and the freshwater intended for the abstraction of drinking water. However, this scenario is considered as a very worst-case approach. In fact this scenario considers a capacity of washing tube of 8000 kg/d; this is a very worst case assumption considering this particular use for laundry disinfection with hand soaking only (and not in washing machine).

Therefore, if we consider that 10% of the capacity of washing tube corresponding to 800 kg/d, which is still a very conservative approach, the risk is considered to be acceptable for the freshwater and groundwater intended for the abstraction of drinking water.

Moreover, during the WG-I-2020, it was concluded that a qualitative assessment for chlorate was sufficient as there are no harmonized endpoint values at the moment and therefore a refinement was not possible without harmonized endpoints. In conclusion, the risks for chlorate cannot be finalized and they cannot be used for decision making.

***Primary and secondary poisoning***

Primary poisoning is not likely to occur as the products are intended for an indoor use. No direct exposure of birds or mammals is therefore expected.

Secondary poisoning

No secondary poisoning is expected for active chlorine as it does not bioaccumulate nor bioconcentrate due to its high water solubility and rapid degradation in the environment.

No secondary poisoning is expected for chlorate as it does not bioaccumulate, as can be seen from its low Log(Kow)< 3.

##### Overall conclusions:

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
| PT 2 | | |
| PT2 – Scenario 1: private swimming pool (maintenance and shock dose) | Acceptable risks for active chlorine  To be in line with the intended uses and scenarios, the following RMM is proposed: ***Application of this product is exclusively allowed in swimming pools with connection to a STP. It is not allowed to directly discharge swimming pool water to the surface water.*** | **Covered uses:**  **PT02:**  - disinfection of private swimming pools  - shock disinfection of private swimming pools  - disinfection of public and private swimming pools  - shock disinfection of public and private swimming pools  **Relevant META-SPC:**  1.1 with relevant RMM  1.2 with relevant RMM |
| PT2 – Scenario 2: public swimming pool (maintenance and shock dose) | Acceptable risks for active chlorine  To be in line with the intended uses and scenarios, the following RMM is proposed: ***Application of this product is exclusively allowed in swimming pools with connection to a STP. It is not allowed to directly discharge swimming pool water to the surface water.*** | **Covered uses:**  **PT02:**  - disinfection of public and private swimming pools  - shock disinfection of public and private swimming pools  **Relevant META-SPC:**  1.2 with relevant RMM |
| PT2 – Scenario 3a: sanitary purpose (general disinfection) | Acceptable risks for active chlorine  No specific RMM required. | **Covered uses:**  **PT02:**  - Disinfection of surfaces (floors) by wipping with mop and bucket  - Disinfection of surfaces (other than floors) by wipping with cloth and bucket  - Disinfection of surfaces by spraying with trigger spray  - Disinfection of surfaces in institutions/industry  - Disinfection of hard surfaces in industries/institutions  - Disinfection of hard surfaces by spraying  **PT03:**  - Disinfection of companion animal housing and associated equipment (as it is only indoor)  **Relevant META-SPC:**  2.1  2.21  2.22  3  4  5  6.1  6.21  6.22  7.11  7.12  7.2  8  10.1  10.2  11  12 |
| PT2 – Scenario 3b: sanitary purpose (toilet bowls) | Acceptable risks for active chlorine and chlorate.  No specific RMM required. | **Covered uses:**  **PT02:**   * Disinfection of toilet bowls * Disinfection of toilet bowls in medical areas * Disinfection of toilet bowls in institutions/industry   **Relevant META-SPC:**  2.1  2.21  2.22  3  4  8  13 |
| PT2 – Scenario 4: Laundry disinfection in closed washing machine, covering hand-washing | Acceptable risks for active chlorine.  No specific RMM required. | **Covered uses:**  **PT02:**   * non professional laundry disinfection with hand soak   **Relevant META-SPC:**  2.1  2.21  2.22  6.1  8 |
| PT2 – Scenario 5: Disinfectants for laundry (professional) | Acceptable risks for active chlorine.  No specific RMM required | **Covered uses:**  **PT02:**   * professional laundry disinfection with hand soak   **Relevant META-SPC:**  6.21  6.22  7.11  7.12  7.2  10.1  10.2 |
| PT2 – Scenario 6: Industrial areas – Large and small scale applications | Acceptable risks for active chlorine.  No specific RMM required. | **Covered uses:**  **PT02:**  - Disinfection of surfaces (other than floors) by wipping with cloth and bucket  - Disinfection of surfaces by spraying with trigger spray  - Disinfection of surfaces in institutions/industry  - Disinfection of hard surfaces in industries/institutions  - Disinfection of hard surfaces by spraying  **PT03:**  - Disinfection of non-porous hard surfaces in veterinary area  **Relevant META-SPC:**  2.1  2.21  2.22  3  4  5  6.1  6.21  6.22  7.11  7.12  7.2  8  10.1  10.2  11  12 |
| PT2 – Scenario 7: Medical sector, room, furniture and object | Acceptable risks for active chlorine.  No specific RMM required. | **Covered uses:**  **PT02:**   * Disinfection of surfaces by spraying with trigger spray * Disinfection of surfaces in medical area * Disinfection of hard surfaces in medical area * Disinfection of hard surfaces by spraying   **Relevant META-SPC:**  5  6.21  6.22  7.11  7.12  7.2  10.1  10.2  11 |
| PT2 – Scenario 8: Anti-lichen and anti-algae treatment of hard surfaces | Risks are foreseen for active chlorine in case of direct releases to the aquatic compartment only.  The following risk mitigation measure should be applied to limit the direct emissions of product to the aquatic compartment**:**  **Do not apply where the product can reach surface water.**  No other specific RMM required. | **Covered uses:**  **PT02:**  - Algaecide and fungicide for outdoor surfaces  **Relevant META-SPC:**  9 with relevant RMM  14 with relevant RMM |
| PT 3 | | |
| PT3 – Scenario 1: Disinfection of animal housing | Acceptable risks for active chlorine.  No specific RMM required. | **Covered uses:**  **PT03:**  - disinfection of non-porous hard surfaces in veterinary healthcare facilities – professional uses (but no release to manure foreseen)  - animal housings (such as kennels, hutches, cages, bee hives, stables, etc.) – professional uses (but no release to manure foreseen)  - livestock (poultry, bovine, etc.) buildings (releases to STP and manure  **Relevant META-SPC**  6.21  6.22  7.11  7.12  7.2  10.1  10.2  11 |
| PT3 – Scenario 2: Disinfection of vehicles for animal transport (mammals as worst case) | Acceptable risks for active chlorine.  No specific RMM required for the META-SPC | **Covered use:**  **PT03:**  Disinfection of vehicles for animal transport  **Relevant META-SPC**  6.21  6.22  7.11  7.12  7.2  8  10.1  10.2  11 |
| PT3 – Scenario 3: Drinking water pipe disinfection by injection | Acceptable risks for active chlorine.  No specific RMM required. | **Covered use:**  **PT03:**  Disinfection of inner surfaces in veterinary water systems  **Relevant META-SPC**:  6.21  6.22  7.11  7.12  7.2 |
| PT 4 | | |
| PT4 – Scenario 1: Disinfection of large scale kitchens and canteens | Acceptable risks for active chlorine.  No specific RMM required for the other META-SPC | **Covered use:**  **PT04:**  - Disinfection of surfaces (other than floors) in contact with food by wiping with cloth and bucket  - Disinfection of surfaces in contact with food  - Disinfection of hard surfaces in contact with food  **Relevant META-SPC:**  2.1  2.21  2.22  6.1  6.21  6.22  7.11  7.12  7.2  8  10.1  10.2  11 |
| PT4 – Scenario 2: Disinfection used in food and feed areas (Entire plants) | Acceptable risks for active chlorine.  No specific RMM required. | **Covered use:**  **PT04:**  - Disinfection of hard surfaces by CIP (also covering PT02 and 03)  - Disinfection of surfaces by CIP (also covering PT02 and 03)  - Disinfection of surfaces in contact with food  - Disinfection of hard surfaces in contact with food  - Disinfection of inner surfaces in human drinking water systems  **PT02 and 03:**  - Disinfection of hard surfaces by CIP  - Disinfection of surfaces by CIP  **Relevant META-SPC:**  6.21  6.22  7.11  7.12  7.2  10.1  10.2  11 |
| PT4 – Scenario 3: Disinfection in milking parlour systems | Acceptable risks for active chlorine.  No specific RMM required. | **Covered use:**  **PT04:**  - Disinfection of hard surfaces by CIP  - Disinfection of surfaces by CIP  - Disinfection of surfaces in contact with food  - Disinfection of hard surfaces in contact with food  **Relevant META-SPC:**  6.21  6.22  7.11  7.12  7.2  10.1  10.2  11 |
|  | | |
|  | | |

***Mixture toxicity***

For the chlorate assessment, a semi-qualitative assessment in groundwater and surface water intended for the abstraction of drinking water has been performed, therefore a mixture toxicity assessment is not considered relevant for the chlorate.

***Aggregated exposure (combined for relevant emmission sources)***

According to the WG-I-2020 Part B, a qualitative assessment for the active substance has been performed due to its high reactivity with organic matter. No aggregated exposure is needed.



*Figure 1: Decision tree on the need for estimation of aggregated exposure*

|  |  |
| --- | --- |
| **Summary table on acceptability** | |
| META-SPC 1.1  No SoC | Acceptable risks for all the PT02 uses.  Nevertheless, the following RMM must be applied for uses:  - disinfection of private swimming pools  - shock disinfection of private swimming pools  ***Application of this product is exclusively allowed in swimming pools with connection to a STP. It is not allowed to directly discharge swimming pool water to the surface water*** |
| META-SPC 1.2  No SoC | Acceptable risks for all the PT02 uses.  Nevertheless, the following RMM must be applied for uses:  - disinfection of public and private swimming pools  - shock disinfection of public and private swimming ***Application of this product is exclusively allowed in swimming pools with connection to a STP. It is not allowed to directly discharge swimming pool water to the surface water*** |
| META-SPC 2.1  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required.  Acceptable risks for all the PT03 uses. No specific RMM required.  Acceptable risks for all the PT04 uses. No specific RMM required. |
| META-SPC 2.21  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required.  Acceptable risks for all the PT03 uses. No specific RMM required.  Acceptable risks for all the PT04 uses. No specific RMM required. |
| META-SPC 2.22  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required.  Acceptable risks for all the PT03 uses. No specific RMM required.  Acceptable risks for all the PT04 uses. No specific RMM required. |
| META-SPC 3  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required. |
| META-SPC 4  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required. |
| META-SPC 5  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required. |
| META-SPC 6.1  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required.  Acceptable risks for all the PT03 uses. No specific RMM required.  Acceptable risks for all the PT04 uses. No specific RMM required. |
| META-SPC 6.21  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required.  Acceptable risks for all the PT03 uses. No specific RMM required.  Acceptable risks for all the PT04 uses. No specific RMM required. |
| META-SPC 6.22  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required.  Acceptable risks for all the PT03 uses. No specific RMM required.  Acceptable risks for all the PT04 uses. No specific RMM required. |
| META-SPC 7.11  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required.  Acceptable risks for all the PT03 uses.  Acceptable risks for all the PT04 uses. No specific RMM required. |
| META-SPC 7.12  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required.  Acceptable risks for all the PT03 uses.  Acceptable risks for all the PT04 uses. No specific RMM required. |
| META-SPC 7.2  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required.  Acceptable risks for all the PT03 uses. No specific RMM required.  Acceptable risks for all the PT04 uses. No specific RMM required. |
| META-SPC 8  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required.  Acceptable risks for all the PT03 uses. No specific RMM required.  Acceptable risks for all the PT04 uses. No specific RMM required. |
| META-SPC 9  No SoC | Acceptable risks for all the PT02 uses.  Nevertheless, the following RMM must be applied for the use “Algaecide and fungicide for outdoor surfaces”:  ***Do not apply where the product can reach surface water.*** |
| META-SPC 10.1  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required.  Acceptable risks for all the PT03 uses. No specific RMM required.  Acceptable risks for all the PT04 uses. No specific RMM required. |
| META-SPC 10.2  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required.  Acceptable risks for all the PT03 uses. No specific RMM required.  Acceptable risks for all the PT04 uses. No specific RMM required. |
| META-SPC 11  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required.  Acceptable risks for all the PT03 uses. No specific RMM required. Acceptable risks for all the PT04 uses. No specific RMM required. |
| META-SPC 12  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required. |
| META-SPC 13  No SoC | Acceptable risks for all the PT02 uses. No specific RMM required. |
| META-SPC 14  No SoC | Acceptable risks for all the PT02 uses.  Nevertheless, the following RMM must be applied for the use “Algaecide and fungicide for outdoor surfaces**”:**  ***Do not apply where the product can reach surface water.*** |

### Measures to protect man, animals and the environment

*[Please refer to summary of the product assessment and to the relevant sections of the assessment report.]*

### Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

*[Please, refer to Guidance for Human Health Risk Assessement, Volume III, Part B - to characterise the risk in case of exposure to several products ]*

# Annexes[[15]](#footnote-16)

## List of studies for the biocidal product family

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title.** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** | **Date of first submission** |
| **Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 4.8 % C.A. PARFUM EUCALYPTUS BATCH 180802 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 3.6 % C.A. PARFUM EUCALYPTUS BATCH 181411 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| Laura MOLIN | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 3.6 % C.A. PARFUM EUCALYPTUS BATCH 181411 AFTER A LONG-TERM STORAGE PROCEDURE FOR 24 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD | 28/12/2018 |
| Study DIrector: Laura Molin | 2019 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 12.5 % C.A. BATCH 180101 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 03/06/2019 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 9.6 % C.A. PARFUM EUCALYPTUS BATCH 180817 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| Manuel Rubina | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 9.6Â°/o C.A. PARFUM EUCALYPTUS BATCH 180817 AFTER A LONG-TERM STORAGE PROCEDURE FOR 10 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT GEL JAVEL 2.6 % C.A. PARFUM EUCALYPTUS BATCH 180809 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT SPRAY JAVEL 1.5 % C.A. PARFUM EUCALYPTUS BATCH 181530 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| Study Director: Laura Molin | february 2019 | ETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT GEL JAVEL 4.5 Â°/4 C.A. PARFUM EUCALYPTUS BATCH 181118 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE |  |
| Laura MOLIN | february 2019 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT GEL JAVEL 4.5 % C.A. PARFUM EUCALYPTUS BATCH 181118 AFTER A LONG-TERM STORAGE PROCEDURE FOR 12 AND 24 MONTHS AT 25 Â°C 60 % R.H. | Yes | PINTAUD |  |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT 2.6 % C.A. PARFUM EUCALYPTUS BATCH 181404 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| Study Director: Laura Molin | 2018-2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT ALCALIN CHLORE MOUSSANT BATCH 181106 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Manuel Rubina | 2018-2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT ALCALIN CHLORE MOUSSANT BATCH 181106 AFTER A LONG-TERM STORAGE PROCEDURE FOR 10 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| The Study Director (Laura Molin) | 2018-2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 2.6 % C.A. PARFUM EUCALYPTUS BATCH 180752 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 4.8 % C.A. PARFUM EUCALYPTUS BATCH 180802 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 3.6 % C.A. PARFUM EUCALYPTUS BATCH 181411 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| Laura MOLIN | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 3.6 % C.A. PARFUM EUCALYPTUS BATCH 181411 AFTER A LONG-TERM STORAGE PROCEDURE FOR 24 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD | 28/12/2018 |
| Study DIrector: Laura Molin | 2019 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 12.5 % C.A. BATCH 180101 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 03/06/2019 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 9.6 % C.A. PARFUM EUCALYPTUS BATCH 180817 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| Manuel Rubina | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 9.6Â°/o C.A. PARFUM EUCALYPTUS BATCH 180817 AFTER A LONG-TERM STORAGE PROCEDURE FOR 10 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT GEL JAVEL 2.6 % C.A. PARFUM EUCALYPTUS BATCH 180809 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT SPRAY JAVEL 1.5 % C.A. PARFUM EUCALYPTUS BATCH 181530 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| Study Director: Laura Molin | 2019 | ETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT GEL JAVEL 4.5 Â°/4 C.A. PARFUM EUCALYPTUS BATCH 181118 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 03/06/2019 |
| Study Director: Laura Molin | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT ALCALIN CHLORE MOUSSANT BATCH 181106 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| Manuel Rubina | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT ALCALIN CHLORE MOUSSANT BATCH 181106 AFTER A LONG-TERM STORAGE PROCEDURE FOR 10 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT 2.6 % C.A. PARFUM EUCALYPTUS BATCH 181404 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| Laura MOLIN | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT 2.6% C.A. PARFUM EUCALYPTUS BATCH 181404 AFTER A LONG-TERM STORAGE PROCEDURE FOR 24 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS PINTAUD Rue Des Bouviers Via Fratta 25 16230 MANSLE | 28/12/2018 |
| Laura MOLIN | 2020 | DETERMINATION OF ALKALINITY OF PRODUCT "EAU DE JAVEL 9.6 % C.A. SPECIAL PISCINE" BATCH 2001230010 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Laura MOLIN | 2020 | DETERMINATION OF ALKALINITY OF PRODUCT "EAU DE JAVEL 3.6 % C.A. NATURE" BATCH 2001230015 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Laura Molin | 2020 | DETERMINATION OF ALKALINITY OF PRODUCT "EAU DE JAVEL 4.8 % C.A. NATURE" BATCH 2001230020 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Laura MOLIN | 2020 | DETERMINATION OF ALKALINITY OF PRODUCT "EAU DE JAVEL 9.6 Â°/o C.A. NATURE" BATCH 2001230030 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Laura MOLIN | 2020 | DETERMINATION OF ALKALINITY OF PRODUCT "EAU DE JAVEL 1.6 % C.A. NATURE" BATCH 2001230035 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Laura MOLIN | 2020 | DETERMINATION OF ALKALINITY OF PRODUCT "EAU DE JAVEL 2.6 Â°/o C.A. NATURE" BATCH 2001230040 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Laura MOLIN | 2020 | DETERMINATION OF CHEMICAL PHYSICAL AND ÃŽECHNICAL PROPERTIES OF THE PRODUCT "EAU DE JAVEL 1.6 Â°/o EUCALYPTUS" BATCH 2001230050 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Study Director: Laura Molin | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT ALCALIN CHLORE MOUSSANT BATCH 181106 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT 2.6 % C.A. PARFUM EUCALYPTUS BATCH 181404 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT 2.6 % C.A. PARFUM EUCALYPTUS BATCH 181404 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| Laura MOLIN | 2018 | DETERMINATION OF CHEMICAL PHYSICAL AND ÃŽECHNICAL PROPERTIES OF THE PRODUCT "EAU DE JAVEL 1.6 Â°/o EUCALYPTUS" BATCH 2001230050 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| The Study Director (Laura Molin) | 2018-2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 2.6 % C.A. PARFUM EUCALYPTUS BATCH 180752 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Laura Molin | 2018-2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 2.6 % C.A. PARFUM EUCALYPTUS BATCH 180752 AFTER A LONG-TERM STORAGE PROCEDURE FOR 24 MONTHS AT 25 60% R.H. | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| The Study Director (Laura Molin) | 2018-2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 4.8 % C.A. PARFUM EUCALYPTUS BATCH 180802 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Manuel Rubina | 2018-2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 4.8 Â°/o C.A. PARFUM EUCALYPTUS BATCH 180802 AFTER A LONG-TERM STORAGE PROCEDURE FOR 10 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| The Study Director (Laura Molin) | 2018-2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 3.6 % C.A. PARFUM EUCALYPTUS BATCH 181411 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Laura MOLIN | 2018-2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 3.6 % C.A. PARFUM EUCALYPTUS BATCH 181411 AFTER A LONG-TERM STORAGE PROCEDURE FOR 24 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD | 05/06/2020 |
| Study DIrector: Laura Molin | 2018-2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 12.5 % C.A. BATCH 180101 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| The Study Director (Laura Molin) | 2018 - 2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 9.6 % C.A. PARFUM EUCALYPTUS BATCH 180817 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Manuel Rubina | 2018 - 2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 9.6Â°/o C.A. PARFUM EUCALYPTUS BATCH 180817 AFTER A LONG-TERM STORAGE PROCEDURE FOR 10 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| The Study Director (Laura Molin) | 2019 - 2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT GEL JAVEL 2.6 % C.A. PARFUM EUCALYPTUS BATCH 180809 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Laura Molin | 2019 - 2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT GEL DE JAVEL 2.6% C.A. PARFUM EUCALYPTUS BATCH 180809 AFTER A LONG-TERM STORAGE PROCEDURE FOR 12 AND 24 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| The Study Director (Laura Molin) | 2018-2010 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT SPRAY JAVEL 1.5 % C.A. PARFUM EUCALYPTUS BATCH 181530 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Laura Molin | 2018-2010 | SPRAY JAVEL 1.5 % EUCALYPTUS" BATCH 2001230055 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Study Director: Laura Molin | 2018-2020 | ETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT GEL JAVEL 4.5 Â°/4 C.A. PARFUM EUCALYPTUS BATCH 181118 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Laura MOLIN | 2018-2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT GEL JAVEL 4.5 % C.A. PARFUM EUCALYPTUS BATCH 181118 AFTER A LONG-TERM STORAGE PROCEDURE FOR 12 AND 24 MONTHS AT 25 Â°C 60 % R.H. | Yes | PINTAUD | 05/06/2020 |
| Study Director: Laura Molin | 2018-2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT ALCALIN CHLORE MOUSSANT BATCH 181106 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Manuel Rubina | 2018-2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT ALCALIN CHLORE MOUSSANT BATCH 181106 AFTER A LONG-TERM STORAGE PROCEDURE FOR 10 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| The Study Director (Laura Molin) | 2018-2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT 2.6 % C.A. PARFUM EUCALYPTUS BATCH 181404 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Manuel Rubina | 2018-2020 | DETERMINATION OF ÃŽECHNICAL PROPERTIES ON PRODUCT SPRAY JAVEL 4.8 % C.A. PARFUM EUCALYPTUS BATCH 181224 AFTER A LONG-TERM STORAGE PROCEDURE FOR 10 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Laura Molin | 2018-2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT SPRAY JAVEL 4.8 Â°/o C.A. PARFUM EUCALYPTUS BATCH 181224 - CHELAB | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| William PEYSSON | 2019 - 2020 | EAU DE JAVEL A 26%C.A. PARFUMEE EUCALYPTUS Stability storage tests Method Room temperature storage procedure in accordance with OECD Guidance document ENV/JM/MONO(2015)32 | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 05/06/2020 |
| William PEYSSON | 2019-2020 | GLP FINAL REPORT EAU DE JAVEL A 48%C.A. PARFUMEE EUCALYPTUS Stability storage tests Method Room temperature storage procedure in accordance with OECD Guidance document ENV/JM/MONO(2015)32 (15-Dec-2016) | Yes | PINTAUD Kevin AGARD Address: Rue Maurice Pintaud 16230 Mansle France | 05/06/2020 |
| William PEYSSON | 2019 - 2020 | EAU DE JAVEL A 36%C.A. PARFUMEE EUCALYPTUS Stability storage tests Method Room temperature storage procedure in accordance with OECD Guidance document ENV/JM/MONO(2015)32 (15-Dec-2016) | Yes | PINTAUD | 05/06/2020 |
| William PEYSSON | 2020 | GLP FINAL REPORT EAU DE JAVEL A 125%C.A. Stability storage tests Method Room temperature storage procedure in accordance with OECD Guidance document ENV/JM/MONO(2015)32 (15-Dec-2016) | Yes | PINTAUD Kevin AGARD Address: Rue Maurice Pintaud 16230 Mansle France | 05/06/2020 |
| William PEYSSON | 2020 | GLP FINAL REPORT EAU DE JAVEL A 96%C.A. PARFUMEE EUCALYPTUS Stability storage tests Method Room temperature storage procedure in accordance with OECD Guidance document ENV/JM/MONO(2015)32 (15-Dec-2016) | Yes | PINTAUD Kevin AGARD Address: Rue Maurice Pintaud 16230 Mansle France | 05/06/2020 |
| William PEYSSON | 2020 | Mid-term REPORT (Not GLP document) GEL JAVEL A 26%C.A. PARFUM EUCALYPTUS Stability storage tests Method Room temperature storage procedure in accordance with OECD Guidance document ENV/JM/MONO(2015)32 (15-Dec-2016) | Yes | PINTAUD Kevin AGARD Address: Rue Maurice Pintaud 16230 Mansle France | 05/06/2020 |
| William PEYSSON |  | Mid-term REPORT (Not GLP document) SPRAY JAVEL A 15%C.A. PARFUM EUCALYPTUS Stability storage tests Method Room temperature storage procedure in accordance with OECD Guidance document ENV/JM/MONO(2015)32 (15-Dec-2016) | Yes | PINTAUD Kevin AGARD Address: Rue Maurice Pintaud 16230 Mansle France | 05/06/2020 |
| William PEYSSON | 2020 | Mid-term REPORT (Not GLP document) GEL JAVEL WC POWER PARFUM EUCALYPTUS Stability storage tests Method Room temperature storage procedure in accordance with OECD Guidance document ENV/JM/MONO(2015)32 (15-Dec-2016) | Yes | PINTAUD Kevin AGARD Address: Rue Maurice Pintaud 16230 Mansle France | 05/06/2020 |
| William PEYSSON | 2020 | Mid-term REPORT (Not GLP document) DETERGENT ALCALIN CHLORE MOUSSANT Stability storage tests Method Room temperature storage procedure in accordance with OECD Guidance document ENV/JM/MONO(2015)32 (15-Dec-2016) | Yes | PINTAUD Kevin AGARD Rue Maurice Pintaud 16230 Mansle France | 05/06/2020 |
| William PEYSSON | 2020 | Mid-term REPORT (Not GLP document) DETERGENT A 26%C.A. PARFUM EUCALYPTUS Stability storage tests | Yes | PINTAUD Kevin AGARD Address: Rue Maurice Pintaud 16230 Mansle France | 05/06/2020 |
| Pierre Adrien ARTHAUD | 2020 | FINAL REPORT (Non GLP study) Special pool bleach Effects of Ultraviolets light on available chlorine in an artificial swimming pool | Yes | PINTAUD Kevin AGARD Address: Rue Maurice Pintaud 16230 Mansle France | 05/06/2020 |
| Laura MOLIN | 2019 | DETERMINATION OF ALKALINITY OF PRODUCT "EAU DE JAVEL 9.6 Â°/o C.A. NATURE" BATCH 2001230030 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE Test Facility: CHELAB Sri Via Fratta 25 31023 Resana (lV) ITALY | 03/06/2019 |
| Manuel Rubina | 2019 | DETERMINATION OF REACTIVITY TOWARD THE CONTAINER MATERIAL ON PRODUCT EAU DE JAVEL 12.5% C.A. BATCH 1909101549 AFTER A LONG-TERM STORAGE PROCEDURE FOR 3 AND 5 MONTHS AT 25 Â°C 60 Â°/o R.H. . | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 03/06/2019 |
| Pierre-Adrien ARTHAUD | 2020 | FINAL REPORT (Non GLP study) Special pool bleach Effects of Ultraviolets light on available chlorine in an artificial swimming pool | Yes | Etablissement PINTAUD Rue des Bouviers 16230 Mansle France | 05/06/2020 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 9.6 % C.A. PARFUM EUCALYPTUS BATCH 180817 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 9.6 % C.A. PARFUM EUCALYPTUS BATCH 180817 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT 2.6 % C.A. PARFUM EUCALYPTUS BATCH 181404 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| The Study Director (Laura Molin) | 2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT SPRAY JAVEL 1.5 % C.A. PARFUM EUCALYPTUS BATCH 181530 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Laura Molin | 2020 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT SPRAY JAVEL 4.8 Â°/o C.A. PARFUM EUCALYPTUS BATCH 181224 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| Laura MOLIN | february 2018 | DETERMINATION OF SURFACE TENSION OF PRODUCT "EAU DE JAVEL 2.6 % C.A. EUCALYPTUS" BATCH 2001230045 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 4.8 % C.A. PARFUM EUCALYPTUS BATCH 180802 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| Manuel Rubina | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 4.8 Â°/o C.A. PARFUM EUCALYPTUS BATCH 180802 AFTER A LONG-TERM STORAGE PROCEDURE FOR 10 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| The Study Director (Laura Molin) | 2019 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 2.6 % C.A. PARFUM EUCALYPTUS BATCH 180752 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 03/06/2019 |
| Manuel Rubina | 2019 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT EAU DE JAVEL 9.6Â°/o C.A. PARFUM EUCALYPTUS BATCH 180817 AFTER A LONG-TERM STORAGE PROCEDURE FOR 10 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 03/06/2019 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT SPRAY JAVEL 1.5 % C.A. PARFUM EUCALYPTUS BATCH 181530 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| Study Director: Laura Molin | 2019 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT ALCALIN CHLORE MOUSSANT BATCH 181106 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 03/06/2019 |
| Manuel Rubina | 2019 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT ALCALIN CHLORE MOUSSANT BATCH 181106 AFTER A LONG-TERM STORAGE PROCEDURE FOR 10 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 03/06/2019 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT DETERGENT 2.6 % C.A. PARFUM EUCALYPTUS BATCH 181404 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| Laura Molin | 2019 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT SPRAY JAVEL 4.8 Â°/o C.A. PARFUM EUCALYPTUS BATCH 181224 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 03/06/2019 |
| Manuel Rubina | 2019 | DETERMINATION OF ÃŽECHNICAL PROPERTIES ON PRODUCT SPRAY JAVEL 4.8 % C.A. PARFUM EUCALYPTUS BATCH 181224 AFTER A LONG-TERM STORAGE PROCEDURE FOR 10 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 03/06/2019 |
| Laura MOLIN | 2020 | DETERMINATION OF CHEMICAL PHYSICAL AND ÃŽECHNICAL PROPERTIES OF THE PRODUCT "EAU DE JAVEL 1.6 Â°/o EUCALYPTUS" BATCH 2001230050 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 05/06/2020 |
| The Study Director (Laura Molin) | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT GEL JAVEL 2.6 % C.A. PARFUM EUCALYPTUS BATCH 180809 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| Laura Molin | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT GEL DE JAVEL 2.6% C.A. PARFUM EUCALYPTUS BATCH 180809 AFTER A LONG-TERM STORAGE PROCEDURE FOR 12 AND 24 MONTHS AT 25 Â°C 60% R.H. | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| Study Director: Laura Molin | 2018 | ETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT GEL JAVEL 4.5 Â°/4 C.A. PARFUM EUCALYPTUS BATCH 181118 | Yes | ETS. PINTAUD Rue Des Bouviers 16230 MANSLE FRANCE | 28/12/2018 |
| Laura MOLIN | 2018 | DETERMINATION OF PHYSICAL CHEMICAL AND TECHNICAL PROPERTIES ON PRODUCT GEL JAVEL 4.5 % C.A. PARFUM EUCALYPTUS BATCH 181118 AFTER A LONG-TERM STORAGE PROCEDURE FOR 12 AND 24 MONTHS AT 25 Â°C 60 % R.H. | Yes | PINTAUD | 28/12/2018 |
| J-C NEYT | 2021 | Mesures de points éclairs, CALNESIS | Yes | PINTAUD | 29/01/2021 |
| J-F Lacroix | 2021 | Essais de corrosion d’un produit liquide, sur l’acier et l’aluminium, suivant le paragraphe 37 du Manuel Epreuves et Critères de l’ONU, 7e édition révisée, rapport R/20/21128A, Analytice | Yes | PINTAUD | 29/01/2021 |
| J-F Lacroix | 2021 | Essais de corrosion d’un produit liquide, sur l’acier et l’aluminium, suivant le paragraphe 37 du Manuel Epreuves et Critères de l’ONU, 7e édition révisée, rapport R/20/21128B, Analytice | Yes | PINTAUD | 29/01/2021 |
| J-F Lacroix | 2021 | Essais de corrosion d’un produit liquide, sur l’acier et l’aluminium, suivant le paragraphe 37 du Manuel Epreuves et Critères de l’ONU, 7e édition révisée, rapport R/20/21128C, Analytice | Yes | PINTAUD | 29/01/2021 |
| J-F Lacroix | 2021 | Essais de corrosion d’un produit liquide, sur l’acier et l’aluminium, suivant le paragraphe 37 du Manuel Epreuves et Critères de l’ONU, 7e édition révisée, rapport R/20/21128D, Analytice | Yes | PINTAUD | 29/01/2021 |
| J-F Lacroix | 2021 | Essais de corrosion d’un produit liquide, sur l’acier et l’aluminium, suivant le paragraphe 37 du Manuel Epreuves et Critères de l’ONU, 7e édition révisée, rapport R/20/21128E, Analytice | Yes | PINTAUD | 29/01/2021 |
| J-F Lacroix | 2021 | Essais de corrosion d’un produit liquide, sur l’acier et l’aluminium, suivant le paragraphe 37 du Manuel Epreuves et Critères de l’ONU, 7e édition révisée, rapport R/20/21128F, Analytice | Yes | PINTAUD | 29/01/2021 |
| Benoit GUY study director | March 2019 | FINAL REPORT Sodium hypochlorite CAS number: 7681-52-9 EC number: 231-668-3 Analytical method validation of Sodium hypochlorite Method SANCO/3030/99 rev.4 Additional impurity validation | Yes | PINTAUD Rue Maurice Pintaud 16230 Mansle France | 05/06/2020 |
| W. PEYSSON G BROT | 2019 - 2020 | DÃ©termination du chlore actif | Yes | PINTAUD | 05/06/2020 |
| Benoit Guy | 2020 | Method validation for the determination of the Sodium hypochlorite content in the products GUIDANCE SANCO/3030/99 rev.5 (Validation of active substance only) | Yes | PINTAUD Rue Maurice Pintaud 16230 Mansle France | 05/06/2020 |
| W. PEYSSON | 2019-2020 | Determination de la quantite de chlorate ANA\_MON\_0103 - Version d - 03/04/2019 Methode validee selon la norme SANCO 3030199 | Yes | No company owner provided | 05/06/2020 |
| W. PEYSSON | 2019 - 2020 | Determination de la quantite de chlorate ANA\_MON\_0103 - Version d - 03/04/2019 Methode validee selon la norme SANCO 3030199 | Yes | No company owner provided | 05/06/2020 |
| Benoit GUY study director | 2019 - 2020 | FINAL REPORT Sodium hypochlorite CAS number: 7681-52-9 EC number: 231-668-3 Analytical method validation of Sodium hypochlorite Method SANCO/3030/99 rev.4 Additional impurity validation | Yes | PINTAUD Rue Maurice Pintaud 16230 Mansle France | 05/06/2020 |
| Benoit GUY study director | 2018 | Eau javel parfumÃ©e Ã  26 % CAS No : NA EC No : NA Analytical method validation | Yes | PINTAUD Rue Maurice Pintaud 16230 Mansle France | 28/12/2018 |
| Benoit GUY | 2020 | Method validation for the determination of the Sodium hypochlorite content in the products | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 05/06/2020 |
| Benoit GUY | 2020 | Validation method for the determination of the impurity sodium chlorate in 10 formulations of bleach, report RRCo-000866\_01, Rovaltain | Yes | PINTAUD | 29/01/2021 |
| Nathalie GARREC | 2019 | Evaluation de lâ€™efficacitÃ© des produits Ã  base dâ€™hypochlorite de sodium destinÃ©s Ã  traiter lâ€™eau des piscines | Yes | No company owner provided | 03/06/2019 |
| Prescilla LEMAITRE Responsable des essais | 2018 | Evaluation de l'activite fongicide selon la norme NF EN 13624: 2013 Produit : Javel 26% c.a. Lot: 180406 Essai partiel sur la souche Aspergillus brasiliensis | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable des essais | 2018 | Evaluation de l'activite fongicide selon la norme NF EN 16438: 2014 Produit : Eau de Javel 26% c.a. Lot : 1820J 14 Essai partiel sur la souche Aspergillus brasiliensis | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable des essais | 2018 | Evaluation de l'activite levuricide selon la norme NF EN 16438: 2014 Produit : Eau de Javel 26% c.a. Lot : 1820114 | Yes | ETABLISSEMENTS PINTAUD Rue M aurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Presscilla LEMAITRE Responsable des essais | 2018 | Evaluation de l'activite bactericide selon la norme NF EN 13697 : 2015 I Produit : Javel 26% c.a. Lot: 180406 Essai partiel vis-a-vis de Pseudomonas aeruginosa et Escherichia coli | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable des essais | 2018 | Evaluation de l'activite bactericide selon la norme NF EN 13697: 2015 Produit : Javel 26% c.a. Lot : 180406 Essai partiel vis-a-vis de Enterococcus hirae et Staphylococcus aureus | Yes | ETABLISSEMENTS PINT AUD Rue Maurice Pintaud F-16230 M ANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable des Essais | 2018 | Evaluation de l'activite fongicide selon la norme NF EN 13697 : 2015 Produit : Javel 26% c.a. Lot: 180406 Essai partiel sur la souche Aspergillus brasiliensis | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16 230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Re sponsable des essais | 2018 | Evaluation de l'activite bactericide selon la norme NF EN 14349 : 2012 Produi t : Eau de Javel 26 % c.a. Lot : 1820J14 Essai partiel sur les souches Staphylococcus aureus et Enterococcus hirae | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable des essais | 2018 | Evaluation de l'activite bactericide selon la norme NF EN 14349: 2012 Produit : Eau de Javel 26% c.a. Lot : 1820J14 Essai partiel sur les souches Pseudomonas aeruginosa et Proteus vulgaris | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Stephanie MOROT-BIZOT | 2018 | DETERMINATION DE L'ACTIVITE VIRUCIDE SELON LA NORME EN 14476+A1 DU PRODUIT EAU DE JAVEL | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Julien MATYSIAK | 2018 | Activite virucide selon le protocole de la norme NF EN 14675 Essai vis-a-vis de Enterovirus bovin de type 1 (ECBO) Produit : Eau de Javel 26% c.a. Lot : 1820J14 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud 16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable des essais | From 17/07/2018 to 26/07/2018 | Evaluation de l'activite bactericide selon la norme NF EN 16437: 2014 Produit : Eau de Javel 26% c.a. Lot : 1820J14 | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France |  |
| Prescilla LEMAITRE Responsable des essais | 2018 | Evaluation de l'activite bactericide selon la norme NF EN 1656: 2010 Produit : Eau de Javel 26% c.a. Lot : 1820J14 Essai partiel sur les souches Staphylococcus aureus et Enterococcus hirae | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable des essais | 2018 | Evaluation de l'activite bactericide selon la norme NF EN 1656: 2010 Produit : Eau de Javel 26% c.a. Lot : 1820J14 Essai partiel sur les souches Pseudomonas aeruginosa et Proteus vulgaris | Yes | ETABLISSEMENTS PINTAUD Rue M aur ice Pin t aud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable des essais | 2018 | Evaluation de l'activite levuricide selon la norme NF EN 1657: 2006 Produit : Eau de Javel 26% c.a. Lot : 1820J14 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE | 2018 | Evaluation de l'activite fongicide selon la norme NF EN 1657: 2006 Produit : Eau de Javel 26% c.a. Lot : 1820J14 Essai partiel sur la souche Aspergillus brasiliensis | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16 230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable des essais | 2018 | Evaluation de l'activite fongicide selon la norme NF EN 13624: 2013 Produit: Gel Javel 26% c.a. Lot: 183 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsab le des essais | 2018 | Evaluation de l'activite bactericide selon la norme NF EN 13697 : 2015 Produit : Gel Javel 26% c.a. Lot: 183 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable des essais | 2018 | Evaluation de l'activite bactericide selon la norme NF EN 13697 : 2015 Produit : Gel Javel 26% c.a. Lot: 1806141102 | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMTAITRE Responsable Essai | 2018 | Evaluation de l'activite fongicide selon la norme NF EN 13697: 2015 Produit: Gel Javel 26% c.a. Lot: 183 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16 230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable des essais | 2018 | Evaluation de l'activite fongicide selon la norme NF EN 13697: 2015 Produit : Gel Javel 26% c.a. Lot: 1806141102 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable essai | 2018 | Essai de suspension pour !'evaluation de l'activite bactericide selon la norme NF EN 13727 : 2015 I: 1 1 Produit : Gel Javel 26% c.a. Lot: 183 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Stephanie MOROT-BIZOT Docteur en microbiologie ChargÃ©e de l'Ã©tude | 2018 | DETERMINATION DE L'ACTIVITE VIRUCIDE SELON LA NORME EN 14476+A1 DU PRODUIT GEL JAVEL | Yes | ETS PINTAUD Rue Maurice PINTAUD 16230 MANSLE FRANCE | 28/12/2018 |
| Prescilla LEMAITRE Responsable des essais | 2018 | Evaluation de l'activite fongicide selon la norme NF EN 13624: 2013 Pro du it : Spray Javel 15% c.a. Lot: 182 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla Lemaitre Responsable des essais | 2018 | Evaluation de l'activite bactericide selon le protocole de la norme NF EN 13697: 2015 Produit : Spray Javel 15% c.a. Lot: 182 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMATITRE Responsable Essai | 2018 | Evaluation de l'activite fongicide selon le protocole de la norme NF EN 13697: 2015 Produit : Spray Javel 15% c.a. Lot: 182 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable des essais | 2018 | Essai de suspension pour !'evaluation de l'activite bactericide selon la norme NF EN 13727 : 2015 Produit : Spray Javel 15% c.a. Lot : 182 I | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Stephanie MOROT-BIZOT Docteur en microbiologie ChargÃ©e de l'Ã©tude | 2018 | DETERMINATION DE L'ACTIVITE VIRUCIDE SELON LA NORME EN 14476+A1 DU PRODUIT SPRAY JAVEL | Yes | ETS PINTAUD Rue Maurice PINTAUD 16230 MANSLE FRANCE | 28/12/2018 |
| Prescilla LEMAITRE | 2019 | Evaluation of the fungicidal activity according to the NF EN 13697: 2015 standard | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| No author provided | 2019 | DETERMINATION DE L'ACTIVITE VIRUCIDE SELON LA NORME EN 14476+A1 DU PRODUIT EAU DE JAVEL | Yes | ETS PINTAUD Rue Maurice PINTAUD 16230 MANSLE FRANCE | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the bactericidal activity according to the NF EN 1276: 2010 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the bactericidal activity according to the NF EN 1276: 2010 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | PINTAUD | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the yeasticidal activity according to the NF EN 13697: 2015 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the bactericidal activity against Legionella according to the NF EN 13623: 2011 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the bactericidal activity according to the NF EN 13697: 2015 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| ETS PINTAUD | 2019 | DETERMINATION DE L'ACTIVITE VIRUCIDE SELON LA NORME EN 14476+A1 DU PRODUIT EAU DE JAVEL | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the yeasticidal activity according to the NF EN 13697: 2015 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the fungicidal activity according to the NF EN 13697: 2015 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the bactericidal activity against Legionella according to the NF EN 13623: 2011 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the bactericidal activity according to the NF EN 13697: 2015 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the bactericidal activity against Legionella according to the NF EN 13623: 2011 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Stephanie MOROT-BIZOT Docteur en microbiologie ChargÃ©e de l'Ã©tude | 2019 | DETERMINATION DE L'ACTIVITE VIRUCIDE SELON LA NORME EN 14476+A1 DU PRODUIT EAU DE JAVEL | Yes | APEX BIOSOLUTIONS 4 rue des Grandes PiÃ¨ces zone Eurespace 25 770 SERRE LES SAPINS ï‚§ NÂ° SIRET 51786053200012 ï‚§ NÂ° TVA intra FR 23517860532 ï‚§ info@apexlabo.com | 03/06/2019 |
| PRescilla LEMAITRE | 2019 | Evaluation of the yeasticidal activity according to the NF EN 13697: 2015 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the fungicidal activity according to the NF EN 13697: 2015 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Stephanie MOROT-BIZOT | 2019 | DETERMINATION DE L'ACTIVITE VIRUCIDE SELON LA NORME EN 14476+A1 DU PRODUIT EAU DE JAVEL | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the yeasticidal activity according to the NF EN 13697: 2015 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the fungicidal activity according to the NF EN 13697: 2015 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the yeasticidal activity according to the NF EN 13697: 2015 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the fungicidal activity according to the NF EN 13697: 2015 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Precilla LEMAITRE | 2019 | Evaluation of the bactericidal activity against Legionella according to the NF EN 13623: 2011 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | Laboratoire MIDAC â€“ 85 C rue Nelson Mandela â€“ 59120 LOOS/LILLE â€“ FRANCE TÃ©l : +33 (0)3 20 90 52 55 â€“ contact@midac-lab.fr | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the bactericidal activity against Legionella according to the NF EN 13623: 2011 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the bactericidal activity against Legionella according to the NF EN 13623: 2011 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 Batch: 1812030857 exp:03/12/2021 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| No author provided | 2019 | Essais sur J.NET EXPERT et SETS EPAISSISANT + EAU DE JAVEL SEC 96 % | Yes | PINTAUD Rue Maurice Pintaud 16230 Mansle | 03/06/2019 |
| Prescilla LEMAITRE | 2018 | Evaluation of the bactericidal activity according to the NF EN 1276 : 2010 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif - Partial test against the strains Staphylococcus aureus and Enterococcus hirae | Yes | PINTAUD | 28/12/2018 |
| Prescilla LEMAITRE | 2019 | Evaluation of the bactericidal activity according to the NF EN 1276 : 2010 standard Product : BEC Eau de Javel ORIGINAL Ã  26% - Partial tests against the strains Pseudomonas aeruginosa Escherichia coli and Enterococcus hirae and Staphylococcus aureus | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the bactericidal activity according to the NF EN 1276 : 2010 standard - BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Partial test against the strains Staphylococcus aureus and Enterococcus hirae | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the bactericidal activity according to the NF EN 1276 : 2010 standard Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif | Yes | PINTAUD | 03/06/2019 |
| Julien MATYSIAK | 2019 | Evaluation of the bactericidal activity according to the NF EN 13697 : 2015 standard - Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Julien MATYSIAK | 2019 | Evaluation of the bactericidal activity according to the NF EN 13697 : 2015 standard - Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif | Yes | PINTAUD | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the bactericidal activity according to the NF EN 13697: 2015 standard - Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the bactericidal activity according to the NF EN 13697 : 2015 standard BEC Eau de Javel Ã  26% de chlore actif | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the bactericidal activity against Legionella according to the NF EN 13623: 2011 standard - BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the yeasticidal activity according to the NF EN 1650 + A1 : 2013 standard - Product : BEC Eau de Javel ORIGINAL Ã  26% de chlore actif Fab: 03/12/2018 | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the yeasticidal activity according to the NF EN 1650 + A1 : 2013 standard - Eau de Javel Ã  26% de chlore actif | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the fungicidal activity according to the NF EN 1650 + A1 : 2013 standard | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2019 | Evaluation of the fungicidal activity according to the NF EN 1650 + A1 - 2013 standard - Eau de Javel ORIGINAL Ã  26% de chlore actif | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 03/06/2019 |
| Prescilla LEMAITRE | 2018 | Essai de suspension pour !'evaluation de l'activite bactericide selon la norme NF EN 13727: 2015 Produit Javel 26% c.a. Lot: 180406 Essai partiel sur les souches Staphylococcus aureus et Enterococcushirae | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-1 6230 M ANSLE Fra nce | 28/12/2018 |
| Prescilla LEMAITRE | 2020 | Evaluation of the bactericidal activity according to the NF EN 13727 : 2015 Product : Eau de Javel Ã  26% c.a. | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 05/06/2020 |
| Prescilla LEMAITRE Responsable des essais | 2018 | Evaluation de l'activite bactericide selon la norme NF EN 13697 : 2015 Produit: Eau de Javel 26% c.a. Lot: 1806141752 Essai partiel sur les souches Pseudomonas aeruginosa et Escherichia coli | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable des essai | 2018 | Evaluation de l'activite bactericide selon la norme NF EN 13697: 2015 Produit : Eau de Javel 26% c.a. Lot: 1806141752 Essai partiel sur la souche Staphylococcus aureus et Enterococcus hirae | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable des essais | 2018 | Evaluation de l'activite levuricide selon la norme NF EN 13697: 2015 Produit : Eau de Javel 26% c.a. Lot: 1806141752 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable Essai | 2018 | Evaluation de l'activite fongicide selon la norme NF EN 13697: 2015 Produit : Eau de Javel 26% c.a. Lot : 1806141752 Essai partiel sur la souche Aspergillus brasiliensis | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pin t aud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMATITRE Responsable essais | 2018 | Essai de suspension pour !'evaluation de l'activite bactericide selon la norme NF EN 13727: 2015 Produit : Jave! 26% c.a. Lot : 180406 Essai partiel sur Jes souches Pseudomonas aeruginosa et Escherichia coli K12 | Yes | ETABLISSEMENTS PINTAUD Rue Ma ur ice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE Responsable des essais | 2018 | Evaluation de l'activite levuricide selon la norme NF EN 13624 : 2013 Produit : Javel 26% c.a. Lot :180406 | Yes | ETABLISSEMENTS PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 28/12/2018 |
| Prescilla LEMAITRE | 2020 | Evaluation of the bactericidal activity according to the NF EN 13697 +A1 : 2019 standard Product : Eau de Javel Ã  26% c.a. | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 05/06/2020 |
| Prescilla LEMAITRE | 2020 | Evaluation of the fungicidal activity according to the NF EN 13697 +A1 : 2019 standard Product : Eau de Javel Ã  26% c.a. Batch : 2002J118758 | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 05/06/2020 |
| Prescilla LEMAITRE | 2020 | Evaluation of the yeasticidal activity according to the NF EN 13697 +A1 : 2019 standard Product : Eau de Javel Ã  26% c.a. | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 05/06/2020 |
| Julien MATYSIAK | 2020 | Evaluation of the virucidal activity according to the NF EN 14476 + A2 : 2019 standard Product :Eau de Javel Ã  96% c.a Bec Special Piscine Batch: 2001200626 Partial test against: Adenovirus Adenoid 75 | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 05/06/2020 |
| Prescilla LEMAITRE | 2020 | Evaluation of the yeasticidal activity according to the NF EN 13624 : 2013 standard Product : Eau de Javel Ã  26% c.a. | Yes | ETS. PINTAUD Rue Maurice Pintaud F-16230 MANSLE France | 05/06/2020 |
| Study Director: Justine THIOT | 2019 | FINAL REPORT Eau de javel 2.6% Daphnia magna Acute immobilisation Test Standard GUIDELINE OECD 202 (2004) | Yes | PINTAUD Rue Maurice Pintaud 16230 Mansle France | 03/06/2019 |
| Study Director Justine THIOT | 2019 | FINAL REPORT Eau de javel 2.6% Pseudokirchneriella subcapitata Growth inhibition test STANDARD GUIDELINE OECD 201 (2006 corrected 28 July 2011) | Yes | PINTAUD Rue Maurice Pintaud 16230 Mansle France | 03/06/2019 |

## Output tables from exposure assessment tools

**Hard surfaces disinfection – Spray application**

* Professional uses

* Non professional uses

**Swimming pool disinfection**

* Professional uses



* Non professional uses



**Inner surfaces Disinfection**



## New information on the active substance

## Residue behaviour

***Dietary exposure***

*[Please include a section for each scenario where food, drinking water or livestock exposure is foreseen. If no exposure is foreseen, then only indicate this and delete the tables and text.]*

Residue definitions

*[Please include the residue definitions for each type of use. If not relevant, delete the title.]*

*List of scenarios*

| **Summary table of main representative dietary exposure scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Type of use1** | **Description of scenario** | **Subject of exposure2** |
| 4.1 | Drinking water |  | Water |
| 4.2 | Drinking water |  | water |

1 e.g. animal husbandry, food industry, professional use, residential use.

2 e.g. chicken, milk, beer

**Scenario [4.1]**

Post application drinking water adults scenario is only relevant for chlorate, as active chlorine concentration is far below concentration for which local effects occur.

**Table 31. applicability domain of scenario 4.1: Post application drinking water adults**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| meta SPC 1.1 | Produits Piscine GP | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| meta SPC 1.2 | Produits Piscine PRO | Min (%) | 13.5 | N.R. |
| Max (%) | 13.5 |
| meta SPC 2.1 | Javel MDD à 2,6%c.a. | Min (%) | 2.6 | N.R. |
| Max (%) | 2.6 |
| meta SPC 2.2 | Javel MDD à 3,6-4,8%c.a. | Min (%) | 3.6 | N.R. |
| Max (%) | 4.8 |
| meta SPC 3 | Produits Gel à 2,6%c.a. | Min (%) | 2.6 | N.R. |
| Max (%) | 2.6 |
| meta SPC 4 | Produits Gel à 1,5%c.a. | Min (%) | 1.5 | N.R. |
| Max (%) | 1.5 |
| meta SPC 5 | Produits Spray à 1,5%c.a. | Min (%) | 1.5 | N.R. |
| Max (%) | 1.5 |
| meta SPC 6.1 | Produits à 9,6 GP | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| meta SPC 6.2 | Produits à 9,6-13,5%c.a. PRO | Min (%) | 9.6 | Scenario 4.1 |
| Max (%) | 13.5 |
| meta SPC 7.1 | Javel à 3,6-4,8%c.a. PRO | Min (%) | 3.6 | Scenario 4.1 |
| Max (%) | 4.8 |
| meta SPC 7.2 | Javel à 2,6%c.a. PRO | Min (%) | 2.6 | Scenario 4.1 |
| Max (%) | 2.6 |
| meta SPC 8 | Produits à 1,6%c.a. | Min (%) | 1.6 | N.R. |
| Max (%) | 1.6 |
| meta SPC 9 | Produits à 9,6%c.a. Parfumés | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| meta SPC 10 | Détergents à 2,6-4,8%c.a. | Min (%) | 2.6 | N.R. |
|  | Max (%) | 4.8 |
| meta SPC 11 | Détergents alcalins chlorés | Min (%) | 6 | N.R. |
| Max (%) | 6 |
| meta SPC 12 | Produits Spray à 4,8%c.a. | Min (%) | 4.8 | N.R. |
| Max (%) | 4.8 |
| meta SPC 13 | Produits Gel WC à 4,5%c.a. | Min (%) | 4.5 | N.R. |
| Max (%) | 4.5 |
| meta SPC 14 | Gel SETS + Javel BEC | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| N .R. : not relevant | | | | |

**Chlorate**

| **Description of Scenario [3.13 bis]** | | |
| --- | --- | --- |
| A.C.working concentration is 0.5 mg/L in swimming conditions. Which corresponds, for the meta-SPC1.2 products as a worst case to 0.00008% chlorate.  Model : ConsExpo Web 1.0.5. Instant application default settings. | | |
|  | Parameters | Value |
| Tier 1 | SoC concentration1 | 0.0000135% |
| Amount ingested2 | 2000g |

1 A.C.working concentration is 0.5 mg/L. Which corresponds, for the meta-SPC6.1 products as a worst case to 0.0000135% chlorate (3.66% chlorate max in 13.5%AC products.

2 Consexpo default for adults.

**Calculations for scenario 4.1 bis**

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [4.1 bis] | 1 | N.R | N.R | 3.8 µg/kg/d | 3.8 µg/kg/d |

Qualitative assessment

The estimated uptake of chlorate due to consumption of drinking water exceeds the ADI (127% ADI). However, the concentration of chlorate due to the use of DAAP19 products remains in levels documented for the presence of chlorate in drinking water (0.0135 mg/kg), slightly above the default MLR of 0.01 mg/kg described as impossible to reach according to the recent regulation (EU) 2020/749.

Therefore, although the absence of risk could not have been demonstrated quantitatively, the potential excess of risk due to the use of DAAP19 products for drinking water can be considered as negligtible.

**Scenario [4.2]**

Post application drinking water children scenario is only relevant for chlorate, as active chlorine concentration is far below concentration for which local effects occur.

**Table 32. applicability domain of scenario 3.9: Post application drinking water children**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| meta SPC 1.1 | Produits Piscine GP | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| meta SPC 1.2 | Produits Piscine PRO | Min (%) | 13.5 | N.R. |
| Max (%) | 13.5 |
| meta SPC 2.1 | Javel MDD à 2,6%c.a. | Min (%) | 2.6 | N.R. |
| Max (%) | 2.6 |
| meta SPC 2.2 | Javel MDD à 3,6-4,8%c.a. | Min (%) | 3.6 | N.R. |
| Max (%) | 4.8 |
| meta SPC 3 | Produits Gel à 2,6%c.a. | Min (%) | 2.6 | N.R. |
| Max (%) | 2.6 |
| meta SPC 4 | Produits Gel à 1,5%c.a. | Min (%) | 1.5 | N.R. |
| Max (%) | 1.5 |
| meta SPC 5 | Produits Spray à 1,5%c.a. | Min (%) | 1.5 | N.R. |
| Max (%) | 1.5 |
| meta SPC 6.1 | Produits à 9,6 GP | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| meta SPC 6.2 | Produits à 9,6-13,5%c.a. PRO | Min (%) | 9.6 | Scenario 4.2 |
| Max (%) | 13.5 |
| meta SPC 7.1 | Javel à 3,6-4,8%c.a. PRO | Min (%) | 3.6 | Scenario 4.2 |
| Max (%) | 4.8 |
| meta SPC 7.2 | Javel à 2,6%c.a. PRO | Min (%) | 2.6 | Scenario 4.2 |
| Max (%) | 2.6 |
| meta SPC 8 | Produits à 1,6%c.a. | Min (%) | 1.6 | N.R. |
| Max (%) | 1.6 |
| meta SPC 9 | Produits à 9,6%c.a. Parfumés | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| meta SPC 10 | Détergents à 2,6-4,8%c.a. | Min (%) | 2.6 | N.R. |
|  | Max (%) | 4.8 |
| meta SPC 11 | Détergents alcalins chlorés | Min (%) | 6 | N.R. |
| Max (%) | 6 |
| meta SPC 12 | Produits Spray à 4,8%c.a. | Min (%) | 4.8 | N.R. |
| Max (%) | 4.8 |
| meta SPC 13 | Produits Gel WC à 4,5%c.a. | Min (%) | 4.5 | N.R. |
| Max (%) | 4.5 |
| meta SPC 14 | Gel SETS + Javel BEC | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| N .R. : not relevant | | | | |

**Chlorate**

| **Description of Scenario [4.2 bis]** | | |
| --- | --- | --- |
| A.C.working concentration is 0.5 mg/L in swimming conditions. Which corresponds, for the meta-SPC1.2 products as a worst case to 0.00008% chlorate.  Model : ConsExpo Web 1.0.5. Instant application default settings. | | |
|  | Parameters | Value |
| Tier 1 | SoC concentration1 | 0.0000135% |
| Amount ingested2 | 800g |

1 A.C.working concentration is 0.5 mg/L. Which corresponds, for the meta-SPC6.1 products as a worst case to 0.0000135% chlorate (3.66% chlorate max in 13.5%AC products.

2 Consexpo default for children.

**Calculations for scenario 4.2 bis**

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [4.2 bis] | 1 | N.R | N.R | 14 µg/kg/d | 14 µg/kg/d |

The estimated uptake of chlorate due to consumption of drinking water exceeds the ADI (467% ADI). However, the concentration of chlorate due to the use of DAAP19 products remains in levels documented for the presence of chlorate in drinking water (0.0135 mg/kg), slightly above the default MLR of 0.01 mg/kg described as impossible to reach according to the recent regulation (EU) 2020/749.

Therefore, although the absence of risk could not have been demonstrated quantitatively, the potential excess of risk due to the use of DAAP19 products for drinking water can be considered as negligtible.

*Information of non-biocidal use of the active substance*

*[Please include a section for each area of other (non-biocidal) use of the active substance. Please insert or delete rows as needed.]*

Residue definitions

*[Please include the residue definitions for each sector of use. If not relevant, delete the title.]*

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use1** | **Intended use** | **Reference value(s) 2** |
| 1. |  |  |  |
| 2. |  |  |  |

1 e.g. plant protection products, veterinary use, food or feed additives

2 e.g. MRLs. Use footnotes for references.

***Dietary exposure***

Due to the high reactivity of chlorine species, residues on surfaces degrade very rapidly (decomposition to physiological sodium and chloride). Hence, residue formation is assumed to be negligible for aqueous solutions of NaOCl. This conclusion is further supported by the conclusions drawn in the ENV part of the dossier.

Finally, no systemic assessment is required for substances such as NaOCl which act by a local mode of action only. The BPC APCP-WGII-2016 concluded that chlorate residues may still be relevant as chlorate is considered a stable metabolite. Sodium chlorate is a by-product of the manufacturing process and can be formed during storage.

Thus, chlorate may represent a worst-case for NaOCl residues. Furthermore, the BPC TOX-WGII-2016 agreed that exposure via food should be assessed during active substance approval so this is available at product authorisation. In the BPC TOX-WGII-2016 it was finally discussed that only chlorate is relevant for the dietary risk assessment.

Reference values were established fort he active substance approbation stage. The relevant reference value for chlorate as agreed during BPC WGIII-2016 is the ADI of 0.003 mg/kg bw (according to EFSA CONTAM Panel, 2015. Scientific Opinion on risks for public health related to the presence of chlorate in food. EFSA Journal 2015; 13:4135).

**Chlorate: Livestock exposure assessment**

**Scenario [4.3]**

**Table 33. applicability domain of scenario 4.3: livestock exposure**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| meta SPC 1.1 | Produits Piscine GP | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| meta SPC 1.2 | Produits Piscine PRO | Min (%) | 13.5 | N.R. |
| Max (%) | 13.5 |
| meta SPC 2.1 | Javel MDD à 2,6%c.a. | Min (%) | 2.6 | Scenario 4.3 |
| Max (%) | 2.6 |
| meta SPC 2.2 | Javel MDD à 3,6-4,8%c.a. | Min (%) | 3.6 | Scenario 4.3 |
| Max (%) | 4.8 |
| meta SPC 3 | Produits Gel à 2,6%c.a. | Min (%) | 2.6 | N.R. |
| Max (%) | 2.6 |
| meta SPC 4 | Produits Gel à 1,5%c.a. | Min (%) | 1.5 | N.R. |
| Max (%) | 1.5 |
| meta SPC 5 | Produits Spray à 1,5%c.a. | Min (%) | 1.5 | N.R. |
| Max (%) | 1.5 |
| meta SPC 6.1 | Produits à 9,6 GP | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| meta SPC 6.2 | Produits à 9,6-13,5%c.a. PRO | Min (%) | 9.6 | Scenario 4.3 |
| Max (%) | 13.5 |
| meta SPC 7.1 | Javel à 3,6-4,8%c.a. PRO | Min (%) | 3.6 | Scenario 4.3 |
| Max (%) | 4.8 |
| meta SPC 7.2 | Javel à 2,6%c.a. PRO | Min (%) | 2.6 | Scenario 4.3 |
| Max (%) | 2.6 |
| meta SPC 8 | Produits à 1,6%c.a. | Min (%) | 1.6 | N.R. |
| Max (%) | 1.6 |
| meta SPC 9 | Produits à 9,6%c.a. Parfumés | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| meta SPC 10 | Détergents à 2,6-4,8%c.a. | Min (%) | 2.6 | Scenario 4.3 |
|  | Max (%) | 4.8 |
| meta SPC 11 | Détergents alcalins chlorés | Min (%) | 6 | Scenario 4.3 |
| Max (%) | 6 |
| meta SPC 12 | Produits Spray à 4,8%c.a. | Min (%) | 4.8 | N.R. |
| Max (%) | 4.8 |
| meta SPC 13 | Produits Gel WC à 4,5%c.a. | Min (%) | 4.5 | N.R. |
| Max (%) | 4.5 |
| meta SPC 14 | Gel SETS + Javel BEC | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| N .R. : not relevant | | | | |

A preliminary livestock exposure and dietary risk assessment for chlorate for intended uses in PT3 has been performed according to the “Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products” (CA-Dec10-Doc.6.2b).

Livestock exposure was calculated using the “BfR Livestock Exposure Calculator” (2012; <http://www.bfr.bund.de/en/assessment> residue\_analytics-54528.html). The assessment includes a screening step as well as a realistic worst-case scenario. The subsequent dietary exposure assessment has been performed according to the EMA “Guideline on risk characterization and assessment of maximum residue limits (MRL) for biocides” (2015) taking into account the standard EMA food basket.

Livestock exposure was calculated with the “BfR Livestock Exposure Calculator” in accordance with the “Guidance on Estimating Livestock Exposure” (2010) for the following uses:

* *Disinfection of areas in which animals are housed by wiping, mopping, brushing - professional use*
* *Disinfection in the means of animal transport by wiping and mopping - professional use*
* *Disinfection of of the feet of animals by crossing a hoof bath – professional use*

As proposed in the “Guidance on Estimating Livestock Exposure” (2010), two calculation steps were performed, i.e. a worst-case screening scenario and – in case the screening led to exposure higher than the trigger value of 0.004 mg/kg bw – a realistic scenario. Details on input parameters and scenarios are provided in the “Read me” spreadsheet of the “BfR Livestock Exposure Calculator”.

A rinsing step was considered, and livestock exposure was performed for two tiers:

* Tier-1 (without rinsing of treated surfaces);
* Tier-2 (with rinsing of the treated surfaces).

In the absence of measured residue data, the assumption was made that 10% (Tier-2a) or 1% (Tier-2b) of chlorate residues remain on the treated surface after rinsing, while 90% or 99%, respectively, of chlorate residues are flushed. This is considered realistic, as chlorate is highly soluble in water: for sodium chlorate, a solubility of 960-1000 g/L is described (EFSA CONTAM Panel, 2015. Scientific Opinion on risks for public health related to the presence of chlorate in food. EFSA Journal 2015; 13:4135). No reduction factor was applied for *dermal exposure from walking through a hoof bath* as feet of animals are not rinsed after the passage through the hoof bath.

It is noticed that chlorate residue formation may depend on the formulation of the products as well as on the storage conditions of the product. No measured data on chlorate residues after application of the theoretical product were available. In the absence of measured residue data, the chlorate content according to sodium hypochlorite specification was used for estimation of chlorate contents in the application solution. According to EN 901:2013, sodium chlorate may be present as a by-product of the production process. In addition, it is expected that sodium chlorate content increases over time in aqueous solutions of NaOCl.

According to the specification criteria for the active chlorine releaser NaOCl, sodium chlorate is present at concentrations ≤3.66%. For an in-use concentration of 1100 mg avCl/L and an application rate of 0.1 L/m², this results in an application rate of 110 mg sodium chlorate/m².

| **Description of Scenario [4.3]** | | |
| --- | --- | --- |
| See detailed description above | | |
|  | Parameters | Value |
| Tier 1 | Maximal application rate | 110 mg/m2 |
| Tier 2 a | Refinement factor (rinsing 90%) | 0.1 |
| Tier 2 b | Refinement factor (rinsing 99%) | 0.01 |

In the screening scenarios (surface treatment of animal housing (floor&wall of stable without partitions) and surface treatment of animal housing (individual animal surrounded by 3/4 walls)) the trigger value of 0.004 mg/kg bw was exceeded at least for some animal species. Thus, a realistic exposure scenario was calculated taking into account that animals are not present in the stables during disinfection and feed is removed from troughs.

The following four scenarios were considered relevant and assessed:

* + - oral – animals licking surfaces
    - oral – direct treatment of feeding trough surface
    - dermal – rubbing against surfaces
    - dermal – dermal exposure from walki*ng through a hoof bath*

As stated in the “Read me” of the “BfR Livestock Exposure Calculator”, not all scenarios apply to all animal species. Consequently, exposure in the three chosen scenarios was calculated for relevant animal species only. Total exposure via all three scenarios was then calculated by summing up the values obtained for the three individual scenarios.

As the trigger value of 0.004 mg/kg bw was exceeded in Tier-1 (i.e. without rinsing), Tier-2a (90% of chlorate residues remaining after rinsing), and Tier-2b (99% of chlorate residues remaining after rinsing), a worst case consumer exposure estimate (WCCE) was performed for the realistic scenarios (Tier-1, Tier-2a and Tier-2b; see Tables in annexe). For this purpose, the standard EMA food basket (according to the EMA Guideline on MRLs (2011 and 2015)) was taken into account.

In Tier 2b, no exposure exceeded 30% of the ADI.

Scenario [4.6] livestock exposure using the BfR livestock exposure estimation tool

**Table 34. applicability domain of scenario 4.6: livestock exposure – BfR livestock exposure estimation tool**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| meta SPC 1.1 | Produits Piscine GP | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| meta SPC 1.2 | Produits Piscine PRO | Min (%) | 13.5 | N.R. |
| Max (%) | 13.5 |
| meta SPC 2.1 | Javel MDD à 2,6%c.a. | Min (%) | 2.6 | Scenario 4.6 |
| Max (%) | 2.6 |
| meta SPC 2.2 | Javel MDD à 3,6-4,8%c.a. | Min (%) | 3.6 | Scenario 4.6 |
| Max (%) | 4.8 |
| meta SPC 3 | Produits Gel à 2,6%c.a. | Min (%) | 2.6 | N.R. |
| Max (%) | 2.6 |
| meta SPC 4 | Produits Gel à 1,5%c.a. | Min (%) | 1.5 | N.R. |
| Max (%) | 1.5 |
| meta SPC 5 | Produits Spray à 1,5%c.a. | Min (%) | 1.5 | N.R. |
| Max (%) | 1.5 |
| meta SPC 6.1 | Produits à 9,6 GP | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| meta SPC 6.2 | Produits à 9,6-13,5%c.a. PRO | Min (%) | 9.6 | Scenario 4.6 |
| Max (%) | 13.5 |
| meta SPC 7.1 | Javel à 3,6-4,8%c.a. PRO | Min (%) | 3.6 | Scenario 4.6 |
| Max (%) | 4.8 |
| meta SPC 7.2 | Javel à 2,6%c.a. PRO | Min (%) | 2.6 | Scenario 4.6 |
| Max (%) | 2.6 |
| meta SPC 8 | Produits à 1,6%c.a. | Min (%) | 1.6 | N.R. |
| Max (%) | 1.6 |
| meta SPC 9 | Produits à 9,6%c.a. Parfumés | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| meta SPC 10 | Détergents à 2,6-4,8%c.a. | Min (%) | 2.6 | Scenario 4.6 |
|  | Max (%) | 4.8 |
| meta SPC 11 | Détergents alcalins chlorés | Min (%) | 6 | Scenario 4.6 |
| Max (%) | 6 |
| meta SPC 12 | Produits Spray à 4,8%c.a. | Min (%) | 4.8 | N.R. |
| Max (%) | 4.8 |
| meta SPC 13 | Produits Gel WC à 4,5%c.a. | Min (%) | 4.5 | N.R. |
| Max (%) | 4.5 |
| meta SPC 14 | Gel SETS + Javel BEC | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| N .R. : not relevant | | | | |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Animal Species |  | Oral - Animals licking surfaces | Oral - Uptake of feed contaminated in trough | | Oral - Direct treatment of feeding trough surface | | Dermal - Rubbing against surfaces | |
| Beef cattle |  | 0,0005 | 0,0005 | | 0,0002 | | 0,00864 | |
| Dairy cattle |  | 0,0004 | 0,0015 | | 0,0003 | | 0,00775 | |
| Calf |  | 0,0012 | 0,0008 | | 0,0003 | | 0,01305 | |
| Fattening pig |  | 0,0024 | 0,0013 | | 0,0004 | | 0,01350 | |
| Breeding pig |  | 0,0009 |  | |  | | 0,00969 | |
| Breeding pig | individual housing |  | 0,0048 | | 0,0007 | |  | |
| Breeding pig | group housing |  | 0,0057 | | 0,0003 | |  | |
| Sheep |  | 0,0032 |  | |  | |  | |
| Lamb |  | 0,0060 |  | |  | |  | |
| Slaughter goat  (= goat kids) |  | 0,0185 |  | |  | | 0,03462 | |
| Lactating goat |  | 0,0034 |  | |  | | 0,01929 | |
| Broilers |  |  |  | |  | |  | |
| Broilers | free range, litter floor |  |  | |  | |  | |
| Broilers | parent broilers, free range (grating floor) |  |  | |  | |  | |
| Broilers | parent broilers in rearing, free range (grating floor) |  |  | |  | |  | |
| Laying hen |  |  | 0,0017 | |  | |  | |
| Laying hen | battery |  |  | | 0,0002 | |  | |
| Laying hen | free range (litter floor) |  |  | |  | |  | |
| Laying hen | free range (grating floor) |  |  | |  | |  | |
| Turkey |  |  |  | |  | |  | |
| Horse |  |  |  | |  | | 0,01215 | |
| Rabbit |  |  |  | |  | |  | |
| Description of Exposure Models/ Assumptions |  | Animal are licking surfaces that were treated with the biocidal product. | Troughs were not covered during biocidal spray treatment of surrounding animal housing walls, so that trough surfaces may be contaminated with the biocidal product. The model assumes that all residues contaminating the trough migrate into next feed batch which is consumed completely by the animal. | | Inner trough surfaces were treated with the biocidal product. The model assumes that all residues on bottom and sides of trough migrate into next feed batch which is consumed completely by the animal. | | Animal rubs on surface treated with the biocidal product. The exposure estimate includes dermal uptake as well as oral intake from grooming | |
| Calculation |  | Exposure=AR\*Atongue\*L/bw\*RF | Exposure=AR\*EF\*Afeed surf/bw\*RF | | Exposure=AR\*Afeed surf/bw\*RF | | Exposure =AR\*BSAcont/bw\*RF | |
| Parameters/ Default Values |  | AR: application rate (mg/m2) | AR: application rate (mg/m2) | | AR: application rate (mg/m2) | | AR: application rate (mg/m2) | |
|  |  | Atongue: tongue surface area (default=0,008 m2, TNsG Table 4) | EF: emission factor for spray application: fraction emitted to floor during surface treatment  (default=0,11, TNsG Table 4) | | Afeed surf: exposed feed surface  (default for direct trough treatment, TNsG Table 2) | | BSAcont: animal body surface area in contact with surface (m2)  (default, TNsG Table 1) | |
|  |  | L: licks per day  (default=10, TNsG Table 4) | Afeed surf: exposed feed surface  (default for treatment of surfaces surrounding trough , TNsG Table 2) | | bw: body weight (kg) (default, TNsG Table 1) | | bw: body weight (kg) (default, TNsG Table 1) | |
|  |  | bw: body weight (kg) (default, TNsG Table 1) | bw: body weight (kg) (default, TNsG Table 1) | | RF: refinement factor (default=1) | | RF: refinement factor (default=1) | |
|  |  | RF: refinement factor (default=1) | RF: refinement factor (default=1) | |  | |  | |
|  |  |  |  | |  | |  | |
|  |  |  |  | |  | |  | |
|  |  |  |  | |  | |  | |
| **Total Estimated Livestock Exposure (mg a.s./kg bw/d)** | | | |  | |  | |  | |
| Sum of all scenarios checked above | |  |  | |  | |  | |
|  |  |  |  | |  | |  | |
| Animal Species |  | Sum of  all routes of exposure |  | |  | |  | |
| Beef cattle |  | 0,0097 |  | |  | |  | |
| Dairy cattle |  | 0,0099 |  | |  | |  | |
| Calf |  | 0,0154 |  | |  | |  | |
| Fattening pig |  | 0,0176 |  | |  | |  | |
| Breeding pig\* |  | 0,0106 |  | |  | |  | |
| Breeding pig\* | individual housing | 0,0056 |  | |  | |  | |
| Breeding pig\* | group housing | 0,0060 |  | |  | |  | |
| Sheep |  | 0,0032 |  | |  | |  | |
| Lamb |  | 0,0060 |  | |  | |  | |
| Slaughter goat (= goat kids) |  | 0,0531 |  | |  | |  | |
| Lactating goat |  | 0,0227 |  | |  | |  | |
| Broilers\* |  | 0,0000 |  | |  | |  | |
| Broilers\* | free range, litter floor | 0,0000 |  | |  | |  | |
| Broilers\* | parent broilers, free range (grating floor) | 0,0000 |  | |  | |  | |
| Broilers\* | parent broilers in rearing, free range (grating floor) | 0,0000 |  | |  | |  | |
| Laying hen\* |  | 0,0017 |  | |  | |  | |
| Laying hen\* | battery | 0,0002 |  | |  | |  | |
| Laying hen\* | free range (litter floor) | 0,0000 |  | |  | |  | |
| Laying hen\* | free range (grating floor) | 0,0000 |  | |  | |  | |
| Turkey |  | 0,0000 |  | |  | |  | |
| Horse |  | 0,0122 |  | |  | |  | |
| Rabbit |  | 0,0000 |  | |  | |  | |
| \*Please note that some scenarios for chicken and pigs distinguish between several housing conditions. | | | | | |  | |  | |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **Standard food basket \*** | | |  |  |  |
|  |  |  | **amount meat eaten (muscle, kidney, liver, fat)** |  |  |  |  |  |
|  |  |  | **[kg]** |  |  | **dietary exposure by meat** | **dietary exposure by milk** | **dietary exposure by eggs** |
| Animal Species |  | Sum of  all routes of exposure |  | **milk [kg]** | **eggs [kg]** | **[mg chlorate]** | **[mg chlorate]** | **[mg chlorate]** |
| Beef cattle |  | 0,0097 | 0,5 |  |  | 0,004869 | 0 | 0 |
| Dairy cattle |  | 0,0099 |  | 1,5 |  | 0 | 0,01485 | 0 |
| Calf |  | 0,0154 | 0,5 |  |  | 0,0076875 | 0 | 0 |
| Fattening pig |  | 0,0176 | 0,5 |  |  | 0,00879 | 0 | 0 |
| Breeding pig\* |  | 0,0106 |  |  |  | 0 | 0 | 0 |
| Breeding pig\* | individual housing | 0,0056 |  |  |  | 0 | 0 | 0 |
| Breeding pig\* | group housing | 0,0060 |  |  |  | 0 | 0 | 0 |
| Sheep |  | 0,0032 | 0,5 |  |  | 0,0016 | 0 | 0 |
| Lamb |  | 0,0060 | 0,5 |  |  | 0,003 | 0 | 0 |
| Slaughter goat (= goat kids) |  | 0,0531 | 0,5 |  |  | 0,02653846 | 0 | 0 |
| Lactating goat |  | 0,0227 |  | 1,5 |  | 0 | 0,03407143 | 0 |
| Broilers\* |  | 0,0000 | 0,5 |  |  | 0 | 0 | 0 |
| Broilers\* | free range, litter floor | 0,0000 | 0,5 |  |  | 0 | 0 | 0 |
| Broilers\* | parent broilers, free range (grating floor) | 0,0000 |  |  |  | 0 | 0 | 0 |
| Broilers\* | parent broilers in rearing, free range (grating floor) | 0,0000 |  |  |  | 0 | 0 | 0 |
| Laying hen\* |  | 0,0017 |  |  | 0,1 | 0 | 0 | 0,00017368 |
| Laying hen\* | battery | 0,0002 |  |  | 0,1 | 0 | 0 | 1,5789E-05 |
| Laying hen\* | free range (litter floor) | 0,0000 |  |  | 0,1 | 0 | 0 | 0 |
| Laying hen\* | free range (grating floor) | 0,0000 |  |  | 0,1 | 0 | 0 | 0 |
| Turkey |  | 0,0000 | 0,5 |  |  | 0 | 0 | 0 |
| Horse |  | 0,0122 | 0,5 |  |  | 0,006075 | 0 | 0 |
| Rabbit |  | 0,0000 | 0,5 |  |  | 0 | 0 | 0 |
| Maximum |  |  |  |  |  | 0,02653846 | 0,03407143 | 0,00017368 |
|  |  |  |  |  |  |  |  |  |
| **Systemic chlorate exposure via animal products** | | | |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  | **ADI [mg/kg bw]** |  |  |  |  |
|  | **chlorate taken up via diet** |  | **systemic exposure to chlorate [mg/kg bw]** | **0,003** |  |  |  |  |
| **Products consumed** | **[mg]** | **body weight [kg]** |  | **% ADI** | **> 30% ADI?** |  |  |  |
| meat | 0,026538462 | 60 | 0,000442308 | 14,74358974 | no |  |  |  |
| milk | 0,034071429 | 60 | 0,000567857 | 18,92857143 | no |  |  |  |
| eggs | 0,000173684 | 60 | 2,89474E-06 | 0,096491228 | no |  |  |  |
| meat + milk + eggs | 0,060783574 | 60 | 0,00101306 | 33,7686524 | no |  |  |  |
|  |  |  |  |  |  |  |  |  |
| \* The **standard food basket** proposed in the EMA guidance on MRL setting (2010) contains: muscle 300 g, liver 100 g, fat 50 g, kidney 50 g, milk 1500 g, eggs 100 g, honey 20 g. | | | | | | | | |
| For calculations, amounts of muscle, liver, kidney and fat were added, resulting in 500 g of animal tissue eaten. | | | | | | |  |  |

**Tableau 36: comparison between highest residue level modelized by type of foodstuff and the corresponding adopted MRL ((UE) 2020/749).**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Max residue level (mg/kg) | Lowest MRL (mg/kg) | Residue level /MRL |
| Meat | 0,0155 | 0,0500 | 0,3101 |
| Milk | 0,0136 | 0,1000 | 0,1360 |
| Eggs | 0,0017 | 0,0500 | 0,0343 |

**Chlorate: transfer of biocides residues into foods - exposure assessment**

**Scenario [4.4]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| meta SPC 1.1 | Produits Piscine GP | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| meta SPC 1.2 | Produits Piscine PRO | Min (%) | 12.5 | N.R. |
| Max (%) | 12.5 |
| meta SPC 2.1 | Javel MDD à 2,6%c.a. | Min (%) | 2.6 | Scenario 4.4 |
| Max (%) | 2.6 |
| meta SPC 2.2 | Javel MDD à 3,6-4,8%c.a. | Min (%) | 3.6 | Scenario 4.4 |
| Max (%) | 4.8 |
| meta SPC 3 | Produits Gel à 2,6%c.a. | Min (%) | 2.6 | N.R. |
| Max (%) | 2.6 |
| meta SPC 4 | Produits Gel à 1,5%c.a. | Min (%) | 1.5 | N.R. |
| Max (%) | 1.5 |
| meta SPC 5 | Produits Spray à 1,5%c.a. | Min (%) | 1.5 | N.R. |
| Max (%) | 1.5 |
| meta SPC 6.1 | Produits à 9,6 GP | Min (%) | 9.6 | Scenario 4.4 |
| Max (%) | 9.6 |
| meta SPC 6.2 | Produits à 9,6-13,5%c.a. PRO | Min (%) | 9.6 | Scenario 4.4 |
| Max (%) | 13.5 |
| meta SPC 7.1 | Javel à 3,6-4,8%c.a. PRO | Min (%) | 3.6 | Scenario 4.4 |
| Max (%) | 4.8 |
| meta SPC 7.2 | Javel à 2,6%c.a. PRO | Min (%) | 2.6 | Scenario 4.4 |
| Max (%) | 2.6 |
| meta SPC 8 | Produits à 1,6%c.a. | Min (%) | 1.6 | N.R. |
| Max (%) | 1.6 |
| meta SPC 9 | Produits à 9,6%c.a. Parfumés | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| meta SPC 10 | Détergents à 2,6-4,8%c.a. | Min (%) | 2.6 | Scenario 4.4 |
|  | Max (%) | 4.8 |
| meta SPC 11 | Détergents alcalins chlorés | Min (%) | 6 | Scenario 4.4 |
| Max (%) | 6 |
| meta SPC 12 | Produits Spray à 4,8%c.a. | Min (%) | 4.8 | N.R. |
| Max (%) | 4.8 |
| meta SPC 13 | Produits Gel WC à 4,5%c.a. | Min (%) | 4.5 | N.R. |
| Max (%) | 4.5 |
| meta SPC 14 | Gel SETS + Javel BEC | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| N .R. : not relevant | | | | |

A dietary risk assessment for chlorate for intended uses in PT4 has been performed according to the Guidance on estimation of dietary risk from consumer exposure to biocidal active substances used in domestic households.

Exposure from foods to biocides residues was calculated using the “BfR Calculator for estimating transfer of biocide residues into foods”, version 2.0. Currently, no agreed and published model is available for the estimation of dietary risk from transfer of biocidal active substances into food in professional settings. Thus, no dietary risk assessment can be provided at this stage for the intended professional uses of the active chlorine releaser NaOCl in PT4. As an approximation, and because professional disinfection of food and feed areas often do not differ significantly from domestic household situations, domestic household consumer exposure model was used to estimate consumer exposure secondary to professional use of food and feed areas disinfectants. As the amount of solution per surface are identical, but the quantity of food to be in contact with disinfected surfaces are generallyconsiderably larger, this constitutes a conservative hypothesis.

Exposure was calculated for the following uses:

* *Disinfection of areas in contact with food - professional use*
* *Disinfection of areas in contact with food – domestic use*

Two calculation steps were performed: a worst-case scenario corresponding to the non respect of rinsing after use, and a scenario corresponding to the professional use, i.e. the surfaces are rinsed after disinfection according to instructions.

A rinsing step was considered, and exposure to biocides residues from food was performed for two tiers:

* Tier-1 (without rinsing of treated surfaces);
* Tier-2 (with rinsing of the treated surfaces).

In the absence of measured residue data, the assumption was made that 10% (Tier-2a) chlorate residues remain on the treated surface after rinsing, while 90% of chlorate residues are flushed. This is considered realistic, as chlorate is highly soluble in water: for sodium chlorate, a solubility of 960-1000 g/L is described (EFSA CONTAM Panel, 2015. Scientific Opinion on risks for public health related to the presence of chlorate in food. EFSA Journal 2015; 13:4135).

It is noticed that chlorate residue formation may depend on the formulation of the products as well as on the storage conditions of the product. No measured data on chlorate residues after application of the theoretical product were available. In the absence of measured residue data, the chlorate content according to sodium hypochlorite specification was used for estimation of chlorate contents in the application solution. According to EN 901:2013, sodium chlorate may be present as a by-product of the production process. In addition, it is expected that sodium chlorate content increases over time in aqueous solutions of NaOCl.

According to the specification criteria for the active chlorine releaser NaOCl, sodium chlorate is present at concentrations ≤5.4% of avCl. For an in-use concentration of 10000 mg avCl/L and an application rate of 0.1 L/m², this results in an application rate of 54 mg sodium chlorate/m² and 42.3 mg chlorate/m².

| **Description of Scenario [8]** | | |
| --- | --- | --- |
| See detailed description above | | |
|  | Parameters | Value |
| Tier 1 | Maximal application rate | 42.3 mg/m2 |
| Tier 2 | Refinement factor (rinsing 90%) | 0.1 |

In Tier 1 corresponding to domestic use, exposure exceeded ADI for all consumer categories, therefore a semi-quantitative assessment was performed according to the CAR of A.C.:

The EFSA Scientific Opinion of the EFSA CONTAM Panel on “Risks for public health related to the presence of chlorate in food” (EFSA Journal 2015; 13:4135) includes a comprehensive dietary exposure and risk assessment for chlorate residues in food and drinking water based on occurrence data.

In brief, the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) evaluated the exposure and risk arising from chlorate residues found in food and drinking water. Occurrence data from European national food authorities and similar bodies was collected and approximately 8000 samples were analysed for chlorate contents (e.g. grains and grain-based products, vegetables and vegetable products, legumes, fruit and fruit products, herbs and spices, milk and dairy products, (non-)alcoholic beverages, composition food, and drinking water). Chlorate content in all food commodities assessed ranged from 3 µg/kg (alcoholic beverages) to 417 µg/kg (herbs and spices) (mean upper bound values). The mean chlorate value for drinking water was 39 µg/L (mean upper bound).

An acute and chronic exposure assessment was performed for different population groups, using consumption data from the EFSA Comprehensive Database and the measured chlorate levels. According to the Scientific Opinion, “mean and 95th percentile acute exposures were below the ARfD [36 µg chlorate/kg bw] for all age groups indicating no concern”. Moreover it is stated that, “chronic exposure of adolescent and adult age classes did not exceed the TDI [3 µg chlorate/kg bw].

However, at the 95th percentile, the TDI was exceeded in all surveys for ‘Infants’ and ‘Toddlers’, and in some surveys in ’Other children’”, indicating that “chronic exposures are of concern in particular in younger age groups with mild or moderate iodine deficiency.”

Chlorate is no longer used as pesticide (according to Commission Decision No 2008/865/EC). Thus, chlorate contamination in food is likely to be mainly derived from biocidal uses of chlorine and hypochlorite. Both substances are widely used for disinfection of surfaces and equipment in food and feed processing areas as well as for disinfection of drinking water (i.e. as biocidal products in PTs 4 and 5), and thus, chlorate residues can be carried-over into food and feed during cleaning, washing and processing steps.

Accordingly, “CONTAM Panel assumes that chlorate residues in food result mainly form the use of chlorinated water for food processing (e.g. washing) and from the disinfection of surfaces and food processing equipment coming into contact with food.” Potential chlorate residues from the application of chlorine and hypochlorite in PTs 4 and 5 are considered to be included in the measured chlorate residue values, and the conclusions drawn by the EFSA CONTAM Panel on chlorate residues cover thus also the dietary risk arising from PT4 and PT5 uses of chlorine and hypochlorite. Since the EFSA Scientific Opinion on chlorate residues provides actual measured data for chlorate residues in food and an exhaustive exposure and risk assessment based on consumption data, the conclusions drawn in the EFSA Scientific Opinion are superior to any dietary risk assessment based on exposure models.

Therefore, although exposure assessment showed overcome of ADI for domestic use, EFSA scientific opinion clearly demonstrate safe use of active chlorine releaser in food and feed areas. Intented domestic uses of DAAP19 products in food and feed areas (PT4) are therefore considered as safe.

In Tier 2 corresponding to professional use, no exposure exceeded the ADI.

**Conclusion**

*[Please give a brief conclusion on the acceptability of the scenario.]*

*Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)*

**Scenario [n]**

*[Please include for each intended representative use scenario a description of scenario; assumptions, parameters and data used for exposure estimation, including refinements if applicable; calculations and result.]*

**Conclusion**

*[Please give a brief conclusion on the acceptability of the scenario.]*

*Estimating transfer of biocidal active substances into foods as a result of non-professional use*

Scenario [4.5] contamination of food by contact with surfaces treated with products of the DAAP19 family using BfR calculator for estimating transfer of biocide residues into food.

**Tableau 35: applicability domain of scenario [4.5] tranfer of residues from surface to foods**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| meta SPC 1.1 | Produits Piscine GP | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| meta SPC 1.2 | Produits Piscine PRO | Min (%) | 12.5 | N.R. |
| Max (%) | 12.5 |
| meta SPC 2.1 | Javel MDD à 2,6%c.a. | Min (%) | 2.6 | Scenario 4.5 |
| Max (%) | 2.6 |
| meta SPC 2.2 | Javel MDD à 3,6-4,8%c.a. | Min (%) | 3.6 | Scenario 4.5 |
| Max (%) | 4.8 |
| meta SPC 3 | Produits Gel à 2,6%c.a. | Min (%) | 2.6 | N.R. |
| Max (%) | 2.6 |
| meta SPC 4 | Produits Gel à 1,5%c.a. | Min (%) | 1.5 | N.R. |
| Max (%) | 1.5 |
| meta SPC 5 | Produits Spray à 1,5%c.a. | Min (%) | 1.5 | N.R. |
| Max (%) | 1.5 |
| meta SPC 6.1 | Produits à 9,6 GP | Min (%) | 9.6 | Scenario 4.5 |
| Max (%) | 9.6 |
| meta SPC 6.2 | Produits à 9,6-13,5%c.a. PRO | Min (%) | 9.6 | Scenario 4.5 |
| Max (%) | 13.5 |
| meta SPC 7.1 | Javel à 3,6-4,8%c.a. PRO | Min (%) | 3.6 | Scenario 4.5 |
| Max (%) | 4.8 |
| meta SPC 7.2 | Javel à 2,6%c.a. PRO | Min (%) | 2.6 | Scenario 4.5 |
| Max (%) | 2.6 |
| meta SPC 8 | Produits à 1,6%c.a. | Min (%) | 1.6 | N.R. |
| Max (%) | 1.6 |
| meta SPC 9 | Produits à 9,6%c.a. Parfumés | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| meta SPC 10 | Détergents à 2,6-4,8%c.a. | Min (%) | 2.6 | Scenario 4.5 |
|  | Max (%) | 4.8 |
| meta SPC 11 | Détergents alcalins chlorés | Min (%) | 6 | Scenario 4.5 |
| Max (%) | 6 |
| meta SPC 12 | Produits Spray à 4,8%c.a. | Min (%) | 4.8 | N.R. |
| Max (%) | 4.8 |
| meta SPC 13 | Produits Gel WC à 4,5%c.a. | Min (%) | 4.5 | N.R. |
| Max (%) | 4.5 |
| meta SPC 14 | Gel SETS + Javel BEC | Min (%) | 9.6 | N.R. |
| Max (%) | 9.6 |
| N .R. : not relevant | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario: Surface treatment with biocidal product** | | |  |  |
| Biocidal product | Meta SPC 6 | product specific information |  |  |
| Active substance | Chlorate | product specific information |  |  |
| concentration of active substance in biocidal product: cas in bp (mg/L) | 3000 | product specific information (worst case chlorate content at virucidal concentration) |  |  |
| maximal application rate of biocidal product: Rappl bp (mL bp/m²) | 100 | product specific information |  |  |
| maximal application rate of active substance: Rappl as (mg as/m²) | 300,00 | calculated as  Rappl as= cas in bp x  (Rappl bp ÷ 1000) |  |  |
| ADI (mg/kg bw/d) | 0,003 |  |  |  |
| ARfD (mg/kg bw/d) (if applicable) | 0,036 | Active chlorine CAR (january 2017) |  |  |
| area in contact with food: Afood contact (m²) | 0,2 | default for  surface treatment |  |  |
| dietary intake fraction (chronic exposure): D (1/d) | 0,5 | default for chronic assessment |  |  |
| dietary intake fraction (acute exposure): D (1/d) | 1 | default for acute assessment |  |  |
| mass transfer efficiency: TF | 0,001 | Cf DBP arrow consortium data "chlorate foodstuff analysis" |  |  |
| optional: RF (additional refinement factor) | 0,01 | realistic asumption that active chlorine containing products are rinsed due to bleaching properties |  |  |
|  |  |  |  |  |
| contamination of food by contact with surfaces treated with products of the DAAP19 family using BfR calculator for estimating transfer of biocide residues into food. | | | |  |
| **Calculation of consumer exposure\*** | **adult  (60 kg bw)** | **toddler  (10 kg bw)** | **child  (23,9 kg bw)** | **infant  (8 kg bw)** |
| **Estimation of chronic consumer exposure via food (mg/kg bw/d)** | 0,000 | 0,000 | 0,000 | 0,000 |
| **Estimation of chronic consumer exposure via food (% ADI)** | 0,2 | 1,0 | 0,4 | 1,3 |
| **Estimation of acute consumer exposure via food (mg/kg bw/d)** | 0,000 | 0,000 | 0,000 | 0,000 |
| **Estimation of acute consumer exposure via food (% ARfD)** | 0,0 | 0,2 | 0,1 | 0,2 |
| \*calculated as Expcons = (Rappl as x Afood contact x D x TF x RF) ÷ bw | | |  |  |

**Conclusion**

Modelization of transfer of chlorate into foodstuff may show difficulties to avoid theorethical exceedance of the ADI of 3%g/kg/d for some uses of DAAP19 family products without risk mitigation measures. However, as chlorate is highly hydrophilic and is likely to be removed by rinsing in a large extend (data to be provided by the arrow consortium on DBPs soon); and as active chlorine containing products are largely rinsed after use even by non-professional users due to bleaching properties, actual exposure via food to chlorate residues is likely to be out of concern. Moreover, exposure to chlorate from DAAP19 products via lifestock exposure was shown to remain well below MRLs which are document to be difficult to comply with ((UE) 2020/749), thus the effects of the residues of chlorate due to the use of DAAP19 products are probably negligible.

**Risk characterisation for human health**

**Reference values to be used in Risk Characterisation**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF** | **Correction for oral absorption** | **Value** |
| NOAECoral | rat 90-d subchronic repeated dose oral (drinking water) study  rat 104-wks chronic repeated dose oral (drinking water) study | 0.1% | 1 | - | 0.1% avCl |
| NOAECdermal |  | 2.6% | 1 | - | 2.6% avCl |
| AECinhalation (chlorine) | monkey 52-wks subchronic repeated dose inhalation study  human volunteer single dose inhalation study  (4-8 h)  human volunteer repeated dose inhalation study (3 d, 6 h/d) | NOAEC 1.5 mg/m3 | 3.2 (intra-species toxicodynamic factor) | - | 0.5 ppm avCl  (1.5 mg avCl/m³) |
| AEC inhalation  (HClO) | No repeated dose inhalation toxicity study on HClO is available since HClO does not exist as such but is only formed in aqueous solutions of chlorine. In the absence of data, the BPC TOX-WGIII-2016 agreed to derive an AECinhalation based on chlorine data (please see above) |  |  |  | 0.5 mg avCl/m³ |
| ARfD | based on human 12-wks repeated dose oral (drinking water) clinical study according to EFSA CONTAM Panel (EFSA Journal 2015;13(6):4135 | Not applicable | Not applicable | Not applicable | 36 µg chlorate/kg bw |
| ADI | based on the TDI for perchlorate (derived from human observations) according to EFSA CONTAM Panel (EFSA Journal 2015;13(6):4135) | Not applicable | Not applicable | Not applicable | 3 µg chlorate/kg bw |

**Maximum residue limits or equivalent**

Residue definitions

*[Please include the residue definitions. If not relevant, delete the title.]*

|  |  |  |  |
| --- | --- | --- | --- |
| **MRLs or other relevant reference values** | **Reference** | **Relevant commodities** | **Value** |
| MRL | (UE) 2020/749) | Meat | 0,0500 |
| MRL | (UE) 2020/749) | Milk | 0,1000 |
| MRL | (UE) 2020/749) | Eggs | 0,0500 |

***Risk for consumers via residues in food***

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Systemic chlorate exposure via animal products** | | | |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  | **ADI [mg/kg bw]** |  |  |  |  |
|  | **chlorate taken up via diet** |  | **systemic exposure to chlorate [mg/kg bw]** | **0,003** |  |  |  |  |
| **Products consumed** | **[mg]** | **body weight [kg]** |  | **% ADI** | **> 30% ADI?** |  |  |  |
| meat | 0,026538462 | 60 | 0,000442308 | 14,74358974 | no |  |  |  |
| milk | 0,034071429 | 60 | 0,000567857 | 18,92857143 | no |  |  |  |
| eggs | 0,000173684 | 60 | 2,89474E-06 | 0,096491228 | no |  |  |  |
| meat + milk + eggs | 0,060783574 | 60 | 0,00101306 | 33,7686524 | no |  |  |  |
|  |  |  |  |  |  |  |  |  |
| \* The **standard food basket** proposed in the EMA guidance on MRL setting (2010) contains: muscle 300 g, liver 100 g, fat 50 g, kidney 50 g, milk 1500 g, eggs 100 g, honey 20 g. | | | | | | | | |
| For calculations, amounts of muscle, liver, kidney and fat were added, resulting in 500 g of animal tissue eaten. | | | | | | |  |  |

**Tableau 36: comparison between highest residue level modelized by type of foodstuff and the corresponding adopted MRL ((UE) 2020/749).**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Max residue level (mg/kg) | Lowest MRL (mg/kg) | Residue level /MRL |
| Meat | 0,0155 | 0,0500 | 0,3101 |
| Milk | 0,0136 | 0,1000 | 0,1360 |
| Eggs | 0,0017 | 0,0500 | 0,0343 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| contamination of food by contact with surfaces treated with products of the DAAP19 family using BfR calculator for estimating transfer of biocide residues into food. | | | |  |
| **Calculation of consumer exposure\*** | **adult  (60 kg bw)** | **toddler  (10 kg bw)** | **child  (23,9 kg bw)** | **infant  (8 kg bw)** |
| **Estimation of chronic consumer exposure via food (mg/kg bw/d)** | 0,000 | 0,000 | 0,000 | 0,000 |
| **Estimation of chronic consumer exposure via food (% ADI)** | 0,2 | 1,0 | 0,4 | 1,3 |
| **Estimation of acute consumer exposure via food (mg/kg bw/d)** | 0,000 | 0,000 | 0,000 | 0,000 |
| **Estimation of acute consumer exposure via food (% ARfD)** | 0,0 | 0,2 | 0,1 | 0,2 |
| \*calculated as Expcons = (Rappl as x Afood contact x D x TF x RF) ÷ bw | | |  |  |

## Summaries of the efficacy studies (B.5.10.1-xx)[[16]](#footnote-17)

## Confidential annex

Please refer to the confidential PAR.

## Other

Argumentation for the risk assessment of DBPs by the applicant:

At the time when the hypochlorite AR was written, it was indicated that it would be useful to perform an assessment on disinfection-by-products, but that given the absence of guidance, this should be done at product authorization. In the meantime, Guidance on the BPR: Volume V Disinfection By-Products v1.0 (2017) has become available, and thus DBPs were included in the environmental risk assessment here.

For active chlorine, a number of DBPs are relevant, e.g. combined available chlorine, and in the presence of organic matter, chlorinated organics and oxidation products as chloride.

A worst case first tier assessment follows the same steps as the a.s., e.g. the most toxic DBP is chosen and PEC/PNECs are calculated assuming 100% conversion. Use of existing information such as literature research and evaluations performed under the former Existing Substances Regulation 793/93/EEC. The key-parameters that govern the nature and quantity of DBPs likely to be formed during use of an active halogen biocide are: pH, nature of the substrates present, applied dose, contact time and temperature. These factors should be evaluated to determine if a risk assessment may be extrapolated from one particular use to another. For unknown DBPs, whole effluent testing (WET) is proposed.

This assessment is relevant for all PTs intended here (PT1-5). For PT3, where the primary receiving compartment is not water but manure and soil, the development of methods for the assessment of DBPs via discharge routes other than water is identified as a subject for further research.

***FR CA proposal on risk Assessment of DBPs for products used for swimming-pool disinfection (PT 2)***

The use of biocidal products containing active substances such as active chlorine leads to the formation of disinfection-by-products (DBPs) due to the reaction of the active substance with organic matter. As part of the authorisation of biocidal products, a risk assessment of the effects of these by products is expected.

In the document Guidance on the BPR – Volume V Disinfection-by-products (version 1.0, January 2017), a strategy is provided for the human health (HH) risk assessment of DBPs. It defines a framework that has to be followed by applicants to demonstrate a safe use of the biocidal product under consideration. The document focuses on PT 2 products specifically for swimming-pool disinfection.

As stated in the document, « *The approach for the human toxicological risk assessment for DBPs from halogenated oxidative biocides in PT2 […], consists of simply comparing measured DBP concentration of selected DBPs to existing limits for swimming- and/or drinking-water for these DBPs*. »

Concerning the existing limits, a list of values to be used is available in the guidance document (see table 2 reported at the end of this document). These values can be used to perform a Tier 1 approach when comparing to DBP concentrations.

Concerning the DBP concentrations, relevant data have been requested to the applicant in the frame of the assessment of the dossier.

Applicant submitted a document entitled « bpr\_RA\_union autorisation\_v2\_01122018.doc » in December 2018, followed by an updated version in December 2019 “DBP\_RA\_version\_3\_18-12-2019.doc”. This document is not specific to the biocidal product for which authorisation is applied. It aims at providing an overall assessment of DBPs. It is being prepared by a consortium of halogenated active substance and BP applicants. It will be here after designated as the « Consortium document ».

The Consortium document, is, as mentioned in the document «[…]  *the first iteration of the risk assessment of disinfection by-products generated from halogenated active substances and biocidal products*. » It compiles the currently available data and literature on formation of some DBPs during the use of active substances of interest such as active chlorine, active bromine and chloramine. Available qualitative and quantitative (worst-case where available) DBP data can be found in the spreadsheets enclosed in Annex. It has to be noted, that these data do not take into account specific measures performed on the product(s) currently under assessment.

As recommended in the guidance, the DBPs selected as markers in the guidance and identified in the Consortium document have been taken into account to perform a Tier 1 risk assessment. Since only few information was available concerning the active substance, pools parameters and the application conditions of the product, as a worst-case approach, the maximum DBP concentrations presented in the excel data sheet “POOLS” have been taken into account.. The available DBP concentrations have been compared to the existing limits from the guidance.

The results are as follows:

**Table 1: Marker DBP concentrations compared to DBP water limits from the guidance**

|  |  |  |  |
| --- | --- | --- | --- |
| **Compounds** | **DBP water guidance Limits in [µg/L]** | **Worst-case measures (pools) Consortium document (2018) [µg/L]** | **Below the limit value (Y/N)** |
| Trichloromethane (chloroform) | ΣTHMs: 50 (chloroform equivalents) | 219.7 | no |
| Tribromomethane (bromoform) | 930.7 |
| Bromodichloromethane | 201.7 |
| Dibromochloromethane | 63.58 |
| Bromate | 100 | no data | missing data |
| Chlorate\* & Chlorite | Σchlorate/chlorite: 30000 | 3661 (chlorate) | yes |
| Monochloroacetic acid | 800 | 96.42 | yes |
| Dichloroacetic acid | 1500 | 6787 | no |
| Trichloroacetic acid | 8000 | 1925 | yes |
| Monobromoacetic acid | 800 | no data | missing data |
| Dibromoacetic acid | 1000 | no data | missing data |
| Tribromoacetic acid | 8000 | no data | missing data |
| Dibromochloroacetic acid | 8000 | no data | missing data |
| Chloral hydrate | 100 | 156.1 | no |
| Bromal hydrate | 100 | no data | missing data |
| Dichloroacetonitrile | 20 | 47 | no |
| Dibromoacetonitrile | 70 | 5.8 | yes |
| Bromochloroacetonitrile | 20 | 13 | yes |

\* The distinction has to be made between chlorate released from the use of the active substance (DBP as presented in the table) and chlorate identified as relevant impurities for some active substance which are specifically assessed in the dossier if necessary.

**Table 2: Marker DBP concentrations compared to DBP air limits from the guidance**

|  |  |  |  |
| --- | --- | --- | --- |
| **Compounds** | **DBP air guidance Limits in [µg/L]** | **Worst-case measures (pools) Consortium document (2018) [µg/L]** | **Below the limit value (Y/N)** |
| Trichloramine | Max value 300 µm/m3 | no data | Missing data |
| Tribromamine | Max value 300 µg/m3 | No data | Missing data |

Taking into account the results of the Tier 1 approach presented above, three cases are identified :

* The marker DBP concentration is below the limit of the guidance, no further assessment is performed (ex : monochloroacetic acid (MCAA), trichloroacetic acid (TCAA)…) ;
* The marker DBP concentration is above the limit of the guidance, a Tier 2 approach should be necessary ;
* No data is available on the marker DBP concentration, no assessment can be made.

Concerning the DBP concentrations exceeding the limit values, a Tier 2 assessment should be required as recommended in the guidance document. However, no specific way forward is given apart generic proposals: « *This 2nd tier can be based on the Tolerable Daily Intake (TDI) as toxicological limit and a reasonable worst case exposure calculation for swimming-pools. One option is to derive a special swimming water limit in this 2nd tier that can be used instead of the drinking-water limit*. »

No Tier 2 approach is proposed in the Consortium Document.

Considering that no agreed practical guidance is available at this time, FR CA considers that at a product authorisation stage, it is not possible to generate the required information and to derive new pertinent limit values for selected DPB within the given timeframe for PB assessment.

As a consequence, FR CA concludes that

* Based on tier 1 approach, risks for human health due to DBPs cannot be ruled out;
* No refined risk assessment can be performed and no conclusion can be drawn with regards to the potential risks for human health due to DBP formation when using the biocidal product for swimming pools disinfections.

For all other uses of biocidal products leading to the formation of DBPs, no guidance is currently available thus, no conclusion can be drawn. Further investigations are necessary to address the point related to the DBP formation after swimming pool disinfection. The current guidance should be completed for Tier 2 assessment by the active substance renewal.

**DBP formation data from literature (source: Consortium document, version 2018)**



1. COMMISSION REGULATION (EU) 2020/749 of 4 June 2020 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorate in or on certain products [↑](#footnote-ref-2)
2. Guidance on the Biocidal Products Regulation -Volume III Human Health - Assessment & Evaluation (Parts B+C) -6. Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products [↑](#footnote-ref-3)
3. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-4)
4. Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating livestock exposure to active substances used in biocidal products -Version 4.0 December 2017 [↑](#footnote-ref-5)
5. Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating livestock exposure to active substances used in biocidal products -Version 4.0 December 2017 [↑](#footnote-ref-6)
6. Assessment report, January 2017 – Active chlorine released from sodium hypochlorite. Italy [↑](#footnote-ref-7)
7. Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses -Version 4.0 December 2017 [↑](#footnote-ref-8)
8. Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses -Version 4.0 December 2017 [↑](#footnote-ref-9)
9. Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses -Version 4.0 December 2017 [↑](#footnote-ref-10)
10. WHO, 2005. Chlorite and chlorate in drinking-water. Background document for development of WHO Guidelines for drinking-water quality. WHO/SDE/WSH/05.08/86 [↑](#footnote-ref-11)
11. EC, 2020: Directive (EU) 2020/2184 of the european parliament and of the council of 16 December 2020 on the quality of water intended for human consumption. [↑](#footnote-ref-12)
12. EC, 2020: Directive (EU) 2020/2184 of the european parliament and of the council of 16 December 2020 on the quality of water intended for human consumption. [↑](#footnote-ref-13)
13. Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses -Version 4.0 December 2017 [↑](#footnote-ref-14)
14. Laitala, K., Klepp, I.G., Henry, B. (2017) Global laundering practices: Alternatives to machine washing. [↑](#footnote-ref-15)
15. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-16)
16. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-17)