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)



HYPOCHLORITE FAMILY - ARKEMA

Product types 4 and 5

Active chlorinereleased from sodium hypochlorite

Case Number in R4BP: BC-PD047385-40

Evaluating Competent Authority: FR

Date: [09/02/2021]

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# CONCLUSION

**Introduction of the application**

France, as rMS, received an application from ARKEMA France for national authorisation for the biocidal product family HYPOCHLORITE FAMILY ARKEMA.

The products from biocidal product family HYPOCHLORITE FAMILY ARKEMA contain 13,1 % of Sodium hypochlorite (corresponding to 12,5 of Active chlorine released from sodium hypochlorite) The product family, composed of one META SPC, is intended to be used by industrial and professional users for the following uses:

* Intended Use 1 - PT4 - disinfection of the inner surfaces in human drinking water systems (pipes, reservoirs, other equipment) by filling or spraying
* Intended Use 2 - PT4 - disinfection of the inner surfaces in veterinary water systems (pipes, reservoirs, other equipment) by filling or spraying
* Intended Use 3 – PT5 - disinfection of water in drinking companies by continuous dosing
* Intended use 4 – PT5 - disinfection of stationary water
* Intended Use 5 – PT5 - disinfection of veterinary water

**Summary and overall conclusion of the assessment**

***Conclusion of the physico chemical and technical properties***

The only product of this family is aqueous dilutions of sodium hypochlorite. Sodium hypochlorite solution is a yellow liquid with a characteristic chlorine odour. A loss of 10% active substance occurs after 14 days of manufacture at room temperature (20°C) in HDPE packaging, meaning that the shelf life is only 14 days. The product should be stored at a temperature below 30°C.

Level of chlorate contents before storage is acceptable, while after 12-14 days at 22.6°C, it exceeds the 5.4% w/w of av. Chlorine limit set in the Assessment Report of active chlorine from sodium hypochlorite.

No change was observed in either the test item aspect or the active chlorine content after storage at 0 ± 2 °C for 7 days. The product is not a foaming formulation and solution is stable. The solution will also decompose in the presence of sunlight/UV. Products should be kept protected from light.

The biocidal product Javel Standard is considered by default corrosive to metal (H290, Met Corr 1, GH05, Danger). The product is not flammable or explosive and does not exhibite oxidizing properties.

The mention EUH031 “Contact with acids liberates toxic gas” and EUH206 “Warning! Do not use together with other products”. May release dangerous gases (chlorine)” also applies to the product.

The analytical methods for determination of the active substance and chlorate are validated.

***Conclusion of the efficacy***

French competent authorities (FR CA) assessed that the product family HYPOCHLORITE FAMILY – ARKEMA has shown a sufficient efficacy for the following claimed uses:

* Intended Use 1 disinfection of the inner surfaces in human drinking water systems (pipes, reservoirs, other equipment) by filling or spraying with clean conditions
  + Mandatory target organisms:
    - Bacteria, yeast: 2 mg av Cl/L, 15 minutes, 20°C.
* Intended Use 2 disinfection of the inner surfaces in veterinary water systems (pipes, reservoirs, other equipment) by filling or spraying with clean conditions
  + Mandatory target organisms:
    - Bacteria, yeast: 2 mg av Cl/L, 15 minutes, 20°C.
* Intended Use 3 disinfection of water in drinking companies by continuous dosing
  + Mandatory target organisms:
    - Bacteria, virus: 0.2 mg av Cl/L, 25 minutes, 15°C.
* Intended Use 5 disinfection of veterinary water
  + Mandatory target organisms:
    - Bacteria, virus: 0.2 mg av Cl/L, 25 minutes, 15°C.

Regarding the intended use 4disinfection of stationary water, in the absence of proper testing, efficacy has not been demonstrated.

Please note that some member states including France, after primary disinfection, request to maintain a residual level of available chlorine in drinking water in the pipes as a precautionary measure. This additional amount, claimed by the applicant as “Secondary disinfection: 0.2 mg/L available chlorine (residual)” has been considered as covered by the primary disinfection.

***Resistance***

No resistance to sodium hypochlorite has been reported in the scientific litterature.

Nevertheless, the authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA)

***Substances of concern (SoCs)***

No substance of concern has been identified. Please see the confidential annex for further details.

**Conclusion on the risk for Human Health**

Meta SPC 1 is classified Skin Corr. 1B (H314) and Eye Dam. 1 (H318). The mention EUH 071: “Corrosive to the respiratory tract” also applies.

*Industrials/professionals*

The risk is considered as acceptable considering local effects of active chlorine and systemic effects of chlorates if the following PPE/RPE are worn during:

* semi-automatic pumping:
* gloves
* coated coverall
* goggles
* mask APF 10
* maintenance of dosing pumps:
* gloves
* coated coverall
* goggles
* any substance/task respirator

*Bystanders*

The risk is considered as acceptable considering local effects of active chlorine and systemic effects of chlorates if the following RPE are worn during:

* semi-automatic pumping:
  + - mask APF 10
* maintenance of dosing pumps:
  + - any substance/task respirator

*General public*

The risk is considered as acceptable considering local effects of active chlorine and systemic effects of chlorates.

**Conclusion on the risk for consumer under indirect exposure via food**

Due to the high reactivity of chlorine species, chlorine species 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 are considered relevant for dietary exposure from the uses of active substance as drinking water disinfectant.

Disinfection of drinking water with sodium hypochlorite would not lead to a concentration of chlorate that will exceed the drinking water limit (WHO, 2005). There is no concern for general public from indirect exposure via drinking water limit or food to either available chlorine or chlorate.

***Conclusion on the risk for the environment***

Risks are acceptable for all the environmental compartments considering a qualitative assessment of the active substance NaOCl and chlorate formed during storage leading to negligible emissions to the environment for

- PT4 for surface disinfection of inner surfaces in human and veterinary drinking water systems (pipes, reservoirs, …)

- PT5 for disinfection of water in drinking water companies, disinfection of veterinary water and disinfection of stationary water in reservoir

Risks of chlorate formed during storage are acceptable for all uses considering a semi-qualitative assessment for groundwater and surface water intended for the abstraction of drinking water.

**GENERAL CONCLUSION:**

The conformity to Article 19.1 criteria, as defined in the Regulation (EU) n°528/2012, for the biocidal product family HYPOCHLORITE FAMILY ARKEMA is reported in the table below, for each use.

|  |  |  |  |
| --- | --- | --- | --- |
| **Target organisms** | **Application rates** | **Use** | **Conclusion** |
| Bacteria, yeast | 2.0 mg av. Cl/L - The product is diluted to 0.0013% (v/v) to obtain an in-use concentration of 2 mg av. Cl/L.  Contact time: 15 minutes, at 20 °C | Intended Uses 1 and 2 – PT4 - Disinfection of inner surfaces in human drinking water and in veterinary water systems (pipes, reservoirs, other equipments) - filling or spraying  Industrial users | Acceptable |
| Acceptable |
| Bacteria,  Viruses | The product is diluted at 0.00013% (v/v) to obtain an in-use concentration of 0.2 mg av Cl/L of active chlorine.  Time delay: 25 minutes at 15 °C | Intended Uses 3 and 5 – PT 5 - Disinfection of water in drinking water companies and veterinary water  Industrial users | Acceptable |
| Intended Use 4 – PT 5 - Disinfection of stationary water in reservoirs  Industrial users | **Not acceptable** :  efficacy not demonstrated |

**With the following risk mitigations measures :**

* The professional bystander needs to observe the same type of RPE as the worker during semi-automatic pumping of the product (APF 10) and maintenance of dosing pumps (any substance/task respirator).
* Avoid contact with treated tools and objects.

During semi-automatic pumping of the product, wear :

* protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information),
* coated coverall (at least category III type 6),
* a respiratory mask at least APF 10 (respiratory mask type to be specified by the authorisation holder within the product information),
* goggles

During maintenance/cleaning of dosing pumps, wear:

* protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information),
* coated coverall (at least category III type 6),
* a respiratory mask (respiratory mask type to be specified by the authorisation holder within the product information),
* goggles

**Presentation of the biocidal product family including classification and labelling**

The description of the biocidal products and of the structure of the biocidal product family is available in the SPC.

The hazard and precautionary statements of the biocidal product family according to the Regulation (EC) 1272/2008 is available in the SPC.

**Description of uses proposed to be authorised**

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

# ASSESSMENT REPORT

**Part I - First information level**

## Summary of the product assessment

### Administrative information

#### Identifier of the product family

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| Hypochlorite family – Arkema |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | ARKEMA France |
| **Address** | 420 rue d’Estienne d’Orves  92705 Colombes Cedex, Paris  France |
| **Authorisation number** | **FR-2021-0004** | |
| **Date of the authorisation** | **09/02/2021** | |
| **Expiry date of the authorisation** | **08/02/2031** | |

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

|  |  |
| --- | --- |
| **Name of manufacturer** | **ARKEMA France – USINE DE JARRIE** |
| **Address of manufacturer** | 420 rue d’Estienne d’Orves  92705 Colombes Cedex Paris  FRANCE |
| **Location of manufacturing sites** | Route Nationale 85  BP1  38560 JARRIE  FRANCE |

|  |  |
| --- | --- |
| **Name of manufacturer** | **BRENNTAG** |
| **Address of manufacturer** | **BRENNTAG CHASSIEU**  5 rue arago  BP 19  69682 CHASSIEU cedex  France |
| **Location of manufacturing sites** | **BRENNTAG MIDI PYRENEES**  1038 Avenue des Terres Noires  81370 SAINT SULPICE  FRANCE |
| **BRENNTAG NORMANDIE**  12 Sente des Jumelles  76710 MONTVILLE  FRANCE |
| **BRENNTAG MEDITERRANEE**  21 Boulevard de l’Europe  13127 VITROLLES  FRANCE |
| **BRENNTAG LOIRE BRETAGNE**  14 route de Plessis Bouchet  44802 SAINT HERBLAIN  FRANCE |
| **BRENNTAG MAINE BRETAGNE**  ZI de la promenade  53290 GREZ EN BOUERE  FRANCE |
| **BRENNTAG CHASSIEU**  5 rue arago  BP 19  69682 CHASSIEU cedex  France |
| **BRENNTAG ILE-DE-France** ZAC du closeau Impasse Lavoisier  77220 TOURNAN EN BRIE  France |

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

|  |  |
| --- | --- |
| **Active substance** | Active chlorine released from sodium hypochlorite |
| **Name of manufacturer** | **ARKEMA FRANCE - USINE DE JARRIE** |
| **Address of manufacturer** | Route Nationale 85  BP 1  38560 JARRIE  FRANCE |
| **Location of manufacturing sites** | Route Nationale 85  BP 1  38560 JARRIE  FRANCE |

**eCa:** the origin ARKEMA is identical to the one reported in the CAR of the active ingredient. The minimum purity set for reference sources in the CAR is as follow:

“aqueous solution with an active chlorine concentration ≤180g/kg. Sodium chlorate is a relevant impurity and should not exceed 5.4% of the active chlorine”, meaning a max content of 0.64% w/w in the biocidal product family.

### 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** | Hypochlorous acid, sodium salt |
| **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** | Aqueous solution with an available (active) chlorine concentration ≤18% w/w (6), in compliance with the EN 901:2013  One relevant impurity is present: sodium chlorate (≤5.4% of the active chlorine, meaning 0.64% in the biocidal product) |
| **Structural formula** | NaOCl |

#### Candidate(s) for substitution

Not applicable

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

#### Details on the compositions of the biocidal family, meta SPC and related products are reported in the confidential annex.

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Pure sodium hypochlorite  *(Active chlorine released from sodium hypochlorite)* |  | Active substance | 7681-52-9 | 231-668-3 | 13.1  *(12.5)* | 13.1  *(12.5)* |

Note that no technical material TC exists for sodium hypochlorite according to 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.

#### Information on technical equivalence

Not applicable, the applicant is a member of Euro Chlor, the applicant which supports the approval of the active substance. The origin Arkema is recognized at EU level according to Article 95. The plant location is also identical to the one mentioned in the CAR of the active substance (PT4&5) and complying with the reference specifications.

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

No substance of concern has been identified. Please see the confidential annex for further details.

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

Please refer to the confidential annex.

#### Type of formulation

|  |
| --- |
| SL – Soluble concentrate, liquid, water based |

**Part II - Second information level - meta SPC 1**

### Meta SPC 1 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 1 |
| --- | --- |

#### Suffix to the authorisation number

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

#### Product type(s)

| **Product type(s)** | 4 and 5 |
| --- | --- |

### Meta SPC 1 composition

#### Qualitative and quantitative information on the composition of the meta SPC 1

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Sodium hypochlorite  (active chlorine released from sodium hypochlorite) | Sodium hypochlorite | Pure active substance as NaClO  *(available chlorine equivalent)* | 7681-52-9 | 231-668-3 | 13.1  *(12.5)* | 13.1  *(12.5)* |
| Technical active substance (as aqueous solution of NaClO) | 100 | 100 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. For this dossier, the technical active substance is an aqueous solution of sodium hypochlorite with a claimed purity of 12.5% w/w (as av. Chlorine)

#### Type(s) of formulation of the meta SPC 1

|  |
| --- |
| SL – Soluble concentrate |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 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. 1B  Eye Dam. 1  Aquatic Acute 1  Aquatic chronic 2 |
| Hazard statement | H290 : May be corrosive to metals  H314: Causes severe skin bruns and eye damage  H318: Causes serious eye damage  H400: Very toxic to aquatic life  H411: Toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H290: May be corrosive to metals  H314: Causes severe skin bruns and eye damage  H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P260: Do not breathe dust/fume/gas/mist/vapours/spray  P264: Wash … thoroughly after handling.  P273: Avoid release to the environment  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): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.  P363: Wash contaminated clothing before reuse.  P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  P310: Immediately call a POISON CENTER or doctor/physician.  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.  P391: Collect spillage  P405: Store locked up.  P501: Dispose of contents/container in accordance with the national regulation |
|  | |
| Note | EUH 031: Contact with acids liberates toxic gas  EUH 206: Warning! Do not use together with other products. May release dangerous gases (chlorine).  EUH 071: Corrosive to the respiratory tract |

### Authorised use(s) of the META SPC 1

#### Use description

Table 1. Use # 1 – Disinfection of inner surfaces in human drinking water systems (pipes, reservoirs, other equipments) - filling or spraying

|  |  |
| --- | --- |
| **Product Type** | 4 |
| **Where relevant, an exact description of the authorised use** | Not relevant for this use. |
| **Target organism (including development stage)** | Bacteria, yeast |
| **Field of use** | Indoor |
| **Application method(s)** | Disinfection of equipment by spraying (low pressure).  The product is pumped into the reservoir of the pressure cleaner. The dilution is not performed manually.  Disinfection of equipment by filling with solution.  The product is pumped directly into the system (filling of equipment with disinfectant solution). |
| **Application rate(s) and frequency** | 2.0 mg av. Cl/L - The product is diluted to 0.0013% (v/v) to obtain an in-use concentration of 2 mg/L of av. Cl/L.  Contact time: 15 minutes, at 20 °C |
| **Category(ies) of users** | Industry, professional |
| **Pack sizes and packaging material** | HDPE Jerrycan 30 – 60L  HDPE Drum 60 – 220L  HDPE IBC: 600 – 1000L |

##### Use-specific instructions for use

|  |
| --- |
| Apply only on non porous surfaces  * Inform the registration holder if the treatment is ineffective. * Clean carefully the surfaces before application of the product * The diluted solution should be used immediately.   .  For spraying application:   * Dose the concentrate in the reservoir of the pressure cleaner to obtain an in-use concentration of 2.0 mg av. Cl/L (dilution 0.0013% (v/v)). * Use a pressure washer or other mechanical sprayer to apply the diluted solution at an application rate of 40 mL/m². * Make sure to wet surfaces completely. Allow to take effect for at least 15 minutes, then rinse (low pressure) with clean water.   For filling application :   * Fill the equipment with the solution by dosing the concentrate to obtain an in-use concentration of 2.0 mg av. Cl/L (dilution 0.0013% (v/v)). * Make sure to wet surfaces completely. Allow to take effect for at least 15 minutes, then rinse (low pressure) with clean water. |

##### 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

|  |
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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 # 2 – Disinfection of inner surfaces in veterinary water systems (pipes, reservoirs, other equipments) by filling or spraying

|  |  |
| --- | --- |
| **Product Type** | 4 |
| **Where relevant, an exact description of the authorised use** | Not relevant for this use. |
| **Target organism (including development stage)** | Bacteria, yeast |
| **Field of use** | Indoor |
| **Application method(s)** | Disinfection of equipment by spraying (low pressure).  The product is pumped into the reservoir of the pressure cleaner. The dilution is not performed manually.  Disinfection of equipment by filling with solution.  The product is pumped directly into the system (filling of equipment with disinfectant solution). |
| **Application rate(s) and frequency** | 2.0 mg av. Cl/L - The product is diluted at 0.0013% (v/v) to obtain an in-use concentration of 2 mg av. Cl/L.  Contact time: 15 minutes, at 20 °C. |
| **Category(ies) of users** | Industry, professional |
| **Pack sizes and packaging material** | HDPE Jerrycan 30 – 60L  HDPE Drum 60 – 220L  HDPE IBC: 600 – 1000L |

##### Use-specific instructions for use

|  |
| --- |
| Apply only on non porous surfaces  * Inform the registration holder if the treatment is ineffective. * Clean carefully the surfaces before application of the product * The diluted solution should be used immediately.   For spraying application:   * Dose the concentrate in the reservoir of the pressure cleaner to obtain an in-use concentration of 2.0 mg av. Cl/L (dilution 0.0013% (v/v)). * Use a pressure washer or other mechanical sprayer to apply the diluted solution at an application rate of 40 ml/m². * Make sure to wet surfaces completely. Allow to take effect for at least 15 minutes, then rinse (low pressure) with clean water.   For filling application:   * Fill the equipment with the solution by dosing the concentrate to obtain an in-use concentration of 2.0 mg av. Cl/L (dilution 0.0013% (v/v)). * Make sure to wet surfaces completely. Allow to take effect for at least 15 minutes, then rinse (low pressure) with clean water. |

##### 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 3. Use # 3 – Disinfection of water in drinking water companies

|  |  |
| --- | --- |
| **Product Type** | 5 |
| **Where relevant, an exact description of the authorised use** | Not relevant for this use |
| **Target organism (including development stage)** | Bacteria, viruses |
| **Field of use** | Indoor  Outdoor |
| **Application method(s)** | Continuous application into water in drinking water systems by drinking water suppliers |
| **Application rate(s) and frequency** | The product is diluted at 0.00013% (v/v) to obtain an in-use concentration of 0.2 mg av Cl/L /L of active chlorine.  time delay: 25 minutes at 15 °C |
| **Category(ies) of users** | Industry, professional |
| **Pack sizes and packaging material** | HDPE Jerrycan 30 – 60L  HDPE Drum 60 – 220L  HDPE IBC: 600 – 1000L |

##### Use-specific instructions for use

|  |
| --- |
| * Dose the concentrate in the drinking water system in order to apply an in-use concentration of 0.2 mg av Cl/L (dilution 0.00013% (v/v)) to water. * National limits on the applied concentration of available chlorine in the water may apply. |

##### 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 4. Use # 4 – Disinfection of veterinary water

|  |  |
| --- | --- |
| **Product Type** | 5 |
| **Where relevant, an exact description of the authorised use** | Not relevant for this use |
| **Target organism (including development stage)** | Bacteria, viruses |
| **Field of use** | Indoor  Outdoor |
| **Application method(s)** | Continuous application into water in drinking water systems by drinking water supplier |
| **Application rate(s) and frequency** | The product is diluted at 0.00013% (v/v) to obtain an in-use concentration of 0.2 mg av. Cl/L  time delay: 25 minutes at 15 °C |
| **Category(ies) of users** | Industry, professional |
| **Pack sizes and packaging material** | HDPE Jerrycan 30 – 60L  HDPE Drum 60 – 220L  HDPE IBC: 600 – 1000L |

##### Use-specific instructions for use

|  |
| --- |
| * Dose the concentrate in the drinking water system in order to apply an in-use concentration of 0.2 mg av. Cl/L (dilution 0.00013% (v/v)) to water. * National limits on the applied concentration of available chlorine in the water may apply. |

##### 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

|  |
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| - |

##### 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

#### Instructions for use

|  |
| --- |
| * Always read the label or leaflet before use and follow all the instructions provided. * Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.). * Inform the registration holder if the treatment is ineffective. * Products should not be used in conjunction with acids or ammonia |

#### Risk mitigation measures

|  |
| --- |
| During semi-automatic pumping of the product, wear :   * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * coated coverall (at least category III type 6), * a respiratory mask at least APF 10 (respiratory mask type to be specified by the authorisation holder within the product information), * goggles   During maintenance/cleaning of dosing pumps, wear:   * protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), * coated coverall (at least category III type 6), * a respiratory mask (respiratory mask type to be specified by the authorisation holder within the product information), * goggles   The professional bystander needs to observe the same type of RPE as the worker during semi-automatic pumping of the product (APF 10) and maintenance of dosing pumps (any substance/task respirator). |

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

|  |
| --- |
| IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.  * IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. * IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. * IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. * In case of impaired consciousness place in recovery position and seek medical advice immediately. * Keep the container or label available. |

#### 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 * Store away from light * Shelf life: 14 days. |

### Other information

|  |
| --- |
| Please note that some member states including France, after primary disinfection, request to maintain a residual level of available chlorine in drinking water in the pipes as a precautionary measure. This additional amount, claimed by the applicant as “Secondary disinfection: 0.2 mg/L available chlorine (residual)” has been considered as covered by the primary disinfection. |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **Javel Standard** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Sodium hypochlorite  (active chlorine released from sodium hypochlorite) | Sodium hypochlorite | Pure active substance as NaClO (*available chlorine equivalent)* | 7681-52-9 | 231-668-3 | 13.1  *(12.5)* |
| Technical active substance (as aqueous solution of NaClO) |  |  | 100 |

Note that no TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. For this dossier, the technical active substance is defined as an aqueous solution of sodium hypochlorite with a claimed purity of 12.5% w/w as av. Chlorine.

### 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 | 30 - 60L | HDPE | HDPE screw cap | Professional | Yes |
| Drum | 30 – 220L | HDPE | HDPE screw cap | Professional | Yes |
| IBC | 600 – 1000L | HDPE | HDPE screw cap | Professional | Yes |

### Documentation

#### Data submitted in relation to product application

See Annex 3.1

#### Access to documentation

The applicant is a member of Euro Chlor and has access to the active substance dossier. (See Section 13 of the IUCLID). No letter of access is required.

## Assessment of the biocidal product family

### Intended use(s) as applied for by the applicant

Table 1. Use # 1.1 – Disinfection of inner surfaces in human drinking water systems (pipes, reservoirs, other equipments) by filling or spraying

|  |  |
| --- | --- |
| **Product Type** | 4 |
| **Where relevant, an exact description of the authorised use** | Not relevant for this use. |
| **Target organism (including development stage)** | Bacteria, yeast |
| **Field of use** | Indoor |
| **Application method(s)** | Disinfection of equipment by spraying (low pressure).  The product is pumped into the reservoir of the pressure cleaner. There is no manual dilution step.  Disinfection of equipment by filling with solution.  The product is pumpeddirectly into the system (filling of equipment with disinfectant solution). |
| **Application rate(s) and frequency** | 40 mL spray per m2 - 2,0 mg av. Cl/L - The product should be diluted to 0.00129765%(v/v) to obtain an in-use concentration of 2 mg/L of active chlorine  Duration of the task: ca 1 hour day (minimum contact time with the disinfection solution: 15 min)  2.0 mg av. Cl/L - The product should be diluted to ca. 0.00129765% (v/v) to obtain an in-use concentration of 2 mg/L of active chlorine.  Contact time: 15 minutes minimum |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Jerrycan: 30 - 60L  Drum: 60 - 220 L  IBC: 600 - 1000 L |

Table 2. Use # 1.2 – Disinfection of inner surfaces in veterinary water systems (pipes, reservoirs, other equipments…) by filling or spraying

|  |  |
| --- | --- |
| **Product Type** | 4 |
| **Where relevant, an exact description of the authorised use** | Not relevant for this use. |
| **Target organism (including development stage)** | Bacteria, yeast |
| **Field of use** | Indoor |
| **Application method(s)** | Disinfection of equipment by spraying (low pressure).  The product is pumped into the reservoir of the pressure cleaner. There is no manual dilution step.  Disinfection of equipment by filling with solution.  The product is pumpeddirectly into the system (filling of equipment with disinfectant solution). |
| **Application rate(s) and frequency** | 40 mL spray per m2 - 2,0 mg av. Cl/L - The product should be diluted to 0.00129765% (v/v) to obtain an in-use concentration of 2 mg/L of active chlorine  Duration of the task: ca 1 hour day (minimum contact time with the disinfection solution: 15 min)  2.0 mg av. Cl/L - The product should be diluted to 0.00129765% (v/v) to obtain an in-use concentration of 2 mg/L of active chlorine.  Contact time: 15 minutes minimum |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Jerrycan: 30 - 60L  Drum: 60 - 220 L  IBC: 600 - 1000 L |

Table 3. Use # 1.3 – Disinfection of water in drinking water companies

|  |  |
| --- | --- |
| **Product Type** | 5 |
| **Where relevant, an exact description of the authorised use** | Not relevant for this use |
| **Target organism (including development stage)** | Bacteria, viruses |
| **Field of use** | Indoor  Outdoor |
| **Application method(s)** | Continuous application into water in drinking water systems by drinking water suppliers.  0.2 mg av Cl/L - The product should be diluted to 0.000129765%(v/v) to obtain an in-use concentration of 0.2 mg/L of active chlorine |
| **Application rate(s) and frequency** | Continuous application to achieve 0.2 mg av Cl/L |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Jerrycan: 30 - 60L  Drum: 60 - 220 L  IBC: 600 - 1000 L |

Table 4. Use # 1.4 – Disinfection of stationary water in reservoirs

|  |  |
| --- | --- |
| **Product Type** | 5 |
| **Where relevant, an exact description of the authorised use** | Not relevant for this use |
| **Target organism (including development stage)** | Bacteria, viruses |
| **Field of use** | Indoor  Outdoor |
| **Application method(s)** | 0.2 mg av Cl/L - The product should be diluted to 0.000129765%(v/v) to obtain an in-use concentration of 0.2 mg/L of active chlorine  Continuous application into water |
| **Application rate(s) and frequency** | Continuous application to achieve 0.2 mg av Cl/L |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Jerrycan: 30 - 60L  Drum: 60 - 220 L  IBC: 600 - 1000 L |

Table 5. Use # 1.5 – Disinfection of veterinary water

|  |  |
| --- | --- |
| **Product Type** | 5 |
| **Where relevant, an exact description of the authorised use** | Not relevant for this use |
| **Target organism (including development stage)** | Bacteria, viruses |
| **Field of use** | Indoor  Outdoor |
| **Application method(s)** | Continuous application into water in drinking water systems by drinking water supplier.  0.2 mg av Cl/L - The product should be diluted to 0.000129765%(v/v) to obtain an in-use concentration of 0.2 mg/L of active chlorine |
| **Application rate(s) and frequency** | Continuous application to achieve 0.2 mg av Cl/L |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Jerrycan: 30 - 60L  Drum: 60 - 220 L  IBC: 600 - 1000 L |

### Physical, chemical and technical properties

The physico chemical properties have been performed using the three formulations Javel Standard, Bactivel 50 and Bactivel 55. The table below summarizes the assessment of the physico chemical properties for the three formulations. Please note that only Javel Standard is now supported for an authorisation. Some data were provided for products which are not any supported. Nevertheless, results are reported below for information and FR CA has precised when data refer to unclaimed products.

The packaging proposed are made of HDPE.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **GLP** | **Reference** | **eCA assessment** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | EPA OPPTS 830.6303 (Physical State) | 12.5 % (Javel Standard) batch 182411608E  13.5% Bactivel 50 batch 182411608A  14.5% Bactivel 55, batch 182411608B | Liquid | Y | Martinez, M.P. (2018)  Report No CH - 626/2018  621/2018  616/2018 | Acceptable. |
| Colour at 20 °C and 101.3 kPa | EPA OPPTS 830.6302 (Color) | 12.5 % (Javel Standard) batch 182411608E  13.5% Bactivel 50 batch 182411608A  14.5% Bactivel 55, batch 182411608B | Yellow | Y | Martinez, M.P. (2018)  Report No CH - 626/2018  621/2018  616/2018 | Acceptable. |
| Odour at 20 °C and 101.3 kPa | EPA OPPTS 830.6304 (Odor) | 12.5 % (Javel Standard) batch 182411608E  13.5% Bactivel 50 batch 182411608A  14.5% Bactivel 55, batch 182411608B | Characteristic (chlorine) | Y | Martinez, M.P. (2018)  Report No CH - 626/2018  621/2018  616/2018 | Acceptable. |
| Acidity / alkalinity | OECD 122  CIPAC MT 75  CIPAC MT 31 | 12.5 % (Javel Standard) batch 182411608E  13.5% Bactivel 50 batch 182411608A  14.5% Bactivel 55, batch 182411608B | Sodium hypochlorite solutions are kept alkaline in order to decrease the degradation rateof hypochlorite to chloride and chlorate.  Javel Standard:  pH (neat): 13.3  pH (1% w/v): 11.4  Alkalinity: 1.47% w/w as NaOH  Bactivel 50  pH (neat): 12.9  pH (1% w/v): 11.0  Alkalinity: 0.49% w/w as NaOH  Bactivel 55  pH (neat): 13.0  pH (1% w/v): 11.0  Alkalinity: 0.51% w/w as NaOH | Y | Martinez, M.P. (2018)  Report No CH - 626/2018  621/2018  616/2018 | Acceptable. |
| Relative density / bulk density |  |  | In storage stability studies, density has been reported in the certificates of analysis:  Javel standard (Lot ref 182411608E): 1.233  Bactivel 50 (Lot ref 182411608A): 1.170  Bactivel 55 (Lot ref 182411608B): 1.202 |  | Martinez, M.P. (2018)  Report No CH - 626/2018  621/2018  616/2018 | Acceptable. |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 (Storage Stability)  GIFAP Monograph No. 17, 2nd edition, June 2009 | 12.5 % (Javel Standard) batch 182411608E  13.5% Bactivel 50 batch 182411608A  14.5% Bactivel 55, batch 182411608B | See below – study performed at 20 deg C. | Y | Martinez, M.P. (2018)  Report No CH - 626/2018  621/2018  616/2018 | No accelerated storage stability studyhas been provided. This is consistent because sodium hypochlorite is not stable at high temperature. Consequently, the products should not be storedat a temperature higher than 30°C. |
| Storage stability test – **long term storage at ambient temperature** | CIPAC MT 46.3 (Storage Stability)  GIFAP Monograph No. 17, 2nd edition, June 2009  Analytical method validated for active chlorine (method 623/2018)  OPPTS 830.6302  OPPTS 830.6303  OPPTS 830.6304  OECD 122  CIPAC MT 75.3  CIPAC MT 31 | 12.5 % (Javel Standard) batch 182411608E | **Packaging tested:** HDPE bottle  **Active substance content(n=3 at each check point)**  Before storage  12.7% w/w active chlorine  Hypochlorite (equivalent, f=0.726): 9.2% w/w hypochlorite)  NaClO (equivalent, f=1.05):13.3% w/w  Sodium chlorate: 3.6g/L (from certificate of analysis lot ref. 182411608E), meaning 0.3%w/w in the product and 2.3% w/w related to active chlorine (<5.4% w/w chlorate/active chlorine set in regulation)  Sodium bromate: 6.5mg/L (from certificate of analysis lot ref. 182411608E)  After storage  10% decrease in active chlorine content is reached in a delay time of 14 -15 days.  At each check point, an aliquot of the sample was used for analysis and the original commercial packaging was re-weighted and re-placed into the thermostatically controlled oven until the next check point.  After 10 days of storage at 20°C  Active Chlorine: 11.8% w/w (-7%) Hypochlorite (equivalent, f=0.726) : 8.6 % w/w  NaOCl (equivalent, f=1.05): 12.4% w/w  After 20 days of storage at 20°C  Active Chlorine: 10.9% w/w (-14%) Hypochlorite (equivalent, f=0.726) : 7.9% w/w  NaOCl (equivalent, f=1.05): 11.5% w/w  After 30 days of storage at 20°C  Active Chlorine: 10.4% w/w (-18%) Hypochlorite (equivalent, f=0.726) : 7.5% w/w  NaOCl (equivalent, f=1.05): 10.9% w/w  After 40 days of storage at 20°C  Active Chlorine: 9.9% w/w (-22%) Hypochlorite (equivalent, f=0.726) : 7.2% w/w  NaOCl (equivalent, f=1.05): 10.4% w/w  **Appearance**  Before storage  Yellow liquid with chlorine odour  After storage (10, 20, 30, 40 days)  Yellow liquid with chlorine odour  **Packaging**  Appearance before and after 10, 20, 30, 40 days storage  No deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena.  Weight variations (n=1 at each check point)  10 days: -0.07%  20 days: -0.02%  30 days: -0.01%  40 days: -0.01%  **pH (neat, n=2 at each check point)**  Before storage: 13.3  After storage  10 days: 13.1  20 days: 13.3  30 days: 13.3  40 days: 13.3  **pH (at 1% w/v in water, n=2 at each check point)**  Before storage: 11.4  After storage  10 days: 11.3  20 days: 11.4  30 days: 11.4  40 days: 11.4  **alkalinity (n=3 at each check point)**  Before storage: 1.47%w/w as NaOH  After storage  10 days: 1.47% w/w as NaOH  20 days: 1.48% w/w as NaOH  30 days: 1.51% w/w as NaOH  40 days: 1.51% w/w as NaOH  **persistent foaming**  According to the composition, no foam is expected to be formed (no surfactants). This has been confirmed with study Halbwachs P (2020) Report No. 19-901026-002 (see results in the endpoint persistent foaming).  **dilution stability**  According to the composition of the products, dilution stability is not relevant. The product is highly soluble and formation of sediment is not expected. Such test would not provided relevant information. | Y | Martinez, M.P. (2018)  Report No CH - 626/2018 | The storage stability study at 20°C has only been performed for 40 days. At each check point (0, 10, 20, 30 and 40 days), a.i content (active chlorine, hypochlorite), pH, alkalinity, appearance of test item and packaging have been reported. The applicant claims a stability of 14 days, based on the extrapolation of the results between the check points t=10d and t=20d and the estimate exceedance of the 10% variations established for the assessment of shelf life. The product can be considered stable up to 14 days .  Dilution stability is not relevant due to the composition (highly soluble product and no sediment expected). Persistent foam is not expected since no surfactants are used. This has been confirmed with a study (see endpoint persistent foaming).  Chlorate content has been measured and results are reported in study RICAU H (2020) Report No. 19-901026-003, described below. |
| Storage stability test – **long term storage at ambient temperature** | CIPAC MT 46.3 (Storage Stability)  Analytical method validated (study 19-901026-004 for active chlorine and 19-901026-005 for sodium c) | 12.5% Javel Standard, batch 1608E | T0 of storage at mean 22.6°C,  Active Chlorine: 12.9 % w/w  NaOCl (equivalent, f=1.05): 13.6 % w/w Chlorate in test item: 0.194% w/w  Sodium chlorate in test item: 0.247% w/wSodium chlorate: 1.9% expressed as % av Cl content  T=12 days of storage at mean 22.6°C,  Active Chlorine: 11.9 % w/w (-7.8%)  NaOCl (equivalent, f=1.05): 12.5 % w/w Chlorate in test item: 0.599% w/w  Sodium chlorate in test item: 0.765% w/wSodium chlorate: 6.4% expressed as % av Cl content  T=14 days of storage at mean 22.6°C,  Active Chlorine: 11.7 % w/w (-9.3%)  NaOCl (equivalent, f=1.05): 12.3 % w/w  Chlorate in test item: 0.645% w/wSodium chlorate in test item: 0.823% w/wSodium chlorate: 7% expressed as % av Cl content | Y | RICAU H (2020) Report No. 19-901026-003 | The content of sodium chlorate related to av. chlorine following storage is higher than the specification (sodium chlorate: max 5.4% of av chlorine)  The maximum level of chlorates in the product has been taken into account in the section human health and is acceptable. |
|  | CIPAC MT 46.3 (Storage Stability)  GIFAP Monograph No. 17, 2nd edition, June 2009  Analytical method validated for active chlorine (method 618/2018)  OPPTS 830.6302  OPPTS 830.6303  OPPTS 830.6304  OECD 122  CIPAC MT 75.3  CIPAC MT 31 | 13.5% Bactivel 50 batch 182411608A | **Packaging tested:** HDPE bottle  **active substance content(n=3 at each check point)**  Before storage  Active chlorine: 13.7% w/w  Hypochlorite (equivalent, f=0.726): 10.0% w/w  Sodium chlorate: 6.1g/L (from certificate of analysis lot ref. 182411608A), meaning 0.5%w/w in the product and 3.8% w/w related to active chlorine (<5.4% w/w chlorate/active chlorine set in regulation)  Sodium bromate: 6.3mg/L (from certificate of analysis lot ref. 182411608A)  After storage  10% decrease in active chlorine content is reached in a delay time of 14 days.  At each check point, an aliquot of the sample was used for analysis and the original commercial packaging was re-weighted and re-placed into the thermostatically controlled oven until the next check point.  After 10 days of storage at 20°C  Active Chlorine: 12.6% w/w (-8%) Hypochlorite (equivalent, f=0.726): 9.1% w/w  NaOCl (equivalent, f=1.05): 13.2% w/w  After 20 days of storage at 20°C  Active Chlorine: 11.8% w/w (-14%) Hypochlorite (equivalent, f=0.726) : 8.5% w/w  NaOCl (equivalent, f=1.05):12.4% w/w  After 30 days of storage at 20°C  Active Chlorine: 10.9% w/w (-20.5%) Hypochlorite (equivalent, f=0.726): 7.9% w/w  NaOCl (equivalent, f=1.05): 11.5% w/w  After 40 days of storage at 20°C  Active Chlorine: 10.1% w/w (-26%) Hypochlorite (equivalent, f=0.726) : 7.3% w/w  NaOCl (equivalent, f=1.05): 10.6% w/w  **Appearance**  Before storage  Yellow liquid with chlorine odour  After storage (10, 20, 30, 40 days)  Yellow liquid with chlorine odour  **Packaging**  Appearance before and after 10, 20, 30, 40 days storage  No deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena.  Weight variations (n=1 at each check point)  10 days: -0.11%  20 days: -0.13%  30 days: -0.12%  40 days: -0.12%  **pH (neat, n=2 at each check point)**  Before storage: 12.9  After storage  10 days: 12.8  20 days: 13.0  30 days: 12.9  40 days: 12.9  **pH (at 1% w/v in water, n=2 at each check point)**  Before storage: 11.0  After storage  10 days: 11.0  20 days: 11.1  30 days: 11.0  40 days: 11.0  **alkalinity (n=3 at each check point)**  Before storage: 0.49% w/w as NaOH  After storage  10 days: 0.49% w/w as NaOH  20 days: 0.48 w/w as NaOH  30 days: 0.48% w/w as NaOH  40 days: 0.47% w/w as NaOH  **persistent foaming**  Persistent foam is not expected since no surfactants are used. This has been confirmed with a study (see endpoint persistent foaming).  **dilution stability**  According to the composition of the products, dilution stability is not relevant. The product is highly soluble and formation of sediment is not expected. Such test would not provided relevant information. | Y | Martinez, M.P. (2018)  Report No CH -  621/2018 | **Please note that this product is not anymore claimed.**  The storage stability study at 20°C has only been performed for 40 days. At each check point (0, 10, 20, 30 and 40 days), a.i content (active chlorine, hypochlorite), pH, alkalinity, appearance of test item and packaging have been reported. The applicant claims a stability of 14 days, based on the extrapolation of the results between the check points t=10d and t=20d and the estimate exceedance of the 10% variations established for the assessment of shelf life. The product can be considered stable up to 14 days .Dilution stability is not relevant due to the composition (highly soluble product and no sediment expected). Persistent foam is not expected since no surfactants are used. This has been confirmed with a study (see endpoint persistent foaming).  Chlorate content has not been monitored for this product. |
|  | CIPAC MT 46.3 (Storage Stability)  GIFAP Monograph No. 17, 2nd edition, June 2009  Analytical method validated for active chlorine (method 609/2018)  OPPTS 830.6302  OPPTS 830.6303  OPPTS 830.6304  OECD 122  CIPAC MT 75.3  CIPAC MT 31 | 14.5% Bactivel 55, batch 182411608B | **Packaging tested:** HDPE bottle  **active substance content(n=3 at each check point)**  Before storage  Active chlorine: 14.7% w/w  Hypochlorite (equivalent): 10.7% w/w  Sodium chlorate: 5.2g/L (from certificate of analysis lot ref. 182411608B), meaning 0.4%w/w in the product and 3% w/w related to active chlorine (<5.4% w/w chlorate/active chlorine set in regulation)  Sodium bromate: 6.5mg/L (from certificate of analysis lot ref. 182411608B)  After storage  10% decrease in active chlorine content is reached in a delay time of 13 - 14 days.  At each check point, an aliquot of the sample was used for analysis and the original commercial packaging was re-weighted and re-placed into the thermostatically controlled oven until the next check point.  After 10 days of storage at 20°C  Active Chlorine: 13.5% w/w (-8%) Hypochlorite (equivalent, f=0.726) : 9.8% w/w  NaOCl (equivalent, f=1.05): 14.2% w/w  After 20 days of storage at 20°C  Active Chlorine: 12.6% w/w (-14%) Hypochlorite (equivalent, f=0.726) : 9.2% w/w  NaOCl (equivalent, f=1.05): 13.2% w/w  After 30 days of storage at 20°C  Active Chlorine: 11.9% w/w (-19%) Hypochlorite (equivalent, f=0.726) : 8.6% w/w  NaOCl (equivalent, f=1.05): 12.5% w/w  After 40 days of storage at 20°C  Active Chlorine: 11.1% w/w (-24.5%) Hypochlorite (equivalent, f=0.726): 8.0% w/w  NaOCl (equivalent, f=1.05): 11.7% w/w  **Appearance**  Before storage  Yellow liquid with chlorine odour  After storage (10, 20, 30, 40 days)  Yellow liquid with chlorine odour  **Packaging**  Appearance before and after 10, 20, 30, 40 days storage  No deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena.  Weight variations (n=1 at each check point)  10 days: -0.10%  20 days: -0.08%  30 days: -0.05%  40 days: -0.07%  **pH (neat, n=2 at each check point)**  Before storage: 13.0  After storage  10 days: 12.9  20 days: 13.0  30 days: 12.9  40 days: 12.9  **pH (at 1% w/v in water, n=2 at each check point)**  Before storage: 11.0  After storage  10 days: 11.0  20 days: 11.1  30 days: 11.1  40 days: 11.0  **alkalinity (n=3 at each check point)**  Before storage: 0.51% w/w as NaOH  After storage  10 days: 0.49% w/w as NaOH  20 days: 0.49% w/w as NaOH  30 days: 0.49% w/w as NaOH  40 days: 0.47% w/w as NaOH  **persistent foaming**  Persistent foam is not expected since no surfactants are used. This has been confirmed with a study (see endpoint persistent foaming).  **dilution stability**  According to the composition of the products, dilution stability is not relevant. The product is highly soluble and formation of sediment is not expected. Such test would not provided relevant information. | Y | Martinez, M.P. (2018)  Report No CH - 616/2018 | **Please note that this product is not anymore claimed.**  The storage stability study at 20°C has only been performed for 40 days. At each check point (0, 10, 20, 30 and 40 days), a.i content (active chlorine, hypochlorite), pH, alkalinity, appearance of test item and packaging have been reported. The applicant claims a stability of 14 days, based on the extrapolation of the results between the check points t=10d and t=20d and the estimate exceedance of the 10% variations established for the assessment of shelf life. The product can be considered stable up to 14 days.  Dilution stability is not relevant due to the composition (highly soluble product and no sediment expected). Persistent foam is not expected since no surfactants are used. This has been confirmed with a study (see endpoint persistent foaming).  Chlorate content has not been monitored for this product. |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3  Analytical method validated (study 19-901026-004, titration) | 12.5% Javel Standard, batch 1608E | At the start of the test, the test item was a homogeneous clear yellow limpid liquid.  The appearance of the test item was considered to be stable after a low temperature stability at 0 ± 2 °C for 7 days, no change was observed in the test item aspect.  Av chlorine before storage: 12.9% w/w  NaClO (equivalent, f=1.05): 13.6% w/w  Av chlorine after storage 7 days at 0°C: 12.8% w/w  NaClO (equivalent, f=1.05): 13.4% w/w  Appearance before storage: homogeneous clear yellow limpid liquid  Appearance after 7 days at 0°C: homogeneous clear yellow limpid liquid | Y | Halbwachs P (2020) Report No 19-901026-001 | Acceptable. The product is stable at low temperature. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | NaOCl solutions are unstable in the presence of UV and increased temperature. Products should be transported in opaque/UV resistant packaging. |  |  | eCA agrees with the applicant that NaOCl is unstable when exposed to light. However, HDPE packaging is not considered barrier to light. For this packaging, the mitigation measure “Store away from light” should be added on the label. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | In water sodium hypochlorite degrades to chlorate and chloride. The degradation rate is a function of the active chlorine concentration and of temperature. For a sodium hypochlorite aqueous solution with an active chlorine concentration of 10% w/w, the half-life is reported to be 800 days at 15 °C; 220 days at 25 °C; 3.5 days at 60 °C; 0.079 days at 100 °C. Whereas, for an active chlorine concentration of 5% w/w, the half-life is reported to be 5000 days at 15°C; 790 days at 25 °C; 13.5 days at 60 °C; 0.25 days at 100°C. |  |  | NaOCl is sensitive to high temperatures. Consequently, the products should not be stored at a temperature higher than 30°C |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | 12.5 % (Javel Standard) batch 182411608E  13.5% Bactivel 50 batch 182411608A  14.5% Bactivel 55, batch 182411608B | There was no visible corrosion in the packaging in the stability studies (PE bottle with vented cap)  The product is a dilution of the active substance therefore read across to the active substance data set is applicable. Thermal stability / Temperature of decomposition - not determined, since sodium hypochlorite in its pure form is highly unstable. Common metals should never be used for the storage and handling of sodium hypochlorite aqueous solutions. Suitable materials are: PVDF,PTFEE, PVC, CPVC. | Y | Martinez, M.P. (2018)  Report No CH - 626/2018  621/2018  616/2018 | Compatibility with HDPE has been demonstrated. |
| Wettability |  |  | Not applicable |  |  | Not relevant for SL formulation. |
| Suspensibility, spontaneity and dispersion stability |  |  | Not applicable |  |  | Not relevant for SL formulation. |
| Wet sieve analysis and dry sieve test |  |  | Not applicable |  |  | Not relevant for SL formulation. |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not applicable |  |  | Not relevant for SL formulation. |
| Disintegration time |  |  | Not applicable |  |  | Not relevant for SL formulation. |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not applicable |  |  | Not relevant for SL formulation. |
| Persistent foaming | CIPAC MT 47.2 | 12.5 % (Javel Standard), batch 1608E | No foam was observed after several inversions of the test item diluted at 0.2 mg/L and 2 mg/L in standard water D at 20 °C ± 2 °C after 10s, 1 min, 3 min and 12 min of standing | Y | Halbwachs P (2020) Report No. 19-901026-002 | Acceptable. The product is a foaming formulation. |
| Flowability/Pourability/Dustability |  |  | Not applicable |  |  | Not relevant for SL formulation. |
| Burning rate — smoke generators |  |  | Not applicable |  |  | Not relevant for SL formulation. |
| Burning completeness — smoke generators |  |  | Not applicable |  |  | Not relevant for SL formulation. |
| Composition of smoke — smoke generators |  |  | Not applicable |  |  | Not relevant for SL formulation. |
| Spraying pattern — aerosols |  |  | Not applicable |  |  | Not relevant for SL formulation. |
| Physical compatibility |  |  | Products are corrosive to metals |  |  | 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 |  |  | Incompatible with acids, ammonia and metals |  |  | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mentions EUH031 “contact with acids liberates toxic gas” and EUH 206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” are proposed by eCA for all products. |
| Degree of dissolution and dilution stability |  |  | Not applicable, The products are the same as the active substance and are aqueous dilutions. |  |  | Not relevant for this family since the products are highly soluble and no sediments are expected to be formed. |
| Surface tension |  |  | The product is a dilution of the active substance therefore read across to the active substance data set is applicable.  The surface tension of the tested solution (sodium hypochlorite aqueous solution with an active chlorine concentration of 24.3% w/w) is 82.4 ± 0.8 mN/m at 20.2-20.3 °C. |  | See CAR | Based on the composition described in annex, cross reading with data from the CAR is acceptable. |
| Viscosity |  |  | The product is a dilution of the active substance therefore read across to the active substance data set is applicable.  Dynamic viscosity is 6.2-6.6 mPa s at 20 ± 0.2 °C; 4.0 mPa s at 40 ± 0.2 °C. |  | See CAR | Based on the composition described in annex, cross reading with data from the CAR is acceptable. |

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| **Conclusion on the physical, chemical and technical properties of the biocidal product family** |
| The product is similar to the technical active substance, i.e. aqueous dilutions of sodium hypochlorite.Sodium hypochlorite solution is a yellow liquid with a characteristic chlorine odour.  No accelerated and low storage stability studies have been provided. Only a storage stability study 40 days at 20°C in HDPE packaging has been provided. A loss of 10% active substance occurs after 14 days of manufacture at room temperature (20°C) in HDPE packaging, meaning that the shelf life is only 14 days . The product should be stored at a temperature below 30°C.  Chlorate contents have been provided. Level before storage is acceptable, while after 12-14 days at 22.6°C, the content exceeds the limit set in regulation (around 7% w/w of av. chlorine, while the limit is 5.4% w/w of av. Chlorine). The maximum level of chlorates in the product has been taken into account in the section human health and is acceptable.  No change was observed in either the test item aspect or the active chlorine content after storage at 0 ± 2 °C for 7 days.  The product does not show signs of foaming at either 0.2 or 2.0 mg/l dilution at 20 ° C.  The solutions will also decompose in the presence of sunlight/UV. Products should be kept protected from light.  Considering the nature of the active substance, the products of the family should not be used in conjunction with acids or ammonia.  **Labelling mention:**  Shelf life: 14 days  Do not store at a temperature higher than 30°C  Keep away from light  EUH031 “Contact with acids liberates toxic gas”  EUH206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)”  The products of the family should not be used in conjunction with acids or ammonia |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa assessment** |
| --- | --- | --- | --- | --- | --- |
| Explosives |  |  | The product is a dilution of the active substance therefore read across to the active substance data set is applicable  A sodium hypochlorite aqueous solution with an active chlorine concentration of 15.9% w/w was considered for explosive properties.  The active substance is not explosive. | See CAR | According to the CAR (confirmatory data peer reviewed in 2018), solutions of NaClO (16.7%) are not explosive. Based on the composition of the products, cross reading is acceptable since data from the CAR are a worst case. |
| Flammable gases |  |  | Not applicable |  | Not relevant |
| Flammable aerosols |  |  | Not applicable |  | Not relevant |
| Oxidising gases |  |  | Not applicable |  | Not relevant |
| Gases under pressure |  |  | Not applicable |  | Not relevant |
| Flammable liquids |  |  | The product is a dilution of the active substance therefore read across to the active substance data set is applicable. Sodium hypochlorite solutions are not known to spontaneously ignite when exposed to air or to emit flammable gases | See CAR | In the CAR, the flash point reported is 111°C (24.3% w/w active chlorine). Based on the composition of the products, cross reading is acceptable since data from the CAR are a worst case. |
| Flammable solids |  |  | Not applicable |  | Not relevant |
| Self-reactive substances and mixtures |  |  | The product is a dilution of the active substance therefore read across to the active substance data set is applicable. The study does not need to be conducted because the substance is an aqueous liquid | See CAR | Not relevant since no compound is classified explosive or self reactive. |
| Pyrophoric liquids |  |  | The product is a dilution of the active substance therefore read across to the active substance data set is applicable. The study does not need to be conducted because the substance is an aqueous liquid | See CAR | Not relevant |
| Pyrophoric solids |  |  | The product is a dilution of the active substance therefore read across to the active substance data set is applicable. The study does not need to be conducted because the substance is an aqueous liquid | See CAR | Not relevant |
| Self-heating substances and mixtures |  |  | The product is a dilution of the active substance therefore read across to the active substance data set is applicable. The study does not need to be conducted because the substance is a liquid | See CAR | 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 |  |  | The product is a dilution of the active substance therefore read across to the active substance data set is applicable. The study does not need to be conducted because the substance is an aqueous liquid | See CAR | 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. |
| Oxidising liquids |  |  | The product is a dilution of the active substance therefore read across to the active substance data set is applicable. | See CAR | According to the CAR (confirmatory data peer reviewed in 2018), solutions of NaClO (25.3%) are not considered as oxidizing liquid. Cross reading is acceptable since data from the CAR are a worst case. |
| Oxidising solids |  |  | Not applicable |  | Not relevant |
| Organic peroxides |  |  | Not applicable |  | Not relevant |
| Corrosive to metals |  |  | Classified for corrosion to metals |  | A classification Met. Corr. 1 has been proposed by default. As the product contains 12.5% of av. Chlorine, this classification is consistent. Sodium hypochlorite solutions are known to be corrive to metals, especially at such level. |
| Auto-ignition temperatures of products (liquids and gases) |  |  | The product is a dilution of the active substance therefore read across to the active substance data set is applicable  The product is a dilution of the active substance therefore read across to the active substance data set is applicable. Auto-ignition/relative self ignition temperature not applicable to sodium hypochlorite aqueous solutions | See CAR | In the CAR, it has been concluded that sodium hypochlorite is not auto-flammable. Based on the composition of the products, cross reading with the CAR is acceptable. |
| Relative self-ignition temperature for solids |  |  | Not applicable |  | Not relevant |
| Dust explosion hazard |  |  | Not applicable |  | Not relevant |

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| **Conclusion on the physical hazards and respective characteristics of the products of meta SPC1 and biocidal product family** |
| The biocidal product Javel Standard is considered by default corrosive to metal. The product is not flammable or explosive and does not possess oxidizing properties.  Labelling:  Met. Corr. 1, H290, GHS05, Danger  *Additional recommendations proposed by the applicant:*  *Product should not be used in conjunction with acids or ammonia*.  Hypochloric acid can react with ammonia, leading to the formation of monochloramine. Therefore this recommendation is relevant. |

### Methods for detection and identification

The applicant has access to the data of the CAR. However, additional validated methods have been submitted in this dossier and they are reported below. Methods have been submitted for each product. However, please note that only Javel Standard is claimed.

**Methods for the determination of active chlorine**

* Report 609/2018: Bactivel 55: validation of the analytical method for the determination of the active ingredient content, M.P Martinez, 2018 (GLP)
* Report 618-2018: Bactivel 50: validation of the analytical method for the determination the active ingredient content, M.P Martinez, (GLP)
* Report 623/2018: Sodium hypochlorite standard: validation of the analytical method for the determination of the active ingredient content (GLP)
* Report 19-901026-004: validation of the analytical method for the determination of active chlorine in JAVEL STANDARD, ZYDOWICZ Philippe (GLP)

Principle: The determination of the active ingredient (a.i.) is performed by titration with a standard thiosulphate solution of an amount of iodine obtained by a reaction between hypochlorite ions and potassium iodide. In presence of an acid, iodine is liberated and then titrated with sodium thiosulfate. Validation data are reported in the table below.

Titration analysis of the test item

Place the test item solution on the magnetic stirring. In this step, the following reaction occurs.

NaClO + 2KI + H2SO4 I2 + NaCl + K2SO4 + H2O

Titrate immediately with the thiosulphate to a pale straw colour, add starch solution and continue the titration until disappearance of the blue colour. In this step, the following reaction occurs.

2 Na2S2O3 + I2 Na2S4O6 + 2 NaI

**Sodium chlorate / Chlorate**

Method 1: Sodium chlorate will be analysed after dissolution of the formulation in water and quantified by ionic chromatography (column Ion Pac AS11-HC-44) using external standards and conductimetric detection (anionic mode). Note that in the following table, contents are expressed as sodium chlorate directly. However, sodium chlorate will dissociate in water and chlorate is measured using ionic chromatography. In the report, linearity has been defined as peak area of chlorate vs concentration of NaClO in calibration standard. Using this approach, the molar ratio chlorate/sodium chlorate is taken into account in the linear regression and contents calculated are directly expressed as sodium chlorate.

*Note: In the following table, recoveries have been calculated according to guidance SANCO 3030/99rev.4. However, following the publication of the new guidance, the calculation performed in the reports is not correct. RMS has reported the determination by the applicant and has also calculated recoveries as explained in this new guidance.The true calculation is performed as followed:*

* *If the initial concentration in the unfortified sample (CU) is less than about 10% of the concentration added (CA) then the total recovery is used. It is calculated in the following way: Total % recovery = 100 x (CF)/(CU + CA) with CF= C final measured in fortified sample*
* *If the initial concentration in the unfortified sample (CU) is more than about 10% of the concentration added (CA) then the marginal recovery is used. It is calculated in the following way: Marginal % recovery = 100 x (CF – CU) /CA with CF= C final measured in fortified sample*

*For this dossier, marginal recovery has been calculated since the initial content was always found to be >10% of the concentration added.*

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| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | **Precision (%)** | **LOQ** | **Reference** |
| Range | Mean |
| **Bactivel 55**  **Batch 182411608B**  Av Cl (a.i.) | Titration | 6 measurements | Linearity was performed with different amounts of the sodium hypochlorite solution (12% active chlorine) reference material  85 – 840 mg of sodium hypochlorite (eq to 10 – 100 mg active chlorine, or 3 to 30% w/w active chlorine content in test item samples) (n=5)  Linear regression with R > 0.99 | A blank reagent test was conducted with all reagents (sulphuric acid, potassium iodide solution, water and starch solution) to check possible interferences in the colour changing at the equivalent point of the titration. No interfering substances reported | Test item spiked at 3 levels (n=2/level)  With nominal addition of 20% of active chlorine (eq to a fortification of approx. 3% w/w av Chlorine/test item)  With nominal addition of 40% of active chlorine (eq to a fortification of approx. 5.6% w/w av Chlorine/test item)  With nominal addition of 60% of active chlorine (eq to a fortification of approx. 8.4% w/w av Chlorine/test item) | 99.6% (n=2)  (RMS calculation using marginal recovery: 99.4-100%)  99.4% (n=2)  (RMS calculation using marginal recovery: 99-99.6%)  99.7% (n=2)  (RMS calculation using marginal recovery: 99.4-99.7%) | 6 samples of the test item were analysed.  Mean= 14.7%  RSD=0.39%  (Horwitz = 1.79%)  (Horrat=0.2; <1: acceptable) | Not applicable | Martinez (2018) Study number: CH - 609/2018 |
| **Bactivel 50**  **Batch 182411608A**  Av Cl (a.i.) | Titration | 6 measurements | Linearity was performed with different amounts of the sodium hypochlorite solution (12% active chlorine) reference material  85 – 840 mg of sodium hypochlorite (eq to 10 – 100 mg active chlorine, or 3 to 30% w/w active chlorine content in test item samples) (n=5)  Linear regression with R > 0.99 | A blank reagent test was conducted with all reagents (sulphuric acid, potassium iodide solution, water and starch solution) to check possible interferences in the colour changing at the equivalent point of the titration. No interfering substances reported | Test item spiked at 3 levels (n=2/level)  With nominal addition of 20% of active chlorine (eq to a fortification of approx. 3% w/w av Chlorine/test item)  With nominal addition of 40% of active chlorine (eq to a fortification of approx. 5.6% w/w av Chlorine/test item)  With nominal addition of 60% of active chlorine (eq to a fortification of approx. 8.4% w/w av Chlorine/test item) | 99.8% (n=2)  (RMS calculation using marginal recovery: 99.8-100.3%)  100% (n=2)  (RMS calculation using marginal recovery: 100-100.2%)  99.9% (n=2)  (RMS calculation using marginal recovery: 99.8-100.1%) | 6 samples of the test item were analysed.  Mean= 13.7%  RSD=0.39%  (Horwitz =1.81%)  (Horrat=0.2; <1: acceptable) | Not applicable | Martinez (2018) Study number: CH - 618/2018 |
| **Sodium Hypochlorite standard**  **Batch 1804066-001**  Av Cl (a.i.) | Titration | 6 measurements | Linearity was performed with different amounts of the sodium hypochlorite solution (12% active chlorine) reference material  85 – 840 mg of sodium hypochlorite (eq to 10 – 100 mg active chlorine, or 3 to 30% w/w active chlorine content in test item samples) (n=5)  Linear regression with R > 0.99 | A blank reagent test was conducted with all reagents (sulphuric acid, potassium iodide solution, water and starch solution) to check possible interferences in the colour changing at the equivalent point of the titration. No interfering substances reported | Test item spiked at 3 levels (n=2/level)  With nominal addition of 20% of active chlorine (eq to a fortification of approx. 3% w/w av Chlorine/test item)  With nominal addition of 40% of active chlorine (eq to a fortification of approx. 5.6% w/w av Chlorine/test item)  With nominal addition of 60% of active chlorine (eq to a fortification of approx. 8.4% w/w av Chlorine/test item) | 100.0% (n=2)  (RMS calculation using marginal recovery: 99.5-100%)  99.9% (n=2)  (RMS calculation using marginal recovery: 99.7-99.9%)  99.9% (n=2)  (RMS calculation using marginal recovery: 99.9-99.9%) | 6 samples of the test item were analysed.  Mean=12.7 %  RSD=0.31%  (Horwitz =1.83%)  (Horrat=0.2; <1: acceptable) | Not applicable | Martinez (2018) Study number: CH - 623/2018 |
| **Av Cl**  **Javel standard, batch 1608E** | Titration | 6 measurements | Linearity was performed with different amounts of the sodium hypochlorite solution (8.43% active chlorine) reference material  225-675 mg of sodium hypochlorite (19.41 – 57.57 mg of active chlorine, eq to around 6 – 20% w/w of active chlorine content in test item samples) (n=5)  Linear regression with  R > 0.99 | A blank reagent test was conducted with all reagents (solvent blank, reference item, test item) to check possible interferences in the colour changing at the equivalent point of the titration. No interfering substances reported | 2 reconstituted samples  Fortification at approx. 3% w/w (av chlorine in test item) | 98.6-98.9% (n=2)  RMS calculation using marginal recovery: 92 – 94% (range authorised: 90 – 110% for a level between ≥1 – <10%) | 5 samples  Mean=13.2% w/w of av chlorine (equivalent to 13.8% w/w of NaClO)  RSD=0.62  (Horwitz = 1.82 and Horrat=0.34)  RMS: Horrat <1, acceptable | Not applicable | Ricau H (2020) Report No. 19-901026-004 |
| **Sodium chlorate (impurity)**  **Javel Standard, batch 1608E** | Ion chromatography | 5 measurements | Linearity was performed with 5 calibration standard ranging from 4.30 mg/L to 16.34 mg/L (eq to 0.05 – 0.2 % w/w sodium chlorate in test item)  Linear regression  r = 1.0000 | Chromatograms have been provided for blank sample,test item, reference item and no interferences were noticed. | 2 reconstituted samples at 2 level  At 0.05% w/w (NaClO3 in test item)  At 0.1% w/w (NaClO3 in test item) | 104.2% (n=2)  RMS calculation using marginal recovery: 115%(n=2) (range authorised: 75 – 125% for a level between  ≥0.01 – <0.1%)  103.5% (n=2)  RMS calculation using marginal recovery: 109% (n=2) (range authorised: 80 – 120% for a level between  ≥0.1 – <1%) | 5 samples  Mean= 0.105% w/w  RSD=0.58%  Horwitz= 3.76%  Horrat = 0.15  RMS: Horrat <1, acceptable | LOQ = 0.0014 g/kg (proposed by applicant based on ratio S/N)  RMS: 1.05 g/kg based on precision results (n=5) | Ricau H (2020) Report No. 19-901026-005 |

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| **Analytical methods for monitoring** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
|  |  |  |  |  |  |  |  |  |  |
| The applicant has a letter of access to the active substance dossier and the analytical methods developed for the active substance. | | | | | | | | | |

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| **Analytical methods for soil** | | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
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| Not required for av Cl.  The applicant has a letter of access to the active substance dossier and the analytical methods developed for the active substance. | | | | | | | | | | |

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| **Analytical methods for air** | | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
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| The applicant has a letter of access to the active substance dossier and the analytical methods developed for the active substance. | | | | | | | | | | |

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| **Analytical methods for water** | | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
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| The applicant has a letter of access to the active substance dossier and the analytical methods developed for the active substance. | | | | | | | | | | |

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| **Analytical methods for animal and human body fluids and tissues** | | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** | |
| Range | Mean | RSD |
|  |  |  |  |  |  |  |  |  | |  |
| Not required for av Cl.  The applicant has a letter of access to the active substance dossier and the analytical methods developed for the active substance. | | | | | | | | | | |

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| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** | | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
|  |  | |  |  |  |  |  |  |  |  |
| Not required for av Cl.  The applicant has a letter of access to the active substance dossier and the analytical methods developed for the active substance. | | | | | | | | | | |

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| **Conclusion on the methods for detection and identification of the product** |
| The product is similar to the active substance.  The analytical methods for determination of the active substance and chlorate in the products are validated.  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

PT4: Food and feed area.

PT5: Drinking water.

The biocidal product HYPOCHLORITE FAMILY - ARKEMA is based on the active substance active chlorine released from hypochlorite sodium, is intended for use in product types (PT) 4 and 5.

The family product is used in PT4 for surface disinfection of inner surfaces in human and veterinary drinking water systems (pipes, reservoirs, …) and in PT5 for disinfection of water in drinking water companies and for the disinfection of stationary water in reservoir.

The product are used by professional users by spraying, by filling, or by continuous application

#### Organisms to be controlled and products, organisms or objects to be protected

The biocidal product family is used to disinfect inner surface in drinking water system or for the disinfection of water in drinking water companies.

The product of the family is used for the purpose of the protection of human and animal health

#### Effects on target organisms, including unacceptable suffering

The products are able to produce a reduction in the number of viable bacterial cells (bactericidal activity), of yeast cells (yeasticidal activity), and of infectious virus particles (virucidal activity) of relevant test organisms under defined conditions.

#### Mode of action, including time delay

Chlorine released from sodium hypochlorite has an unspecific mode of action.

However, it is known that its bactericidal effect is due to the fact that activity results in the membranes being partly destroyed and the bacteria are not able to multiply. (CARs: Evaluation of active substances Assessment Report, Active chlorine released from sodium hypochlorite, Product-types 2 and 4, January 2017).

Contact times for the different activities claimed are determined in the efficacy tests (see table below).

#### Efficacy data

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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*** | *PT4*  *PT5* | *Bactivel 50*  *14.7%*  *(Sodium hypochlorite liquid)*  *14% active chlorine* | *Pseudomonas aeruginosa,*  *Escherichia coli*  *Staphylococcus aureus*  *Enterococcus hirae* | *EN1276:2010*  *(phase 2, step 1).* | Contact time 5 minutes  Temperature:  20°C ± 1°C  Soiling: clean conditions 0.3 g/L BSA  Concentration tested:  0.005 ml/L, 0.007 ml/L and 0.009 ml/L  Criteria: at least a 5 log reduction | Bactericidal concentration:  0.009 ml/L equivalent to 1.49 mg av. Cl/L | *S. Colombo (2018)*  *RCH-771-2018*  *6.7-01*  *IC1* |
| ***yeasticide***  ***Fungicide*** | *PT4*  *PT5* | *Bactivel 50*  *14.7%*  *(Sodium hypochlorite liquid)*  *14% active chlorine* | *Candida albicans* | *EN1650+A1:2013*  *(phase 2, step 1).* | Contact time 15 minutes  Temperature:  20°C ± 1°C  Soiling: clean conditions 0.3 g/L BSA  Concentration tested:  0.008 mL/L, 0.010 mL/L and 0.012 mL/L  Criteria at least 4 Log reduction | Yeasticidal concentration:  0.010 mL/L  equivalent to 1.65 mg av. Cl/L | *S. Colombo (2018)*  *RCH-774-2018*  *6.7-02*  *IC1* |
| ***Bactericide*** | *PT4*  *PT5* | *Bactivel 50*  *14.7%*  *(Sodium hypochlorite liquid)*  *14% active chlorine* | *Pseudomonas aeruginosa,*  *Escherichia coli*  *Staphylococcus aureus*  *Enterococcus hirae* | *EN 13697:2015*  *(phase 2, step 2)*  *Bacteria* | Contact time 5 minutes  Temperature:  20°C ± 1°C  Soiling: clean conditions 0.3 g/L BSA (0.85 % v/v skimmed milk for (P. aeruginosa))  Concentration tested:  0.005 ml/L, 0.007 ml/L, 0.009 ml/L  Criteria at least 4 Log reduction | Bactericidal concentration  0.009 ml/L  equivalent to 1.49 mg av. Cl/L | *E. Zennaro (2018)*  *RCH 780-2018*  *6.7-03*  *IC1* |
| ***Virucide*** | *PT5* | *Bactivel 50*  *14.7%*  *(Sodium hypochlorite liquid).*  *14% active chlorine* | *Polio virus Type 1*  *Adenovirus Type 5*  *Murine norovirus S99* | *EN 14476*  *(P2S1)*  *Virucidal suspension test* | Contact time 60 minutes  Temperature : 20 °C  Soiling: clean condition 0.3 g/L BSA  Concentrations tested:  0.3 mL/L, 3.0 mL/L, 6.0 mL/L  Criteria at least 4 log reduction | Virucidal concentration: 3 mL/L  equivalent to 496 mg av. Cl/L | *S. Carluccio (2018)*  *STULV18AA1907*  *6.7-04*  *IC1* |
| ***Bactericide***  ***Virucide*** | *PT5* | *Bactivel 50*  *14.7%*  *(Sodium hypochlorite)*  *14% active chlorine* | *Escherichia coli*  *Enterococcus faecium*  *Bacteriophage PRD 1* | *UBA Simulated Use Test* | Contact time 10 and 25 minutes  DOC: 2.0 mg/L  Temperature 16°C  pH7.5, Volume flow rate 393 L/h  Concentration tested:  0.2 mg av. Cl/L  Criteria 2 log reduction in 10 minute and 4 log in 25 minutes. | *E. coli* :  4.5 log red, 10 min  5 log red, 25 min  *E. faecium* :  > 4.6 Log red, 10 and 25 min  Bacteriophage PRD1  >4.4 log red, 10 min  >4.7 log red, 25 minutes  The bactericidal and virucidal efficacy is demonstrated at the application rate of 0.2 mg av. Cl/L. | *Grunert et al (2018)*  *7681-52-9*  *6.7-05*  *IC1* |
| ***Virucide*** | *PT5* | *Bactivel 50*  *14.7%*  *(Sodium hypochlorite)*  *14 % active chlorine* | *Bacteriophage MS 2* | *UBA Simulated Use Test* | Contact time 10 et 25 minutes  DOC: 2.0 mg/L  Temperature 13.8°C  pH7.1, Volume flow rate 411 L/h  Concentration tested:  0.2 mg av. Cl/L  Criteria 2 log reduction in 10 minute and 4 log in 25 minutes. | Bacteriophage MS2  2.8 log red, 10 min  4.5 log red, 25 minutes  The phagicidal efficacy is demonstrated at the application rate of 0.2 mg av. Cl/L. | *Grunert et al (2018)*  *7681-52-9*  *6.7-19*  *IC1* |
| ***Bactericide*** | *PT4*  *PT5* | *Bactivel 55*  *15.7%*  *(Sodium hypochlorite liquid)*  *15% active chlorine* | *Pseudomonas aeruginosa,*  *Escherichia coli*  *Staphylococcus aureus*  *Enterococcus hirae* | *EN1276:2010 (phase 2, step 1).* | Contact time 5 minutes  Temperature:  20°C ± 1°C  Soiling: clean conditions 0.3 g/L BSA  Concentration tested: 0.004ml/L,0.006ml/L, 0.008ml/L  Criteria: at least 5 log reduction | Bactericidal concentration:  0.006 ml/L  equivalent to 1.06 mg av. Cl/L | *S. Colombo*  *(2018)*  *RCH-770-2018*  *6.7-06*  *IC1* |
| ***Yeasticide***  ***Fungicide*** | *PT4*  *PT5* | *Bactivel 55*  *15.7%*  *(Sodium hypochlorite liquid)*  *15% active chlorine* | *Candida albicans* | *EN1650+A1:2013*  *(phase 2, step 1).* | Contact time: 15 minutes  Temperature:  20°C ± 1°C  Soiling: clean conditions 0.3 g/L BSA  Concentration tested:  0.007 ml/L, 0.009 ml/L, 0.011 ml/L  Criteria: at least 4 log reduction | Yeasticidal concentration:  0.009 mL/L  equivalent to 1.59 mg av. Cl/L | *S. Colombo (2018)*  *RCH-773-2018*  *6.7-07*  *IC1* |
| ***Bactericide*** | *PT4*  *PT5* | *Bactivel 55*  *15.7%*  *(Sodium hypochlorite liquid)*  *15 % active chlorine* | *Pseudomonas aeruginosa*  *Escherichia coli.*  *Staphylococcus aureus.*  *Enterococcus hirae.* | *EN 13697:2015*  *(phase 2, step 2)*  *Bacteria* | Contact time: 5 minutes  Temperature:  20°C ± 1°C  Soiling: clean conditions 0.3 g/L BSA (0.85% skimmed milk for P. aeruginosa))  Concentration tested:  0.004 ml/L, 0.006 ml/L, 0.008 ml/L  Criteria at least 4 Log reduction. | Bactericidal concentration:  0.008 ml/L  equivalent to 1.42 mg av. Cl/L | *S. Colombo*  *(2018)*  *RCH 779-2018*  *6.7-08*  *IC1* |
| ***Virucide*** | *PT4*  *PT5* | *Bactivel 55*  *15.7 %*  *(Sodium hypochlorite liquid)*  *15% active chlorine* | *Polio virus Type 1*  *Adenovirus Type 5*  *Murine norovirus S99* | *EN 14476*  *(P2S1)*  *Virucidal suspension test* | Contact time 60 minutes  Temperature: 20 °C  Soiling: clean condition 0.3 g/L BSA  Concentration tested:  0.3 ml/L, 3.0 ml/L, 6.0 ml/L  Criteria at least 4 Log reduction | Virucidal concentration: 3 mL/L  equivalent to 530 mg av. Cl/L | *S. Carluccio*  *STULV18AA1908*  *6.7-09*  *IC1* |
| ***Bactericide***  ***Virucide*** | *PT5* | *Bactivel 55*  *15.7%*  *(Sodium hypochlorite)*  *15% active chlorine* | *Escherichia coli*  *Enterococcus faecium*  *Bacteriophage*  *MS2*  *PRD 1* | *UBA Simulated Use Test* | Contact time 10 et 25 minutes  Temperature 16°C  DOC: 2.0 mg/L  pH7.4, Volume flow rate 421.3 L/h  Concentration tested:  0.2 mg av. Cl/L  Criteria 2 logs reduction in 10 minute and 4 logs in 25 minutes. | Bacteria:  *E. coli* :  >5.4 log red, 10 min  >5.4 log red, 25 min  *E. faecium* :  >4.9 Log red, 10 min  > 4.8 log red, 25 min  Bacteriophage MS2  >4.8 log red, 10 min  >4.2 log red, 25 minutes  Bacteriophage PRD1  >4.3 log red, 10 min  >4.0 log red, 25 minutes  The bactericidal and phagicidal efficacy is demonstrated at the application rate of 0.2 mg/L av. Cl/L | *Zehlike and Grunert*  *(2018)*  *No report number*  *6.7-10* |
| ***Bactericide*** | *PT4*  *PT5* | *Sodium Hypochlorite Standard*  *13.7%*  *(Sodium hypochlorite liquid)*  13.0% active chlorine | *Pseudomonas aeruginosa,*  *Escherichia coli,*  *Staphylococcus aureus,*  *Enterococcus hirae* | *EN1276:2010 (phase 2, step 1).* | Contact time 5 minutes  Temperature:  20°C ± 1°C  Soiling: clean conditions 0.3 g/L BSA  Concentration tested:  0.005 ml/L, 0.007 ml/L and 0.009 ml/L  Criteria: at least 5 log reduction | Bactericidal concentration:  0.007 ml/L  equivalent to 1.12 mg av. Cl/L | *S. Colombo*  *(2018)*  *RCH-772-2018*  *6.7-11*  *IC1* |
| ***yeasticide***  ***fungicide*** | *PT4*  *PT5* | *Sodium Hypochlorite Standard*  *13.7%*  *(Sodium hypochlorite liquid)*  13.0% active chlorine | *Candida albicans* | *EN1650+A1:2013*  *(phase 2, step 1).* | Contact time: 15 minutes  Temperature:  20°C ± 1°C  Soiling: clean conditions 0.3 g/L BSA  Concentration tested:  0.008 ml/L, 0.010 ml/L, 0.012 ml/L  Criteria: at least 4 log reduction | Yeasticidal concentration:  0.010 ml/L  equivalent to 1.60 mg av. Cl/L | *S. Colombo*  *(2018)*  *RCH-775-2018*  *6.7-12*  *IC1* |
| ***Bactericide*** | *PT4*  *PT5* | *Sodium Hypochlorite Standard*  *13.7%*  *(Sodium hypochlorite liquid)*  *13% active chlorine* | *Pseudomonas aeruginosa.*  *Escherichia coli.*  *Staphylococcus aureus.*  *Enterococcus hirae.* | *EN 13697:2015*  *(phase 2, step 2)*  *Bacteria* | Contact time: 5 minutes  Temperature:  20°C ± 1°C  Soiling: clean conditions 0.3 g/L BSA  0.85% skimmed milk for P. aeruginosa)  Concentration tested:  0.005ml/L,0.007ml/L, 0.009ml/L  criteria at least 4 Log reduction. | Bactericide concentration:  0.009 ml/L  equivalent to 1.44 mg av. Cl/L | *S. Colombo*  *(2018)*  *RCH 781-2018*  *6.7-13*  *IC1* |
| ***Virucide*** | *PT4*  *PT5* | *Sodium Hypochlorite Standard*  *13.7 % w/w*  *(Sodium hypochlorite liquid)*  *13% active chlorine* | *Polio virus Type 1*  *Adenovirus Type 5*  *Murine norovirus S99* | *EN 14476*  *(phase 2, step 2)*  *Virucidal suspension test* | Contact time 60 minutes  Temperature : 20 °C  Soiling: clean condition 0.3 g/L BSA  Concentrations tested:  0.3 mL/L, 3.0 mL/L, 6.0 mL/L  Criteria at least 4 log reduction | Virucidal concentration: 3 mL/L  equivalent to 458 mg av. Cl/L | *S. Carluccio*  *(2018)*  *STULV18AA1904*  *6.7-14*  *IC1* |
| ***Bactericide***  ***Virucide*** | *PT5* | *Sodium Hypochlorite Standard*  *13.7% w/w*  *(Sodium hypochlorite liquid)*  *13% active chlorine* | *Escherichia coli*  *Enterococcus faecium*  *Bacteriophage*  *MS2*  *PRD 1* | *UBA Simulated Use Test* | Contact time 10 et 25 minutes  DOC: 2.0 mg/L  Temperature 15°C  pH7.5, Volume flow rate 394 L/h  Concentration tested:  0.2 mg av. Cl/L  Criteria 2 logs reduction in 10 minute and 4 logs in 25 minutes. | *E. coli* :  5.4 log red, 10 min and 25 min  *E. faecium* :  > 5.1 Log red, 10 and 25 min  Bacteriophage MS2  3.9 log red, 10 min  >4.5 log red, 25 minutes  Bacteriophage PRD1  >4.1 log red, 10 min  and 25 minutes  The bactericidal and virucidal efficacy is demonstrated at the application rate of 0.2 mg av. Cl/L | *Zehlike and Grunert*  *(2018)*  *No report reference*  *6.7-15*  *IC1* |
| ***Bactericide*** | *PT4*  *PT5* | *Sodium Hypochlorite Standard*  *13.7%*  *(Sodium hypochlorite liquid)*  *13% active chlorine* | *Escherichia coli*  *Enterococcus hirae* | *Based on the methodology EN 1276* | Contact time: 10 and 25 minutes  Temperature 20 °C  Interfering substance: None.  Concentration tested:  0.0003 ml/L, 0.0012 ml/L, 0.002 ml/L  Criteria:  At least 2 Log in 10 min  At least 4 Log in 25 min | Efficacy criteria is fulfilled for all target organisms at the concentration of 0.0003 mL/L without the presence of interfering substance. | *S. colombo*  *(2018)*  *RCH-969/2018*  *6.7-16*  *IC1*  *(supportive data in the absence of soiling)* |
| ***Bactericide*** | *PT4*  *PT5* | *Bactivel 50*  *14.7%*  *(Sodium hypochlorite)*  *14 % active chlorine* | *Escherichia coli*  *Enterococcus hirae* | *Based on the methodology EN 1276* | Contact time: 10 and 25 minutes  Temperature 20 °C  Interfering substance: None.  Concentration tested:  0.0003 ml/L, 0.0012 ml/L, 0.002 ml/L  Criteria:  At least 2 Log in 10 min  At least 4 Log in 25 min | Efficacy criteria is fulfilled for all organisms at the concentration of 0.0003 mL/L without the presence of interfering substance. | *S. colombo*  *(2018)*  *RCH-967/2018*  *6.7-17*  *IC1*  *(supportive data in the absence of soiling)* |
| ***Bactericide*** | *PT4*  *PT5* | *Bactivel 55*  *15.7%*  *(Sodium hypochlorite)*  *15% active chlrone* | *Escherichia coli*  *Enterococcus hirae* | *Based on the methodology EN 1276* | Contact time: 10 and 25 minutes  Temperature 20 °C  Interfering substance: None.  Concentration tested:  0.0003 ml/L, 0.0012 ml/L, 0.002 ml/L  Criteria:  At least 2 Log in 10 min  At least 4 Log in 25 min | Efficacy criteria is fulfilled for all target organisms at the concentration of 0.0003 mL/L without the presence of interfering substance. | *S. Colombo*  *(2018)*  *RCH-968/2018*  *6.7-18*  *IC1*  *(supportive data in the absence of soiling)* |
| Yeasticide | PT4  PT5 | Javel Standard  13.1 % w/w  *(Sodium hypochlorite)*  *12.5% active chlorine* | *Candida albicans* | EN 13697: 2019  *(phase 2, step 2)* | Contact times: 2, 5 and 15 minutes.  Temperature: 20 °C  Soiling: clean conditions 0.3 g/L BSA.  Test Concentration: 2.0 mg av. Cl/L  Criteria at least 3 log reduction | Yeasticidal concentration: 2.0 mg av. Cl/L  5 minutes contact time  Clean conditions  20°C | S. Morot – Bizot (2020)  255D35-2019-01\_EN 13697  6.7-20  IC1 |
| Bactéricide | PT4  PT5 | Javel Standard  13.1 % w/w  *(Sodium hypochlorite)*  *12.5% active chlorine* | *Pseudomonas aeruginosa*,  Escherichia coli  *Staphylococcus aureus*  *Enterococcus hirae* | EN 1276: 2019  *(phase 2, step 1).* | Contact times: 5, 10 and 15 minutes.  Temperature: 15 °C  Soiling: clean conditions 0.3 g/L BSA.  Test Concentration: 2.0 mg av.Cl/L  3 replicates  Criteria at least 5 log reduction | Bactericidal concentration:  2.0 mg/L mg av. Cl/L  10 minutes contact time  Clean conditions  15°C | 6.7-21  255D35-2019-02\_EN 1276 |
| ***Virucide*** | PT5 | Javel Standard  13.1 % w/w  *(Sodium hypochlorite)*  *12.5% active chlorine* | Polio virus Type 1  Adenovirus Type 5  Murine norovirus S99 | EN 14476  *(phase 2, step 1).*  Virucidal suspension test | Contact times: 10, 15 and 25 minutes  Temperature: 15 °C  Soiling: clean conditions 0.3 g/L BSA.  15°C  Concentration tested: 2.0 mg av. Cl/L  Criteria: at least 4 log reduction | Virucidal efficacy demonstrated at the dose of 2.0 mg av. Cl/L for a contact time of 25 minutes | 6.7-22  255D35-2019-03\_EN 14476 |
| ***Bactericide***  ***Virucide*** | PT5 | Javel Standard  13.1 % w/w  *(Sodium hypochlorite)*  *12.5% active chlorine* | *Escherichia coli*  *Enterococcus faecium*  Bacteriophage PRD *1*  Bacteriophage MS 2 | UBA Simulated Use Test | Contact time: 5 and 15 minutes.  Temperature 15°C  Interfering substance: 2.0mg/L DOC  Test Concentration: 2.0 mg av. Cl/L  Criteria:  At least 2 Log in 10 min  At least 4 Log in 25 min | *E. coli* :  5.04 log red, 5 min  5.57 log red, 15 min  *E. faecium* :  5.11 Log red, 5 min  5.51 log red, 15 min  Bacteriophage MS2  3.91 log red, 5 min  4.56 log red, 15 minutes  Bacteriophage PRD1  3.94 log red, 5 min  4.72 log red, 15 minutes  The bactericidal and virucidal efficacy is demonstrated at the application rate of 2 mg av. Cl/L | 6.7-23  318D45-2019 |

Note: Following a request for additional data, the applicant has restricted the family to the product JAVEL STANDARD 12.5 % w/w active chlorine. Nevertheless, taking into account the composition of the products tested and the tested dilutions, the results of the efficacy studies performed with the other formulations than the product JAVEL STANDARD 12.5 % w/w active chlorine are suitable to support the efficacy of the HYPOCHLORITE FAMILY – ARKEMA family.

The main points are summarised in the table above

For PT4 uses: disinfection of inner surfaces in human drinking water systems and in veterinary water systems (pipes, reservoirs, other equipment) by filling or spraying, test are performed with the products BACTIVEL 50 (14 % w/w active chlorine), BACTIVEL 55 (15 % w/w active chlorine), SODIUM HYPOCHLORITE STANDARD (13 % w/w active chlorine) and JAVEL STANDARD (12.5 % active chlorine):

* Bactericidal activity is demonstrated both in phase 2, step 1 and step 2 tests (EN 1276 and EN 13697), at 20 °C, with a contact time of 5 minutes with clean conditions (0.3 g/L BSA). In these conditions, bactericidal efficacy is shown at the in-use concentration of around 1.5 mg av Cl/L
* Yeasticidal activity is demonstrated in phase 2 step 1 test (EN 1650) with a contact time of 15 minutes, and in phase 2 step 2 test (EN 13697) with a contact time of 5 min, at 20 °C with clean conditions (0.3 g/L BSA). In these conditions, yeasticidal efficacy is demonstrated at the in-use concentration of 2 mg av Cl/L.

For PT5 uses: disinfection of water in drinking –water companies, disinfection of veterinary water and disinfection of stationary water, in reservoirs by continuous application, tests are performed with several formulations that differ only on the content of active chlorine:

* Bacterial activity is demonstrated in phase 2 step 1 test (EN 1276), with a contact time of 10 minutes, at 15 °C, in clean conditions (0.3 g/L BSA). In these conditions, bactericidal efficacy is demonstrated at the in-use concentration of 2 mg av Cl/L.
* Virucidal activity is demonstrated in phase 2 step 1 test (EN 14476), at 15°C, with a contact time of 25 minutes with clean conditions (0.3 g/L BSA). In these conditions, virucidal efficacy is demonstrated at the in-use concentration of 2 mg av Cl/L.

The efficient dose, in these phase 2 step 1 tests is higher than the application rate claimed in the dossier (0.2 mg av Cl/L).

According to the guidance on the Biocidal product Regulation Vol. II Efficacy – Assessment and Evaluation (Parts B+C) version 3.0 (April 2018), passing modified EN1276 and EN 14476 tests is a basic requirement for PT5. Based on the current information there is enough evidence that the active chlorine-based products (most widely used water disinfectants), cannot pass these tests at typical use concentrations that have long been established. In addition, it was acknowledged that the active chlorine concentration in drinking water cannot be increased to a level that passes these criteria. Consequently, at WGI-2020, it was agreed that the modified EN 1276 and EN 14476 tests mentioned in the guidance are considered as not obligatory for PT 5 active chlorine-based disinfectants. Efficacy of such products should be demonstrated based on a simulated-use test and/or fiel test.

* Bacterial and virucidal (phages) activities are demonstrated in a simulated-use test (method UBA), at 15 °C at the both contact times of 10 and 25 minutes but also at the contact times of 5 and 15 minutes, at 0.2 mg/L av. Cl/L.

Regarding the disinfection of stationary water, the Efficacy guidance requests a simulated-use test, in order to demonstrate proper distribution of the disinfectant in the reservoir. The simulated-use test based on the UBA methodology provided for the use of disinfection of water in drinking water companies or veterinary water is not representative of the distribution of the product that occurs in reservoir. Therefore, that the efficacy is not demonstrated for this use.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) assessed that the product of the HYPOCHLORITE FAMILY - ARKEMA family has shown a sufficient efficacy for the following use claimed:   * Use 1 disinfection of the inner surfaces in human drinking water systems (pipes, reservoirs, other equipment) by filling or spraying with clean conditions   + Mandatory target organisms:     - Bacteria, yeast: 2 mg av Cl/L, 15 minutes, 20°C. * Use 2 disinfection of the inner surfaces in veterinary water systems (pipes, reservoirs, other equipment) by filling or spraying with clean conditions   + Mandatory target organisms:     - Bacteria, yeast: 2 mg av Cl/L, 15 minutes, 20°C. * Use 3 disinfection of water in drinking companies by continuous dosing   + Mandatory target organisms:     - Bacteria, virus: 0.2 mg av Cl/L, 25 minutes, 15°C. * Use 5 disinfection of veterinary water   + Mandatory target organisms:     - Bacteria, virus: 0.2 mg av Cl/L, 25 minutes, 15°C.   Regarding the use 4disinfection of stationary water, in the absence of appropriate simulated-use test, efficacy has not been demonstrated.  Please note that some member states including France, after primary disinfection, request to maintain a residual level of available chlorine in drinking water in the pipes as a precautionary measure. This additional amount, claimed by the applicant as “Secondary disinfection: 0.2 mg/L available chlorine (residual)” has been considered as covered by the primary disinfection. |

#### Occurrence of resistance and resistance management

According to the Assessment Report of Active chlorine released from sodium hypochlorite (January 2017), although different species vary in their sensitivity to active chlorine, development of acquired resistance is not expected since its multiple molecular sites of attack on the surface and within the microbial cells. Active chlorine is in fact regarded by experts [see IFH (International Scientific Forum on Home Hygiene) review October 2003 and Submission to SCENIHR, February 2008)] 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 its 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. Adaptation of organisms to hypochlorite can be determined by comparison of the Minimum Inhibitory Concentration (MIC) but this is not relevant in practice as the actual use concentrations are much higher and thus a sufficient margin of safety is provided.

No management strategies are necessary as acquired resistance to active chlorine has not developed nor will develop due to its reactive nature and unspecific mode of action. 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.

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

French competent authorities (FR CA) assessed that the product of the HYPOCHLORITE FAMILY - ARKEMA family has shown a sufficient efficacy for the following use claimed:

* Use 1 disinfection of the inner surfaces in human drinking water systems (pipes, reservoirs, other equipment) by filling or spraying with clean conditions
  + Mandatory target organisms:
    - Bacteria, yeast: 2 mg av Cl/L, 15 minutes, 20°C.
* Use 2 disinfection of the inner surfaces in veterinary water systems (pipes, reservoirs, other equipment) by filling or spraying with clean conditions
  + Mandatory target organisms:
    - Bacteria, yeast: 2 mg av Cl/L, 15 minutes, 20°C.
* Use 3 disinfection of water in drinking companies by continuous dosing
  + Mandatory target organisms:
    - Bacteria, virus: 0.2 mg av Cl/L, 25 minutes, 15°C.
* Use 5 disinfection of veterinary water
  + Mandatory target organisms:
    - Bacteria, virus: 0.2 mg av Cl/L, 25 minutes, 15°C.

Regarding the use 4disinfection of stationary water, in the absence of appropriate simulated-use test, efficacy has not been demonstrated.

Please note that some member states including France, after primary disinfection, request to maintain a residual level of available chlorine in drinking water in the pipes as a precautionary measure. This additional amount, claimed by the applicant as “Secondary disinfection: 0.2 mg/L available chlorine (residual)” has been considered as covered by the primary disinfection.

#### Relevant information if the product is intended to be authorised for use with other biocidal product(s)

none

### Risk assessment for human health

No *in vitro* or *in vivo* study was conducted. Classification is determined following active substance harmonized classification of ECHA and by using the calculation method described in the Guidance on the Application of the CLP Criteria Version 5.0 (July 2017).

Please see Confidential annex for more details on classification of the product.

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Corrosive to the skin |
| Justification for the value/conclusion | The product is an aqueous suspension of the active substance.  Considering the content in active substance (12.5%), a classification Skin Corr. 1B H314 (in accordance with Regulation EC/1272/2008) is needed. |
| Classification of the product according to CLP | Classification **Skin corrosive, category 1B - H314: Causes severe skin bruns and eye damage** is required. |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | The product is considered to cause serious eye damage. |
| Justification for the value/conclusion | Considering the content in active substance in the product (12,5%), a classification Eye Dam. 1 H318 (in accordance with Regulation EC/1272/2008) is needed. |
| Classification of the product according to CLP | Classification **Serious eye damage cat. 1 - H318: Causes serious eye damage** is required. |

***Respiratory tract irritation***

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| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | The product is expected to be corrosive to the respiratory tract due to the corrosive properties of the active substance.  However according to the Guidance on the Application of the CLP Criteria, a classification for corrosivity (H314) is considered to implicitly cover the potential to cause respiratory tract irritation. |
| Classification of the product according to CLP | Not classified but the mention **EUH 071: corrosive to the respiratory tract** is required. |

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitising to the skin. |
| Justification for the value/conclusion | According to the composition, none of the component is toxicologically relevant for skin sensitisation.  Therefore, no classification for skin sensitisation is required. |
| Classification of the product according to CLP | Not classified. |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusionused in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not sensitising to the respiratory system. |
| Justification for the value/conclusion | According to the composition, none of the components is toxicologically relevant for respiratory sensitisation. |
| Classification of the product according to CLP and DSD | Not classified. |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not acutely toxic via oral route. |
| Justification for the selected value | None of the components triggers the classification for acute oral toxicity. |
| Classification of the product according to CLP | Not classified. |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not acutely toxic via inhalation route. |
| Justification for the selected value | None of the components is classified for acute toxicity by inhalation. |
| Classification of the product according to CLP and DSD | Not classified. |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not acutely toxic via dermal route. |
| Justification for the selected value | None of the components is classified for acute dermal toxicity. |
| Classification of the product according to CLP and DSD | Not classified. |

***Information on dermal absorption***

**Active chlorine**(released by sodium hypochlorite)

Dermal absorption is considered as not relevant because chlorine-related toxicity is 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.

**Chlorates**

No dermal absorption study has been provided by applicant and no relevant data on chlorates dermal absorption has been found.

Considering concentration of chlorates in the product (0.645%) and according to the EFSA guidance on dermal absorption (2017), a default dermal absorption value of 50% has been applied (concentration of chlorates < 5%).

***Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)***

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, no co-formulant has been identified as SOC.

***Available toxicological data relating to a mixture***

Not relevant.

***Other***

Not relevant.

#### Exposure assessment

**Active substance (active chlorine released by sodium hypochlorite)**

*Presentation and concentration of active chlorine*

HYPOCHLORITE FAMILY ARKEMA is a water-based product containing 13.1% w/w sodium hypochlorite (NaClO). In water, sodium hypochlorite (NaOCl) is hydrolyzed to hypochlorous acid (HClO). Hypochlorous acid is in equilibrium with the hypochlorite ion (ClO-) and chlorine (Cl2).

Together, the chlorine species hypochlorous acid (HClO), hypochlorite ion (ClO-) and chlorine (Cl2) are defined as active chlorine or available chlorine (avCl).

The ratio of Cl2/HClO/ClO─ is pH dependent (see figure below). At pH values > 10, the hypochlorite anion (ClO-) is the predominant species, whereas none of the volatile species in equilibrium (hypochlorous acid and chlorine) are virtually present. As an ionic species, the hypochlorite anion has a high water solubility and is unlikely to evaporate. Therefore, only exposure to aerosols of ClO- (as avCl) is considered relevant. The minute 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.



Available chlorine is expressed as equivalent content of Cl2.

The concentration of active chlorine released from sodium hypochlorite in the product has been calculated based on the specification of the technical active substance presented in the CAR of sodium hypochlorite and the content of technical active substance in the product (13.1 % w/w).

To obtain the concentration of active chlorine released from sodium hypochlorite in the product, the content of sodium hypochlorite has been divided by the conversion factor of 1.05, which leads to a concentration of active chlorine of **12.5%** in the concentrate product.

For PT4 uses, the product is diluted in water to 0.0013% (v/v) in order to apply an in-use concentration of available chlorine of 2 mg av Cl/l. Therefore, after dilution, active chlorine concentration is **0.00016%** (v/v) (12.5 × 0.0013%).

For PT5 uses, the product is diluted in water to 0.00013% (v/v) in order to apply an in-use concentration of available chlorine of 0.2 mg av Cl/l. Therefore, after dilution, active chlorine concentration is **0.000016%** (v/v) (12.5 × 0.00013%).

*Mode of action and routes of exposure*

The primary mode of action of NaClO is characterised by **local effects**. NaClO does not become systematically available upon dermal contact, ingestion or inhalation. Any systemic effects seen in animal studies (at high doses) are considered to be secondary to local irritation/corrosion.

Consequently, only a local exposure and risk assessment have been performed for all relevant routes of exposure:

* Dermal exposure: a semi-quantitative (Tier 1) assessment is performed with the dermal NOAEC of 1% avCl. Estimated exposure corresponds to the concentration of active chlorine (in the product or in the in-use dilution, depending on the scenario, expressed in percentage) to which the operator is exposed. If needs be, a qualitative (Tier 2) assessment is performed according to the Guidance on BPR: Volume III Part B+C, Version 4.0 December 2017.
* Oral exposure: when relevant, a semi-quantitative (Tier 1) assessment is performed with the oral NOAEC of 0.1% avCl; estimated exposure corresponds to the concentration of active chlorine (in the product or in the in-use dilution, depending on the scenario, expressed in percentage) to which the operator is exposed.
* Inhalation exposure: exposure towards aerosols and vapours (as active chlorine) is conceivable. A quantitative assessment (Tier 1 and Tier 2) is performed with the AEC of 0.5 mg/m3. Estimated exposure corresponds to the concentration of active chlorine inhaled (in mg/m3) to which the operator is exposed.

**Chlorate**

Sodium chlorate is a relevant impurity of the active substance sodium hypochlorite and can be formed during storage. The stability test shows a maximum content of 7% for sodium chlorate (expressed as % of active chlorine content) after 14 days (final time of the stability study), which is above the specification limit for sodium chlorate (max 5,4% of active chlorine content) set during active substance approval. As sodium chlorate presents an acute toxicity by oral route (harmonized classification Acute Tox. 4 - **H302**) and **systemic effects**, the toxicity of chlorate is not covered by the active substance one. Therefore, a systemic risk assessment has to be performed.

The systemic risk assessment has been performed for chlorate, for which ARfD (0.036 mg/kg bw/d) and ADI[[2]](#footnote-3) (0.003 mg/kg bw/d) have been proposed by the EFSA. ADI has been used as AELlong term and ARfD as AELshort term.

A content of chlorate of **0.645%** has been calculated in the concentrate product (refer to the Physical, Chemical and technical part). The product being diluted at 0.0013% (PT4 uses) or 0.00013% (PT5 uses), chlorate concentration after dilution of the product is respectively **0.0000084%** (PT4) and **0.00000084%** (PT5).

**Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product**

| **Summary table: relevant paths of human exposure** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use (including bystander)** | **General public** | **Via food** |
| Inhalation | Yes | Yes | No | No | Yes | Yes | No |
| Dermal | Yes | Yes | No | No | No | Yes | No |
| Oral | No | No | No | No | No | Yes | Yes |

HYPOCHLORITE FAMILY ARKEMA is used by industrials/professionals for:

* Disinfection of inner surfaces in human drinking water systems (pipes, reservoirs, other equipments) by filling or spraying (**Use 1**)
* Disinfection of inner surfaces in veterinary water systems (pipes, reservoirs, other equipments) by filling or spraying (**Use 2**)
* Disinfection of water in drinking water companies (**Use 3**)
* Disinfection of stationary water in reservoirs (**Use 4**)
* Disinfection of veterinary water (**Use 5**)

**Uses 1-2:**

Two types of application are claimed: filling and spraying.

*Primary exposure*

Dermal and inhalation exposure of the worker (industrial/professional) is expected during:

* semi-automatic pumping of the product into inner surfaces (for filling application) or into the sprayer (for spraying application)
* spraying application
* maintenance/cleaning of dispensing pumps.

*Secondary exposure*

Professional bystander can be secondary exposed by inhalation during or following the use of the product, especially during semi-automatic pumping and spraying application. Dermal contact with treated surfaces is considered to be non-relevant due to the high reactivity of chlorine species such as NaClO and the very rapid degradation of residues on surfaces. Decomposition to physiological sodium and chloride ions occurs and no consequent health hazards are expected. Furthermore, the applied in-use solutions are of a low concentration. Hence, residue formation and chronic secondary exposure is assumed to be negligible for aqueous solutions of NaClO.

**Uses 3-4-5:**

One type of application is claimed: continuous application into drinking water systems and reservoirs of water. It is equivalent to the Cleaning In Place (CIP) mentioned in the CAR of sodium hypochlorite for PT5 (2017).

*Primary exposure*

Dermal and inhalation exposure of the worker (industrial/professional) is expected during semi-automatic pumping and maintenance/cleaning of dispensing pumps. No exposure is expected during application (closed system).

*Secondary exposure*

Professional bystander can be secondary exposed by inhalation during or following the use of the product, especially during semi-automatic pumping. Dermal contact with treated surfaces is considered to be non-relevant due to the high reactivity of chlorine species such as NaClO and the very rapid degradation of residues on surfaces. Decomposition to physiological sodium and chloride ions occurs and no consequent health hazards are expected. Furthermore, the applied in-use solutions are of a low concentration. Hence, residue formation and chronic secondary exposure is assumed to be negligible for aqueous solutions of NaClO.

Secondary exposure is also foreseen for general public during showering (dermal/inhalation exposure) and consumption of chlorinated drinking water (oral exposure).

***List of scenarios***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: scenarios** | | | |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| **PRIMARY EXPOSURE** | | | |
| 1. | Semi-automatic pumping of biocidal product | Uses 1-2-3-4-5  **Primary Exposure -** Dermal and inhalation (aerosols) exposure  The product is pumped from the packaging (jerrycan, drum or IBC) either directly to the inner surfaces of drinking water systems (pipes, reservoirs, other equipments) or directly into the reservoir of a sprayer. | Industrials/ Professionals |
| 2. | Spraying application (mixing and loading included) | Uses 1-2  **Primary Exposure -** Dermal and inhalation (aerosols) exposure  The product is mixed with water and sprayed with a low pressure sprayer on inner surfaces of water systems. | Industrials/ Professionals |
| 3. | Maintenance/Cleaning of dispensing pumps | Uses 1-2-3-4-5  **Primary Exposure** - Dermal and inhalation (aerosols) exposure  Exposure towards residues during maintenance/cleaning of the dispensing pumps. | Industrials/ Professionals |
| **SECONDARY EXPOSURE** | | | |
| 4. | Post-application exposure | Uses 1-2-3-4-5  **Secondary Exposure** - Inhalation (aerosols) exposure  Exposure to the aerosols in the proximity of the worker who proceeds to the connecting/disconnecting of the containers to the pumping system. | Bystander |
| 5. | Post application exposure | Uses 1-2  **Secondary Exposure** - Inhalation (aerosols) exposure  Exposure to the aerosols in the proximity of the worker who proceeds to the spray application on inner surfaces of water systems. | Bystander |
| 6. | Showering | Uses 3-4  **Secondary Exposure** – Dermal/Inhalation (aerosols and vapors) exposure  Exposure during showering with chlorinated water. | General public |
| 7. | Consumption of chlorinated drinking water | Uses 3-4  **Secondary Exposure** – Oral exposure  Exposure during consumption with chlorinated drinking water. | General public |

***Industrial exposure***

*Scenario [1] – Semi-automatic pumping of biocidal product*

| **Description of Scenario [1]** | | | |
| --- | --- | --- | --- |
| HYPOCHLORITE FAMILY ARKEMA is a liquid delivered in jerrycans (30-60L), drums (60-220L) and IBC (600-1000L).  Considering the high volume of the packaging and applicant’s data, it is considered that the product is pumped and distributed by a semi-automatic process. During this step, the worker exposure takes place during hoses coupling/decoupling product container to automated dosing/dispensing systems. Therefore, dermal and inhalation exposure (aerosols) are expected for active chlorine (local exposure) and chlorates (systemic exposure).  To determine dermal and inhalation exposure (aerosols), Mixing and Loading Model 7 (semi-) automated loading/pumping is used (HEEG Opinion 1).  A duration of 10 minutes is taken into consideration (RMS assumption).  After semi-automatic pumping, the product is either dosed automatically into the inner surfaces of water systems (for filling) or into the reservoir of the sprayer (for spraying), depending of the type of application). | | | |
| **Chlorates (systemic exposure)** | | | |
|  | Parameters | Value | Reference |
|  | Chlorate concentration | 0.645% (see calculation in the introduction of exposure assessment) |  |
| Duration (min) | 10 | Expert judgment |
| Dermal exposure – (mg p.b /min) | 138 | Mixing and Loading Model 7 (semi-) automated loading/pumping (HEEG Opinion 1) |
| Inhalation exposure – (mg p.b /m3) | 22 | Mixing and Loading Model 7 (semi-) automated loading/pumping (HEEG Opinion 1) |
| Dermal absorption (chlorates) | 50% | Default value |
| Inhalation rate (m3/hr) | 1.25 | Ad Hoc Recommendation 14 (2017) |
| Body weight (kg) | 60 | Ad Hoc Recommendation 14 (2017) |
| Tier 2 | Dermal exposure – (mg p.b /min)  gloves and coated coverall included in the model | 1.38 | Mixing and Loading Model 7 (semi-) automated loading/pumping (HEEG Opinion 1) |
| **Active chlorine (local exposure)** | | | |
|  | Parameters | Value | Reference |
|  | Active chlorine concentration | 12.5% (see calculation in the introduction of exposure assessment) |  |
| Tier 2 (inhalation exposure) | RPE | APF 10 | HEEG Opinion 9 (2010) |

***Calculations for Scenario [1]***

*Active chlorine (local exposure)*

Quantitative assessment for inhalation exposure:

| **Summary table: estimated exposure from industrial/professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation exposure (mg/m3)** |
| Scenario [1] | 1/no RPE | 2.75 |
| Scenario [1] | 2/ RPE APF 10 | 0.28 |

Semi-quantitative assessment for dermal exposure:

| **Summary table: estimated exposure from industrial/professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **NaClO av Cl concentration (%)** |
| Scenario [1] | 1/no PPE | 12.5 |

*Chlorate (systemic exposure)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from industrial/professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| Scenario [1] | 1/no PPE | 4.93E-04 | 7.42E-02 | 7.47E-02 |
| Scenario [1] | 2/gloves and coated coverall | 4.93E-04 | 7.42E-04 | 1.23E-03 |

*Scenario [2] – Application with low pressure sprayer (mixing and loading included)*

| **Description of Scenario [2]** | | | |
| --- | --- | --- | --- |
| HYPOCHLORITE FAMILY ARKEMA is automatically dosed into the inner surfaces by filling application (equivalent to the Cleaning In Place) or applied with a low pressure sprayer.  For filling application, no exposure is expected (closed system).  During spray application, dermal and inhalation exposure (aerosols) are expected for active chlorine (local exposure) and chlorates (systemic exposure) and assessed with Spraying Model 1 (BHEEM, 2015). The model covers the dilution of the product with water.  Considering the type of treated surfaces, an exposure duration of 120 minutes is taken into consideration. This choice of value is reinforced by the value proposed in the Excel spreadsheet PT4 for spraying in the BHHEM, 2015. | | | |
| **Chlorates (systemic exposure)** | | | |
|  | Parameters | Value | Reference |
|  | Chlorate concentration | 0.0000084% (see calculation in the introduction of exposure assessment) |  |
| Duration (min) | 120 | BHEEM, 2015 |
| Dermal exposure – Hand (mg b.p/min)  Gloves included in the model | 10.7 (75th percentile) | Spraying Model 1 (BHEEM, 2015) |
| Dermal exposure – Body (mg b.p/min) | 92 (75th percentile) | Spraying Model 1 (BHEEM, 2015) |
| Inhalation (mg b.p/m3) | 104 (50th percentile) | Spraying Model 1 (BHEEM, 2015) |
| Dermal absorption (chlorates) | 50% | Default value |
| Inhalation rate (m3/hr) | 1.25 | Ad Hoc Recommendation 14 (2017) |
| Body weight (kg) | 60 | Ad Hoc Recommendation 14 (2017) |
| **Active chlorine (local exposure)** | | | |
|  | Parameters | Value | Reference |
|  | Active chlorine concentration | 0.00016% (see calculation in the introduction of exposure assessment) |  |

***Calculations for Scenario [2]***

*Active chlorine (local exposure)*

Quantitative assessment for inhalation exposure:

| **Summary table: estimated exposure from industrial/professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation exposure (mg/m3)** |
| Scenario [2] | 1/no RPE | 0.00017 |

Semi-quantitative assessment for dermal exposure:

| **Summary table: estimated exposure from industrial/professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **NaClO av Cl concentration (%)** |
| Scenario [2] | 1/no PPE | 0.00016 |

*Chlorate (systemic exposure)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from industrial/professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| Scenario 2 | 1/gloves | 3.64E-07 | 8.63E-06 | 8.99E-06 |

*Scenario [3] – Maintenance/cleaning of dosing pumps*

| **Description of Scenario [3]** | | | |
| --- | --- | --- | --- |
| Dermal and inhalation exposure to the concentrated product can occur during maintenance/cleaning of dispensing pumps.  Exposure potential is predominantly to the hands and body, resulting from accidental touching of contaminated surfaces. Considering the volatility of the active chlorine and chlorate, inhalation exposure is considered relevant.  According to the similar scenario assessed in the CAR of sodium hypochlorite for CIP (repair of broken stock tank), the exposure has been modelled with Mixing and Loading Model 7 manual loading/pouring of liquids (HEEG Opinion 1).  An exposure duration of 5 min is taken into consideration (RMS assumption). | | | |
| **Chlorates (systemic exposure)** | | | |
|  | Parameters | Value | Reference |
|  | Chlorate concentration | 0.645% (see calculation in the introduction of exposure assessment) |  |
| Duration (min) | 5 | Expert judgment |
| Dermal exposure (mg b.p/min) | 101 | Mixing and Loading Model 7 manual loading/pouring of liquids (HEEG Opinion 1) |
| Inhalation (mg b.p/m3) | 0.94 | Mixing and Loading Model 7 manual loading/pouring of liquids (HEEG Opinion 1) |
| Dermal absorption (chlorates) | 50% | Default value |
| Inhalation rate (m3/hr) | 1.25 | Ad Hoc Recommendation 14 (2017) |
| Body weight (kg) | 60 | Ad Hoc Recommendation 14 (2017) |
| **Active chlorine (local exposure)** | | | |
|  | Parameters | Value | Reference |
|  | Active chlorine concentration | 12.5% (see calculation in the introduction of exposure assessment) |  |

***Calculations for Scenario [3]***

*Active chlorine (local exposure)*

Quantitative assessment for inhalation exposure:

| **Summary table: estimated exposure from industrial/professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation exposure (mg/m3)** |
| Scenario [3] | 1/no RPE | 0.12 |

Semi-quantitative assessment for dermal exposure:

| **Summary table: estimated exposure from industrial/professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **NaClO av Cl concentration (%)** |
| Scenario [3] | 1/no PPE | 12.5 |

*Chlorates (systemic exposure)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from industrial/professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| Scenario 3 | 1/no PPE | 1.05E-05 | 2.71E-02 | 2.72E-02 |

*Combined scenarios*

***Active chlorine***

Combined exposure is not relevant based on the absence of systemic effects after exposure towards 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.

***Chlorate***

For filling, the product is automatically dosed into the closed system by dispensing pumps, thus no exposure of worker is expected during application. Therefore, no combined scenario is expected for this type of application.

A combined exposure scenario is only expected for semi-automatic pumping and spraying application.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated combined exposure from industrial/professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| Scenario 1+2 | 1/gloves during spraying | 4.93E-04 | 7.42E-02 | 7.47E-02 |
| Scenario 1+2 | 2/gloves and coated coverall during semi-automatic pumping  gloves during spraying | 4.93E-04 | 7.50E-04 | 1.24E-03 |

*Scenario [4] – Secondary exposure – Exposure to the aerosols in the proximity of worker during semi-automatic pumping*

| **Description of Scenario [4]** | | | |
| --- | --- | --- | --- |
| Bystanders can be secondary exposed to the aerosols in the proximity of worker during semi-automatic pumping.  Exposure upon dermal contact with treated surfaces is considered to be non-relevant. Due to the high reactivity of chlorine species such as NaOCl, residues on surfaces degrade very rapidly.  To determine inhalation exposure (aerosols) of active chlorine and chlorate, the same model and parameters as scenario 1 have been used (Mixing and Loading Model 7 (semi-) automated loading/pumping). | | | |
| **Chlorates (systemic exposure)** | | | |
|  | Parameters | Value | Reference |
|  | Chlorate concentration | 0.645% (see calculation in the introduction of exposure assessment) |  |
| Duration (min) | 10 | Expert judgment |
| Inhalation exposure – (mg p.b /m3) | 22 | Mixing and Loading Model 7 (semi-) automated loading/pumping (HEEG Opinion 1) |
| Inhalation rate (m3/hr) | 1.25 | Ad Hoc Recommendation 14 (2017) |
| Body weight (kg) | 60 | Ad Hoc Recommendation 14 (2017) |
| **Active chlorine (local exposure)** | | | |
|  | Parameters | Value | Reference |
|  | Active chlorine concentration | 12.5% (see calculation in the introduction of exposure assessment) |  |
| Tier 2 (inhalation exposure) | RPE | APF 10 | HEEG Opinion 9 (2010) |

***Calculations for Scenario [4]***

*Active chlorine (local exposure)*

Quantitative assessment for inhalation exposure:

| **Summary table: estimated exposure from industrial/professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation exposure (mg/m3)** |
| Scenario [4] | 1/no RPE | 2.75 |
| Scenario [4] | 2/ RPE APF 10 | 0.28 |

*Chlorate (systemic exposure)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from industrial/professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| Scenario [4] | 1/no PPE | 4.93E-04 | n.a | 4.93E-04 |

*Scenario [5] – Secondary exposure – Exposure to the aerosols in the proximity of worker during spray application*

Inhalation exposure of bystanders can occur in the proximity of worker during spray application. Unlike the operator, no dermal exposure is expected. Therefore, the inhalation exposure is expected to be very low and covered by exposure assessment of application with a low pressure sprayer (scenario 2).

***Non-professional exposure***

Not relevant.

***Exposure of the general public***

*Scenario [6] - Showering with chlorinated water*

| **Description of Scenario [6]** | | | |
| --- | --- | --- | --- |
| General public (adult, child, toddler, infant) is exposed to chlorine species and chlorates during showering with chlorinated drinking water by dermal/inhalation routes.  ***Active chlorine***  For dermal route, a semi-quantitative exposure assessment has been performed. Therefore, no model has been used.  For inhalation route, aerosols of NaOCl are expected to be generated by the water spurt of the shower head, leading to active chlorine exposure. Therefore, the exposure can be considered similar to a spray application. Therefore, a quantitative exposure assessment of aerosols has been performed using **Consumer product spraying and dusting model 2 – Handheld trigger spray** (BHHEM, 2015).  In addition, chlorinated drinking water has a near neutral pH (between 6.5 and 9.5). At this pH value, hypochlorous acid (HClO) is the predominant species and exposure to vapours of HClO is also considered relevant. According to the PT5 CAR of active chlorine released from sodium hypochlorite (2017), a quantitative exposure assessment for vapors has also been performed using **ConsExpo**.  The inhalation exposure during this task has been considered as the sum of aerosols and vapors exposure (mg/m3).  ***Chlorates***  Drinking water quality controls are performed by healthcare authorities to not exceed the chlorate drinking water limit of 0.7 mg/l set by WHO in 2015[[3]](#footnote-4). Consequently, drinking water used during showering is expected to respect this limit.  Therefore, no systemic exposure assessment to chlorates during showering with chlorinated water has been considered relevant. | | | |
| **Active chlorine (local exposure)** | | | |
|  | Parameters | Value | Reference |
|  | Active chlorine concentration | 0.000016% (see calculation in the introduction of exposure assessment) |  |
|  | **Parameters for ConsExpo (vapour exposure)** | **Value** | **Reference** |
|  | Molecular weight (g/mol) | 52.5 | CAR active chlorine released from sodium hypochlorite (2017) |
|  | Vapour pressure (Pa) | 725 |
|  | Room volume (m3) | 2.5 |
|  | Ventilation rate (/hr) | 2 |
|  | Applied amount (kg) | 50 |
|  | Release area (m2) | 1 |

***Calculations for Scenario [6]***

*Active chlorine (local exposure)*

Quantitative assessment for inhalation exposure:

| **Summary table: estimated exposure for general public** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation exposure (mg/m3)** |
| Scenario [6] | 1/no RPE | Aerosols : 0.000002  Vapors : 0.0003  Total (aerosols + vapors) : 0.0003 |

Semi-quantitative assessment for dermal:

| **Summary table: estimated exposure for general public** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **NaClO av Cl concentration (%)** |
| Scenario [6] | 1/no PPE | 0.000016 |

*Chlorate (systemic exposure)*

Not relevant (see above).

*Scenario [7] – Consumption of drinking chlorinated water*

The general public is orally exposed to chlorine species and chlorate during consumption of chlorinated drinking water.

***Active chlorine***

A semi-quantitative exposure assessment has been performed for the oral exposure route.

Available chlorine concentration (%) = 0.000016%

***Chlorate***

Exposure to chlorate is assessed in the dietary risk assessment. Please see the corresponding assessment in “dietary exposure” part.

*Combined scenarios*

***Active chlorine***

Combined exposure is not relevant based on the absence of systemic effects after exposure towards 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.

***Chlorates***

A combined exposure is expected with the scenario showering and consumption of water.

Systemic exposure during showering is considered very weak compared to those during consumption of water. Therefore, combined exposure is expected to be in the same order that exposure during consumption of water.

***Monitoring data***

Not relevant.

***Dietary exposure***

Sodium hypochlorite is widely used for disinfection of surfaces and equipment in food and feed processing areas as well as for disinfection of drinking water, and thus, residues can be carried-over into food and feed during cleaning, washing and processing steps. Hence consideration to indirect exposure via drinking water is relevant.

Residue definitions

**Nature of residue:**

Due to the high reactivity of chlorine species, chlorine species degrade very rapidly (decomposition to physiological sodium and chloride). Hence, residue formation (other than chlorate) 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.  Consequently, chlorates is a relevant compound to assess in drinking water.

*List of scenarios*

*Please note that the applicant submitted three different scenarios that they have been considered as not relevant by eCA. They are presented in ANNEX RESIDUE as informative data.*

Considering all the intended uses as PT4 and PT5, the uses as PT5 in drinking water are considered as the worst case for exposure. Indeed with regards to the proposed PT4 applications for disinfection of drinking water equipment, the equipment is intended to be rinsed with potable water and the residues sent to drain with the rinsing water. The applicant mentioned, “the equipment will be rinsed with potable water and the residues sent to drain with the rinsing water. There will be no dietary transfer other than to drinking water which has already considered to be assessed”. Indeed this specific instruction for use is mentioned for PT 4: “Release to drain and rinse (low pressure) with clean water.”

For the proposed PT5 applications, humans and animals are directly exposed to the treated water with direct ingestion. Therefore, the other uses are considered as covered by the PT5 assessment below, consequently only the exposure via consumption of drinking water is presented.

**Exposure to chlorate via drinking water:**

In line with the last approach to assess and limit the presence of chlorate in drinking water, FR as eCA proposes the following assessment:

Dietary exposure to available chlorine and chlorate from drinking water disinfection for disinfection of drinking water equipment was assessed and considered acceptable in the CAR[[4]](#footnote-5):

*“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 professional uses of the active chlorine releaser in PT4 and PT5****.”***

Concerning chlorates, EU approach[[5]](#footnote-6) which is still under discussion, proposes that:

* Art 22: *Member States shall take the measures necessary to ensure that water intended for human consumption complies with the parametric values set in Annex I, part B, for the following parameters: Chlorate, Chlorite, Bisphenol-A, Haloacetic Acids, Microcystin-LR, PFAS total, Sum of PFASs, Uranium, by [3 years after end-date for transposition].*
* *Part B: Parametric value of 0,7 mg/l shall be applied when a disinfection method that generates chlorate, in particular chlorine dioxide, is used for disinfection of water intended for human consumption. Where possible, without compromising disinfection, Member States shall strive for a lower value.*

In the framework of this dossier, the applicant submitted data from UBA project, which is a quantitative determination of the efficacy of drinking water disinfectants. As part of the R&D project, determination of chlorate and perchlorate in sodium hypochlorite treated water has been realised (UBA testing, Nov 2018, provided by applicant). This demonstrates that for the typical dose of 0.5 mg/L available chlorine, a maximum 360 µg/L of chlorate is measured in drinking water. This is a worst case considering the 0.2 mg/L of active chlorine claimed in this dossier.

As stated above, the provisional guideline value for drinking water for chlorate is 0.7 mg/L (WHO 2005 and EC 2020). According to the conclusions of the BPC TOX-WG-IV-2016, it has to be demonstrated at product authorisation stage that disinfection of drinking water with sodium hypochlorite would not lead to a concentration of chlorate that will exceed the drinking water limit.

Hence considering that the data from UBA project show that concentration of chlorate of 0.36 mg/L in drinking water will not exceed the limit for chlorate in drinking water of 0.7 mg/L, no further assessment is considered necessary.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Threshold concentration Limit in drinking water** | **Maximum measured concentration from studies** | **Acceptable**  **(yes/no)** |
| Exposure to treated water – drinking water  Chlorate | 1 | 0.7 mg/L | 0.36 mg/L | Yes |

This concentration of chlorate in drinking water is well below the threshold concentration of 0.7 mg/L.

*Information of non-biocidal use of the active substance*

*Not relevant*

*Estimating Livestock Exposure to Active Substances used in Biocidal Products*

Not relevant (see above)As the expected chlorate concentration in treated water is below the trigger value of 0.7 mg/L, there is no concern for the BP resulting chlorate in drinking water neither for consumers nor for livestock.

#### Risk characterisation for human health

Reference values to be used in Risk Characterisation

**Active clorine**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | AF | **Correction for oral absorption** | **Value** |
| NOAEC oral | 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 |
| NOAEC dermal | human (dermatitis patients) 48 h-patch test study | 1% | 1 | - | 1% avCl |
| 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 |

Chlorate

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | AF | **Correction for oral absorption** | **Value** |
| ARfD  (chlorate) | 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  (chlorate) | 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**

|  |  |  |  |
| --- | --- | --- | --- |
| **MRLs or other relevant reference values** | **Reference** | **Relevant commodities** | **Value** |
| Drinking water limit – chlorate | WHO, 2005 WHO/SDE/WSH/05.08/86[[6]](#footnote-7) | **Drinking water** | **0.7 mg/L** |
| Drinking water limit – chlorate | Water Directive  Proposed limit (EC 2020[[7]](#footnote-8)) | 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 and animal matrices | From 0.05 to 0.7 mg/kg |

**Specific reference value for groundwater**

*[If it is proposed to derive a value according to BPR Annex VI point 68, other than the maximum permissible concentration laid down by Directive 98/83/EC, please include the argumentation and the calculations here. Otherwise, please delete this chapter.]*

***Risk for industrial/professional users***

**Use 1** – Disinfection of inner surfaces in human drinking water systems (pipes, reservoirs, other equipments)

**Use 2** – Disinfection of inner surfaces in veterinary water systems (pipes, reservoirs, other equipments) by filling or spraying

**Application by spraying**

Active chlorine semi-quantitative and quantitative risk assessment (local effects)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Oral** | | **Dermal** | | **Inhalation** | |
| **Task/**  **Scenario** | **Tier** | **Exposure**  **(% NaClO as avCl)** | **% NOAEC**  **(NOAEC oral : 0.1% avCl)** | **Exposure**  **(% NaClO as avCl)** | **% NOAEC**  **(NOAEC dermal : 1% avCl)** | **Exposure**  **(mg/m3 of NaClO and/or HClO as avCl)** | **% AEC**  **(0.5 mg/m3 avCl)** |
| Scenario 1 – Semi-automatic pumping | Tier 1 | n.r. | - | 12.5 | **1250** | 2.75 | **550** |
| Tier 2 | n.r. | - | 12.5 | Qualitative assessment (see below) | RPE APF 10 : 0.28 | 55 |
| Scenario 2 –  Spray application | Tier 1 | n.r. | - | 0.00016 | 0.016 | 0.00017 | 0.03 |
| Scenario 3 – Maintenance/ cleaning of dosing pumps | Tier 1 | n.r. | - | 12.5 | **1250** | 0.12 | 24 |
| Tier 2 | n.r. | - | 12.5 | Qualitative assessment  (see below) | 0.12 | 24 |
| Scenario 4 – Bystander exposition during semi-automatic pumping | Tier 1 | n.r. | - | n.r. | - | 2.75 | **550** |
| Tier 2 | n.r. | - | n.r. | - | RPE APF 10 : 0.28 | 55 |
| Scenario 5 -Bystander exposition during spray application | Tier 1 | n.r. | - | n.r. | - | Negligible and covered by scenario 2 | Negligible and covered by scenario 2 |

Chlorate (systemic effects)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **AEL long term or short term**  **(as ADI or ARfD depending on scenario)**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** |
| Scenario 1 – Semi-automatic pumping | Tier 1/no PPE | 0.003 (ADI\*) | 7.47E-02 | **2489** |
| Tier 2/gloves + coated coverall | 0.003 (ADI\*) | 1.23E-03 | 41 |
| Scenario 2  Spray application | Tier 1/gloves | 0.003 (ADI\*) | 8.99E-06 | 0.3 |
| Scenario 3 – Maintenance/cleaning of dosing pumps | Tier 1/no PPE | 0.036 (ARfD\*\*) | 2.72E-02 | 75 |
| Scenario 4 - Bystander exposition during semi-automatic pumping | Tier 1/no RPE | 0.036 (ARfD\*\*) | 4.93E-04 | 1.4 |
| Scenario 5 - Bystander exposition during spray application | Tier 1/no RPE | 0.036 (ARfD\*\*) | Negligible and covered by scenario 2 | Negligible and covered by scenario 2 |

Combined exposure (chlorate)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** |
| Scenario 1+2 (semi-automatic pumping + spray application) | 1/gloves during spray application | 0.003 | 7.47E-02 | **2489** |
| 2/gloves + coated coverall for semi-automatic pumping  gloves during spray application | 0.003 | 1.24E-03 | 41 |

**Conclusion related to the (semi-)quantitative local risk assessment for active chlorine for use 1-2 - Application by spraying:**

A semi-quantitative local risk assessment was performed for the dermal and inhalation route of exposure for active chlorine.

* *Dermal route*

For scenario 1 (semi-automatic pumping) and scenario 3 (maintenance/cleaning of dispensing pumps), the semi-quantitative risk assessment lead to an unacceptable risk. Therefore, a qualitative assessment was performed in addition according to “Guidance on BPR: Volume III Part B+C, Version 4.0 December 2017” (see below).

For all other scenarios, the risk is acceptable.

* *Inhalation route*

For scenario 1 (semi-automatic pumping) and scenario 4 (bystander exposition during semi-automatic pumping), the risk is acceptable with a RPE APF 10.

For all other scenarios, the risk is acceptable without RPE.

**Conclusion related to the systemic risk assessment for chlorate for use 1-2 - Application by spraying:**

A quantitative systemic risk assessment was performed for the dermal and inhalation route of exposure for chlorate.

The risk for worker during semi-automatic pumping (scenario 1) is acceptable if gloves and coated coverall are worn. The risk for worker during spray application (scenario 2) is acceptable if gloves are worn.

The risk for worker during maintenance/cleaning of dispensing pumps (scenario 3) is acceptable without PPE.

The combined risk for the worker is acceptable if gloves and coated coverall are worn during semi-automatic pumping (scenario 1) and gloves during spraying application (scenario 2).

For bystander (scenario 4-5), the risk is acceptable without PPE.

**Qualitative local risk assessment for active chlorine – Industrial exposure to the concentrated product (application by spraying):**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | **Characteristics of the product** | | | | | | **Recommendations for acceptable risk (according to BPR Guidance Vol III Part B+C)** | | **Risk** |
| *Hazard category* | *Effects in terms of C&L* | *Additional relevant hazard information* | *PT* | *Who is*  *exposed?* | *Tasks,*  *uses,*  *processes* | *Potential*  *exposure*  *route* | *Frequency*  *and*  *duration*  *of*  *potential*  *exposure* | *Degree*  *of potential*  *exposure*  *(mg/m3)* | *Conclusion on risk assessment* |
| Very high | Skin Corr.  1B  H314  Eye Dam.1, H318  EUH071 | - | 4-5 | Industrial/ Professional | Semi-automatic pumping  Maintenance of dosing pumps | Dermal  Ocular  Inhalation | Few minutes per day or less | High level of containment,  practically no exposure; no  splashes, no hand to eye transfer,  no (liquid or solid) aerosol  formation | The risk is acceptable considering the following PPE:  - substance/task appropriate gloves  - protection coverall  - chemical goggles  - substance/task respirator |

**Conclusion related to qualitative local risk assessment for chlorate for use 1-2 -Application by spraying:**

During the manipulation of the concentrated product (semi-automatic pumping and maintenance of dosing pumps), the risk is acceptable considering the following PPE:

* substance/task appropriate gloves
* protection coverall
* chemical goggles
* substance/task respirator

**Application by automatic filling**

Active chlorine semi-quantitative and quantitative risk assessment (local effects)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Oral** | | **Dermal** | | **Inhalation** | |
| **Task/**  **Scenario** | **Tier** | **Exposure**  **(% NaClO as avCl)** | **% NOAEC**  **(NOAEC oral : 0.1% avCl)** | **Exposure**  **(% NaClO as avCl)** | **% NOAEC**  **(NOAEC dermal : 1% avCl)** | **Exposure**  **(mg/m3 of NaClO and/or HClO as avCl)** | **% AEC**  **(0.5 mg/m3 avCl)** |
| Scenario 1 – Semi-automatic pumping | Tier 1 | n.r. | - | 12.5 | **1250** | 2.75 | **550** |
| Tier 2 | n.r. | - | 12.5 | Qualitative assessment (see below) | RPE APF 10 : 0.28 | 55 |
| Scenario 3 – Maintenance/ cleaning of dosing pumps | Tier 1 | n.r. | - | 12.5 | **1250** | 0.12 | 24 |
| Tier 2 | n.r. | - | 12.5 | Qualitative assessment  (see below) | 0.12 | 24 |
| Scenario 4 – Bystander exposition during semi-automatic pumping | Tier 1 | n.r. | - | n.r. | - | 2.75 | **550** |
| Tier 2 | n.r. | - | n.r. | - | RPE APF 10 : 0.28 | 55 |

Chlorate (systemic effects)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **AEL long term or short term**  **(as ADI or ARfD depending on scenario)**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** |
| Scenario 1 – Semi-automatic pumping | Tier 1/no PPE | 0.003 (ADI\*) | 7.47E-02 | **2489** |
| Tier 2/gloves + coated coverall | 0.003 (ADI\*) | 1.23E-03 | 41 |
| Scenario 3 – Maintenance/cleaning of dosing pumps | Tier 1/no PPE | 0.036 (ARfD\*\*) | 2.72E-02 | 75 |
| Scenario 4 - Bystander exposition during semi-automatic pumping | Tier 1/no RPE | 0.036 (ARfD\*\*) | 4.93E-04 | 1.4 |

Combined exposure (chlorate)

Scenario 3 and 4 being acute exposure scenarios, no combined exposure is expected.

**Conclusion related to the (semi-)quantitative local risk assessment for active chlorine for use 1-2 - Application by automatic filling:**

A (semi-)quantitative local risk assessment was performed for the dermal and inhalation route of exposure for active chlorine.

* *Dermal route*

For scenario 1 (semi-automatic pumping) and scenario 3 (maintenance/cleaning of dispensing pumps), semi quantitative risk assessment lead to an unacceptable risk. Therefore, a qualitative assessment was performed in addition according to “Guidance on BPR: Volume III Part B+C, Version 4.0 December 2017” (see below).

For all other scenarios, the risk is acceptable.

* *Inhalation route*

For scenario 1 (semi-automatic pumping) and scenario 4 (bystander exposition during semi-automatic pumping), the risk is acceptable with a RPE APF 10.

For all other scenarios, the risk is acceptable without RPE.

**Conclusion related to the systemic risk assessment for chlorate for use 1-2 - Application automatic filling:**

A quantitative systemic risk assessment was performed for the dermal and inhalation route of exposure for chlorate.

The risk for worker during semi-automatic pumping (scenario 1) is acceptable if gloves and coated coverall are worn.

The risk during maintenance/cleaning of dosing pumps (scenario 3) is acceptable without PPE.

For bystander (scenario 4), the risk is acceptable without PPE.

**Qualitative local risk assessment for active chlorine – Industrial exposure to the concentrated product (automatic filling)**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | **Characteristics of the product** | | | | | | **Recommendations for acceptable risk (according to BPR Guidance Vol III Part B+C)** | | **Risk** |
| *Hazard category* | *Effects in terms of C&L* | *Additional relevant hazard information* | *PT* | *Who is*  *exposed?* | *Tasks,*  *uses,*  *processes* | *Potential*  *exposure*  *route* | *Frequency*  *and*  *duration*  *of*  *potential*  *exposure* | *Degree*  *of potential*  *exposure*  *(mg/m3)* | *Conclusion on risk assessment* |
| Very high | Skin Corr.  1B  H314  Eye Dam.1, H318  EUH071 | - | 4-5 | Industrial/ Professional | Semi-automatic pumping  Maintenance of dosing pumps | Dermal  Ocular  Inhalation | Few minutes per day or less | High level of containment,  practically no exposure; no  splashes, no hand to eye transfer,  no (liquid or solid) aerosol  formation | The risk is acceptable considering the following PPE:  - substance/task appropriate gloves  - protection coverall  - chemical goggles  - substance/task respirator |

**Conclusion related to qualitative local risk assessment for chlorate for use 1-2 -Application by automatic filling:**

During the manipulation of the concentrated product (semi-automatic pumping and maintenance of dosing pumps), the risk is acceptable considering the following PPE:

* substance/task appropriate gloves
* protection coverall
* chemical goggles
* substance/task respirator

**Use 3** – Disinfection of water in drinking water companies

**Use 4** – Disinfection of stationary water in reservoirs

**Use 5** – Disinfection of veterinary water

**Application by automatic filling**

Active chlorine semi-quantitative and quantitative risk assessment (local effects)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Oral** | | **Dermal** | | **Inhalation** | |
| **Task/**  **Scenario** | **Tier** | **Exposure**  **(% NaClO as avCl)** | **% NOAEC**  **(NOAEC oral : 0.1% avCl)** | **Exposure**  **(% NaClO as avCl)** | **% NOAEC**  **(NOAEC dermal : 1% avCl)** | **Exposure**  **(mg/m3 of NaClO and/or HClO as avCl)** | **% AEC**  **(0.5 mg/m3 avCl)** |
| Scenario 1 – Semi-automatic pumping | Tier 1 | n.r. | - | 12.5 | **1250** | 2.75 | **550** |
| Tier 2 | n.r. | - | 12.5 | Qualitative assessment (see below) | RPE APF 10 : 0.28 | 55 |
| Scenario 3 – Maintenance/ cleaning of dosing pumps | Tier 1 | n.r. | - | 12.5 | **1250** | 0.12 | 24 |
| Tier 2 | n.r. | - | 12.5 | Qualitative assessment  (see below) | 0.12 | 24 |
| Scenario 4 – Bystander exposition during semi-automatic pumping | Tier 1 | n.r. | - | n.r. | - | 2.75 | **550** |
| Tier 2 | n.r. | - | n.r. | - | RPE APF 10 : 0.28 | 55 |

Chlorate (systemic effects)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **AEL long term or short term**  **(as ADI or ARfD depending on scenario)**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** |
| Scenario 1 – Semi-automatic pumping | Tier 1/no PPE | 0.003 (ADI\*) | 7.47E-02 | **2489** |
| Tier 2/gloves + coated coverall | 0.003 (ADI\*) | 1.23E-03 | 41 |
| Scenario 3 – Maintenance/cleaning of dosing pumps | Tier 1/no PPE | 0.036 (ARfD\*\*) | 2.72E-02 | 75 |
| Scenario 4 - Bystander exposition during semi-automatic pumping | Tier 1/no RPE | 0.036 (ARfD\*\*) | 4.93E-04 | 1.4 |

Combined exposure (chlorate)

Scenario 3 and 4 being acute exposure scenarios, no combined exposure is expected.

**Conclusion related to the (semi-)quantitative local risk assessment for active chlorine for use 3-4-5 - Application by automatic filling:**

A (semi-)quantitative local risk assessment was performed for the dermal and inhalation route of exposure for active chlorine.

* *Dermal route*

For scenario 1 (semi-automatic pumping) and scenario 3 (maintenance/cleaning of dispensing pumps), semi quantitative risk assessment lead to an unacceptable risk. Therefore, a qualitative assessment was performed in addition according to “Guidance on BPR: Volume III Part B+C, Version 4.0 December 2017” (see below).

For all other scenarios, the risk is acceptable.

* *Inhalation route*

For scenario 1 (semi-automatic pumping) and scenario 4 (bystander exposition during semi-automatic pumping), the risk is acceptable with a RPE APF 10.

For all other scenarios, the risk is acceptable without RPE.

**Conclusion related to the systemic risk assessment for chlorate for use 3-4-5 - Application automatic filling:**

A quantitative systemic risk assessment was performed for the dermal and inhalation route of exposure for chlorate.

The risk for worker during semi-automatic pumping (scenario 1) is acceptable if gloves and coated coverall are worn.

The risk during maintenance/cleaning of dosing pumps (scenario 3) is acceptable without PPE.

For bystander (scenario 4), the risk is acceptable without PPE.

**Qualitative local risk assessment for active chlorine – Industrial exposure to the concentrated product (automatic filling)**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | **Characteristics of the product** | | | | | | **Recommendations for acceptable risk (according to BPR Guidance Vol III Part B+C)** | | **Risk** |
| *Hazard category* | *Effects in terms of C&L* | *Additional relevant hazard information* | *PT* | *Who is*  *exposed?* | *Tasks,*  *uses,*  *processes* | *Potential*  *exposure*  *route* | *Frequency*  *and*  *duration*  *of*  *potential*  *exposure* | *Degree*  *of potential*  *exposure*  *(mg/m3)* | *Conclusion on risk assessment* |
| Very high | Skin Corr.  1B  H314  Eye Dam.1, H318  EUH071 | - | 4-5 | Industrial/ Professional | Semi-automatic pumping  Maintenance of dosing pumps | Dermal  Ocular  Inhalation | Few minutes per day or less | High level of containment,  practically no exposure; no  splashes, no hand to eye transfer,  no (liquid or solid) aerosol  formation | The risk is acceptable considering the following PPE:  - substance/task appropriate gloves  - protection coverall  - chemical goggles  - substance/task respirator |

**Conclusion related to qualitative local risk assessment for chlorate for use 1-2 – Application by automatic filling:**

During the manipulation of the concentrated product (semi-automatic pumping and maintenance of dosing pumps), the risk is acceptable considering the following PPE:

* substance/task appropriate gloves
* protection coverall
* chemical goggles
* substance/task respirator

**Conclusion**

The risk is considered as acceptable considering local effects of active chlorine and systemic effects of chlorates if the following PPE/RPE are worn during:

* semi-automatic pumping:
* Gloves
* Coated coverall
* Goggles
* Mask APF 10
* maintenance of dosing pumps:
* Gloves
* Coated coverall
* Goggles
* Substance/task respirator

The professional bystander needs to observe the same type of RPE as the worker during semi-automatic pumping of the product (APF 10) and during maintenance of dosing pumps (substance/task respirator).

***Risk for non-professional users***

Not relevant.

***Risk for the general public***

**Use 1** – Disinfection of inner surfaces in human drinking water systems (pipes, reservoirs, other equipments)

**Use 2** – Disinfection of inner surfaces in veterinary water systems (pipes, reservoirs, other equipments) by filling or spraying

**Use 5** – Disinfection of veterinary water

Not relevant.

**Use 3** – Disinfection of water in drinking water companies

**Use 4** – Disinfection of stationary water in reservoirs

Active chlorine semi-quantitative and quantitative risk assessment (local effects)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Oral** | | **Dermal** | | **Inhalation** | |
| **Task/**  **Scenario** | **Tier** | **Exposure**  **(NaClO as avCl)**  **%** | **% NOAEC**  **(NOAEC oral : 0.1% avCl)** | **Exposure**  **(NaClO as avCl)**  **%** | **% NOAEC**  **(NOAEC dermal : 1% avCl)** | **Exposure**  **(NaClO and/or HClO as avCl)**  **mg/m3** | **% AEC**  **NOAEC inhalation : 0.5 mg/m3 avCl** |
| Scenario 6 – Showering with chlorinated water | Tier 1 | nr | - | 0.000016 | 0.0016 | 0.0003 | 0.05 |
| Scenario 7 –  Consumption of chlorinated water | Tier 1 | 0.000016 | 0.016 | nr | - | nr | - |

n.r. not relevant

Chlorate (systemic effects)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **General public** | **AEL**  **mg/kg bw/d (as ADI)** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** |
| Scenario 7 –  Consumption of chlorinated water | Tier 1 |  |  | Covered by the dietary risk assessment |  |

Combined exposure (chlorate)

Not relevant.

**Conclusion related to the semi-quantitative local risk assessment for active chlorine for use 3-4 - Application by automatic filling:**

A semi-quantitative local risk assessment was performed for the oral, dermal and inhalation route of exposure for active chlorine.

* *Oral route*

For scenario 7 (consumption of chlorinated water), the semi-quantitative risk assessment for oral route lead to an acceptable risk.

* *Dermal route*

For scenario 6 (showering with chlorinated water), the semi-quantitative risk assessment for dermal route lead to an acceptable risk.

* *Inhalation route*

For scenario 6 (showering with chlorinated water), the semi-quantitative risk assessment for inhalation route lead to an acceptable risk.

**Conclusion related to the systemic risk assessment for chlorate for use 3-4 - Application by automatic filling:**

Drinking water quality controls are performed by healthcare authorities to not exceed the chlorate drinking water limit of 0.7 mg/l set by WHO in 2015[[8]](#footnote-9). Consequently, drinking water used during showering (scenario 6) is expected to respect this limit.

Therefore, no systemic risk assessment to chlorates during showering with chlorinated water has been considered relevant.

For scenario 7 (consumption of chlorinated water), the systemic risk assessment is considered covered by the dietary risk assessment. Therefore, the risk is acceptable.

**Conclusion**

For general public, the risk is considered as acceptable considering local effects of active chlorine and systemic effects of chlorate.

***Risk for consumers via residues in food***

see above § dietary exposure.

***Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product***

*Not applicable*

### Risk assessment for animal health

Oral exposure of animals during drinking water consumption is considered covered by the assessment performed for human drinking water consumption for both active chlorine (see scenario 7 semi-quantitative risk assessment) and chlorate (see dietary risk assessment part). An acceptable risk has been observed for this scenario in humans.

**Conclusion**

The risk for animal health is acceptable.

### Risk assessment for the environment

The biocidal product HYPOCHLORITE FAMILY - ARKEMA is applied by professional user as:

- PT4 for surface disinfection of inner surfaces in human and veterinary drinking water systems (pipes, reservoirs, …)

- PT5 for disinfection of water in drinking water companies, disinfection of veterinary water and disinfection of stationary water in reservoir.

Note: Following a request for additional data, the applicant has restricted the family to the product JAVEL STANDARD 12.5 % w/w active chlorine and withdraw the other products.

Active substance

The products is a soluble concentrate containing 13.1% w/w sodium hypochlorite equivalent to 12.5 % w/w active chlorine. The active substance within the product family is active chlorine released from sodium hypochlorite (CAS: 7681-52-9). According to the active substance’s assessment report (2017), 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 Available Chlorine or FAC (in practice, only HClO and OCl─ are usually present because Cl2 is formed only at pH < 4) and combined chlorine (such as chloramines). It is difficult to separate the contribution to toxicity of FAC from that of the combined chlorine species. For studies where the percentage of FAC in TRC was measured, the toxicity endpoints were expressed as FAC/L as well.

Available 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 / MWNaClO = 71/74.5)
* or 1 g active chlorine equivalent to 1.05 g sodium hypochlorite (MWNaClO / MWCl2 = 74.5 / 71).

Substance of Concern

No substance of concern has been identified (see confidential annex for further details).

Chlorate formation during storage

The maximal sodium chlorate content after 14 days storage exceeds the reference specification (around 7% w/w of av. chlorine, while the limit is 5.4% w/w of av. Chlorine ; refer to section 2.2.2). Consequently, a risk assessment for chlorate is needed.

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 environmental risk assessment of DBPs has been provided by the applicant in a separate DBP RA document (see IUCLID DBP substance data set – Section 13). An extract of the evaluation relevant to drinking water disinfection is given in Annex 3.7. As underlined by the applicant, the risk assessment is still under development and will be amended as agreement on PNEC values and exposure concentrations 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

No new environmental studies have been conducted on the products. All agreed endpoints have been taken from the final Assessment Report Active substance released from sodium hypochlorite in water (2017). The predicted no effect concentration values (PNEC) are summarised in the table below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PNEC** | **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 partitioning 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 non-volatile 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. | | | |
| mammals |

***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***

All relevant data can be extrapolated from the active substance Active chlorine released from sodium hypochlorite (AR, 2017). Testing of the product is not required.

The products do not contain any classified ingredients other than the active substance (active chlorine released from sodium hypochlorite). Thus, the environmental hazard classification of the products is driven by the active substance classified as **Aquatic Acute 1, H400 (M=10), Aquatic chronic 1, H410 (M=1)** according to the Regulation (EC) No 1272/2008 (CLP). The classification **H400, H411** applies to all the META-SPC within the family considering a concentration of the active substance in products between 25 and 2.5%.

***Further Ecotoxicological studies***

No data available.

***Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)***

No data available.

***Supervised trials to assess risks to non-target organisms under field conditions***

No data available.

***Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk***

No data available.

***Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)***

Secondary ecological effects are not expected.

***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 further studies on fate and behaviour have been conducted, given that sufficient data are available for the active substance within the associated Assessment Report (2017). Testing of the product is not required.

***Leaching behaviour (ADS)***

According to Guidance on the Biocidal Products Regulation Volume IV: Environment Part A: Information Requirements, Version 1.2, May 2018, 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 presented. Please refer to the AR (2017).

***Testing for distribution and dissipation in water and sediment (ADS)***

No new data presented. Please refer to the AR (2017).

***Testing for distribution and dissipation in air (ADS)***

No new data presented. Please refer to the AR (2017).

***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 data submitted. The biocidal family does not contain any product intended to be sprayed near surface waters.

***If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)***

No data submitted. Not relevant for the biocidal family intended uses.

#### Exposure assessment

General information

|  |  |
| --- | --- |
| Assessed PT | PT 4 |
| Assessed scenarios | **Scenario 1: Disinfection of inner surfaces in drinking water system by industry/professionals** |
| ESD(s) used | Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas, JRC Scientific and Technical Reports, Report nr. EUR 25117 EN, Publications Office of the European Union, Luxembourg, 2011 |
| Approach | Average consumption |
| Distribution in the environment | Calculated based on Guidance for BPR IV Part B+C (2017).  NaOCl PT 4 CAR (2017) |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Scenario 1  Production: No  Formulation No  Use: Yes  Service life: No |
| Remarks | This scenario was already assessed and approved in the CAR for a 14% NaOCl product. |

|  |  |
| --- | --- |
| Assessed PT | PT 5 |
| Assessed scenarios | **Scenario 2: Disinfection of drinking water for humans and animals, and of stationary water in reservoirs by industry/professionals** |
| ESD(s) used | Emission Scenario Document for Product Type 5:  Emission Scenario Document on Drinking Water Disinfectants (Herrmann and Wagner (2003) |
| Approach | Average consumption |
| Distribution in the environment | Calculated based on Guidance for BPR IV Part B+C (2017).  NaOCl PT 5 CAR (2017); |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Scenario 1  Production: No  Formulation No  Use: Yes  Service life: No |
| Remarks | This scenario was already assessed and approved in the CAR for a 14% NaOCl product dosed at 0.5 mg/L to drinking water. |

***Emission estimation***

##### **Scenario 1: Disinfection of inner surfaces in drinking water system**

The products are used for the disinfection of inner surfaces in human drinking water systems and in veterinary water systems (pipes, reservoirs, other equipments) by filling or spraying. This does not include the small-scale re-disinfection of potable water on farms or cleaning of farm drinking water supply equipment. Release to manure is not applicable. Moreover, in the case of this type of active substance with a high reactivity to organic matter, releases to the STP cover emissions *via* manure considering the high level of organic matter in this last system.

A concentration of 2 mg avCl/L is used for the disinfection. There is no specific scenario available for the intended use. However, the exposure “Assessment of entire plants (e.g.breweries, dairies, beverage processing plants) (IHO 2006)” from ESD PT4 (Table 5, p.14-15 is considered appropriate to assess this use. A similar use was assessed for the NaOCl active substance approval (scenario PT4b – CIP in food and beverage industry; AR, 2017).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | |
| **Input** | **Symbol** | **Unit** | **Value** | **Remarks** |
| Active ingredient applied | Qai | [kg chlorine/y] | 228 | Pick list value (Table 6; ESD for PT 4, 2011) |
| Chlorate from stockage | Qai | [kg chlorate/y] | 11.76 | Based on the maximum concentration of chlorate obtained in long term stability assay (0.645 %) |
| 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  Hypochlorite  Chlorate | Elocal waste water | [kg av Cl/d]  [kg chlorate/d] | 9.87E-01  5.09E-02 | - |

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 1 h is proposed as 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 = 4.39 x 10-20 kg av Cl/d |

Considering the very low emission rate 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.

The emission rates of chlorate in the local STP was calculated to be **5.09 x 10-2 kg Chlorate/d**.

##### **Scenario 2: Disinfection of drinking water for humans and animals, and of stationary drinking water in reservoirs**

Disinfection of drinking water is described in the ESD for PT5 (2003). Although this document does not make any distinction between different types of water disinfection, this scenario can be considered as a worst case for release to the STP for the disinfection of water in drinking water companies, disinfection of stationary water in reservoirs and disinfection of veterinary water using 0.2 mg avCl/L. In the case of this type of active substance with a high reactivity to organic matter, releases to the STP cover potential emissions *via* manure considering the high level of organic matter in this last system.

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. A sewer residence time of 1 h is proposed as 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. No degradation was considered for chlorates.

The input parameters relevant for the emission estimation are listed in table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Variable/parameter** | **Unit** | **Symbol** | **S/D/O/P** | **Value** | **Remark** |
| Maximum concentration of disinfectant in drinking water at the tap | [mg avCl/L] | Cdrinking water | S | 0.2 | Information provided by the applicant |
| Concentration of chlorate in drinking water at the tap | [mg chlorate/L] | Cdrinking water | S | 0.01 | Based on the maximum concentration of chlorate obtained in long term stability assay (0.645 %) |
| Reaction rate constant in sewer system for active chlorine | [h-1] | k | S | 44.6 | AR (2017) |
| Residence time in municipal sewer system | [hr] | T | D | 1 | ESD, page 14 |
| **Output**: Cinfluent = Influent concentration of disinfectant in the STP [mg/L] | | | | | |
| **Calculation**: ***Cinlfuent = Cdrinkingwater\* EXP(-k \*t)*** | | | | **= 8.89 x 10-21 mg av Cl/L**  **= 1.03 x 10-02 mg Chlorate/L (corresponding to Elocal STP of 2.06E-02 kg/d)** | |

The influent concentration of active chlorine in the local STP after one hour residence time in the sewer system was calculated to be **8.89 x 10-21 mg av Cl/L** considering that the whole amount of wastewater reaching the STP (2000 m³/d) was disinfected with hypochlorite.

The influent concentration of chlorate in the local STP was calculated to be **1.03 x 10-2 mg Chlorate/L** considering that the whole amount of wastewater reaching the STP (2000 m³/d) was disinfected with hypochlorite.

***Fate and distribution in exposed environmental compartments***

| **Identification of relevant receiving compartments based on the exposure pathway – Av Cl** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Representative scenario** | **STP** | **Freshwater incl. sediment** | **Marine** | **Soil incl. groundwater** | **Air** |
| **PT4** | | | | | |
| Disinfection of surface in dringking water system | Q | Q | Q | Q | - |
| **PT5** | | | | | |
| Disinfection of drinking water | Q | Q | Q | Q | Q |

Q: Qualitative assesssment

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Identification of relevant receiving compartments based on the exposure pathway – Chlorate** | | | | | | |
| **Representative scenario** | **STP** | **Freshwater intented for the abstraction of drinking water** | **Marine** | Soil | Groundwater | Air |
| **PT4** | | | | | | |
| Disinfection of surface in dringking water system | a | SQ | a | a | SQ |  |
| **PT5** | | | | | | |
| Disinfection of drinking water | a | SQ | a | a | SQ |  |

SQ: Semi qualitative assessment ; a : covered by the active substance 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 20°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 20 oC) | 5.2E-09 | Pa/m3/mol | Estimated |
| Biodegradability | Not applicable to inorganic substances | [-] | Not readily biodegradable |
| DT50 for degradation in soil | 1E+06 | d (at 12ºC) | Not Readily biodegradable |
| Rate constant for soil biodegradation | 6.96E-07 | d-1 (at 12ºC) |  |

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***

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values – Active substance NaOCl** | | | | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECseawater** | **PECseased** | **PECsoil** | **PECGW** | **PECair** |
| [mg/L] | [mg/l] | [mg/kgwwt] | [mg/l] | [mg/kgwwt] | [mg/m3] | [μg/l] | [mg/m3] |
| **Scenario 1:** Disinfection of inner surfaces in drinking water system | - | - | - | - | - | - | - | - |
| **Scenario 2:** Disinfection of drinking water | - | - | - | - | - | - | - | - |

- Negligible emissions based on a qualitative assessment

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values - Chlorate** | | | | | | | | | |
|  | **PECSTP** | **PECwater1** | **PECsed** | **PECseawater** | **PECseased** | **PECsoil** | **PECGW** | **PECair** |
| [mg/m3] | [mg/l] | [mg/kgwwt] | [mg/l] | [mg/kgwwt] | [mg/m3] | [μg/l] | [mg/m3] |
| **Scenario 1** Disinfection of surface in dringking water system | - | 2.54E-03 | - | - | - | - | 5.52E-01 | - |
| **Scenario 2**  Disinfection of drinking water | - | 1.03E-03 | - | - | - | - | 2.24E-01 | - |
| 1 Freshwater intended for the abstraction of drinking water | | | | | | | | | |

- Negligible emissions based on a qualitative assessment

***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. Primary poisoning is not expected for the intended uses.

#### Risk characterisation

Due to the high reactivity of the active substance with organic matter, indirect releases from the disinfection of inner surfaces in human and veterinary drinking water systems (pipes, reservoirs, …) (scenario 1) and from the disinfection of water in drinking water companies, disinfection of veterinary water and disinfection of stationary water in reservoir (scenario 2) 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 and surface water intended for the abstraction of drinking water 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 for the abstraction of drinking water.

***Atmosphere***

Qualitative conclusion: Hypochlorite might enter the atmosphere due to volatilisation from the STP. Exposure assessment in the AR showed emission to air via this pathway is negligible. As the adsorption of hypochlorite to aerosol particles, the volatilisation from water into air and the adsorption of hypochlorite onto soil are all very low, hypochlorite will remain in the aqueous phase and degrade very rapidly. Exposure of the atmosphere is thus considered to be negligible. There are no indications that active chlorine contributes to depletion of the ozone layer as it is not listed as ‘controlled substance’ in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. Therefore, the risks for the air compartment are considered acceptable.

***Sewage treatment plant (STP)***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
| **PEC/PNECSTP** | **NaOCl** | **Chlorate** |
| **Scenario 1** Disinfection of surface in drinking water system | Negligible | Negligible |
| **Scenario 2**  Disinfection of drinking water | Negligible | Negligible |

**Conclusion:** Risks are considered acceptable for the scenario 1 and 2 based on a qualitative assessment with negligible emissions.

***Aquatic compartment***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |  |
|  | **PEC/PNECwater NaOCl / chlorate** | **PEC/PNECsed NaOCl / chlorate** | **PEC/PNECFreshwater intented for the abstraction of drinking water\***  **chlorate** |
| **Scenario 1** Disinfection of surface in drinking water system | Negligible | Negligible | 3.62E-03 |
| **Scenario 2**  Disinfection of drinking water | Negligible | Negligible | 1.47E-03 |

\* drinking water limit value of 700 µg chlorate/L (WHO drinking Water Limit) for water disinfected by chloration. Using the worst case data from the UBA testing (2018) ie, 360 µg/L of chlorate measured in drinking water instead of the calculated 10 µg/L (see section 2.2.8.2.2), the ratio remain well below the threshold concentration of 700 µg/L.

**Conclusion:** Risks are considered acceptable for the scenario 1 and 2 considering a qualitative assessment with negligible emissions for the active substance, as well as semi qualitative assessment for chlorate in freshwater intended for the abstraction of drinking water.

***Terrestrial compartment***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
| **PEC/PNECSoil** | **NaOCl** | **Chlorate** |
| **Scenario 1** Disinfection of surface in dringking water system | Negligible | Negligible |
| **Scenario 2**  Disinfection of drinking water | Negligible | Negligible |

**Conclusion:** Risks are considered acceptable for the scenario 1 and 2 considering a qualitative assessment with negligible emissions.

***Groundwater***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
| **PEC/PNECGW** | **NaOCl** | **Chlorate\*** |
| **Scenario 1** Disinfection of surface in dringking water system | Negligible | 7.89E-04 |
| **Scenario 2**  Disinfection of drinking water | Negligible | 3.20E-04 |

\*drinking water limit value of 700 µg chlorate/L (WHO drinking Water Limit) for water disinfected by chloration. Using the worst case data from the UBA testing (2018) ie, 360 µg/L of chlorate measured in drinking water instead of the calculated 10 µg/L (see section 2.2.8.2.2), the ratio remain well below the threshold concentration of 700 µg/L.

**Conclusion:** Risks are considered acceptable for the scenario 1 and 2 considering a qualitative assessment with negligible emissions for the active substance, as well as considering the semi qualitative assessment of chlorate in freshwater intended for the abstraction of drinking water.

***Primary and secondary poisoning***

Active chlorine does not bioaccumulate and does not concentrate in the food chain. The low BCF indicates that the risk for birds and mammals is low regarding secondary poisoning. Primary poisoning is not expected for the intended uses.

***Mixture toxicity***

Non-relevant as the product contain only one active substance and none of the coformulants are of environmental concern.

***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. Consequently, the aggregated exposure is not relevant.



*Figure 1: Decision tree on the need for estimation of aggregated exposure*

The aggregate risks assessment presented below sums up the chlorate emissions from all uses:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated ΣPEC/PNEC values - Chlorate** | | | | | | |
|  | **ΣPEC/PNECSTP** | **ΣPEC/PNECwater1** | **ΣPEC/PNECsed** | **ΣPEC/PNECsoil** | **ΣPECGW** | **ΣPECair** |
|  | NR | 5.09E-03 | NR | NR | 1.11E-03 | NR |

1 Freshwater intented for the abstraction of drinking water - NR: Not Relevant

**Conclusion:** Aggregated risks for chlorate are acceptable for all compartments.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| Risks are acceptable for all the environmental compartments considering a qualitative assessment of the active substance NaOCl and chlorate formed during storage leading to negligible emissions to the environment for  - PT4 for surface disinfection of inner surfaces in human and veterinary drinking water systems (pipes, reservoirs, …)  - PT5 for disinfection of water in drinking water companies, disinfection of veterinary water and disinfection of stationary water in reservoir  Risks linked to chlorate formed during storage are acceptable for all uses considering a semi-qualitative assessment for groundwater and surface water intended for the abstraction of drinking 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.

### Comparative assessment

Not applicable

# Annexes[[9]](#footnote-10)

## List of studies for the biocidal product family

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** |
| Martinez, M.P. | 2018 | Sodium Hypochlorite Standard: Determination of the Accelerated Storage Stability and Corrosion Characteristics  Testing laboratory: ChemService S.r.l. Controlli e Ricerche GLP Studies Department Via F.lli Beltrami, 15 20026 Novate Milanese - MI - (Italy)  Report no. CH - 626/2018  GLP  Unpublished | Y | ARKEMA |
| Martinez, M.P. | 2018 | Sodium Hypochlorite Standard: validation of the analytical method for the determination of the active ingredient content  Testing laboratory: ChemService S.r.l. Controlli e Ricerche GLP Studies Department Via F.lli Beltrami, 15 20026 Novate Milanese - MI - (Italy)  Report no. CH – 623/2018  GLP  Unpublished | Y | ARKEMA |
| Zydowicz Philippe | 2020 | Chemical stability after a low temperature storage procedure for 7 days at 0°C +- 2°C on JAVEL STANDARD  Testing laboratory: DEFITRACES, Brindas, France  Report No. 19-901026-001  GLP  Unpublished | Y | ARKEMA |
| Zydowicz Philippe | 2020 | Persistent foaming test on JAVEL STANDARD  Testing laboratory: DEFITRACES, Brindas, France  Report No. 19-901026-002  GLP  Unpublished | Y | ARKEMA |
| Zydowicz Philippe | 2020 | Determination of the content of active chlorine and sodium chlorate during a kinetic study in one batch of in JAVEL STANDARD  Testing laboratory: DEFITRACES, Brindas, France  Report No. 19-901026-003  GLP  Unpublished | Y | ARKEMA |
| Zydowicz Philippe | 2020 | Validation of the analytical method for the determination of active chlorine in JAVEL STANDARD  Testing laboratory: DEFITRACES, Brindas, France  Report No. 19-901026-004  GLP  Unpublished | Y | ARKEMA |
| Zydowicz Philippe | 2020 | Validation of the analytical method for the determination of sodium chlorate in JAVEL STANDARD  Testing laboratory: DEFITRACES, Brindas, France  Report No. 19-901026-005  GLP  Unpublished | Y | ARKEMA |

## Output tables from exposure assessment tools

****

## New information on the active substance

## Residue behaviour

* 1. Applicant assessment

| **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) |
| 5. | Indirect | #1.3  #1.4 | Secondary  Exposure to treated water – drinking water - Human | General public  Proposed by applicant |
| 6 | Indirect | #1.5 | Secondary  Exposure to treated water – drinking water - veterinary | Livestock  Proposed by applicant |
| 7 | Indirect | #1.5 | Secondary  Exposure to residues in diet from exposed livestock | General public  Proposed by applicant |

***Dietary exposure***

Dietary exposure to available chlorine and chlorate from drinking water disinfection were assessed and considered acceptable in the CAR;

Chlorine:

The active substance and products are only classified for local effects; skin corrosion. Systemic toxicity is secondary to the local effects, therefore a only a semi-quantitative risk is performed for the local effects taking into account the classification of the product.

In drinking water, exposure is to available chlorine (HOCl) not to sodium hypochlorite. Available chlorine is typically maintained at a dose of 0.5 mg/L. At this in-use concentration the substance would not be classified.

Systemic exposure to chlorate via drinking water is only relevant for the oral route.

*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 professional uses of the active chlorine releaser NaOCl in PT5.*

The proposed PT 4 applications are for disinfection of drinking water equipment only. The equipment will be rinsed with potable water and the residues sent to drain with the rinsing water. There will be no dietary transfer other than to drinking water which has already considered to be assessed.

* *Scenario [5] Exposure to treated water – Drinking water*

|  |  |  |
| --- | --- | --- |
| **Description of Scenario [5]** | | |
| This scenario has been assessed as acceptable under the active substance evaluation  Efficacy has been shown at 0.2 mg/L available chlorine. For the purposes of risk assessment, the typical dose of 0.5 mg/L available chlorine will be used.  The general public is exposed to chlorine species by consumption of chlorinated drinking water.  A semi-quantitative exposure assessment was performed for the oral exposure route.  Exposure to chlorate residues is assessed in the dietary risk assessment  Exposure was modelled using ConsExpo Web, using the Disinfectants Factsheet; drinking water disinfectants post application scenario | | |
|  | Parameters1 | Value |
| Tier 1 | Concentration of active substance in water | 0.5 mg/L av Chlorine (0.00005%) |
| Concentration of chlorate in water5 | 360 µg/L |
| Amount ingested - adult2 | 2000g |
| Amount ingested – child4 | 1000g |
| Amount ingested – infant4 | 750g |
| Body weight - adult3 | 60 kg |
| Body weight - Child3 | 10 kg |
| Body weight - Infant3 | 5 kg |

1 PT 5 CAR: Document IIB, Annex I –r

2 CONSEXPO Web Version 1.0.1 3-7-2017 – Disinfection factsheet

3 HEEG Opinion 17: Default human factor values for use in exposure assessments for biocidal products (TMII 2013)

4. ECHA Guidance on Human Health RA Vol III Parts B+C (2017)

5. Maximum chlorate concentration measured in UBA project; Chlorate and perchlorate determination in sodium hypochlorite treated water, as part of the R&D project: Quantitative determination of the efficacy of drinking water disinfectants (UBA testing, Nov 2018)

| **Summary table: systemic exposure to the general public - chlorate** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Inhalation uptake (mg/kg/bw/day)** | **Dermal uptake (mg/kg/bw/day)** | **Oral uptake (mg/kg/bw/day)** | **Total uptake (mg/kg/bw/day)** |
| Scenario 5  Adult  Child  infant | 1 | n.a | n.a | 0.012  0.036  0.054 | 0.012  0.036  0.054 |

* *Scenario [6] Disinfection of animal drinking water*

| **Description of Scenario [6] Disinfection of animal drinking water** | | |
| --- | --- | --- |
| Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017;  Chapter 6, Section 6.5.2.– screening on four livestock indicator species as described in the SANCO Guidance; chicken including laying hens, dairy cattle, beef cattle, pig:  *(water consumption\*C\_prod)/bw*  The median value of **0.004 mg / kg livestock bw** of external exposure over 1 day is the threshold for triggering Tier II assessment and further steps across all livestock species.  The concentration of chlorate applied via drinking water applications is taken from the efficacy simulation study performed by UBA and applies to the efficacious dose of 0.2 mg/L av Cl. | | |
|  | | Parameters1 | Value |
| Tier 1 | | Concentration in drinking water1 | 0.36 mg chlorate/L |
| Trigger value | 0.004 mg / kg livestock bw |
| Drinking water intake  Broiler Chicken  Cattle  Pig  Laying hen | 0.25L  115L  15.0L  0.25L |
| Bodyweight  Broiler Chicken  Cattle  Pig  Laying hen | 1.7 kg  650 kg  260 kg  1.9 kg |

5. Maximum chlorate concentration measured in UBA project; Chlorate and perchlorate determination in sodium hypochlorite treated water, as part of the R&D project: Quantitative determination of the efficacy of drinking water disinfectants (UBA testing, Nov 2018)

| **Internal dose received by the animal and WCCE - Chlorate** | | | | |
| --- | --- | --- | --- | --- |
| Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017  Chapter 6  WCCE is determined as 30% of ADI.  Trigger value is 0.004 mg/kg bw | | | | |
|  |  | Parameters | Oral exposure  (mg/kg bw/day) | Total exposure  (mg/kg bw/day) |
| 6 | Disinfection of animal drinking water  Broiler  Cattle  Pig  Laying hen |  | 5.29E-~~05~~02  6.37E-~~05~~02  2.08E-~~05~~02  4.74E-~~05~~02 | 5.29E-02  6.37E-02  2.08E-02  4.74E-02 |

* *Scenario [7] Exposure to residues in diet from exposed livestock*

|  |  |  |
| --- | --- | --- |
| **Description of Scenario [7]** | | |
| See Scenario 6 | | |
|  | Parameters1 | Value |
| Tier 1 | Maximum concentration of chlorate estimated in livestock from consumption of drinking water – cattle  Total from all livestock exposures | 6.37E-02 mg/kg bw/day  1.848E-01 mg/kg bw/day |

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment – systemic - chlorate** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Exposed group**  **(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw)** | **Estimated**  **dermal uptake**  **(mg/kg bw)** | **Estimated oral uptake (external)**  **(mg/kg bw)** | **Estimated total uptake**  **(mg/kg bw/day)** |
| 5. Exposure to treated water – drinking water  Chlorate | General public  Adult  Child  Infant | 1 | n.a | n.a | 0.012  0.036  0.054 | 0.012  0.036  0.054 |
| 6. Disinfection of animal drinking water | Disinfection of animal drinking water  Broiler  Cattle  Pig  Laying hen | 1 |  |  |  | 5.29E-02  6.37E-02  2.08E-02  4.74E-02 |
| 7. Exposure to residues in diet from exposed livestock | General public | 1 |  |  |  | 6.37E-02 |

***Monitoring data***

Maximum chlorate concentration measured in UBA project; Chlorate and perchlorate determination in sodium hypochlorite treated water, as part of the R&D project: Quantitative determination of the efficacy of drinking water disinfectants (UBA testing, Nov 2018).

UBA simulated use test. Monitoring of the water shows that at the efficacious dose rate of the product (0.2 mg/L available chlorine), 360 µg/L of chlorate is present.

The limit for chlorate in drinking water is 0.07 mg/L

***Risk for consumers via residues in food***

Available chlorine (HOCl)

Local irritation effects are the primary and the most sensitive effects of sodium hypochlorite exposure and systemic effects are of less significance. It is relevant to determine only external values for dermal and inhalation exposure for humans.

At the in-use concentration in drinking water (0.00005%) the substance is not classified for local effects.

Chlorate

Chlorate is a degradation product of sodium hypochlorite and will be added to drinking water with the product. A systemic risk assessment is required for the general public exposed to the degradation product from drinking treated water.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **ADI**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario 5  Adult  Child  infant | 1 | - | 0.003 | 0.012  0.036  0..054 | 400  1200  1800 | **No** |

The FAO/WHO toxicological reference value of 0.01 mg/kg bw for chronic risk assessment is used in determination of the drinking water limit concentration for chlorate (currently set at 0.7 mg/L). Using this Reference Value which considers not only oral but also dermal and inhalation exposures:

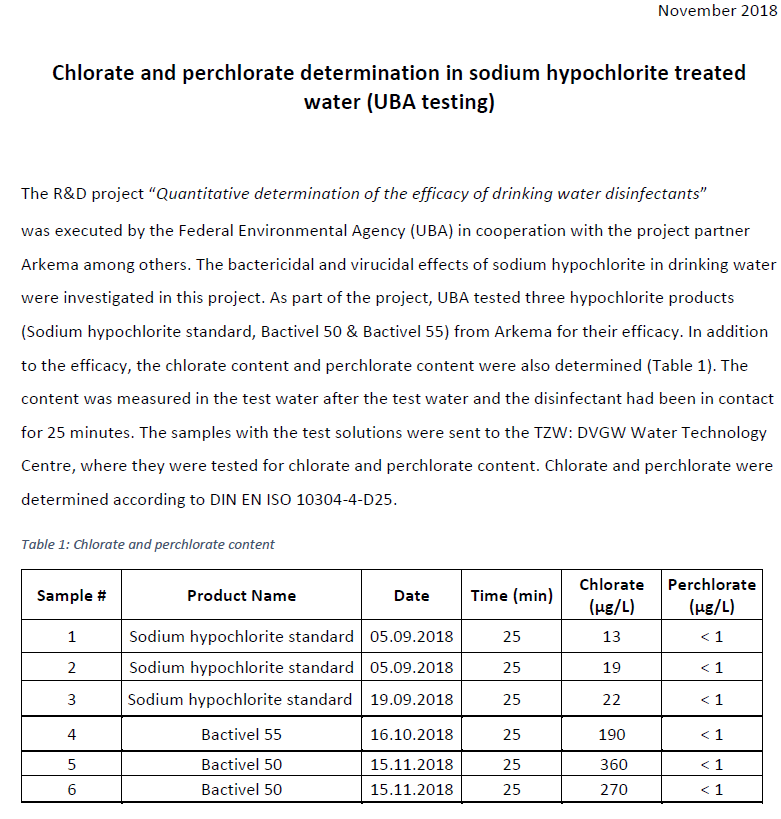
|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **Drinking water chronic**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ Ref value**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario 5  Adult  Child  infant | 1 | - | 0.01 | 0.012  0.036  0.054 | 120  360  540 | **No** |

The concentration of chlorate applied via drinking water applications of 360 µg/L is the maximum chlorate concentration measured in UBA project; Chlorate and perchlorate determination in sodium hypochlorite treated water, as part of the R&D project: Quantitative determination of the efficacy of drinking water disinfectants (UBA testing, Nov 2018) and applies to the efficacious dose of 0.2 mg/L av Cl. is below the threshold concentration for chlorate in drinking water of 0.7 mg/L.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Threshold concentration Limit in drinking water (DWD)** | **Measured maximum concentration from studies** | **Acceptable**  **(yes/no)** |
| Scenario 5  Exposure to treated water – drinking water  Chlorate | 1 | 0.7 mg/L | 0.36 mg/L | Yes |

* 1. Additionnal document submitted by Applicant

Maximum chlorate concentration measured in UBA project; Chlorate and perchlorate determination in sodium hypochlorite treated water, as part of the R&D project: Quantitative determination of the efficacy of drinking water disinfectants (UBA testing, Nov 2018).



## Summaries of the efficacy studies (B.5.10.1-xx)[[10]](#footnote-11)

## Confidential annex

See the confidential PAR

## Environmental risk assessment of disinfection-by-products (DBPs)

Extracted from the separate DBP RA document relevant to drinking water disinfection – see IUCLID DBP substance data set – Section 13.

Exposure levels- drinking water

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Worst case exposure levels based on 100ug/l THM** | |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  | **HIWATE Study** | |  | **US EPA** | |  |  |  |  |
|  | **High Br Sites** | **Low Br Sites** |  | **High Br Sites** | **Low Br Sites** |  |  |  |  |
|  | **ug/l** | **ug/l** |  | **ug/l** | **ug/l** |  |  |  |  |
| **THM** | 100 | 100 |  |  |  |  |  |  |  |
| **HAA** | 90 | 60 |  |  |  |  |  |  |  |
| **HAN** | 10 | 7.5 |  |  |  |  |  |  |  |
| **HK** | 1 | 15 |  |  |  |  |  |  |  |
| **CH** | 3 | 7 |  |  |  |  |  |  |  |
| **CP** | 0 | 7 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
| **Trihalomethanes ug/l** | | |  |  |  |  |  |  |  |
| **Chloroform** |  |  |  | 37.7 | 83.9 |  |  |  |  |
| **BDCM** |  |  |  | 44.4 | 27.4 |  |  |  |  |
| **CDBM** |  |  |  | 34.6 | 8.5 |  |  |  |  |
| **Bromoform** |  |  |  | 9.6 | 1.4 |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
| **Haloacetic Acids ug/l** | | |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
| **MCA** |  |  |  | 2.9 | 12.83 |  | 3.00% | 8.80% |  |
| **MBA** | 1.2 | 0.0 |  | 1.9 | 0 |  | 1.90% | 0.00% |  |
| **BCA** | 13.0 | 1.4 |  | 17.3 | 8.49 |  | 18.00% | 5.80% |  |
| **BDCA** | 10.9 | 8.0 |  | 12.5 | 14.01 |  | 13.00% | 9.60% |  |
| **DBA** | 35.0 | 0.0 |  | 12.9 | 0 |  | 13.40% | 0.00% |  |
| **DBCA** | 35.8 | 0.0 |  | 9.7 | 0 |  | 10.00% | 0.00% |  |
| **DCA** | 10.8 | 26.0 |  | 20.3 | 50 |  | 21.10% | 34.30% |  |
| **TCA** | 13.6 | 46.1 |  | 14.2 | 60.53 |  | 14.80% | 41.50% |  |
| **TBA** |  |  |  | 4.7 | 0 |  | 4.80% | 0.00% |  |
|  |  |  |  |  |  |  | 96.2 | 145.9 |  |
| **Haloacetonitriles ug/l** | | |  |  |  |  |  |  |  |
| **DCAN** | 1.56 | 6.44 |  | 5.03 | 10.7 |  |  |  |  |
| **BCAN** | 3.21 | 1.49 |  | 3.70 | 1.8 |  |  |  |  |
| **DBAN** | 7.34 | 0.56 |  | 2.19 | 1.4 |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
| **Haloketones ug/l** | | |  |  |  |  |  |  |  |
| **DCP** | 0.00 | 0.00 |  | 0.9 | 2.1 |  |  |  |  |
| **TCP** | 0.49 | 7.32 |  | 1.5 | 10.1 |  |  |  |  |
| **TBP** | 0.11 | 0.00 |  | 0.0 | 0.0 |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  | Based on peak area compared to Tribromopropanone | |  |  |  |  |  |  |  |
| **TBAcetaldehyde** | 0.5 | 0 |  | 0.7 | 0.0 |  |  |  |  |
| **Dibromophenol** | 0.1 | 0.05 |  |  |  |  |  |  |  |
| **Tribromophenol** | 0.1 | 0.05 |  |  |  |  |  |  |  |

The worst case values from the table above were used to determine the risk assessment for drinking water applications.

**Emissions**

**Scenario [14] Disinfection of human drinking water**

Scenario: Disinfection of drinking water for use by humans and animals (Disinfection of drinking water for use by animals by profs and non-profs;

Disinfection of drinking water for use by humans by profs and non-profs)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | |
| **Input** | **Value** | **Unit** | **Symbol** | **Remarks** |
| Scenario: *Disinfection of drinking water* | | | | |
| Maximum concentration of disinfectant in drinking water at the tap | [ | [mg/L] | Cdrinking water |  |
| Residence time in municipal sewer system | 1 | [hr] | T | D; ESD, p.14 |
| Volume of influent | 2000 | m³ | Vinfluent | D; guidance vol IV part B |
| **Output: Elocalwater = *Cinfluent \*Vinfluent = Cdrinkingwater\* EXP(-k \*t) \* Vinfluent*** | | | | |
| Elocalwater | | | = [ ]kg/d | |

**Scenario [15] Disinfection of veterinary drinking water**

Scenario: Disinfection of drinking water for use by humans and animals (Disinfection of drinking water for use by animals by profs and non-profs;

Disinfection of drinking water for use by humans by profs and non-profs)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | |
| **Input** | **Value** | **Unit** | **Symbol** | **Remarks** |
| Scenario: *Disinfection of drinking water* | | | | |
| Maximum concentration of disinfectant in drinking water at the tap |  | [mg/L] | Cdrinking water |  |
| Residence time in municipal sewer system | 1 | [hr] | T | D; ESD, p.14 |
| Volume of influent | 2000 | m³ | Vinfluent | D; guidance vol IV part B |
| **Output: Elocalwater = *Cinfluent \*Vinfluent = Cdrinkingwater\* EXP(-k \*t) \* Vinfluent*** | | | | |
| Elocalwater | | | = [..] kg/d | |

***Summary of local releases***

| **SCENARIO** | **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | | | |
| --- | --- | --- | --- | --- | --- |
|  |  | **Chloroform** | **DBCM** | **DCBM** | **MCAA** |
| [14] Disinfection of human drinking water | STP | **1.68E-01** | **6.9E-02** | **8.9E-02** | **2.4E-03** |
| [15] Disinfection of veterinary drinking water | STP | **1.68E-01** | **6.9E-02** | **8.9E-02** | **2.4E-03** |

| **SCENARIO** | **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | | | |
| --- | --- | --- | --- | --- | --- |
|  |  | **DCAA** | **TCAA** | **MBAA** | **DBAA** |
| [14] Disinfection of human drinking water | STP | **5.2E-02** | **9.2E-02** | **2.4E-03** | **7.0E-02** |
| [15] Disinfection of veterinary drinking water | STP | **5.2E-02** | **9.2E-02** | **2.4E-03** | **7.0E-02** |

| **SCENARIO** | **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | | | |
| --- | --- | --- | --- | --- | --- |
|  |  | **TBAA** | **DBCAA** | **BCAA** | **DCAN** |
| [14] Disinfection of human drinking water | STP | **9.4E-03** | **7.2E-02** | **2.6E-02** | **1.3E-02** |
| [15] Disinfection of veterinary drinking water | STP | **9.4E-03** | **7.2E-02** | **2.6E-02** | **1.3E-02** |

***Risk Assessment***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | |
| Representative scenario | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW1** | **PECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] | [mg/m3] |

**Trichloromethane (Chloroform)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 1.48E-02 | 1.48E-03 | 4.74E-03 | 7.91E-03 | 3.43E-03 | 3.79E-05 |
| [15] Disinfection of veterinary drinking water | 1.48E-02 | 1.48E-03 | 4.74E-03 | 7.91E-03 | 3.43E-03 | 3.79E-05 |

**Dibromochloromethane (DBCM)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 3.43E-03 | 3.43E-03 | 1.36E-03 | 4.88E-03 | 1.66E-03 | 1.71E-05 |
| [15] Disinfection of veterinary drinking water | 3.43E-03 | 3.43E-03 | 1.36E-03 | 4.88E-03 | 1.66E-03 | 1.71E-05 |

**Dichlorobromomethane (DCBM)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 9.31E-03 | 9.31E-04 | 3.05E-03 | 4.54E-03 | 1.92E-03 | 1.92E-05 |
| [15] Disinfection of veterinary drinking water | 9.31E-03 | 9.31E-04 | 3.05E-03 | 4.54E-03 | 1.92E-03 | 1.92E-05 |

**Monochloroacetic acid (MCAA)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 1.20E-03 | 1.20E-04 | 1.38E-04 | 1.04E-05 | 1.74E-02 | 3.31E-10 |
| [15] Disinfection of veterinary drinking water | 1.20E-03 | 1.20E-04 | 1.38E-04 | 1.04E-05 | 1.74E-02 | 3.31E-10 |

***Dichloroacetic acid (DCAA)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 2.59E-02 | 2.59E-03 | 3.80E-03 | 5.16E-04 | 6.06E-01 | 8.09E-09 |
| [15] Disinfection of veterinary drinking water | 2.59E-02 | 2.59E-03 | 3.80E-03 | 5.16E-04 | 6.06E-01 | 8.09E-09 |

***Trichloroacetic acid (TCAA)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 4.58E-02 | 4.58E-03 | 8.53E-03 | 2.17E-03 | 2.18E-03 | 8.24E-10 |
| [15] Disinfection of veterinary drinking water | 4.58E-02 | 4.58E-02 | 8.53E-03 | 2.17E-03 | 2.18E-03 | 8.24E-10 |

***Monobromoacetic acid (MBAA)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 1.20E-03 | 1.20E-04 | 1.38E-04 | 1.04E-05 | 1.74E-02 | 3.31E-10 |
| [15] Disinfection of veterinary drinking water | 1.20E-03 | 1.20E-04 | 1.38E-04 | 1.04E-05 | 1.74E-02 | 3.31E-10 |

***Dibromoacetic acid (DBAA)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 3.49E-02 | 3.49E-03 | 3.49E-03 | 6.16E-04 | 9.37E-01 | 1.20E-10 |
| [15] Disinfection of veterinary drinking water | 3.49E-02 | 3.49E-03 | 3.49E-03 | 6.16E-04 | 9.37E-01 | 1.20E-10 |

***Tribromoacetic acid (TBAA)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 4.65E-03 | 4.65E-04 | 1.17E-03 | 5.80E-04 | 3.54E-01 | 2.81E-12 |
| [15] Disinfection of veterinary drinking water | 4.65E-03 | 4.65E-04 | 1.17E-03 | 5.80E-04 | 3.54E-01 | 2.81E-12 |

***Dibromochloroacetic acid (DBCAA)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 3.54E-02 | 3.54E-03 | 8.25E-03 | 2.34E-03 | 1.49E-03 | 2.87E-08 |
| [15] Disinfection of veterinary drinking water | 3.54E-02 | 3.54E-03 | 8.25E-03 | 2.34E-03 | 1.49E-03 | 2.87E-08 |

***Bromochloroacetic acid (BCAA)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 5.80E-04 | 5.80E-05 | 7.24E-05 | 1.63E-04 | 3.42E-05 | 6.89E-06 |
| [15] Disinfection of veterinary drinking water | 5.80E-04 | 5.80E-05 | 7.24E-05 | 1.63E-04 | 3.42E-05 | 6.89E-06 |

***Dichloroacetonitrile (DCAN)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 6.28E-03 | 6.28E-04 | 6.94E-04 | 4.27E-05 | 6.95E-02 | 8.14E-08 |
| [15] Disinfection of veterinary drinking water | 6.28E-03 | 6.28E-04 | 6.94E-04 | 4.27E-05 | 6.95E-02 | 8.14E-08 |

***Dibromoacetonitrile (DBAN)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 7.20E-03 | 7.20E-04 | 7.34E-05 | 6.35E-05 | 9.43E-02 | 6.96E-08 |
| [15] Disinfection of veterinary drinking water | 7.20E-03 | 7.20E-04 | 7.34E-05 | 6.35E-05 | 9.43E-02 | 6.96E-08 |

***Bromochloroacetonitrile (BCAN)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 3.15E-03 | 3.15E-04 | 3.59E-04 | 2.43E-05 | 7.67E-05 | 3.10E-08 |
| [15] Disinfection of veterinary drinking water | 3.15E-03 | 3.15E-04 | 3.59E-04 | 2.43E-05 | 7.67E-05 | 7.67E-08 |

***Summary table of PEC/PNEC values***

***STP***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | | | |
|  | **PEC/PNECSTP** | | | |
|  | **Chloroform** | **DBCM** | **DCBM** | **MCAA** |
| [14] Disinfection of human drinking water | **3.09E-01** | **<0.001** | **<0.001** | **<0.001** |
| [15] Disinfection of veterinary drinking water | **3.09E-01** | **<0.001** | **<0.001** | **<0.001** |
|  | **DCAA** | **TCAA** | **MBAA** | **DBAA** |
| [14] Disinfection of human drinking water | **1.62E-02** | **<0.001** | **<0.001** | **2.18E-02** |
| [15] Disinfection of veterinary drinking water | **1.62E-02** | **<0.001** | **<0.001** | **2.18E-02** |
|  | **TBAA** | **DBCAA** | **BCAA** | **DCAN** |
| [14] Disinfection of human drinking water | **<0.001** | **2.21E-02** | **<0.001** | **1.66E-03** |
| [15] Disinfection of veterinary drinking water | **<0.001** | **2.21E-02** | **<0.001** | **1.66E-03** |
|  | **DBAN** | **BCAN** | **Chloral hydrate** |  |
| [14] Disinfection of human drinking water |  | **No PNEC** | **N/A** |  |
| [15] Disinfection of veterinary drinking water |  | **No PNEC** | **N/A** |  |

***Aquatic compartment***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECseawater** | **PEC/PNECseased** |

***Chloroform***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 1.02E-02 | 1.02E-02 | 5.75E-02 | <0.001 |
| [15] Disinfection of veterinary drinking water | 1.02E-02 | 1.02E-02 | 5.75E-02 | <0.001 |

***Dibromochloromethane (DBCM)***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 5.44E-02 | 5.44E-02 | 5.49E-01 | <0.001 |
| [15] Disinfection of veterinary drinking water | 5.44E-02 | 5.44E-02 | 5.49E-01 | <0.001 |

***Dichlorobromomethane (DCBM)***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 1.20E-02 | 1.20E-02 | 5.71E-02 | <0.001 |
| [15] Disinfection of veterinary drinking water | 1.20E-02 | 1.20E-02 | 5.71E-02 | <0.001 |

***Monochloroacetic acid (MCAA)***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 1.20E-02 | 1.20E-02 | 1.20E-02 | <0.001 |
| [15] Disinfection of veterinary drinking water | 1.20E-02 | 1.20E-02 | 1.20E-02 | <0.001 |

***Dichloroacetic acid (DCAA)***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 2.59E-02 | 2.59E-02 | 2.60E-02 | <0.001 |
| [15] Disinfection of veterinary drinking water | 2.59E-02 | 2.59E-02 | 2.60E-02 | <0.001 |

***Trichloroacetic acid (TCAA)***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 2.44E-02 | 2.44E-02 | 2.46E-02 | <0.001 |
| [15] Disinfection of veterinary drinking water | 2.44E-02 | 2.44E-02 | 2.46E-02 | <0.001 |

***Monobromoacetic acid (MBAA)***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 1.20E-02 | 1.20E-02 | 1.20E-02 | <0.001 |
| [15] Disinfection of veterinary drinking water | 1.20E-02 | 1.20E-02 | 1.20E-02 | <0.001 |

***Dibromoacetic acid (DBAA)***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 3.434 | 3.434 | 3.434 | <0.001 |
| [15] Disinfection of veterinary drinking water | 3.434 | 3.434 | 3.434 | <0.001 |

***Tribromoacetic acid (TBAA)***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | <0.001 | <0.001 | <0.001 | <0.001 |
| [15] Disinfection of veterinary drinking water | <0.001 | <0.001 | <0.001 | <0.001 |

***Dibromochloroacetic acid (DBCAA)***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 8.65E-02 | 8.65E-02 | 8.74E-02 | <0.001 |
| [15] Disinfection of veterinary drinking water | 8.65E-02 | 8.65E-02 | 8.74E-02 | <0.001 |

***Bromochloroacetic acid (BCAA)***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 1.42E-03 | 1.42E-03 | 3.17E-02 | <0.001 |
| [15] Disinfection of veterinary drinking water | 1.42E-03 | 1.42E-03 | 3.17E-02 | <0.001 |

***Dichloroacetonitrile (DCAN)***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 14.955 | 14.955 | 15.333 | <0.001 |
| [15] Disinfection of veterinary drinking water | 14.955 | 14.955 | 15.333 | <0.001 |

***Dibromoacetonitrile (DBAN)***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 9.726 | 9.716 | 9.92 | <0.001 |
| [15] Disinfection of veterinary drinking water | 9.726 | 9.716 | 9.92 | <0.001 |

***Bromochloroacetonitrile (BCAN)***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [14] Disinfection of human drinking water | 5.426 | 5.426 | 5.534 | <0.001 |
| [15] Disinfection of veterinary drinking water | 5.426 | 5.426 | 5.534 | <0.001 |

***Terrestrial compartment***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Calculated PEC/PNEC values** | | | | | | |
|  | **Chloroform** | | **DBCM** | | **DCBM** | |
|  | **PEC/PNECsoil** | **Cporewater - EUSES [µg/L]** | **PEC/PNECsoil** | **Cporewater - EUSES [µg/L]** | **PEC/PNECsoil** | **Cporewater - EUSES [µg/L]** |
| [14] Disinfection of human drinking water | 2.60E-02 | 3.43E-03 | 2.85E-01 | 1.66E-03 | 2.72E-02 | 1.92E-03 |
| [15] Disinfection of veterinary drinking water | 2.60E-02 | 3.43E-03 | 2.85E-01 | 1.66E-03 | 2.72E-02 | 1.92E-03 |
|  | **MCAA** | | **DCAA** | | **TCAA** | |
| [14] Disinfection of human drinking water | 2.48E-03 | 1.74E-02 | 7.67E-03 | 6.06E-01 | 1.30E-02 | 2.18E-03 |
| [15] Disinfection of veterinary drinking water | 2.48E-03 | 1.74E-02 | 7.67E-03 | 6.06E-01 | 1.30E-02 | 2.18E-03 |
|  | **MBAA** | | **DBAA** | | **TBAA** | |
| [14] Disinfection of human drinking water | 2.48E-03 | 1.74E-02 | 1.113 | 9.37E-01 | <0.001 | 3.54E-01 |
| [15] Disinfection of veterinary drinking water | 2.48E-03 | 1.74E-02 | 1.113 | 9.37E-01 | <0.001 | 3.54E-01 |
|  | **DBCAA** | | **BCAA** | | **DCAN** | |
| [14] Disinfection of human drinking water | 4.17E-02 | 1.49E-03 | <0.001 | < 0.01 | 2.681 | 6.95E-02 |
| [15] Disinfection of veterinary drinking water | 4.17E-02 | 1.49E-03 | <0.001 | < 0.01 | 2.681 | 6.95E-02 |
|  | **DBAN** | | **BCAN** | |  | |
| [14] Disinfection of human drinking water | 1.942 | 9.43E-02 | 1.025 | < 0.01 |  |  |
| [15] Disinfection of veterinary drinking water | 1.942 | 9.43E-02 | 1.025 | < 0.01 |  |  |

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. The ADI and ARfD for chlorate have been agreed during BPC WGIII-2016 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. [↑](#footnote-ref-3)
3. 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-4)
4. Assessment report, January 2017 – Active chlorine released from sodium hypochlorite. Italy [↑](#footnote-ref-5)
5. EC 2020 on going: EC 2017/0332(COD) : Proposal for a Directive of the European Parliament and of the Council on the quality of water intended for human consumption (recast Brussels, 5 February 2020, 5813/20 ENV 60 SAN 36 CONSOM 18 CODEC 82) [↑](#footnote-ref-6)
6. 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-7)
7. EC 2017/0332(COD) : Proposal for a Directive of the European Parliament and of the Council on the quality of water intended for human consumption (recast Brussels, 5 February 2020, 5813/20 ENV 60 SAN 36 CONSOM 18 CODEC 82 [↑](#footnote-ref-8)
8. 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-9)
9. 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-10)
10. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-11)