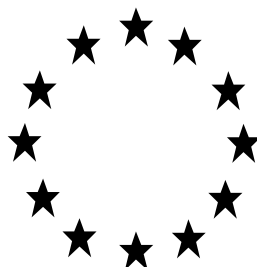


Regulation (EU) No 528/2012 concerning the
making available on the market and use of biocidal
products

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

(submitted by the evaluating Competent Authority)



FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 –
SOPRODIS

Product types 2 and 4

[Lactic acid as included in the Union list of approved
active substances]

Case Number in R4BP: [BC-CP051387-29]

Evaluating Competent Authority: [FR]

Date: [December 2023]

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1 CONCLUSION

INTRODUCTION OF THE APPLICATION

The products of the biocidal family FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS consist of products containing 1.44 to 28.8 % of the active substance L(+) lactic acid.

Products of biocidal family FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS are applied as surface disinfectant against bacteria, yeasts and virus, depending of the uses, for professionals or non-professionals users.

The biocidal product family (BPF) is composed of 10 META SPC and 34 different uses:

| Uses | Meta SPC 1 | Meta SPC 2 | Meta SPC 3 | Meta SPC 4 | Meta SPC 5 | Meta SPC 6 | Meta SPC 7 | Meta SPC 8 | Meta SPC 9 | Meta SPC 10 |
|--|------------|------------|------------|------------|------------|------------|------------|------------|------------|-------------|
| Use #1 - Manual spraying – professionals – PT2 – soluble concentrate | X | X | X | X | X | X | | | | |
| Use #2 - Spraying/foaming mural equipment with automated dilution (liquid/foam spraying) – professionals – PT2 – soluble concentrate | X | X | X | X | X | X | | | | |
| Use #3 - Manual dipping/soaking – professionals – PT2 – soluble concentrate | X | X | X | X | X | X | | | | |
| Use #4 – Wiping / mopping / brushing / scrubbing – professionals – PT2 – soluble concentrate | X | X | X | X | X | X | | | | |
| Use #5 - Disinfection of equipment by automatic spraying in cleaning washer – professionals – PT2 – soluble concentrate | | | | | | X | | | | |
| Use #6 - Disinfection of cleaning washer by automatic application – professionals – PT2 – soluble concentrate | | | | | | X | | | | |
| Use #7 – Cleaning-in-place – professionals – PT2 – soluble concentrate | | | | | | X | | | | |
| Use #9 - Manual spraying – professionals – PT4 – soluble concentrate | X | X | X | X | X | X | | | | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Use #10 - Spraying/foaming mural equipment with automated dilution (liquid/foam spraying) – professionals – PT4 – soluble concentrate | X | X | X | X | X | X | | | | |
| Use #11 - Manual dipping/soaking– professionals – PT4 – soluble concentrate | X | X | X | X | X | X | | | | X |
| Use #12 – Wiping / mopping / brushing / scrubbing – professionals – PT4 – soluble concentrate | X | X | X | X | X | X | | | | |
| Use #13 - Disinfection of equipment by dish washing machine and crate washer – professionals – PT4 – soluble concentrate | | | | | | X | | | | |
| Use #14 - Disinfection of dish washing machine and crate washer by automatic spraying– professionals – PT4 – soluble concentrate | | | | | | X | | | | |
| Use #15 – Cleaning-in-place – professionals – PT4 – soluble concentrate | | | | | | X | | | | |
| Use #17 - Manual spraying – professionals – PT2 – RTU product | | | | | | | X | | | |
| Use #18 – Manual spraying using a trigger sprayer - professionals – PT2 – RTU product | | | | | | | X | X | | |
| Use #19 – Wiping / mopping / brushing / scrubbing – professionals – PT2 – RTU product | | | | | | | X | X | X | |
| Use #20 – Direct spreading/flooding – professionals – PT2 – RTU product | | | | | | | X | X | X | |
| Use #21 - Manual spraying – professionals – PT4 – RTU product | | | | | | | X | | | |
| Use #22 – Manual spraying using a trigger sprayer - professionals – PT4 – RTU product | | | | | | | X | | | |
| Use #23 – Wiping / mopping / brushing / scrubbing – | | | | | | | X | X | X | |

| | | | | | | | | | | |
|--|---|--|--|---|---|--|---|---|---|--|
| professionals – PT4 – RTU product | | | | | | | | | | |
| Use #24 – Manual spraying using a trigger sprayer – general public – PT2 – RTU product | | | | | | | X | | | |
| Use #25 – Wiping / mopping / brushing / scrubbing – general public – PT2 – RTU product | | | | | | | X | X | X | |
| Use #26 – Direct spreading/flooding – general public – PT2 – RTU product | | | | | | | X | X | X | |
| Use #27 – Manual spraying using a trigger sprayer – general public – PT4 – RTU product | | | | | | | X | | | |
| Use #28 – Wiping / mopping / brushing / scrubbing – general public – PT4 – RTU product | | | | | | | X | X | X | |
| Use #29 – Manual spraying using a trigger sprayer - general public – PT2 – soluble concentrate | X | | | X | X | | | | | |
| Use #30 – Wiping / mopping / brushing / scrubbing – general public – PT2 – soluble concentrate | X | | | X | X | | | | | |
| Use #31 – Manual spraying using a trigger sprayer - general public – PT4 – soluble concentrate | X | | | X | X | | | | | |
| Use #32 – Wiping / mopping / brushing / scrubbing – general public – PT4 – soluble concentrate | X | | | X | X | | | | | |
| Use #33 – Manual spraying using a trigger sprayer - professionals – PT2 – soluble concentrate | X | | | X | X | | | | | |
| Use #34 – Manual spraying using a trigger sprayer – professionals – PT4 – soluble concentrate | X | | | X | X | | | | | |
| Use #35 – Disinfection of the inner surfaces of small kitchen appliances without circulation – professionals – PT4 – soluble concentrate | | | | | | | X | | | |

| | | | | | | | | | | |
|---|--|--|--|--|--|---|--|--|--|--|
| Use #36 – Disinfection of the inner surfaces of small kitchen appliances by CIP – professionals – PT4 – soluble concentrate | | | | | | X | | | | |
|---|--|--|--|--|--|---|--|--|--|--|

Uses #8 and #16 have been withdrawn by applicant during the instruction of this application.

SUMMARY AND OVERALL CONCLUSION OF THE ASSESSMENT

Physico-chemical properties and analytical methods

The physico-chemical properties of the biocidal product family have been described and considered acceptable in the conditions of use detailed in the SPC.

For all Meta SPC of the family, based on the accelerated storage studies, the stability data indicate a shelf life of 2 years at ambient temperature when stored in commercial packaging material. The final reports of the ongoing long term storage studies should be provided in post authorisation.

The labels of the products state: "Protect from frost" and "Keep away from direct sunlight". Products of Meta SPC 1, 2, 8, 9 and 10 should not be stored above 40°C.

The labels of the products of Meta SPCs 1, 2, 3, 4, 5 and 10 state: "During the product dilution, pour almost all water first, then the product, then the remaining of the water."

Products of Meta SPC 1, 2, 3 and 6 are classified H290.

Products from other meta SPC are not classified for physical hazards.

Analytical methods provided for the determination of the active substance in the products are acceptable.

Efficacy

The biocidal family FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS has been shown to be efficacious for the products of the all the META-SPC for the following uses:

- Disinfection of PT2 hard surfaces (household, institutions, industries and medical)
- Disinfection of PT4 hard surfaces (household areas, institutions, industries (except milk industries))

Nevertheless, for some uses and target organisms, application rates and contact times were modified according the efficacy data provided. More information is detailed in the efficacy section and in the SPC.

Moreover, for META-SPC6, no efficacy study (simulated-use test or field test) has been submitted to support the efficacy for the disinfections of dish washing machine, crate washer and cleaning washer. Therefore, efficacy for these uses is not demonstrated.

Substances of concern (SoCs)

One co-formulant included in the product was identified as substance of concern for human health. Some co-formulants could also display indication of possible endocrine

activity. It was however not possible to conclude on whether these co-formulants meet the scientific criteria for the determination of endocrine disrupting properties as laid down in Regulation (EU) 2017/2100. Further investigations should therefore take place under Regulation (EU) 1907/2006.

Risk for Human Health

For the industrial and professional users, the risk is acceptable for:

- products of meta-SPC 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 for all the claimed uses,

considering the qualitative risk assessment for local effects, with the application of risk mitigation measures (RMM) and the wear of personal protective equipment (PPE) listed in the SPC.

For non-professional users:

- The risk is acceptable for products of meta-SPC 9 for all the claimed uses, considering the qualitative risk assessment for local effects, with the application of the risk mitigation measures (RMM) listed in the SPC.
- The risk is acceptable for products of meta-SPC 7 for the application by mopping, wiping, scrubbing, brushing and direct spreading in sanitary facilities, considering the qualitative risk assessment for local effects, with the application of the risk mitigation measures (RMM) listed in the SPC.
- The risk is acceptable for products of meta-SPC 8 only for the application by direct spreading/flooding in sanitary facilities considering the qualitative risk assessment for local effects, with the application of the risk mitigation measures (RMM) listed in the SPC.
- The risk is not acceptable for products of meta-SPC 1, 4, 5, 7, 8 for the application by trigger spray and mopping/wiping/scrubbing/brushing considering the qualitative risk assessment for local effects.

Risk for consumer under indirect exposure via food

By definition, PT 2 biocidal product is not intended for direct application to humans or animals and is not used for direct contact with food or feedingstuffs.

Regarding the intended uses on PT 4, residues in food, feed or drinking water might be expected.

Nevertheless, based in the low concentration of L(+) lactic acid, the endogenous production and the authorized uses of this active substance as food additive (E 270), significant indirect exposure via intended uses is not expected.

Risk for the environment

The environmental risk assessment has been conducted only for the active substance L(+) Lactic acid.

It has been demonstrated that uses of the BPF does not pose a risk to the environmental compartments. No specific risk mitigation measure is required.

Overall conclusion

The conformity to the uniform principles, as defined in the Regulation (EU) n°528/2012, for the biocidal product family is reported in the table below, for each use.

P : Professional users

NP : Non-professional users

A : Acceptable

NA : Non Acceptable

| N° use | PT | Meta-SPC | Use | Target organisms | User | Formulation | Conclusion | |
|--------|----|-------------|--|--|------|---------------------|--|---|
| 1 | 2 | 1,2,3,4,5,6 | Disinfection of hard surfaces and equipment by manual liquid spraying | Bacteria Yeast Viruses (meta-SPC 4, 5 and 7 only) | P | Soluble concentrate | A | |
| 9 | 4 | | | | | | | A |
| 17 | 2 | 7 | | | | RTU | A | |
| 21 | 4 | | | | | | A | |
| 2 | 2 | 1,2,3,4,5,6 | Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) | Bacteria Yeast Viruses (meta-SPC 4, 5 only) | P | Soluble concentrate | A | |
| 10 | 4 | | | | | | A | |
| 3 | 2 | 1,2,3,4,5,6 | Disinfection of hard surfaces of equipment by manual dipping/soaking | Bacteria Yeast Viruses (meta-SPC 4, 5 only) | P | Soluble concentrate | A | |
| 11 | 4 | | | | | | A | |
| 4 | 2 | 1,2,3,4,5,6 | Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing | Bacteria Yeast Viruses (meta-SPC 4, 5 and 7 only) | P | Soluble concentrate | A | |
| 12 | 4 | | | | | | A | |
| 19 | 2 | 7,8,9 | | | | RTU | A | |
| 23 | 4 | | | | | | A | |
| 25 | 2 | 7,8,9 | | | NP | RTU | N (Meta SPC 8) Human health A (Meta SPC 7-9) | |
| 28 | 4 | | | | | | N (Meta SPC 8) Human health A (Meta SPC 7-9) | |
| 30 | 2 | 1,4,5 | | | | Soluble concentrate | N Human health | |
| 32 | 4 | | | | | | N Human health | |
| 5 | 2 | 6 | Disinfection of equipment by automatic spraying in cleaning washer | Bacteria Yeast | P | Soluble concentrate | N Efficacy not demonstrated | |
| 13 | 4 | 6 | Disinfection of equipment by dish washing machine and crate washer | Bacteria Yeast | P | Soluble concentrate | N Efficacy not demonstrated | |

| | | | | | | | |
|----|---|-------|---|-------------------------------------|----|---------------------|--|
| 6 | 2 | 6 | Disinfection of cleaning washer by automatic application | Bacteria Yeast | P | Soluble concentrate | N Efficacy not demonstrated |
| 14 | 4 | 6 | Disinfection of dish washing machine and crate washer by automatic spraying | Bacteria Yeast | P | Soluble concentrate | N Efficacy not demonstrated |
| 7 | 2 | 6 | Disinfection of inner surfaces by CIP | Bacteria Yeast | P | Soluble concentrate | A |
| 15 | 4 | | | | | | A |
| 18 | 2 | 7,8 | Disinfection of hard surfaces (small surfaces) and equipment by manual liquid spraying using a trigger sprayer | Bacteria | P | RTU | A |
| 22 | 4 | 7 | | | | | A |
| 24 | 2 | 1,4,5 | | Yeast | NP | Soluble concentrate | N Human health |
| 27 | 4 | | | Viruses (meta-SPC 4, 5 and 7 only) | | | N Human health |
| 29 | 2 | | | A | | | |
| 31 | 4 | P | | Viruses (meta-SPC 4, 5 and 7 only) | P | Soluble concentrate | N Human health |
| 33 | 2 | | | | | | A |
| 34 | 4 | A | | | | | |
| 20 | 2 | 7,8,9 | Disinfection of toilets bowls and sanitary facilities by direct spreading/flooding | Bacteria | P | RTU | A |
| 26 | | | | Yeast | | | |
| | | | | Viruses (meta-SPC 7 only) | NP | | |
| 35 | 2 | 6 | Disinfection of the inner surfaces of small kitchen appliances without circulation | Bacteria Yeast | P | Soluble concentrate | A |
| 36 | 4 | 6 | Disinfection of the inner surfaces of small kitchen appliances by CIP – Professionals – PT4 – Soluble concentrate | Bacteria Yeast | P | Soluble concentrate | A |

2 ASSESSMENT REPORT

PART I - FIRST INFORMATION LEVEL

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

| Identifier | Country (if relevant) |
|---|-----------------------|
| Famille de produits Acide Lactique TP2-4 – SOPRODIS | France |

2.1.1.2 Authorisation holder

| Name and address of the authorisation holder | Name | SOPRODIS |
|--|---------------------|---|
| | Address | 44 Rue du LANGUEDOC 11200 LEZIGNAN CORBIERES France |
| Authorisation number | FR-2023-0071 | |
| Date of the authorisation | 19/12/2023 | |
| Expiry date of the authorisation | 18/12/2033 | |

2.1.1.3 Manufacturer(s) of the products of the family

| Name of manufacturer | SOPRODIS |
|---------------------------------|---|
| Address of manufacturer | 44 Rue du LANGUEDOC 11200 LEZIGNAN CORBIERES France |
| Location of manufacturing sites | 44 Rue du LANGUEDOC 11200 LEZIGNAN CORBIERES France |

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

| Active substance | L(+) lactic acid |
|---------------------------------|--|
| Name of manufacturer | Corbion Purac Bioquimica sa |
| Address of manufacturer | Gran Vial 19-25 08160 MONTMELÓ Spain |
| Location of manufacturing sites | Gran Vial 19-25 08160 MONTMELÓ Spain Arkelsedijk 46 NL-4200 GORINCHEM Netherlands |
| Active substance | L(+) lactic acid |
| Name of manufacturer | Jungbunzlauer S.A. |

| | |
|--|--|
| Address of manufacturer | ZI Portuaire - BP 32 F-67390 Marcklosheim France |
| Location of manufacturing sites | Jungbunzlauer S.A. ZI Portuaire - BP 32 F-67390 Marcklosheim France |

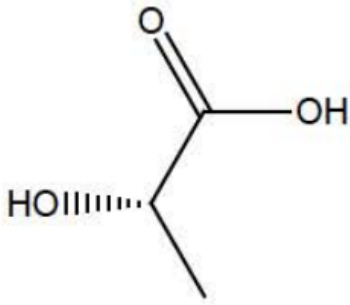
2.1.2 Product family composition and formulation

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

2.1.2.1 Identity of the active substance

| Main constituent(s) | |
|--|--|
| ISO name | L(+) lactic acid |
| IUPAC or EC name | (S)-2-Hydroxypropanoic acid |
| EC number | 201-196-2 |
| CAS number | 79-33-4 |
| Index number in Annex VI of CLP | - |
| Minimum purity / content | minimum purity of the active substance as manufactured \geq 95.5% w/w |
| Structural formula |  |

2.1.2.2 Candidate(s) for substitution

L(+) lactic acid does not meet the criteria for substitution laid down in article 10 of the BPR (Regulation (EU) No. 528/2012) and is therefore not a candidate for substitution.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|---|---|------------------------------|------------|-----------|-------------|---------|
| | | | | | Min | Max |
| L(+) lactic acid | 2-Hydroxypropionic acid | Pure active substance* | 79-33-4 | 201-196-2 | 1.44 | 28.8 |
| | | Technical active substance** | | | 1.51 | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0 | 0.011 % |

*based on the content of active substance in the TK used for the formulation of the biocidal product (80% w/w for lactic acid).

**calculated and based on the minimum purity of active substance: 95.5% w/w for lactic acid.

2.1.2.4 Information on technical equivalence

The sources of the active substance (Corbion Purac Bioquimica sa) are the same as those evaluated for inclusion in the Union list of approved active substances.

The source (Jungbunzlauer S.A.) is considered technically equivalent compared to the reference source.

2.1.2.5 Information on the substance(s) of concern

For Human Health, the substance CMIT/MIT is considered as Substance of Concern in Meta SPCs 1-2-3-5 and 10.

Please see the confidential annex for further details.

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

The biocidal product contains the active substance "Lactic Acid", which is not considered to have endocrine disrupting properties.

None of the co-formulants contained in the SOPRODIS TP-2-4 are regulatory identified as endocrine disruptors or have significant ED properties.

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

Please refer to Confidential Annex for further details.

2.1.2.7 Type of formulation

| |
|--|
| AL: Any other liquid (meta SPC 7, 8, 9). SL: Soluble concentrate (meta SPC 1, 2, 3, 4, 5, 6, 10). |
|--|

PART II - SECOND INFORMATION LEVEL - META SPC 1**2.1.3** Meta SPC 1 administrative information**2.1.3.1** Meta SPC identifier

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

2.1.3.2 Suffix to the authorisation number

| | |
|----------|--|
| Number 1 | |
|----------|--|

2.1.3.3 Product type(s)

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

2.1.4 Meta SPC 1 composition**2.1.4.1** Qualitative and quantitative information on the composition of the meta SPC 1

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|---|----------------------------|-------------------|------------------|--------------------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 24 |
| | | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0-0.011% |

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

| |
|-------------------------|
| SL: Soluble concentrate |
|-------------------------|

2.1.5 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 Skin sens.1A |
| Hazard statement | H290: May be corrosive to metals H314 : Causes severe skin burns and eye damage H318: Causes serious eye damage H317 : May cause an allergic skin reaction |
| Labelling | |
| Signal words | Danger |
| Hazard statements | H290: May be corrosive to metals H314: Causes severe skin burns and eye damage H317 : May cause an allergic skin reaction |

| Classification | |
|--------------------------|---|
| Precautionary statements | <p>P101: If medical advice is needed, have product container or label at hand.</p> <p>P102: Keep out of reach of children.</p> <p>P103: Read label before use.</p> <p>P234 : keep only in original packaging.</p> <p>P260: Do not breathe spray.</p> <p>P264: Wash hands thoroughly after handling.</p> <p>P280: Wear protective gloves/ protective clothing/ eye protection</p> <p>P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.</p> <p>P303+P361+P353: IF ON SKIN (or hair): Remove/Remove off immediately all contaminated clothing. Rinse skin with water/shower.</p> <p>P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P310. Immediately call a POISON CENTER or doctor/physician</p> <p>P321: Specific treatment (see ... on the label).</p> <p>P363: Wash contaminated clothing before reuse.</p> <p>P390: Absorb spillage to prevent material damage.</p> <p>P406: Store in a corrosive resistant/... container with a resistant inner liner.</p> <p>P333 + P313: If skin irritation or rash occur: Get medical advice/attention</p> <p>P302+ P352: IF ON SKIN : Wash with plenty of water</p> <p>P501: Dispose of contents/containers in accordance with local regulations.</p> |
| Note | EUH071: Corrosive to the respiratory tract. |

2.1.6 Authorised use(s) of the META SPC 1

2.1.6.1 Use description

Table 1. Use # 1 – Disinfection of hard surfaces and equipment by manual liquid spraying – Professionals - PT2 – Soluble concentrate (Use 1)

| | |
|---|-----|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |

| | |
|--|---|
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual surface spraying |
| Application rate(s) and frequency | At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 5L HDPE Jerrican with distributor pump 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.6.1.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.6.1.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.6.2 Use description

Table 2. Use # 2 – Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) – Professionals - PT2 – Soluble concentrate (Use 2)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual spraying with a mural cleaning station (liquid/foam spraying) with automated dilution. |
| Application rate(s) and frequency | At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.6.2.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.6.2.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.6.3 Use description

Table 1. Use # 3 – Disinfection of hard surfaces of equipment by manual dipping/soaking– Professionals - PT2 – Soluble concentrate (Use 3)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual dipping/soaking |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 18% v/v, 15 minutes. At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle |

| |
|---|
| 1L HDPE Dosing bottle 5L HDPE Jerrican with distributor pump 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |
|---|

2.1.6.3.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.6.3.2 Use-specific risk mitigation measures

- The professional user has to wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
- Do not immerse hands in the bath.
- Let the equipment soak for the necessary time in the bath of cleaning/disinfectant solution, then empty the bath, and finish by rinsing without touching the equipment that has remained in the tank.

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

-

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

-

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

-

2.1.6.4 Use description

Table 2. Use # 4 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT2 – Soluble concentrate (Use 4)

| | |
|---|-------------------|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |

| | |
|--|---|
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 18% v/v, 15 minutes. At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 20 mL HDPE Cartridge to be used with trigger spray 0.5, 0.75, 1L and 1L bottle 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 5L HDPE Jerrican with distributor pump 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.6.4.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.6.4.2 Use-specific risk mitigation measures

- For professional users: wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
- Pour the solution direct on the surface and wipe with a cloth / brush for wiping activities
- A mop/brush with a handle has to be used to apply the in-use solution
- Do not immerse hands in the solution

For professional bystander :

- Do not touch the surface until it is completely dried

For general public :

- Do not touch the surface until it is rinsed and completely dried"
- Children should not be present during disinfection and until the surface is rinsed and dried"

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

-

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

-

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

-

2.1.6.5 Use description

Table 3. Use # 5 – Disinfection of hard surfaces and equipment by manual liquid spraying – Professionals - PT4 – Soluble concentrate (Use 9)

| | |
|---|---|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual surface spraying |
| Application rate(s) and frequency | At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 5L HDPE Jerrican with distributor pump 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.6.5.1 Use-specific instructions for use

-

2.1.6.5.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.6.6 Use description

Table 4. Use # 6 – Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) – Professionals - PT4 – Soluble concentrate (Use 10)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |

| | |
|--|---|
| Application method(s) | Manual spraying with a mural cleaning station (liquid/foam spraying) with automated dilution. |
| Application rate(s) and frequency | At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.6.6.1 Use-specific instructions for use

-

2.1.6.6.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.6.7 Use description

Table 3. Use # 7 – Disinfection of hard surfaces and equipment by manual dipping/soaking– Professionals - PT4 – Soluble concentrate (Use 11)

| | |
|---|---|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual dipping/soaking |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 18% v/v, 15 minutes At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 5L HDPE Jerrican with distributor pump 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.6.7.1 Use-specific instructions for use

-

2.1.6.7.2 Use-specific risk mitigation measures

- The professional user has to wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
- Do not immerse hands in the bath
- Let the equipment soak for the necessary time in the bath of cleaning/disinfectant solution, then empty the bath, and finish by rinsing without touching the equipment that has remained in the tank.

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

-

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

-

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

-

2.1.6.8 Use description

Table 4. Use # 8 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT4 – Soluble concentrate (Use 12)

| | |
|---|---|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 18% v/v, 15 minutes. At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 20 mL HDPE Cartridge to be used with trigger spray 0.5, 0.75, 1L and 1L bottle 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 5L HDPE Jerrican with distributor pump 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.6.8.1 Use-specific instructions for use

-

2.1.6.8.2 Use-specific risk mitigation measures

- For professional users: wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
- Pour the solution direct on the surface and wipe with a cloth / brush for wiping activities
- A mop/brush with a handle has to be used to apply the in-use solution
- Do not immerse hands in the solution

For professional bystander :

- Do not touch the surface until it is completely dried

For general public :

- Do not touch the surface until it is rinsed and completely dried"
- Children should not be present during disinfection and until the surface is rinsed and dried"

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

-

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

-

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

-

2.1.6.9 Use description

Table 5. Use # 9 – Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer – Professionals - PT2 – Soluble concentrate in cartridge (Use 33)

| | |
|---|-----|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |

| | |
|--|---|
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual surface spraying with a trigger sprayer (liquid/foam spraying). |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 18% v/v, 15 minutes. At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20 mL HDPE Cartridge to be used with trigger spray 0.5, 0.75, 1L and 1L bottle |

2.1.6.9.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.6.9.2 Use-specific risk mitigation measures

For professional users:

- Wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, and the rinsing.
- Wear gloves, coverall goggles and a respiratory protective equipment against aerosol (material to be specified by the authorisation holder within the product information) during the application by trigger spray.

For professional bystander :

- Do not be present in the treatment area during disinfection process by trigger. If it is necessary to be present, wear same RPE and PPE as the professional user.
- Do not touch the surface until it is completely dried

For general public :

- Do not be present in the treatment area during disinfection process by trigger.
- Do not touch the surface until it is rinsed and completely dried"
- Children should not be present during disinfection and until the surface is rinsed and dried"

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

-

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

-

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

-

2.1.6.10 Use description

Table 6. Use # 10 – Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer - Professionals - PT4 – Soluble concentrate in cartridge (Use 34)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual surface spraying with a trigger sprayer (liquid/foam spraying). |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 18% v/v, 15 minutes. At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20 mL HDPE Cartridge to be used with trigger spray 0.5, 0.75, 1L and 1L bottle |

2.1.6.10.1 Use-specific instructions for use

-

2.1.6.10.2 Use-specific risk mitigation measures

For professional users:

- Wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, and the rinsing.
- Wear gloves, coverall goggles and a respiratory protective equipment against aerosol (material to be specified by the authorisation holder within the product information) during the application by trigger spray.

For professional bystander :

- Do not be present in the treatment area during disinfection process by trigger. If it is necessary to be present, wear same RPE and PPE as the professional user.
- Do not touch the surface until it is completely dried

For general public :

- Do not be present in the treatment area during disinfection process by trigger.
- Do not touch the surface until it is rinsed and completely dried”
- Children should not be present during disinfection and until the surface is rinsed and dried”

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

-

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

-

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

-

2.1.7 General directions for use of the meta SPC 1

2.1.7.1 Instructions for use

- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.
- Products have been tested against bacteria, including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes* at 20°C and 40°C and *Lactobacillus brevis* at 40°C.
- During the product dilution, pour almost all water first, then the product, then the remaining of the water.

2.1.7.2 Risk mitigation measures

-

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

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

2.1.7.4 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.

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

- Protect from frost.
- Keep away from direct sunlight.
- Do not store above 40°C.
- Shelf-life = 2 years.
- Keep out of reach of children and non-target animals/pets

2.1.8 Other information

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

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

| Trade name(s) | | PRODUCT 1-1 - Soprodís | | | |
|---|---|-------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 24 |
| | | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| Trade name(s) | | PRODUCT 1-2 - Soprodís | | | |
|---|---|-------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 24 |
| | | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| Trade name(s) | | PRODUCT 1-3 - Soprodís | | | |
|-----------------------------|--|-------------------------------|--|--|--|
| Authorisation number | | | | | |

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|---|----------------------------|------------|-----------|-------------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 24 |
| | | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

PART II - SECOND INFORMATION LEVEL - META SPC 2

2.1.10 Meta SPC 2 administrative information

2.1.10.1 Meta SPC identifier

| | |
|-----------------------|------------|
| Identification | META SPC 2 |
|-----------------------|------------|

2.1.10.2 Suffix to the authorisation number

| | |
|----------|--|
| Number 2 | |
|----------|--|

2.1.10.3 Product type(s)

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

2.1.11 Meta SPC 2 composition

2.1.11.1 Qualitative and quantitative information on the composition of the meta SPC 2

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|------------------|------------|-----------------------|------------|-----------|-------------|
| L(+) lactic acid | | Pure active substance | 79-33-4 | 201-196-2 | 24 |

| | | | | | |
|---|---|----------------------------|------------|-----------|----------|
| | 2-Hydroxypropanoic acid | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0-0.011% |

2.1.11.2 Type(s) of formulation of the meta SPC 2

SL: Soluble concentrate

2.1.12 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2

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

| | |
|-----------------------|--|
| Classification | |
| Hazard category | Met. Corr.1 Skin corr.1B Eye Dam.1 Skin sens.1A |
| Hazard statement | H290: May be corrosive to metals H314: Causes severe skin burns and eye damage H318: Causes serious eye damage H317 : May cause an allergic skin reaction H412 : Harmful to aquatic life with long lasting effects |
| Labelling | |
| Signal words | Danger |
| Hazard statements | H290: May be corrosive to metals H314: Causes severe skin burns and eye damage H317 : May cause an allergic skin reaction H412 : Harmful to aquatic life with long lasting effects |

| Classification | |
|--------------------------|--|
| Precautionary statements | <p>P234 : Keep only in original packaging.</p> <p>P260: Do not breathe spray.</p> <p>P264: Wash hands thoroughly after handling.</p> <p>P280: Wear protective gloves/ protective clothing/ eye protection.</p> <p>P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.</p> <p>P303+P361+P353: IF ON SKIN (or hair): Remove/Remove off immediately all contaminated clothing. Rinse skin with water/shower.</p> <p>P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P310. Immediately call a POISON CENTER or doctor/physician</p> <p>P321: Specific treatment (see ... on the label).</p> <p>P363: Wash contaminated clothing before reuse.</p> <p>P390: Absorb spillage to prevent material damage.</p> <p>P406: Store in a corrosive resistant/... container with a resistant inner liner.</p> <p>P333 + P313: If skin irritation or rash occur: Get medical advice/attention</p> <p>P273: Avoid release to the environment.</p> <p>P501: Dispose of contents/containers in accordance with local regulations.</p> |
| Note | EUH071: Corrosive to the respiratory tract. |

2.1.13. Authorised use(s) of the META SPC 2

2.1.13.1 Use description

Table 5. Use # 1 – Disinfection of hard surfaces and equipment by manual liquid spraying – Professionals - PT2 – Soluble concentrate (Use 1)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual surface spraying |
| Application rate(s) and frequency | At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |

| | |
|--|---|
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 5L HDPE Jerrican with distributor pump 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |
|--|---|

2.1.13.1.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.13.1.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.13.2 Use description

Table 6. Use # 2 – Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) – Professionals - PT2 – Soluble concentrate (Use 2)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual spraying with a mural cleaning station (liquid/foam spraying) with automated dilution. |
| Application rate(s) and frequency | At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.13.2.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.13.2.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.13.3 Use description

Table 7. Use # 3 – Disinfection of hard surfaces of equipment by manual dipping/soaking- Professionals - PT2 – Soluble concentrate (Use3)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual dipping/soaking. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 20% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5 to 30L HDPE Jerrican 5-10-20L LDPE/PET Bag in box (cubitainer) 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.13.3.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.13.3.2 Use-specific risk mitigation measures

- The professional user has to wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.

- Do not immerse hands in the bath
- Let the equipment soak for the necessary time in the bath of cleaning/disinfectant solution, then empty the bath, and finish by rinsing without touching the equipment that has remained in the tank.

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

-

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

-

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

-

2.1.13.4 Use description

Table 8. Use # 4 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT2 – Soluble concentrate (Use 4)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 20% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5 to 30L HDPE Jerrican 5-10-20L LDPE/PET Bag in box (cubitainer) |

| |
|--|
| 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |
|--|

2.1.13.4.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.13.4.2 Use-specific risk mitigation measures

- For professional users: wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
- Pour the solution direct on the surface and wipe with a cloth / brush for wiping activities
- A mop/brush with a handle has to be used to apply the in-use solution
- Do not immerse hands in the solution

For professional bystander :

- Do not touch the surface until it is completely dried

For general public :

- Do not touch the surface until it is rinsed and completely dried"
- Children should not be present during disinfection and until the surface is rinsed and dried"

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

-

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

-

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

-

2.1.13.5 Use description

Table 9. Use # 5 – Disinfection of hard surfaces and equipment by manual liquid spraying – Professionals - PT4 – Soluble concentrate (Use 9)

| | |
|---|-----|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |

| | |
|--|--|
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual surface spraying |
| Application rate(s) and frequency | At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.13.5.1 Use-specific instructions for use

-

2.1.13.5.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.13.6 Use description

Table 10. Use # 6 – Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) – Professionals - PT4 – Soluble concentrate (Use 10)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual spraying with a mural cleaning station (liquid/foam spraying) with automated dilution. |
| Application rate(s) and frequency | At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.13.6.1 Use-specific instructions for use

-

2.1.13.6.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.

- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.13.7 Use description

Table 11. Use # 7 – Disinfection of hard surfaces and equipment by manual dipping/soaking- Professionals - PT4 – Soluble concentrate (Use 11)

| | |
|---|---|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual dipping/soaking. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 20% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5 to 30L HDPE Jerrican 5-10-20L LDPE/PET Bag in box (cubitainer) 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.13.7.1 Use-specific instructions for use

-

2.1.13.7.2 Use-specific risk mitigation measures

- The professional user has to wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
- Do not immerse hands in the bath
- Let the equipment soak for the necessary time in the bath of cleaning/disinfectant solution, then empty the bath, and finish by rinsing without touching the equipment that has remained in the tank.

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

-

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

-

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

-

2.1.13.8 Use description

Table 12. Use # 8 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT4 – Soluble concentrate (Use 12)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 20% v/v, 30 minutes. At a temperature of 40°C: |

| | |
|--|---|
| | - Bacteria and yeasts: 8% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5 to 30L HDPE Jerrican 5-10-20L LDPE/PET Bag in box (cubitainer) 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.13.8.1 Use-specific instructions for use

-

2.1.13.8.2 Use-specific risk mitigation measures

- For professional users: wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
- Pour the solution direct on the surface and wipe with a cloth / brush for wiping activities.
- A mop/brush with a handle has to be used to apply the in-use solution.
- Do not immerse hands in the solution.

For professional bystander :

- Do not touch the surface until it is completely dried.

For general public :

- Do not touch the surface until it is rinsed and completely dried".
- Children should not be present during disinfection and until the surface is rinsed and dried".

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

-

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

-

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

-

2.1.14 General directions for use of the meta SPC 2**2.1.14.1** Instructions for use

- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.
- Products have been tested against bacteria, including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes* at 20°C and 40°C and *Lactobacillus brevis* at 40°C.
- During the product dilution, pour almost all water first, then the product, then the remaining of the water.

2.1.14.2 Risk mitigation measures

-

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

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

2.1.14.4 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.

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

- Protect from frost.
- Keep away from direct sunlight.
- Do not store above 40°C.
- Shelf-life = 2 years.

2.1.15 Other information

-

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2**2.1.16** Trade name(s), authorisation number and specific composition of each individual product

| | | | | | |
|---|--|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRIM VERT DDM ; PRIM VERT 4D CONC ; PRIM VERT SAN SYSTEM S1 ; PRIM VERT SURF SYSTEM S2 ; PRIM VERT SOL SYSTEM S3 ; CLARINE NATURA S3D CONC ; CLARINE NATURA DDM ; BPRO DEGRAISSANT DESINFECTANT CONCENTRE ; BPRO DETARTRANT DESINFECTANT CONCENTRE ; BPRO SANITAIRES SYSTEM S1 ; BPRO SURFACES SYSTEM S2 ; BPRO SOLS SYSTEM PURE S3 | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 24 |
| | | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|-----------------------------|-------------------------------|-----------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 2-2 - Soprodis | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |

| | | | | | |
|---|---|----------------------------|------------|-----------|--------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 24 |
| | | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

PART II - SECOND INFORMATION LEVEL - META SPC 3

2.1.17 Meta SPC 3 administrative information

2.1.17.1 Meta SPC identifier

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

2.1.17.2 Suffix to the authorisation number

| | |
|----------|--|
| Number 3 | |
|----------|--|

2.1.17.3 Product type(s)

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

2.1.18 Meta SPC 3 composition

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

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|-------------------------|----------------------------|------------|-----------|-------------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 24 |
| | | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |

| | | | | | |
|---|---|----------------------|------------|-----------|----------|
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0-0.011% |
|---|---|----------------------|------------|-----------|----------|

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

SL: Soluble concentrate

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

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

| Classification | |
|-----------------------|--|
| Hazard category | Met. Corr.1 Skin corr.1B Eye Dam.1 Skin sens.1A |
| Hazard statement | H290: May be corrosive to metals H314: Causes severe skin burns and eye damage H318: Causes serious eye damage H317 : May cause an allergic skin reaction H412 : Harmful to aquatic life with long lasting effects |
| Labelling | |
| Signal words | Danger |
| Hazard statements | H290: May be corrosive to metals H314: Causes severe skin burns and eye damage H317 : May cause an allergic skin reaction H412 : Harmful to aquatic life with long lasting effects |

| Classification | |
|--------------------------|--|
| Precautionary statements | <p>P234 : keep only in original packaging. P260: Do not breathe. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/ protective clothing/ eye 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. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310. Immediately call a POISON CENTER or doctor/physician P321: Specific treatment (see ... on the label). P363: Wash contaminated clothing before reuse. P390: Absorb spillage to prevent material damage. P406: Store in a corrosive resistant/... container with a resistant inner liner. P333 + P313: If skin irritation or rash occur: Get medical advice/attention P302+ P352: IF ON SKIN : Wash with plenty of water P273: Avoid release to the environment. P501: Dispose of contents/containers in accordance with local regulations.</p> |
| Note | EUH071: Corrosive to the respiratory tract. |

2.1.20 Authorised use(s) of the META SPC 3

2.1.20.1 Use description

Table 13. Use # 1 – Disinfection of hard surfaces and equipment by manual liquid spraying
– Professionals - PT2 – Soluble concentrate (Use 1)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual surface spraying |
| Application rate(s) and frequency | At a temperature of 40°C: - Bacteria and yeasts: 6% v/v, 15 minutes. |

| | |
|--|---|
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.20.1.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.20.1.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.20.2 Use description

Table 14. Use # 2 – Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) – Professionals - PT2 – Soluble concentrate (Use 2)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual spraying with a mural cleaning station (liquid/foam spraying) with automated dilution. |
| Application rate(s) and frequency | At a temperature of 40°C: - Bacteria and yeasts: 6% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.20.2.1 Use-specific instructions for use

- | |
|--|
| - For healthcare settings: clean carefully the surfaces before application of the product. |
|--|

2.1.20.2.2 Use-specific risk mitigation measures

| |
|--|
| For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing. |
|--|

| |
|-----------------------------|
| For professional bystander: |
|-----------------------------|

- | |
|--|
| - Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user. |
| - Do not touch the surface until it is completely dried. |

| |
|---------------------|
| For General public: |
|---------------------|

- | |
|---|
| - Do not be present in the treatment area during disinfection process by compression sprayer. |
| - Do not touch the surface until it is rinsed and completely dried. |
| - Children should not be present during disinfection and until the surface is rinsed and dried. |

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

-

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

-

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

-

2.1.20.3 Use description

Table 15. Use # 3 – Disinfection of hard surfaces of equipment by manual dipping/soaking– Professionals - PT2 – Soluble concentrate (Use 3)

| | |
|---|--|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual dipping/soaking. |
| Application rate(s) and frequency | At a temperature of 20°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 25% v/v, 15 minutes. - Bacteria and yeasts: 20% v/v, 30 minutes. At a temperature of 40°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 6% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.20.3.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.20.3.2 Use-specific risk mitigation measures

- The professional user has to wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
- Do not immerse hands in the bath
- Let the equipment soak for the necessary time in the bath of cleaning/disinfectant solution, then empty the bath, and finish by rinsing without touching the equipment that has remained in the tank.

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

-

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

-

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

-

2.1.20.4 Use description

Table 16. Use # 4 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT2 – Soluble concentrate (Use 4)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 25% v/v, 15 minutes. - Bacteria and yeasts: 20% v/v, 30 minutes. |

| | |
|--|---|
| | At a temperature of 40°C: - Bacteria and yeasts: 6% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.20.4.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.20.4.2 Use-specific risk mitigation measures

- For professional users: wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
 - Pour the solution direct on the surface and wipe with a cloth / brush for wiping activities
 - A mop/brush with a handle has to be used to apply the in-use solution
 - Do not immerse hands in the solution
- For professional bystander :
- Do not touch the surface until it is completely dried
- For general public :
- Do not touch the surface until it is rinsed and completely dried"
 - Children should not be present during disinfection and until the surface is rinsed and dried"

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

-

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

-

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

-

2.1.20.5 Use description

Table 17. Use # 5 – Disinfection of hard surfaces and equipment by manual liquid spraying
– Professionals - PT4 – Soluble concentrate (Use 9)

| | |
|---|---|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual surface spraying |
| Application rate(s) and frequency | At a temperature of 40°C: - Bacteria and yeasts: 6% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.20.5.1 Use-specific instructions for use

-

2.1.20.5.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.

- Do not touch the surface until it is completely dried.
- For General public:
- Do not be present in the treatment area during disinfection process by compression sprayer.
 - Do not touch the surface until it is rinsed and completely dried.
 - Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.20.6 Use description

Table 18. Use # 6 – Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) – Professionals - PT4 – Soluble concentrate (Use 10)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual spraying with a mural cleaning station (liquid/foam spraying) with automated dilution. |
| Application rate(s) and frequency | At a temperature of 40°C: - Bacteria and yeasts: 6% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.20.6.1 Use-specific instructions for use

-

2.1.20.6.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.20.7 Use description

Table 19. Use # 7 – Disinfection of hard surfaces and equipment by manual dipping/soaking– Professionals - PT4 – Soluble concentrate (Use 11)

| | |
|---|-----|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |

| | |
|--|--|
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual dipping/soaking. |
| Application rate(s) and frequency | At a temperature of 20°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 25% v/v, 15 minutes. - Bacteria and yeasts: 20% v/v, 30 minutes. At a temperature of 40°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 6% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.20.7.1 Use-specific instructions for use

-

2.1.20.7.2 Use-specific risk mitigation measures

- The professional user has to wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
- Do not immerse hands in the bath.
- Let the equipment soak for the necessary time in the bath of cleaning/disinfectant solution, then empty the bath, and finish by rinsing without touching the equipment that has remained in the tank.

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

-

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

-

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

-

2.1.20.8 Use description

Table 20. Use # 8 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT4 – Soluble concentrate (Use 12)

| | |
|---|---|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 25% v/v, 15 minutes. - Bacteria and yeasts: 20% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 6% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.20.8.1 Use-specific instructions for use

-

2.1.20.8.2 Use-specific risk mitigation measures

- For professional users: wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
- Pour the solution direct on the surface and wipe with a cloth / brush for wiping

activities

- A mop/brush with a handle has to be used to apply the in-use solution
- Do not immerse hands in the solution

For professional bystander :

- Do not touch the surface until it is completely dried.

For general public :

- Do not touch the surface until it is rinsed and completely dried”.
- Children should not be present during disinfection and until the surface is rinsed and dried”.

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

-

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

-

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

-

2.1.21 General directions for use of the meta SPC 3

2.1.21.1 Instructions for use

- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.
- Products have been tested against bacteria, including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes* at 20°C and 40°C and *Lactobacillus brevis* at 40°C.
- During the product dilution, pour almost all water first, then the product, then the remaining of the water.

2.1.21.2 Risk mitigation measures

-

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

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

2.1.21.4 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.

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

- Protect from frost.
- Keep away from direct sunlight.
- Shelf-life = 2 years.

2.1.22 Other information

-

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

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

| | |
|-----------------------------|-------------------------------|
| Trade name(s) | PRODUCT 3-1 - Soprodis |
| Authorisation number | |

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|---|----------------------------|------------|-----------|-------------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 24 |
| | | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| Trade name(s) | PRODUCT 3-2 - Soprodis | | | | |
|---|---|----------------------------|------------|-----------|-------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 24 |
| | | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

PART II - SECOND INFORMATION LEVEL - META SPC 4

2.1.24 Meta SPC 4 administrative information**2.1.24.1** Meta SPC identifier

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

2.1.24.2 Suffix to the authorisation number

| | |
|----------|--|
| Number 4 | |
|----------|--|

2.1.24.3 Product type(s)

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

2.1.25 Meta SPC 4 composition**2.1.25.1** Qualitative and quantitative information on the composition of the meta SPC 4

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|-------------------------|----------------------------|------------|-----------|-------------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 24 |
| | | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |

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

| |
|-------------------------|
| SL: Soluble concentrate |
|-------------------------|

2.1.26 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 4**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| Classification | |
|-----------------------|--|
| Hazard category | Skin corr.1B Eye Dam.1 |
| Hazard statement | H314: Causes severe skin burns and eye damage H318: Causes serious eye damage |
| Labelling | |

| Classification | |
|--------------------------|---|
| Signal words | Danger |
| Hazard statements | H314: Causes severe skin burns and eye damage |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand P102: Keep out of reach of children P103: Read label before use P260: Do not breathe spray. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/ protective clothing/ eye 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. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310. Immediately call a POISON CENTER or doctor/physician P321: Specific treatment (see ... on the label). P363: Wash contaminated clothing before reuse. |
| Note | EUH071: Corrosive to the respiratory tract. |

2.1.27 Authorised use(s) of the META SPC 4

2.1.27.1 Use description

Table 21. Use # 1 – Disinfection of hard surfaces and equipment by manual liquid spraying
– Professionals - PT2 – Soluble concentrate (Use 1)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual surface spraying |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 12% v/v, 30 minutes. - Virus: 17.5% v/v, 60 minutes At a temperature of 40°C: - Bacteria and yeasts: 5% v/v, 15 minutes. |

| | |
|--|---|
| | - Virus: 17.5% v/v, 30 minutes |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 5L HDPE Jerrican with distributor pump 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.27.1.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.27.1.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.27.2 Use description

Table 22. Use # 2 – Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) – Professionals - PT2 – Soluble concentrate (Use 2)

| | |
|---|--|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual spraying with a mural cleaning station (liquid/foam spraying) with automated dilution |
| Application rate(s) and frequency | At a temperature of 20°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 12% v/v, 30 minutes. - Virus: 17.5% v/v, 60 minutes At a temperature of 40°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 5% v/v, 15 minutes. - Virus: 17.5% v/v, 30 minutes |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.27.2.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.27.2.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and

dried.

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

-

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

-

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

-

2.1.27.3 Use description

Table 23. Use # 3 – Disinfection of hard surfaces of equipment by manual dipping/soaking– Professionals - PT2 – Soluble concentrate (Use 3)

| | |
|---|--|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual dipping/soaking. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 20% v/v, 15 minutes. - Bacteria and yeasts: 12% v/v, 30 minutes. - Virus: 17.5% v/v, 60 minutes At a temperature of 40°C: - Bacteria and yeasts: 5% v/v, 15 minutes. - Virus: 17.5% v/v, 30 minutes |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 5L HDPE Jerrican with distributor pump 5 to 30L HDPE Jerrican 60-220L HDPE Drum |

1000L HDPE Bulk container (IBC)

2.1.27.3.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.27.3.2 Use-specific risk mitigation measures

- The professional user has to wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
- Do not immerse hands in the bath.
- Let the equipment soak for the necessary time in the bath of cleaning/disinfectant solution, then empty the bath, and finish by rinsing without touching the equipment that has remained in the tank.

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

-

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

-

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

-

2.1.27.4 Use description

Table 24. Use # 4 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT2 – Soluble concentrate (Use 4)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |

| | |
|--|---|
| Application rate(s) and frequency | At a temperature of 20°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 20% v/v, 15 minutes. - Bacteria and yeasts: 12% v/v, 30 minutes. - Virus: 17.5% v/v, 60 minutes At a temperature of 40°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 5% v/v, 15 minutes. - Virus: 17.5% v/v, 30 minutes |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20 mL HDPE Cartridge to be used with trigger spray 0.5, 0.75, 1L and 1L bottle 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 5L HDPE Jerrican with distributor pump 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.27.4.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.27.4.2 Use-specific risk mitigation measures

- For professional users: wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
 - Pour the solution direct on the surface and wipe with a cloth / brush for wiping activities
 - A mop/brush with a handle has to be used to apply the in-use solution
 - Do not immerse hands in the solution
- For professional bystander :
- Do not touch the surface until it is completely dried
- For general public :
- Do not touch the surface until it is rinsed and completely dried"
 - Children should not be present during disinfection and until the surface is rinsed and dried"

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

-

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

-

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

-

2.1.27.5 Use description

Table 5. Use # 5 – Disinfection of hard surfaces and equipment by manual liquid spraying – Professionals - PT4 – Soluble concentrate (Use 9)

| | |
|---|---|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual surface spraying |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 12% v/v, 30 minutes. - Virus: 17.5% v/v, 60 minutes At a temperature of 40°C: - Bacteria and yeasts: 5% v/v, 15 minutes. - Virus: 17.5% v/v, 30 minutes |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 5L HDPE Jerrican with distributor pump 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.27.5.1 Use-specific instructions for use

-

2.1.27.5.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.27.6 Use description

Table 25. Use # 6 – Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) – Professionals - PT4 – Soluble concentrate (Use 10)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |

| | |
|--|---|
| Application method(s) | Manual spraying with a mural cleaning station (liquid/foam spraying) with automated dilution |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 12% v/v, 30 minutes. - Virus: 17.5% v/v, 60 minutes At a temperature of 40°C: - Bacteria and yeasts: 5% v/v, 15 minutes. - Virus: 17.5% v/v, 30 minutes |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.27.6.1 Use-specific instructions for use

-

2.1.27.6.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.27.7 Use description

Table 26. Use # 7 – Disinfection of hard surfaces and equipment by manual dipping/soaking– Professionals - PT4 – Soluble concentrate (Use11)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual dipping/soaking. |
| Application rate(s) and frequency | At a temperature of 20°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 20% v/v, 15 minutes. - Bacteria and yeasts: 12% v/v, 30 minutes. - Virus: 17.5% v/v, 60 minutes At a temperature of 40°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 5% v/v, 15 minutes. - Virus: 17.5% v/v, 30 minutes |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20 mL HDPE Cartridge to be used with trigger spray 0.5, 0.75, 1L and 1L bottle 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 5L HDPE Jerrican with distributor pump 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.27.7.1 Use-specific instructions for use

-

2.1.27.7.2 Use-specific risk mitigation measures

- The professional user has to wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.

- Do not immerse hands in the bath
- Let the equipment soak for the necessary time in the bath of cleaning/disinfectant solution, then empty the bath, and finish by rinsing without touching the equipment that has remained in the tank.

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

-

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

-

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

-

2.1.27.8 Use description

Table 27. Use # 8 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT4 – Soluble concentrate (Use 12)

| | |
|---|---|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | At a temperature of 20°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 20% v/v, 15 minutes. - Bacteria and yeasts: 12% v/v, 30 minutes. - Virus: 17.5% v/v, 60 minutes At a temperature of 40°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 5% v/v, 15 minutes. - Virus: 17.5% v/v, 30 minutes |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 20 mL HDPE Cartridge to be used with trigger spray 0.5, 0.75, 1L and 1L bottle 100mL to 2L HDPE/PET Bottle |

| | |
|--|--|
| | 1L LDPE Dosing bottle 1L HDPE Dosing bottle 5L HDPE Jerrican with distributor pump 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |
|--|--|

2.1.27.8.1 Use-specific instructions for use

-

2.1.27.8.2 Use-specific risk mitigation measures

- For professional users: wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
 - Pour the solution direct on the surface and wipe with a cloth / brush for wiping activities
 - A mop/brush with a handle has to be used to apply the in-use solution
 - Do not immerse hands in the solution
- For professional bystander :
- Do not touch the surface until it is completely dried
- For general public :
- Do not touch the surface until it is rinsed and completely dried"
 - Children should not be present during disinfection and until the surface is rinsed and dried

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

-

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

-

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

-

2.1.27.9 Use description

Table 28. Use # 9 – Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer – Professionals - PT2 – Soluble concentrate in cartridge (Use 33)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual surface spraying with a trigger sprayer (liquid/foam spraying). |
| Application rate(s) and frequency | At a temperature of 20°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 20% v/v, 15 minutes. - Bacteria and yeasts: 12% v/v, 30 minutes. - Virus: 17.5% v/v, 60 minutes. At a temperature of 40°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 5% v/v, 15 minutes. - Virus: 17.5% v/v, 30 minutes |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20 mL HDPE Cartridge to be used with trigger spray 0.5, 0.75, 1L and 1L bottle |

2.1.27.9.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.27.9.2 Use-specific risk mitigation measures

- For professional users:
- Wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, and the rinsing.
 - Wear gloves, coverall goggles and a respiratory protective equipment against aerosol (material to be specified by the authorisation holder within the product information) during the application by trigger spray.
- For professional bystander :
- Do not be present in the treatment area during disinfection process by trigger. If it is necessary to be present, wear same RPE and PPE as the professional user.
 - Do not touch the surface until it is completely dried.
- For general public :
- Do not be present in the treatment area during disinfection process by trigger.
 - Do not touch the surface until it is rinsed and completely dried.
 - Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.27.10 Use description

Table 290. Use # 10 – Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer - Professionals - PT4 – Soluble concentrate in cartridge (Use 34)

| | |
|---|---|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual surface spraying with a trigger sprayer (liquid/foam spraying). |
| Application rate(s) and frequency | At a temperature of 20°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 20% v/v, 15 minutes. - Bacteria and yeasts: 12% v/v, 30 minutes. - Virus: 17.5% v/v, 60 minutes. At a temperature of 40°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 5% v/v, 15 minutes. - Virus: 17.5% v/v, 30 minutes |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20 mL HDPE Cartridge to be used with trigger spray 0.5, 0.75, 1L and 1L bottle |

2.1.27.10.1 Use-specific instructions for use

-

2.1.27.10.2 Use-specific risk mitigation measures

For professional users:

- Wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, and the rinsing.
- Wear gloves, coverall goggles and a respiratory protective equipment against aerosol (material to be specified by the authorisation holder within the product information) during the application by trigger spray.

For professional bystander :

- Do not be present in the treatment area during disinfection process by trigger. If it is necessary to be present, wear same RPE and PPE as the professional user.
- Do not touch the surface until it is completely dried.

For general public :

- Do not be present in the treatment area during disinfection process by trigger.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.28 General directions for use of the meta SPC 4**2.1.28.1** Instructions for use

- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.
- Products have been tested against bacteria, including *Enterobacter cloacae*, *Salmonella Typhimurium*, *Campylobacter jejuni* and *Listeria monocytogenes* at 20°C and 40°C and *Lactobacillus brevis* at 40°C and against virus including *bovine coronavirus* at 20°C and *Murine parvovirus* at 40°C.
- During the product dilution, pour almost all water first, then the product, then the remaining of the water.

2.1.28.2 Risk mitigation measures

-

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

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

2.1.28.4 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.

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

- Protect from frost.
- Keep away from direct sunlight.
- Shelf-life = 2 years.
- Keep out of reach of children and non-target animals/pets.

2.1.29 Other information

-

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4**2.1.30** Trade name(s), authorisation number and specific composition of each individual product

| Trade name(s) | PRODUCT 4-1 - Soprodís | | | | |
|---|-------------------------|----------------------------|------------|-----------|-------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 24 |
| | | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |

| Trade name(s) | PRODUCT 4-2 - Soprodís | | | | |
|---|-------------------------|----------------------------|------------|-----------|-------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 24 |
| | | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |

PART II - SECOND INFORMATION LEVEL - META SPC 5

2.1.31 Meta SPC 5 administrative information**2.1.31.1** Meta SPC identifier

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

2.1.31.2 Suffix to the authorisation number

| | |
|----------|--|
| Number 5 | |
|----------|--|

2.1.31.3 Product type(s)

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

2.1.32 Meta SPC 5 composition**2.1.32.1** Qualitative and quantitative information on the composition of the meta SPC 5

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|---|---|----------------------------|------------|-----------|-------------|---------|
| | | | | | Min | Max |
| L(+) lactic acid | 2-Hydroxypropionic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 | 28.8 |
| | | Technical active substance | | | 30.16 | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0 | 0.011 % |

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

| |
|-------------------------|
| SL: Soluble concentrate |
|-------------------------|

2.1.33 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 5**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| Classification | |
|--------------------------|---|
| Hazard category | Skin corr.1B Eye Dam.1 Skin sens.1A |
| Hazard statement | H314: Causes severe skin burns and eye damage H318: Causes serious eye damage H317 : May cause an allergic skin reaction |
| Labelling | |
| Signal words | Danger |
| Hazard statements | H314: Causes severe skin burns and eye damage H317 : May cause an allergic skin reaction |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand P102:Keep out of reach of children P103:Read label before use P260: Do not breathe spray. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/ protective clothing/ eye 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. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310. Immediately call a POISON CENTER or doctor/physician P321: Specific treatment (see ... on the label). P363: Wash contaminated clothing before reuse. P333 + P313: If skin irritation or rash occur: Get medical advice/attention P302+ P352: IF ON SKIN : Wash with plenty of water P273: Avoid release to the environment. P501: Dispose of contents/containers in accordance with local regulations. |
| Note | EUH071: Corrosive to the respiratory tract. |

2.1.34 Authorised use(s) of the META SPC 5

2.1.34.1 Use description

Table 30. Use # 1 – Disinfection of hard surfaces and equipment by manual liquid spraying
– Professionals - PT2 – Soluble concentrate (Use 1)

| | |
|---------------------|-----|
| Product Type | PT2 |
|---------------------|-----|

| | |
|---|---|
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual surface spraying |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 12.5% v/v, 30 minutes. - Virus: 12.5% v/v, 60 minutes. At a temperature of 40°C: - Bacteria and yeasts: 10% v/v, 15 minutes. - Bacteria and yeasts: 4% v/v, 30 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.34.1.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.34.1.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.34.2 Use description

Table 31. Use # 2 – Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) – Professionals - PT2 – Soluble concentrate (Use 2)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual spraying with a mural cleaning station (liquid/foam spraying) with automated dilution. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 12.5% v/v, 30 minutes. - Virus: 12.5% v/v, 60 minutes. At a temperature of 40°C: - Bacteria and yeasts: 10% v/v, 15 minutes. - Bacteria and yeasts: 4% v/v, 30 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.34.2.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.34.2.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.34.3 Use description

Table 32. Use # 3 – Disinfection of hard surfaces of equipment by manual dipping/soaking– Professionals - PT2 – Soluble concentrate (Use 3)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual dipping/soaking. |

| | |
|--|---|
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 12.5% v/v, 30 minutes. - Virus: 12.5% v/v, 60 minutes. At a temperature of 40°C: - Bacteria and yeasts: 10% v/v, 15 minutes. - Bacteria and yeasts: 4% v/v, 30 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.34.3.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.34.3.2 Use-specific risk mitigation measures

- The professional user has to wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
- Do not immerse hands in the bath.
- Let the equipment soak for the necessary time in the bath of cleaning/disinfectant solution, then empty the bath, and finish by rinsing without touching the equipment that has remained in the tank.

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

-

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

-

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

-

2.1.34.4 Use description

Table 33. Use # 4 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT2 – Soluble concentrate (Use 4)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | At a temperature of 20°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 12.5% v/v, 30 minutes. - Virus: 12.5% v/v, 60 minutes. At a temperature of 40°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 10% v/v, 15 minutes. - Bacteria and yeasts: 4% v/v, 30 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20 mL HDPE Cartridge to be used with trigger spray 0.5, 0.75, 1L and 1L bottle 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.34.4.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.34.4.2 Use-specific risk mitigation measures

- For professional users: wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
- Pour the solution direct on the surface and wipe with a cloth / brush for wiping activities.
- A mop/brush with a handle has to be used to apply the in-use solution.

- Do not immerse hands in the solution.

For professional bystander :

- Do not touch the surface until it is completely dried.

For general public :

- Do not touch the surface until it is rinsed and completely dried.

- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.34.5 Use description

Table 5. Use # 5 – Disinfection of hard surfaces and equipment by manual liquid spraying – Professionals - PT4 – Soluble concentrate (Use 9)

| | |
|---|---|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual surface spraying |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 12.5% v/v, 30 minutes. - Virus: 12.5% v/v, 60 minutes. At a temperature of 40°C: - Bacteria and yeasts: 10% v/v, 15 minutes. - Bacteria and yeasts: 4% v/v, 30 minutes. |
| Category(ies) of users | Professionals |

| | |
|--|---|
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |
|--|---|

2.1.34.5.1 Use-specific instructions for use

-

2.1.34.5.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.34.6 Use description

Table 6. Use # 6 – Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) – Professionals - PT4 – Soluble concentrate (Use 10)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual spraying with a mural cleaning station (liquid/foam spraying) with automated dilution. |
| Application rate(s) and frequency | At a temperature of 20°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 12.5% v/v, 30 minutes. - Virus: 12.5% v/v, 60 minutes. At a temperature of 40°C: <ul style="list-style-type: none"> - Bacteria and yeasts: 10% v/v, 15 minutes. - Bacteria and yeasts: 4% v/v, 30 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.34.6.1 Use-specific instructions for use

-

2.1.34.6.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and

dried.

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

-

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

-

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

-

2.1.34.7 Use description

Table 34. Use # 7 – Disinfection of hard surfaces and equipment by manual dipping/soaking– Professionals - PT4 – Soluble concentrate (Use 11)

| | |
|---|---|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual dipping/soaking. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 12.5% v/v, 30 minutes. - Virus: 12.5% v/v, 60 minutes. At a temperature of 40°C: - Bacteria and yeasts: 10% v/v, 15 minutes. - Bacteria and yeasts: 4% v/v, 30 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) |

| |
|--|
| 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |
|--|

2.1.34.7.1 Use-specific instructions for use

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

2.1.34.7.2 Use-specific risk mitigation measures

- | |
|--|
| <ul style="list-style-type: none"> - The professional user has to wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing. - Do not immerse hands in the bath. - Let the equipment soak for the necessary time in the bath of cleaning/disinfectant solution, then empty the bath, and finish by rinsing without touching the equipment that has remained in the tank. |
|--|

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

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

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

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

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

2.1.34.8 Use description

Table 35. Use # 8 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT4 – Soluble concentrate (Use 12)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |

| | |
|--|---|
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 12.5% v/v, 30 minutes. - Virus: 12.5% v/v, 60 minutes. At a temperature of 40°C: - Bacteria and yeasts: 10% v/v, 15 minutes. - Bacteria and yeasts: 4% v/v, 30 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20 mL HDPE Cartridge to be used with trigger spray 0.5, 0.75, 1L and 1L bottle 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.34.8.1 Use-specific instructions for use

-

2.1.34.8.2 Use-specific risk mitigation measures

- For professional users: wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
 - Pour the solution direct on the surface and wipe with a cloth / brush for wiping activities
 - A mop/brush with a handle has to be used to apply the in-use solution
 - Do not immerse hands in the solution
- For professional bystander :
- Do not touch the surface until it is completely dried
- For general public :
- Do not touch the surface until it is rinsed and completely dried
 - Children should not be present during disinfection and until the surface is rinsed and dried

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

-

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

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

-

2.1.34.9 Use description

Table 36. Use # 9 – Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer – Professionals - PT2 – Soluble concentrate in cartridge (Use 33)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual surface spraying with a trigger sprayer (liquid/foam spraying). |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 12.5% v/v, 30 minutes. - Virus: 12.5% v/v, 60 minutes. At a temperature of 40°C: - Bacteria and yeasts: 10% v/v, 15 minutes. - Bacteria and yeasts: 4% v/v, 30 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20 mL HDPE Cartridge to be used with trigger spray 0.5, 0.75, 1L and 1L bottle |

2.1.34.9.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.34.9.2 Use-specific risk mitigation measures

For professional users:

- Wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, and the rinsing.

- Wear gloves, coverall goggles and a respiratory protective equipment against aerosol (material to be specified by the authorisation holder within the product information) during the application by trigger spray.
- For professional bystander :
- Do not be present in the treatment area during disinfection process by trigger. If it is necessary to be present, wear same RPE and PPE as the professional user.
 - Do not touch the surface until it is completely dried.
- For general public :
- Do not be present in the treatment area during disinfection process by trigger.
 - Do not touch the surface until it is rinsed and completely dried
 - Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.34.10 Use description

Table 370. Use # 10 – Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer - Professionals - PT4 – Soluble concentrate in cartridge (Use 34)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |

| | |
|--|---|
| Application method(s) | Manual surface spraying with a trigger sprayer (liquid/foam spraying). |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 12.5% v/v, 30 minutes. - Virus: 12.5% v/v, 60 minutes. At a temperature of 40°C: - Bacteria and yeasts: 10% v/v, 15 minutes. - Bacteria and yeasts: 4% v/v, 30 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20 mL HDPE Cartridge to be used with trigger spray 0.5, 0.75, 1L and 1L bottle |

2.1.34.10.1 Use-specific instructions for use

-

2.1.34.10.2 Use-specific risk mitigation measures

For professional users:

- Wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, and the rinsing.
- Wear gloves, coverall goggles and a respiratory protective equipment against aerosol (material to be specified by the authorisation holder within the product information) during the application by trigger spray.

For professional bystander :

- Do not be present in the treatment area during disinfection process by trigger. If it is necessary to be present, wear same RPE and PPE as the professional user.
- Do not touch the surface until it is completely dried.

For general public :

- Do not be present in the treatment area during disinfection process by trigger.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.35 General directions for use of the meta SPC 5

2.1.35.1 Instructions for use

- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.
- Products have been tested against bacteria, including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes* at 20°C and 40°C and *Lactobacillus brevis* at 40°C and against virus including *bovine coronavirus* and human *rotavirus* at 20°C.
- During the product dilution, pour almost all water first, then the product, then the remaining of the water.

2.1.35.2 Risk mitigation measures

-

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

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

2.1.35.4 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.

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

- Protect from frost.
- Keep away from direct sunlight.
- Shelf-life = 2 years.
- Keep out of reach of children and non-target animals/pets.

2.1.36 Other information

-

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

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

| | |
|----------------------|-------------------------------|
| Trade name(s) | PRODUCT 5-1 - Soprodís |
|----------------------|-------------------------------|

| Authorisation number | | | | | |
|---|---|----------------------------|-------------------|------------------|--------------------|
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | |
|----------------------|--|
| Trade name(s) | PRIM VERT DDM + CLARINE NATURA DDM + DDA400 BPRO AGRO DDM-AL ELIPRO A-NDMA BLUtec SAN VERONESE Nettoyant détartrant désinfectant Sanitaire INOVEO Nettoyant détartrant désinfectant Sanitaire SANTO GREEN Nettoyant détartrant désinfectant Sanitaire TECHLINE Nettoyant détartrant désinfectant Sanitaire RESOLUTIONS Nettoyant détartrant désinfectant Sanitaire ECO ATTITUDE Nettoyant détartrant désinfectant Sanitaire VERONESE Dégraissant désinfectant Alimentaire INOVEO Dégraissant désinfectant Alimentaire SANTO GREEN Dégraissant désinfectant Alimentaire TECHLINE Dégraissant désinfectant Alimentaire RESOLUTIONS Dégraissant désinfectant Alimentaire |
|----------------------|--|

| ECO ATTITUDE Dégraissant désinfectant Alimentaire NDDS400 | | | | | |
|---|---|----------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| Trade name(s) PRODUCT 5-3 - Soprodís | | | | | |
|---|---|----------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|---|--|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-4 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|---|--|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-5 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|----------------------|-------------------------------|--|--|--|--|
| Trade name(s) | PRODUCT 5-6 - Soprodís | | | | |
|----------------------|-------------------------------|--|--|--|--|

| Authorisation number | | | | | |
|---|--|----------------------------|-------------------|------------------|--------------------|
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| Trade name(s) | PRODUCT 5-7 - Soprodis | | | | |
|---|--|----------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| Trade name(s) | PRODUCT 5-8 - Soprodis | | | | |
|-----------------------------|-------------------------------|--|--|--|--|
| Authorisation number | | | | | |

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|--|----------------------------|------------|-----------|-------------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| Trade name(s) | PRODUCT 5-9 - Soprodís | | | | |
|---|--|----------------------------|------------|-----------|-------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| Trade name(s) | PRODUCT 5-10 - Soprodís | | | | |
|----------------------|-------------------------|----------|------------|-----------|-------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |

| | | | | | |
|---|--|----------------------------|------------|-----------|--------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|---|--|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-11 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|-----------------------------|---------------------------------|-----------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-12 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |

| | | | | | |
|---|---|----------------------------|------------|-----------|--------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|---|---|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-13 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|-----------------------------|---------------------------------|-----------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-14 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |

| | | | | | |
|---|---|----------------------------|------------|-----------|--------|
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|---|---|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-15 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|-----------------------------|---------------------------------|-----------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-16 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |

| | | | | | |
|---|---|----------------------------|------------|-----------|--------|
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|---|---|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-17 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|-----------------------------|---------------------------------|-----------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-18 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |

| | | | | | |
|---|---|----------------------------|------------|-----------|--------|
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|---|---|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-19 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|-----------------------------|---------------------------------|-----------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-20 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |

| | | | | | |
|---|---|----------------------------|------------|-----------|--------|
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|---|---|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-21 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|-----------------------------|--------------------------------|-----------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-22 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |

| | | | | | |
|---|--|----------------------------|------------|-----------|--------|
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|---|--|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-23 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|-----------------------------|--------------------------------|-----------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-24 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |

| | | | | | |
|---|---|----------------------------|------------|-----------|--------|
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|---|---|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-25 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|-----------------------------|--------------------------------|-----------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-26 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |

| | | | | | |
|---|--|----------------------------|------------|-----------|--------|
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|---|--|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-27 - Soprodis | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|-----------------------------|--------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 5-28 - Soprodis | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |

| | | | | | |
|---|---|----------------------|------------|-----------|--------|
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

PART II - SECOND INFORMATION LEVEL - META SPC 6

2.1.38 Meta SPC 6 administrative information

2.1.38.1 Meta SPC identifier

| | |
|-----------------------|------------|
| Identification | META SPC 6 |
|-----------------------|------------|

2.1.38.2 Suffix to the authorisation number

| | |
|----------|--|
| Number 6 | |
|----------|--|

2.1.38.3 Product type(s)

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

2.1.39 Meta SPC 6 composition

2.1.39.1 Qualitative and quantitative information on the composition of the meta SPC 6

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|-------------------------|----------------------------|------------|-----------|-------------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 24 |
| | | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |

2.1.39.2 Type(s) of formulation of the meta SPC 6

| |
|-------------------------|
| SL: Soluble concentrate |
|-------------------------|

2.1.40 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 6

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 |
| Hazard statement | H290: May be corrosive to metals H314: Causes severe skin burns and eye damage H318: Causes serious eye damage |
| Labelling | |
| Signal words | Danger |
| Hazard statements | H290: May be corrosive to metals H314: Causes severe skin burns and eye damage |
| Precautionary statements | P234 : keep only in original packaging. P260: Do not breathe spray. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/ protective clothing/ eye 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. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310. Immediately call a POISON CENTER or doctor/physician P321: Specific treatment (see ... on the label). P363: Wash contaminated clothing before reuse. P390: Absorb spillage to prevent material damage. P406: Store in a corrosive resistant/... container with a resistant inner liner. |
| Note | EUH071: Corrosive to the respiratory tract. |

2.1.41 Authorised use(s) of the META SPC 6

2.1.41.1 Use description

Table 38. Use # 1 – Disinfection of hard surfaces and equipment by manual liquid spraying
– Professionals - PT2 – Soluble concentrate (Use 1)

| | |
|---------------------|-----|
| Product Type | PT2 |
|---------------------|-----|

| | |
|---|---|
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual surface spraying |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 9% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 5% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.41.1.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.41.1.2 Use-specific risk mitigation measures

- For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried.

For General public:

- Do not be present in the treatment area during disinfection process by compression sprayer.
- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.41.2 Use description

Table 39. Use # 2 – Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) – Professionals - PT2 – Soluble concentrate (Use 2)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual spraying with a mural cleaning station (liquid/foam spraying) with automated dilution. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 9% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 5% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.41.2.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.41.2.2 Use-specific risk mitigation measures

- For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.
- For professional bystander:
- Do not be present in the treatment area during disinfection process by spraying. If it is necessary to be present, wear same PPE as the professional user.
 - Do not touch the surface until it is completely dried.
- General public:
- Do not be present in the treatment area during disinfection process by spraying.
 - Do not touch the surface until it is rinsed and completely dried.
 - Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.41.3 Use description

Table 40. Use # 3 – Disinfection of hard surfaces of equipment by manual dipping/soaking– Professionals - PT2 – Soluble concentrate (Use3)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual dipping/soaking. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 9% v/v, 30 minutes. |

| | |
|--|---|
| | At a temperature of 40°C: - Bacteria and yeasts: 5% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.41.3.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.41.3.2 Use-specific risk mitigation measures

- For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

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

-

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

-

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

-

2.1.41.4 Use description

Table 41. Use # 4 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT2 – Soluble concentrate (Use 4)

| | |
|---|-----|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |

| | |
|--|---|
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 9% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 5% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20 mL HDPE Cartridge to be used with trigger spray 0.5, 0.75, 1L and 1L bottle 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.41.4.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.41.4.2 Use-specific risk mitigation measures

- For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander :

- Do not touch the surface until it is completely dried.

For general public:

- Do not touch the surface until it is rinsed and completely dried.
- Children should not be present during disinfection and until the surface is rinsed and dried.

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

-

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

-

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

-

2.1.41.5 Use description

Table 42. Use # 7 – Disinfection of inner surfaces by CIP – Professionals - PT2 – Soluble concentrate (Use 7)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in industries (including cosmetic and pharmaceutical industries). |
| Application method(s) | Cleaning-in-place. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 9% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 5% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.41.5.1 Use-specific instructions for use

-

2.1.41.5.2 Use-specific risk mitigation measures

For professional user:

- Wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading and maintenance of the circuit system.
- Wear gloves, protective coverall, chemical goggles and a respiratory protective equipment (material to be specified by the authorisation holder within the product information) during maintenance of the dosing pumps.

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

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

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

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2.1.41.6 Use description

Table 43. Use # 8 – Disinfection of hard surfaces and equipment by manual liquid spraying
– Professionals - PT4 – Soluble concentrate (Use 9)

| | |
|---|---|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual surface spraying |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 9% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 5% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5-10-20L LDPE/PET Bag in box (cubitainer) |

| |
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| 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |
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2.1.41.6.1 Use-specific instructions for use

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|---|
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2.1.41.6.2 Use-specific risk mitigation measures

| |
|---|
| <ul style="list-style-type: none"> - For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing. <p>For professional bystander:</p> <ul style="list-style-type: none"> - Do not be present in the treatment area during disinfection process by compression/knapsack sprayer. If it is necessary to be present, wear same PPE as the professional user.” - Do not touch the surface until it is completely dried. <p>General public:</p> <ul style="list-style-type: none"> - Do not be present in the treatment area during disinfection process by spraying. - Do not touch the surface until it is rinsed and completely dried. - Children should not be present during disinfection and until the surface is rinsed and dried. |
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2.1.41.6.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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

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

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2.1.41.7 Use description

Table 44. Use # 9 – Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) – Professionals - PT4 – Soluble concentrate (Use 10)

| | |
|---------------------|-----|
| Product Type | PT4 |
|---------------------|-----|

| | |
|---|--|
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual spraying with a mural cleaning station (liquid/foam spraying) with automated dilution. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 9% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 5% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.41.7.1 Use-specific instructions for use

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2.1.41.7.2 Use-specific risk mitigation measures

For professional user :wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander:
-Do not be present in the treatment area during disinfection process by spraying. If it is necessary to be present, wear same PPE as the professional user."
-Do not touch the surface until it is completely dried

General public:
-Do not be present in the treatment area during disinfection process by spraying.
-Do not touch the surface until it is rinsed and completely dried;
-Children should not be present during disinfection and until the surface is rinsed and dried

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

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

[Empty box for disposal instructions]

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

[Empty box for storage conditions]

2.1.41.8 Use description

Table 45. Use # 10 – Disinfection of hard surfaces and equipment by manual dipping/soaking– Professionals - PT4 – Soluble concentrate (Use11)

| | |
|---|---|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual dipping/soaking. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 9% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 5% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.41.8.1 Use-specific instructions for use

-

2.1.41.8.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

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

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

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

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2.1.41.9 Use description

Table 46. Use # 11 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT4 – Soluble concentrate (Use 12)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 9% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 5% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20 mL HDPE Cartridge to be used with trigger spray 0.5, 0.75, 1L and 1L bottle 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle |

| |
|--|
| 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |
|--|

2.1.41.9.1 Use-specific instructions for use

-

2.1.41.9.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander :

- Do not touch the surface until it is completely dried

For general public:

- Do not touch the surface until it is rinsed and completely dried
- Children should not be present during disinfection and until the surface is rinsed and dried

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

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

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

2.1.41.10 Use description

Table 47. Use # 14 – Disinfection of inner surfaces by CIP – Professionals - PT4 – Soluble concentrate (Use15)

| | |
|---------------------|-----|
| Product Type | PT4 |
|---------------------|-----|

| | |
|---|---|
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries). |
| Application method(s) | Cleaning in place |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 9% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 5% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.41.10.1 Use-specific instructions for use

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2.1.41.10.2 Use-specific risk mitigation measures

For professional user:

-wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading and maintenance of the circuit system.

-wear gloves, protective coverall, chemical goggles and a respiratory protective equipment (material to be specified by the authorisation holder within the product information) during maintenance of the dosing pumps.

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

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

[Empty box for disposal instructions]

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

[Empty box for storage conditions]

2.1.41.11 Use description

Table 48. Use # 15 – Disinfection of the inner surfaces of small kitchen appliances without circulation – Professionals – PT4 – Soluble concentrate (Use 35)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Disinfection of inner surfaces without circulation. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 9% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 5% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET pods 20mL HDPE cartridges 1L LDPE Dosing bottle 1L HDPE Dosing bottle |

2.1.41.11.1 Use-specific instructions for use

-

2.1.41.11.2 Use-specific risk mitigation measures

For professional user:
 -wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading and maintenance of the circuit system.

-wear gloves, protective coverall, chemical goggles and a respiratory protective equipment (material to be specified by the authorisation holder within the product information) during maintenance of the dosing pumps.

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

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

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

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2.1.41.12 Use description

Table 49. Use # 16 – Disinfection of the inner surfaces of small kitchen appliances by CIP – Professionals – PT4 – Soluble concentrate (Use 36)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Disinfection of inner surfaces with circulation. |
| Application rate(s) and frequency | At a temperature of 20°C: - Bacteria and yeasts: 9% v/v, 30 minutes. At a temperature of 40°C: - Bacteria and yeasts: 5% v/v, 15 minutes. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET pods 20mL HDPE cartridges 1L LDPE Dosing bottle 1L HDPE Dosing bottle |

2.1.41.12.1 Use-specific instructions for use

-

2.1.41.12.2 Use-specific risk mitigation measures

For professional user:

-wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading and maintenance of the circuit system.

-wear gloves, protective coverall, chemical goggles and a respiratory protective equipment (material to be specified by the authorisation holder within the product information) during maintenance of the dosing pumps.

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

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

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

2.1.42 General directions for use of the meta SPC 6

2.1.42.1 Instructions for use

- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.
- Products have been tested against bacteria, including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes* at 20°C and 40°C and *Lactobacillus brevis* at 40°C.

2.1.42.2 Risk mitigation measures

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

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

2.1.42.4 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.

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

- Protect from frost.
- Keep away from direct sunlight.
- Shelf-life = 2 years.

2.1.43 Other information

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PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6

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

| | |
|----------------------|-------------------------------|
| Trade name(s) | PRODUCT 6-1 - Soprodís |
|----------------------|-------------------------------|

| | | | | | |
|---|-------------------------|----------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 24 |
| | | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |

| | | | | | |
|---|-------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 6-2 - Soprodis | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 24 |
| | | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |

| | | | | | |
|---|---|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | ELIPRO A-NDA ; BPRO AGRO DD-AL ; DDA400M | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 24 |
| | | Technical active substance | | | 25.13 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 30 |

PART II - SECOND INFORMATION LEVEL - META SPC 7**2.1.45** Meta SPC 7 administrative information**2.1.45.1** Meta SPC identifier

| | |
|-----------------------|------------|
| Identification | META SPC 7 |
|-----------------------|------------|

2.1.45.2 Suffix to the authorisation number

| | |
|----------|--|
| Number 7 | |
|----------|--|

2.1.45.3 Product type(s)

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

2.1.46 Meta SPC 7 composition**2.1.46.1** Qualitative and quantitative information on the composition of the meta SPC 7

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|---|-------------------------|----------------------------|------------|-----------|-------------|------|
| | | | | | Min | Max |
| L(+) lactic acid | 2-Hydroxypropionic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 | 1.44 |
| | | Technical active substance | | | 1.51 | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 | 1.8 |

2.1.46.2 Type(s) of formulation of the meta SPC 7

| |
|----------------------|
| AL: Any other liquid |
|----------------------|

2.1.47 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 7**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| | |
|-----------------------|--------------------------|
| Classification | |
| Hazard category | Skin Irri.2 Eye dam.1 |

| Classification | |
|--------------------------|--|
| Hazard statement | H315: Causes skin irritation H318 : Causes serious eye damage |
| Labelling | |
| Signal words | Danger |
| Hazard statements | H315: Causes skin irritation H318 : Causes serious eye damage |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand P102: Keep out of reach of children P103: Read label before use P264: Wash hands thoroughly after handling. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physician P321: Specific treatment (see ... on this label). P332+P313: If skin irritation occurs: Get medical advice/attention. P337+P313: If eye irritation persists: Get medical advice/attention. P362+P364: Take off contaminated clothing and wash before reuse. P280: Wear protective gloves/ protective clothing/ eye protection. P273: Avoid release to the environment. P501: Dispose of contents/containers in accordance with local regulations. |
| Note | |

2.1.48 Authorised use(s) of the META SPC 7

2.1.48.1 Use description

Table 50. Use # 1 – Disinfection of hard surfaces and equipment by manual liquid spraying
– Professionals - PT2 – RTU product (Use 17)

| | |
|---|----------------------------|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |

| | |
|--|--|
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual surface spraying |
| Application rate(s) and frequency | Ready to use product. Contact time: - Bacteria and yeasts: 15 minutes, 20°C - Enveloped viruses: 15 min, 20°C - Virus: 60 minutes, 20°C |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 500mL to 1L HDPE/PET Prefilled trigger spray 750mL HDPE Angled bottle 1L HDPE Bottle with handle 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.48.1.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.48.1.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during loading, application and rinsing.

For professional bystander:

- Do not be present in the treatment area during disinfection process by spraying. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried

General public:

- Do not be present in the treatment area during disinfection process.
- Do not touch the surface until it is rinsed and completely dried
- Children should not be present during disinfection and until the surface is rinsed and dried

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

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

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

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2.1.48.2 Use description

Table 51. Use # 2 – Disinfection of hard surfaces (small surfaces) and equipment by manual liquid spraying using a trigger sprayer – Professionals - PT2 – RTU product (Use 18)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual surface spraying with a trigger sprayer (liquid/foam spraying). |
| Application rate(s) and frequency | Ready to use product. Contact time: <ul style="list-style-type: none"> - Bacteria and yeasts: 15 minutes, 20°C - Enveloped viruses: 15 min, 20°C - Virus: 60 minutes, 20°C |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 500mL to 1L HDPE/PET Prefilled trigger spray 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 5L HDPE Jerrican with distributor pump 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.48.2.1 Use-specific instructions for use

- | |
|---|
| <ul style="list-style-type: none"> - For healthcare settings: clean carefully the surfaces before application of the product. - |
|---|

2.1.48.2.2 Use-specific risk mitigation measures

For professional user :wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during application by trigger spray and rinsing

For professional bystander:
 -Do not be present in the treatment area during disinfection process by spraying. If it is necessary to be present, wear same PPE as the professional user.
 -Do not touch the surface until it is completely dried

General public:
 -Do not be present in the treatment area during disinfection process.
 -Do not touch the surface until it is rinsed and completely dried
 -Children should not be present during disinfection and until the surface is rinsed and dried

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

[Empty box]

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

[Empty box]

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

[Empty box]

2.1.48.3 Use description

Table 52. Use # 3 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT2 – RTU product (Use19)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |

| | |
|--|--|
| Application rate(s) and frequency | Ready to use product. Contact time: <ul style="list-style-type: none">- Bacteria and yeasts: 15 minutes, 20°C- Enveloped viruses: 15 min, 20°C- Virus: 60 minutes, 20°C |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 500mL to 1L HDPE/PET Prefilled trigger spray 750mL HDPE Angled bottle 1L HDPE Bottle with handle 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.48.3.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.
-

2.1.48.3.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander :

- Do not touch the surface until it is completely dried

For general public:

- Do not touch the surface until it is rinsed and completely dried
- Children should not be present during disinfection and until the surface is rinsed and dried

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

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

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

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2.1.48.4 Use description

Table 53. Use # 4 – Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding – Professionals - PT2 – RTU product (Use 20)

| | |
|---|--|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in private and public areas: institutions, industries, |
| Application method(s) | Direct spreading/flooding. |
| Application rate(s) and frequency | Ready to use product. Contact time: <ul style="list-style-type: none"> - Bacteria and yeasts: 15 minutes, 20°C - Enveloped viruses: 15 min, 20°C - Virus: 60 minutes, 20°C |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 750mL HDPE Angled bottle 1L HDPE Bottle with handle 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.48.4.1 Use-specific instructions for use

| |
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| - |
|---|

2.1.48.4.2 Use-specific risk mitigation measures

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|---|
| For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during pouring and brushing. |
|---|

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

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

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

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2.1.48.5 Use description

Table 54. Use # 5 – Disinfection of hard surfaces and equipment by manual liquid spraying – Professionals - PT4 – RTU product (Use 21)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual surface spraying |
| Application rate(s) and frequency | Ready to use product. Contact time: - Bacteria and yeasts: 15 minutes, 20°C - Enveloped viruses: 15 min, 20°C - Virus: 60 minutes, 20°C |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 500mL to 1L HDPE/PET Prefilled trigger spray 750mL HDPE Angled bottle 1L HDPE Bottle with handle 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.48.5.1 Use-specific instructions for use

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2.1.48.5.2 Use-specific risk mitigation measures

For professional user :wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during application by spray and rinsing

For professional bystander:

-Do not be present in the treatment area during disinfection process by spraying. If it is necessary to be present, wear same PPE as the professional user.

-Do not touch the surface until it is completely dried

General public:

-Do not be present in the treatment area during disinfection process.

-Do not touch the surface until it is rinsed and completely dried

-Children should not be present during disinfection and until the surface is rinsed and dried

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

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

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

2.1.48.6 Use description

Table 55. Use # 6 – Disinfection of hard surfaces (small surfaces) and equipment by manual liquid spraying using a trigger sprayer – Professionals - PT4 – RTU product (Use 22)

| | |
|---|----------------------------|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |

| | |
|--|--|
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual surface spraying with a trigger sprayer (liquid/foam spraying). |
| Application rate(s) and frequency | Ready to use product. Contact time: - Bacteria and yeasts: 15 minutes, 20°C - Enveloped viruses: 15 min, 20°C - Virus: 60 minutes, 20°C |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 500mL to 1L HDPE/PET Prefilled trigger spray 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.48.6.1 Use-specific instructions for use

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2.1.48.6.2 Use-specific risk mitigation measures

For professional user :wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during application by trigger spray and rinsing

For professional bystander:

- Do not be present in the treatment area during disinfection process by spraying. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried

General public:

- Do not be present in the treatment area during disinfection process.
- Do not touch the surface until it is rinsed and completely dried
- Children should not be present during disinfection and until the surface is rinsed and dried

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

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

[Empty box for disposal instructions]

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

[Empty box for storage conditions]

2.1.48.7 Use description

Table 56. Use # 7 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT4 – RTU product (Use 23)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | Ready to use product. Contact time: <ul style="list-style-type: none"> - Bacteria and yeasts: 15 minutes, 20°C - Enveloped viruses: 15 min, 20°C - Virus: 60 minutes, 20°C |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 500mL to 1L HDPE/PET Prefilled trigger spray 750mL HDPE Angled bottle 1L HDPE Bottle with handle 5L HDPE Jerrican with distributor pump 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.48.7.1 Use-specific instructions for use

-

2.1.48.7.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander :

- Do not touch the surface until it is completely dried

For general public:

- Do not touch the surface until it is rinsed and completely dried
- Children should not be present during disinfection and until the surface is rinsed and dried

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

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

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

2.1.48.8 Use description

Table 8. Use # 8 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – General public - PT2 – RTU product (Use 25)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in private areas, households |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | Ready to use product. Contact time: <ul style="list-style-type: none"> - Bacteria and yeasts: 15 minutes, 20°C - Enveloped viruses: 15 min, 20°C - Virus: 60 minutes, 20°C |

| | |
|--|--|
| Category(ies) of users | General public |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 500mL to 1L HDPE/PET Prefilled trigger spray 1L HDPE Bottle with handle 5L HDPE Jerrican with distributor pump 10L HDPE Jerrican with distributor pump |

2.1.48.8.1 Use-specific instructions for use

-

2.1.48.8.2 Use-specific risk mitigation measures

For non professional user during loading, application and rinsing :

- Wash hands after use
- Avoid contact with eyes and skin
- Avoid splashes and spills
- The packaging must be adapted with a child proof closure

For general public :

- Do not touch the surface until it is rinsed and totally dried
- Children should not be present during disinfection and until the surface is rinsed and dry

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

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

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

- Keep out of reach of children and non-target animals/pets

2.1.48.9 Use description

Table 57. Use # 9 – Disinfection of toilets bowls and sanitary facilities by direct spreading/flooding – General public - PT2 – RTU product (Use 26)

| | |
|---------------------|-----|
| Product Type | PT2 |
|---------------------|-----|

| | |
|---|--|
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in private areas, households |
| Application method(s) | Direct spreading/flooding |
| Application rate(s) and frequency | Ready to use product. Contact time: - Bacteria and yeasts: 15 minutes, 20°C - Enveloped viruses: 15 min, 20°C - Virus: 60 minutes, 20°C |
| Category(ies) of users | General public |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 750mL HDPE Angled bottle 1L HDPE Bottle with handle 5L HDPE Jerrican with distributor pump 10L HDPE Jerrican with distributor pump |

2.1.48.9.1 Use-specific instructions for use

-

2.1.48.9.2 Use-specific risk mitigation measures

For non professional user during application and rinsing :

- Wash hands after use
- Avoid any contact with eyes and skin
- Avoid splashes and spills
- The packaging must be adapted with a child proof closure

For general public :

- Do not touch the surface until it is rinsed and totally dried
- Children should not be present during disinfection and until the surface is rinsed and dry

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

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

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

| |
|---|
| - Keep out of reach of children and non-target animals/pets |
|---|

2.1.48.10 Use description

Table 58. Use # 10 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – General public - PT4 – RTU product (Use 28)

| | |
|---|---|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast Virus |
| Field of use | Indoors disinfection in private areas, domestic kitchens. |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | Ready to use product. Contact time: <ul style="list-style-type: none"> - Bacteria and yeasts: 15 minutes, 20°C - Enveloped viruses: 15 min, 20°C - Virus: 60 minutes, 20°C |
| Category(ies) of users | General public |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 500mL to 1L HDPE/PET Prefilled trigger spray 1L HDPE Bottle with handle 5L HDPE Jerrican with distributor pump 10L HDPE Jerrican with distributor pump |

2.1.48.10.1 Use-specific instructions for use

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

2.1.48.10.2 Use-specific risk mitigation measures

| |
|--|
| <p>For non professional user during application and rinsing :</p> <ul style="list-style-type: none"> -Wash hands after use -Avoid contact with eyes and skin |
|--|

- Avoid splashes and spills
- The packaging must be adapted with a child proof closure

For general public :

- Do not touch the surface until it is rinsed and totally dried
- Children should not be present during disinfection and until the surface is rinsed and dry

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

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

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

- Keep out of reach of children and non-target animals/pets

2.1.49 General directions for use of the meta SPC 7

2.1.49.1 Instructions for use

- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.
- Products have been tested against bacteria, including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes* at 20°C against virus including *bovine coronavirus*, *rotavirus* and *influenza virus* at 40°C.

2.1.49.2 Risk mitigation measures

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

- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a poison centre or a doctor
- IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a poison centre or a doctor
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. If medical advice is needed, have product container or label at hand

2.1.49.4 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.

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

- Protect from frost.
- Keep away from direct sunlight.
- Shelf-life = 2 years.

2.1.50 Other information

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PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 7**2.1.51** Trade name(s), authorisation number and specific composition of each individual product

| | | | | | |
|-----------------------------|-------------------------------|-----------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-1 - Soprodis | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |

| | | | | | |
|---|-------------------------|----------------------------|---------|-----------|------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|-------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-2 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|-------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-3 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|-----------------------------|-------------------------------|-----------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-4 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |

| | | | | | |
|---|-------------------------|----------------------------|---------|-----------|------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|-------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-5 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|-------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-6 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|-----------------------------|-------------------------------|-----------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-7 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |

| | | | | | |
|---|-------------------------|----------------------------|---------|-----------|------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|-------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-8 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|-------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-9 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|-----------------------------|--------------------------------|-----------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-10 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |

| | | | | | |
|---|-------------------------|----------------------------|---------|-----------|------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|---------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-11 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|---------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-12 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|-----------------------------|---------------------------------|-----------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-13 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |

| | | | | | |
|---|-------------------------|----------------------------|---------|-----------|------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|---------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-14 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|---------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-15 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|-----------------------------|---------------------------------|-----------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-16 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |

| | | | | | |
|---|-------------------------|----------------------------|---------|-----------|------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|---------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-17 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|---------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-18 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|-----------------------------|---------------------------------|-----------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-19 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |

| | | | | | |
|---|-------------------------|----------------------------|---------|-----------|------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|---------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-20 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|---|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRIM VERT Spray DDA CLARINE NATURA Spray DD BPRO Nettoyant dégraissant désinfectant Surfaces | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|----------------------|---|--|--|--|--|
| Trade name(s) | PRIM VERT 4D CLARINE NATURA S3D BPRO Nettoyant détartrant désinfectant Sanitaires DDA400 PAE | | | | |
|----------------------|---|--|--|--|--|

| | | | | | |
|---|--|----------------------------|-------------------|------------------|--------------------|
| | VERONESE Dégraissant désinfectant Alimentaire PAE INOVEO Dégraissant désinfectant Alimentaire PAE SANTO GREEN Dégraissant désinfectant Alimentaire PAE TECHLINE Dégraissant désinfectant Alimentaire PAE RESOLUTIONS Dégraissant désinfectant Alimentaire PAE ECO ATTITUDE Dégraissant désinfectant Alimentaire PAE NDDS400 PAE VERONESE Nettoyant détartrant désinfectant Sanitaire PAE INOVEO Nettoyant détartrant désinfectant Sanitaire PAE SANTO GREEN Nettoyant détartrant désinfectant Sanitaire PAE TECHLINE Nettoyant détartrant désinfectant Sanitaire PAE RESOLUTIONS Nettoyant détartrant désinfectant Sanitaire PAE ECO ATTITUDE Nettoyant détartrant désinfectant Sanitaire PAE | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|-----------------------------|--------------------------------|-----------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-23 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |

| | | | | | |
|---|--|----------------------------|--|--|------|
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|--------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-24 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|--------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-25 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|-----------------------------|--------------------------------|-----------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-26 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |

| | | | | | |
|---|--|----------------------------|--|--|------|
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|--------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-27 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|--------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-28 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|-----------------------------|--------------------------------|-----------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-29 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |

| | | | | | |
|---|--|----------------------------|--|--|------|
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|--------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-30 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|--------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-31 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|-----------------------------|--------------------------------|-----------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-32 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |

| | | | | | |
|---|--|----------------------------|--|--|------|
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|--------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-33 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|---|--------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-34 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

| | | | | | |
|-----------------------------|--------------------------------|-----------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 7-35 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 1.44 |

| | | | | | |
|---|--|----------------------------|--|--|------|
| | | Technical active substance | | | 1.51 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 1.8 |

PART II - SECOND INFORMATION LEVEL - META SPC 8

2.1.52 Meta SPC 8 administrative information

2.1.52.1 Meta SPC identifier

| | |
|-----------------------|------------|
| Identification | META SPC 8 |
|-----------------------|------------|

2.1.52.2 Suffix to the authorisation number

| | |
|----------|--|
| Number 8 | |
|----------|--|

2.1.52.3 Product type(s)

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

2.1.53 Meta SPC 8 composition

2.1.53.1 Qualitative and quantitative information on the composition of the meta SPC 8

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|-------------------------|----------------------------|------------|-----------|-------------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

2.1.53.2 Type(s) of formulation of the meta SPC 8

| |
|----------------------|
| AL: Any other liquid |
|----------------------|

2.1.54 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 8

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

| Classification | |
|--------------------------|--|
| Hazard category | Skin corr.1B Eye Dam.1 |
| Hazard statement | H314: Causes severe skin burns and eye damage H318: Causes serious eye damage |
| Labelling | |
| Signal words | Danger |
| Hazard statements | H314: Causes severe skin burns and eye damage |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand P102: Keep out of reach of children P103: Read label before use P260: Do not breathe spray. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/ protective clothing/ eye 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. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310. Immediately call a POISON CENTER or doctor/physician P321: Specific treatment (see ... on the label). P363: Wash contaminated clothing before reuse. P273: Avoid release to the environment. P501: Dispose of contents/containers in accordance with local regulations. |
| Note | EUH071: Corrosive to the respiratory tract. |

2.1.55 Authorised use(s) of the META SPC 8

2.1.55.1 Use description

Table 59. Use # 1 – Disinfection of hard surfaces (small surfaces) and equipment by manual liquid spraying using a trigger sprayer – Professionals - PT2 – RTU product (Use 18)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Manual surface spraying with a trigger sprayer (liquid/foam spraying). |
| Application rate(s) and frequency | Ready to use product. 60 minutes, 20°C |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 500mL to 1L HDPE/PET Prefilled trigger spray 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.55.1.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.
-

2.1.55.1.2 Use-specific risk mitigation measures

For professional user :

- wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during loading and rinsing
- wear gloves, protective coverall chemical goggles and a respiratory protective equipment (material to be specified by the authorisation holder within the product information) during application.

For professional bystander:

- Do not be present in the treatment area during disinfection process by spraying. If it is necessary to be present, wear same PPE as the professional user.
- Do not touch the surface until it is completely dried

General public:

- Do not be present in the treatment area during disinfection process.
- Do not touch the surface until it is rinsed and completely dried

-Children should not be present during disinfection and until the surface is rinsed and dried

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

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

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

2.1.55.2 Use description

Table 60. Use # 2 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT2 – RTU product ()

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | Ready to use product. 60 minutes, 20°C |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 500mL to 1L HDPE/PET Prefilled trigger spray 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.55.2.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.
-

2.1.55.2.2 Use-specific risk mitigation measures

For professional user :

- wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during loading, application and rinsing
- Pour the solution direct on the surface and wipe with a cloth / brush
- A mop/brush with a handle has to be used to apply the solution
- Do not immerse hands in the solution

For professional bystander:

- Do not touch the surface until it is completely dried

General public:

- Do not touch the surface until it is rinsed and completely dried
- Children should not be present during disinfection and until the surface is rinsed and dried

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

[Empty box]

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

[Empty box]

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

[Empty box]

2.1.55.3 Use description

Table 61. Use # 3 – Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding – Professionals - PT2 – RTU product (Use20)

| | |
|---|-------------------|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |

| | |
|--|---|
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Direct spreading/flooding. |
| Application rate(s) and frequency | Ready to use product. 60 minutes, 20°C |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 750mL HDPE Angled bottle 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.55.3.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.55.3.2 Use-specific risk mitigation measures

For professional user :
-wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during application by pouring and brushing

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

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

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

2.1.55.4 Use description

Table 62. Use # 4 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT4 – RTU product (Use23)

| | |
|---|-----|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |

| | |
|--|---|
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | Ready to use product. 60 minutes, 20°C |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 500mL to 1L HDPE/PET Prefilled trigger spray 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.55.4.1 Use-specific instructions for use

-

2.1.55.4.2 Use-specific risk mitigation measures

For professional user :

- wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during loading, application and rinsing
- Pour the solution direct on the surface and wipe with a cloth / brush
- A mop/brush with a handle has to be used to apply the solution
- Do not immerse hands in the solution

For professional bystander:

- Do not touch the surface until it is completely dried

General public:

- Do not touch the surface until it is rinsed and completely dried
- Children should not be present during disinfection and until the surface is rinsed and dried

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

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

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

[Empty box]

2.1.55.5 Use description

Table 5. Use # 5 – Disinfection of toilets bowls and sanitary facilities by direct spreading/flooding – General public - PT2 – RTU product (Use 26)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private areas, households |
| Application method(s) | Direct spreading/flooding |
| Application rate(s) and frequency | Ready to use product. 60 minutes, 20°C |
| Category(ies) of users | General public |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 750mL HDPE Angled bottle |

2.1.55.5.1 Use-specific instructions for use

-

2.1.55.5.2 Use-specific risk mitigation measures

For non professional user during pouring and brushing :

- Wash hands after use
- Avoid any contact with eyes and skin
- Avoid any splashes and spills

For general public :

- Do not touch the surface until it is rinsed and totally dried
- Children should not be present during disinfection and until the surface is rinsed and dry

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

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

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

- Keep out of reach of children and non-target animals/pets

2.1.56 General directions for use of the meta SPC 8

2.1.56.1 Instructions for use

- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.

2.1.56.2 Risk mitigation measures

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

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

2.1.56.4 Instructions for safe disposal of the product and its packaging

- Don't 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.

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

- Protect from frost.
- Keep away from direct sunlight.
- Do not store above 40°C.
- Shelf-life = 2 years.

2.1.57 Other information

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 8

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

| | | | | | |
|---|-------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 8-1 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| | | | | | |
|---|-------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | BPRO GEL WC 6 | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| | | | | | |
|---|-------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 8-3 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| Trade name(s) | | Product 8-4 - Soprodís | | | |
|---|-------------------------|-------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| Trade name(s) | | Product 8-5 - Soprodís | | | |
|---|-------------------------|-------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| Trade name(s) | | Product 8-6 - Soprodís | | | |
|---|-------------------------|-------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| Trade name(s) | | Product 8-7 - Soprodís | | | |
|---|-------------------------|-------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| Trade name(s) | | Product 8-8 - Soprodís | | | |
|---|-------------------------|-------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| Trade name(s) | | Product 8-9 - Soprodís | | | |
|---|-------------------------|-------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| Trade name(s) | | Product 8-10 - Soprodís | | | |
|---|-------------------------|--------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| Trade name(s) | | Product 8-11 - Soprodís | | | |
|---|-------------------------|--------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| Trade name(s) | | Product 8-12 - Soprodís | | | |
|---|-------------------------|--------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| Trade name(s) | | Product 8-13 - Soprodís | | | |
|---|-------------------------|--------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| Trade name(s) | | Product 8-14 - Soprodís | | | |
|---|-------------------------|--------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| Trade name(s) | | Product 8-15 - Soprodís | | | |
|---|-------------------------|--------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| Trade name(s) | | Product 8-16 - Soprodís | | | |
|---|-------------------------|--------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| Trade name(s) | | Product 8-17 - Soprodís | | | |
|---|-------------------------|--------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| Trade name(s) | | Product 8-18 - Soprodís | | | |
|---|-------------------------|--------------------------------|-------------------|------------------|--------------------|
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| | | | | | |
|---|--------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 8-19 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| | | | | | |
|---|--------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 8-20 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

| | | | | | |
|---|--|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRIM VERT GEL 4D+ ; CLARINE NATURA GEL S3D + ; BPRO Gel Nettoyant désinfectant puissant | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 6 |
| | | Technical active substance | | | 6.28 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 7.5 |

PART II - SECOND INFORMATION LEVEL - META SPC 9**2.1.59** Meta SPC 9 administrative information**2.1.59.1** Meta SPC identifier

| | |
|-----------------------|------------|
| Identification | META SPC 9 |
|-----------------------|------------|

2.1.59.2 Suffix to the authorisation number

| | |
|----------|--|
| Number 9 | |
|----------|--|

2.1.59.3 Product type(s)

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

2.1.60 Meta SPC 9 composition**2.1.60.1** Qualitative and quantitative information on the composition of the meta SPC 9

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|-------------------------|----------------------------|------------|-----------|-------------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

2.1.60.2 Type(s) of formulation of the meta SPC 9

| |
|----------------------|
| AL: Any other liquid |
|----------------------|

2.1.61 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 9**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| Classification | |
|--------------------------|---|
| Hazard category | Skin Irri. 2 Eye Dam. 1 |
| Hazard statement | H315: Causes skin irritation H318: Causes serious eye damage |
| Labelling | |
| Signal words | Danger |
| Hazard statements | H315: Causes skin irritation H318: Causes serious eye damage |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand P102: Keep out of reach of children P103: Read label before use P264: Wash hands thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection. P302+P352: IF ON SKIN: Wash with plenty of soap and water P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physician P321: Specific treatment (see ... on this label). P332+P313: If skin irritation occurs: Get medical advice/attention. P362+P364: Take off contaminated clothing and wash before reuse. P273: Avoid release to the environment. P501: Dispose of contents/containers in accordance with local regulations. |
| Note | |

2.1.62 Authorised use(s) of the META SPC 9

2.1.62.1 Use description

Table 63. Use # 1 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT2 – RTU product (Use 19)

| | |
|---|-----|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |

| | |
|--|---|
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | Ready to use product. 60 minutes, 20°C |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 1L HDPE Bottle with handle 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.62.1.1 Use-specific instructions for use

- For healthcare settings: clean carefully the surfaces before application of the product.

2.1.62.1.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander :

- Do not touch the surface until it is completely dried

For general public:

- Do not touch the surface until it is rinsed and completely dried
- Children should not be present during disinfection and until the surface is rinsed and dried

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

-

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

-

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

-

2.1.62.2 Use description

Table 64. Use # 2 – Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding – Professionals - PT2 – RTU product (Use20)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private and public areas: institutions, industries (including cosmetic and pharmaceutical industries), and health care facilities (excluding the hospitals) |
| Application method(s) | Direct spreading/flooding. |
| Application rate(s) and frequency | Ready to use product. 60 minutes, 20°C |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 750mL HDPE Angled bottle 1L HDPE Bottle with handle 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.62.2.1 Use-specific instructions for use

| |
|--|
| - For healthcare settings: clean carefully the surfaces before application of the product. |
|--|

2.1.62.2.2 Use-specific risk mitigation measures

| |
|---|
| For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during pouring and brushing. |
|---|

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

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

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

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

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

-

2.1.62.3 Use description

Table 65. Use # 3 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – Professionals - PT4 – RTU product (Use23)

| | |
|---|---|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | Ready to use product. 60 minutes, 20°C |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 500mL to 1L HDPE/PET Prefilled trigger spray 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.62.3.1 Use-specific instructions for use

-

2.1.62.3.2 Use-specific risk mitigation measures

For professional user: wear gloves, protective coverall and chemical goggles (material to be specified by the authorisation holder within the product information) during mixing and loading, application and rinsing.

For professional bystander :

-Do not touch the surface until it is completely dried

For general public:

-Do not touch the surface until it is rinsed and completely dried

-Children should not be present during disinfection and until the surface is rinsed and dried

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

-

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

-

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

-

2.1.62.4 Use description

Table 66. Use # 4 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – General public - PT2 – RTU product (Use 25)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private areas, households |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |
| Application rate(s) and frequency | Ready to use product. 60 minutes, 20°C |
| Category(ies) of users | General public |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 500mL to 1L HDPE/PET Prefilled trigger spray |

2.1.62.4.1 Use-specific instructions for use

-

2.1.62.4.2 Use-specific risk mitigation measures

For non professional user during application and rinsing :

- Wash hands after use
- Avoid contact with eyes and skin
- Avoid splashes and spills
- The packaging must be adapted with a child proof closure

For general public :

- Do not touch the surface until it is rinsed and totally dried
- Children should not be present during disinfection and until the surface is rinsed and dry

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

-

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

-

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

- Keep out of reach of children and non-target animals/pets

2.1.62.5 Use description

Table 67. Use # 5 – Disinfection of toilets bowls and sanitary facilities by direct spreading/flooding – General public - PT2 – RTU product (Use 26)

| | |
|---|---|
| Product Type | PT2 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private areas, households |
| Application method(s) | Direct spreading/flooding |
| Application rate(s) and frequency | Ready to use product. 60 minutes, 20°C |
| Category(ies) of users | General public |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 750mL HDPE Angled bottle 1L HDPE Bottle with handle |

2.1.62.5.1 Use-specific instructions for use

-

2.1.62.5.2 Use-specific risk mitigation measures

For non professional user during application and rinsing :

- Wash hands after use
- Avoid contact with eyes and skin
- Avoid splashes and spills
- The packaging must be adapted with a child proof closure

For general public :

- Do not touch the surface until it is rinsed and totally dried
- Children should not be present during disinfection and until the surface is rinsed and dry

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

-

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

-

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

- Keep out of reach of children and non-target animals/pets

2.1.62.6 Use description

Table 68. Use # 6 – Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing – General public - PT4 – RTU product (Use 28)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in private areas, domestic kitchens. |
| Application method(s) | Wiping/mopping/brushing/scrubbing without mechanical action. |

| | |
|--|---|
| Application rate(s) and frequency | Ready to use product. 60 minutes, 20°C |
| Category(ies) of users | General public |
| Pack sizes and packaging material | 100mL to 2L HDPE/PET Bottle 500mL to 1L HDPE/PET Prefilled trigger spray 1L HDPE Bottle with handle |

2.1.62.6.1 Use-specific instructions for use

-

2.1.62.6.2 Use-specific risk mitigation measures

For non professional user during application and rinsing :
-Wash hands after use
-Avoid contact with eyes and skin
-Avoid splashes and spills
-The packaging must be adapted with a child proof closure

For general public :
-Do not touch the surface until it is rinsed and totally dried
-Children should not be present during disinfection and until the surface is rinsed and dry

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

-

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

-

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

- Keep out of reach of children and non-target animals/pets

2.1.63 General directions for use of the meta SPC 9

2.1.63.1 Instructions for use

- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.

2.1.63.2 Risk mitigation measures

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

- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid
- IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a poison centre or a doctor
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor
- If medical advice is needed, have product container or label at hand

2.1.63.4 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.

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

- Protect from frost.
- Keep away from direct sunlight.
- Do not store above 40°C.
- Shelf-life = 2 years.

2.1.64 Other information

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 9

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

| | | | | | |
|---|-------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 9-1 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

| | | | | | |
|---|---|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | BPRO GEL WC 2,9 BLUTEC SAN PAE | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

| | | | | | |
|-----------------------------|-------------------------------|-----------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 9-3 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |

| | | | | | |
|---|-------------------------|----------------------------|---------|-----------|-------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

| | | | | | |
|---|-------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 9-4 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

| | | | | | |
|---|-------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 9-5 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

| | | | | | |
|-----------------------------|-------------------------------|-----------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 9-6 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |

| | | | | | |
|---|-------------------------|----------------------------|---------|-----------|-------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

| | | | | | |
|---|-------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 9-7 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

| | | | | | |
|---|-------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 9-8 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

| | | | | | |
|-----------------------------|-------------------------------|-----------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 9-9 - Soprodís | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |

| | | | | | |
|---|-------------------------|----------------------------|---------|-----------|-------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

| | | | | | |
|---|---------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 9-10 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

| | | | | | |
|---|---------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 9-11 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

| | | | | | |
|-----------------------------|---------------------------------|-----------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 9-12 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |

| | | | | | |
|---|-------------------------|----------------------------|---------|-----------|-------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

| | | | | | |
|---|---------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 9-13 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

| | | | | | |
|---|---------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 9-14 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

| | | | | | |
|-----------------------------|---------------------------------|-----------------|-------------------|------------------|--------------------|
| Trade name(s) | Product 9-15 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |

| | | | | | |
|---|-------------------------|----------------------------|---------|-----------|-------|
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

| | | | | | |
|---|--|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRIM VERT GEL 4D CLARINE NATURA GEL S3D BPRO Gel Nettoyant détartrant désinfectant Sanitaires BLUTEC 4D | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 2.9 |
| | | Technical active substance | | | 3.04 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 3.625 |

PART II - SECOND INFORMATION LEVEL - META SPC 10

2.1.66 Meta SPC 10 administrative information

2.1.66.1 Meta SPC identifier

| | |
|-----------------------|-------------|
| Identification | META SPC 10 |
|-----------------------|-------------|

2.1.66.2 Suffix to the authorisation number

| | |
|-----------|--|
| Number 10 | |
|-----------|--|

2.1.66.3 Product type(s)

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

2.1.67 Meta SPC 10 composition**2.1.67.1** Qualitative and quantitative information on the composition of the meta SPC 10

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|---|---|-------------------------|----------------------------|-----------|-------------|-------|
| L(+) | lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 | |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% | |

2.1.67.2 Type(s) of formulation of the meta SPC 10

| |
|-------------------------|
| SL: Soluble concentrate |
|-------------------------|

2.1.68 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 10**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| Classification | |
|-----------------------|--|
| Hazard category | Skin corr.1B Eye Dam.1 Skin sens.1A |
| Hazard statement | H314: Causes severe skin burns and eye damage H318: Causes serious eye damage H317 : May cause an allergic skin reaction |
| Labelling | |
| Signal words | Danger |
| Hazard statements | H314: Causes severe skin burns and eye damage H317: May cause an allergic skin reaction |

| Classification | |
|--------------------------|--|
| Precautionary statements | <p>P260: Do not breathe spray.</p> <p>P264: Wash hands thoroughly after handling.</p> <p>P280: Wear protective gloves/ protective clothing/ eye protection.</p> <p>P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.</p> <p>P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.</p> <p>P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P310. Immediately call a POISON CENTER or doctor/physician</p> <p>P321: Specific treatment (see ... on the label).</p> <p>P363: Wash contaminated clothing before reuse.</p> <p>P333 + P313: If skin irritation or rash occur: Get medical advice/attention</p> <p>P302+ P352: IF ON SKIN : Wash with plenty of water</p> <p>P273: Avoid release to the environment.</p> <p>P501: Dispose of contents/containers in accordance with local regulations.</p> |
| Note | EUH071: Corrosive to the respiratory tract. |

2.1.69. Authorised use(s) of the META SPC 10

2.1.69.1 Use description

Table 69. Use # 1 – Disinfection of hard surfaces and equipment by manual dipping/soaking– Professionals - PT4 – Soluble concentrate (Use 11)

| | |
|---|--|
| Product Type | PT4 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bacteria Yeast |
| Field of use | Indoors disinfection in agri-food industries (excluding milk industries), food and feed areas (collective central kitchens, food shops and restaurants). |
| Application method(s) | Manual dipping/soaking. |
| Application rate(s) and frequency | At a temperature of 40°C: - Bacteria and yeasts: 20% v/v, 15 minutes. |

| | |
|--|---|
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | 20mL PE+PET Pods 100mL to 2L HDPE/PET Bottle 1L LDPE Dosing bottle 1L HDPE Dosing bottle 1 to 5 L HDPE Pouch 5-10-20L LDPE/PET Bag in box (cubitainer) 5 to 30L HDPE Jerrican 60-220L HDPE Drum 1000L HDPE Bulk container (IBC) |

2.1.69.1.1 Use-specific instructions for use

-

2.1.69.1.2 Use-specific risk mitigation measures

The professional user has to wear gloves, coverall and goggles (material to be specified by the authorisation holder within the product information) during the mixing and loading, the application and the rinsing.
-Do not immerse hands in the bath
-Let the equipment soak for the necessary time in the bath of cleaning/disinfectant solution, then empty the bath, and finish by rinsing without touching the equipment that has remained in the tank

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

-

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

-

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

-

2.1.70 General directions for use of the meta SPC 10**2.1.70.1** Instructions for use

- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.
- Products have been tested against bacteria, including *Enterobacter cloacae*, *Salmonella Typhimurium*, *Campylobacter jejuni* and *Listeria* and *Lactobacillus brevis* at 40°C.
- During the product dilution, pour almost all water first, then the product, then the remaining of the water.

2.1.70.2 Risk mitigation measures**2.1.70.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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

2.1.70.4 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.

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

- Protect from frost.
- Keep away from direct sunlight.
- Do not store above 40°C.
- Shelf-life = 2 years.

2.1.71 Other information

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

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 10

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

| Trade name(s) | | PRODUCT 10-1 - Soprodiss | | | | |
|---|---|----------------------------|------------|-----------|-------------|--|
| Authorisation number | | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 | |
| | | Technical active substance | | | 30.16 | |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 | |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% | |

| Trade name(s) | | PRODUCT 10-2 - Soprodiss | | | | |
|----------------------|-------------------------|----------------------------|------------|-----------|-------------|--|
| Authorisation number | | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 | |
| | | Technical active substance | | | 30.16 | |

| | |
|---|----|
| <i>Content in the biocidal product family of the TK containing the active substance</i> | 36 |
|---|----|

| | | | | | |
|-----------------------------|---------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 10-3 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |

| | |
|---|----|
| <i>Content in the biocidal product family of the TK containing the active substance</i> | 36 |
|---|----|

| | | | | | |
|---|---|----------------------|------------|-----------|--------|
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |
|---|---|----------------------|------------|-----------|--------|

| | | | | | |
|-----------------------------|---------------------------------|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 10-4 - Soprodiss | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |

| | |
|---|----|
| <i>Content in the biocidal product family of the TK containing the active substance</i> | 36 |
|---|----|

| | | | | | |
|---|---|----------------------|------------|-----------|--------|
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |
|---|---|----------------------|------------|-----------|--------|

| | | | | | |
|---|---|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRODUCT 10-5 - Soprodis | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

| | | | | | |
|---|---|----------------------------|-------------------|------------------|--------------------|
| Trade name(s) | PRIM VERT VD ; CLARINE NATURA VD ; BPRO Plonge manuelle désinfectante AL | | | | |
| Authorisation number | | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| L(+) lactic acid | 2-Hydroxypropanoic acid | Pure active substance | 79-33-4 | 201-196-2 | 28.8 |
| | | Technical active substance | | | 30.16 |
| <i>Content in the biocidal product family of the TK containing the active substance</i> | | | | | 36 |
| Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) | Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one | Substance of concern | 55965-84-9 | 611-341-5 | 0.011% |

2.1.73 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) | Meta SPC |
|-------------------------|------------------------------|---------------------------|---------------------------------|---|---|----------------|
| Bottle | 0.1L to 2L | HDPE/PET | Screw cap | General public / Professional | Yes | All |
| | | | Push pull cap | | | |
| | | | Degassing cap | | | |
| | | | Flip top cap | | | |
| | | | Self-sealing cap | | | |
| Jerrican | 5L, 10L | HDPE | With distributor or pump | General public/professional | Yes | 1,3,4,5,7 |
| Angled bottle | 0.75 L | HDPE | Screw cap | General public / Professional | Yes | 7,8,9 |
| | | | Cap with inside plug | | | |
| | | | Degassing cap | | | |
| Bottle with handle | 1 L | HDPE | Screw cap | General public / Professional | Yes | 1,3,5,7,9,10 |
| | | | Cap with inside plug | | | |
| | | | Degassing cap | | | |
| Prefilled trigger spray | 0.50- 0.75-1L | HDPE/PET | Trigger spray* | General public / Professional | Yes | 7,8 |
| | | | Child-resistant Trigger spray * | | | |
| Dosing bottle | 1L | LDPE | Screw cap | General public/ Professional | Yes | 1,2,3,4,5,6,10 |
| | | HDPE | Degassing cap | | | |
| | | | Dosing cap | | | |

| Type of packaging | Size/volume of the packaging | Material of the packaging | Type and material of closure(s) | Intended user (e.g. professional, non-professional) | Compatibility of the product with the proposed packaging materials (Yes/No) | Meta SPC |
|---|------------------------------|---------------------------|---------------------------------|---|---|--------------|
| Pouch | 1-5 L | HDPE | Screw cap | Professional | Yes | 2,3,5,6,10 |
| Jerrican | 5 to 30L | HDPE | Screw cap | Professional | Yes | All meta spc |
| | | | Degassing cap | | | |
| | | | Child-resistant screw cap | | | |
| | | | Tap | | | |
| | | | Degassing cap | | | |
| Drum | 60-220L (60-220L) | HDPE | Tap | Professional | Yes | All meta spc |
| | | | Screw cap | | | |
| Bulk container (IBC) | 1000L | HDPE | Degassing cap | Professional | Yes | All meta spc |
| | | | Tap | | | |
| | | | Tap | | | |
| Bag in box (cubitainer) | 5-10-20L | LDPE/PET | / | Professional | yes | 2,3,5,6,7,10 |
| Cartridge to be used with trigger spray 0.5, 0.75, 1L and 1L bottle | 20 mL | HDPE | / | General public/Professional | Yes | 1,4,5,6 |
| Pods (dosettes) | 20 ml | PE+PET | | Professional | Yes | 1,4,5,6, 10 |

*Type of trigger spray used for products of Meta SPC 7:

- Type GUALA TS1 FOAM V3
- Type GUALA TS3 SNAPON FOX STD SPRAY
- Type GUALA TS1 FOAM V2

-
- Type EPROPLAST ST1204
 - Type OpUs FO vi
 - Type TR343 28-410
 - Type GUALA TS1 STD Spray
 - SILGAN E23081
 - Type of trigger spray used for products of Meta SPC 8:
 - Type GUALA TS1 FOAM V2

2.1.74 Documentation

2.1.74.1 Data submitted in relation to product application

Please refer to annex in section 3.1

2.1.74.2 Access to documentation

Letters of access to the data of L(+) Lactic Acid (PT2 – PT4) has been submitted and allows the asset owner to refer to active substance data.

2.2 Assessment of the biocidal product family

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

Uses #8 and #16 have been withdrawn by applicant during the instruction of this application.

| Uses | Meta SPC 1 | Meta SPC 2 | Meta SPC 3 | Meta SPC 4 | Meta SPC 5 | Meta SPC 6 | Meta SPC 7 | Meta SPC 8 | Meta SPC 9 | Meta SPC 10 |
|---|------------|------------|------------|------------|------------|------------|------------|------------|------------|-------------|
| Use #1 - Manual spraying – professionals – PT2 – soluble concentrate | X | X | X | X | X | X | | | | |
| Use #2 - Spraying/foaming mural equipment with automated dilution (liquid/foam spraying) – professionals – PT2 – soluble concentrate | X | X | X | X | X | X | | | | |
| Use #3 - Manual dipping/soaking – professionals – PT2 – soluble concentrate | X | X | X | X | X | X | | | | |
| Use #4 – Wiping / mopping / brushing / scrubbing – professionals – PT2 – soluble concentrate | X | X | X | X | X | X | | | | |
| Use #5 - Disinfection of equipment by automatic spraying in cleaning washer – professionals – PT2 – soluble concentrate | | | | | | X | | | | |
| Use #6 - Disinfection of cleaning washer by automatic application – professionals – PT2 – soluble concentrate | | | | | | X | | | | |
| Use #7 – Cleaning-in-place – professionals – PT2 – soluble concentrate | | | | | | X | | | | |
| Use #9 - Manual spraying – professionals – PT4 – soluble concentrate | X | X | X | X | X | X | | | | |
| Use #10 - Spraying/foaming mural equipment with automated dilution (liquid/foam spraying) – professionals – PT4 – soluble concentrate | X | X | X | X | X | X | | | | |

| | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|
| Use #11 - Manual dipping/soaking- professionals – PT4 – soluble concentrate | X | X | X | X | X | X | | | | X |
| Use #12 – Wiping / mopping / brushing / scrubbing – professionals – PT4 – soluble concentrate | X | X | X | X | X | X | | | | |
| Use #13 - Disinfection of equipment by dish washing machine and crate washer – professionals – PT4 – soluble concentrate | | | | | | X | | | | |
| Use #14 - Disinfection of dish washing machine and crate washer by automatic spraying- professionals – PT4 – soluble concentrate | | | | | | X | | | | |
| Use #15 – Cleaning-in-place – professionals – PT4 – soluble concentrate | | | | | | X | | | | |
| Use #17 - Manual spraying – professionals – PT2 – RTU product | | | | | | | X | | | |
| Use #18 – Manual spraying using a trigger sprayer - professionals – PT2 – RTU product | | | | | | | X | X | | |
| Use #19 – Wiping / mopping / brushing / scrubbing – professionals – PT2 – RTU product | | | | | | | X | X | X | |
| Use #20 – Direct spreading/flooding – professionals – PT2 – RTU product | | | | | | | X | X | X | |
| Use #21 - Manual spraying – professionals – PT4 – RTU product | | | | | | | X | | | |
| Use #22 – Manual spraying using a trigger sprayer - professionals – PT4 – RTU product | | | | | | | X | | | |
| Use #23 – Wiping / mopping / brushing / scrubbing – professionals – PT4 – RTU product | | | | | | | X | X | X | |
| Use #24 – Manual spraying using a trigger | | | | | | | X | | | |

| | | | | | | | | | | |
|--|---|--|--|---|---|--|---|---|---|--|
| sprayer – general public – PT2 – RTU product | | | | | | | | | | |
| Use #25 – Wiping / mopping / brushing / scrubbing – general public – PT2 – RTU product | | | | | | | X | X | X | |
| Use #26 – Direct spreading/flooding – general public – PT2 – RTU product | | | | | | | X | X | X | |
| Use #27 – Manual spraying using a trigger sprayer – general public – PT4 – RTU product | | | | | | | X | | | |
| Use #28 – Wiping / mopping / brushing / scrubbing – general public – PT4 – RTU product | | | | | | | X | X | X | |
| Use #29 – Manual spraying using a trigger sprayer - general public – PT2 – soluble concentrate | X | | | X | X | | | | | |
| Use #30 – Wiping / mopping / brushing / scrubbing – general public – PT2 – soluble concentrate | X | | | X | X | | | | | |
| Use #31 – Manual spraying using a trigger sprayer - general public – PT4 – soluble concentrate | X | | | X | X | | | | | |
| Use #32 – Wiping / mopping / brushing / scrubbing – general public – PT4 – soluble concentrate | X | | | X | X | | | | | |
| Use #33 – Manual spraying using a trigger sprayer - professionals – PT2 – soluble concentrate | X | | | X | X | | | | | |
| Use #34 – Manual spraying using a trigger sprayer – professionals – PT4 – soluble concentrate | X | | | X | X | | | | | |
| Use #35 – Disinfection of the inner surfaces of small kitchen appliances without circulation – professionals – PT4 – soluble concentrate | | | | | | | X | | | |
| Use #36 – Disinfection of the inner surfaces of small kitchen appliances by CIP | | | | | | | X | | | |

<FR CA>

< FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 -
SOPRODIS >

<PT2, 4>

| | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|
| - professionals - PT4 - soluble concentrate | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|

2.2.2 Physical, chemical and technical properties

The biocidal products family is composed of 10 Meta SPCs. 7 of these are SL formulations (to be diluted in water before use) while the other three Meta SPCs (meta SPC 7-8-9) are ready-to-use (AL formulations).

A series of studies were carried out to determine all relevant physico-chemical parameters of the products of the family and their storage stabilities. The physico-chemical properties and/or stability of some products/Meta SPCs are covered by studies performed on other mixtures, whose composition is representative of the formulas they cover. Here is a summary of the bridging performed:

- The properties and stability of the products of Meta SPC 1 are covered by tests performed on the product 1-3, which is the formulation of Meta SPC 1 containing the highest concentration of perfume. The nature of perfume used has not been considered to have an impact on the properties or stability of the products.
- The properties and stability of the product of Meta SPC 2 are covered by tests performed on the product 1-3, except for the acidity. Indeed, the compositions of Meta SPCs 1 and 2 are very similar, except for the presence of an additional pH regulator in Meta SPC 1. The acidity of Meta SPC 2 was assessed on product 2-1.
- The properties and stability of the products of Meta SPC 3 are covered by tests performed on the product 3-2, which is the formulation of Meta SPC 3 containing the highest concentration of perfume.
- The properties and stability of the products of Meta SPC 4 are covered by tests performed on the product 4-1. All products of Meta SPC 4 have the same composition except for the nature of the perfume.
- The properties and stability of the products of Meta SPC 5 are covered by tests performed on the product 5-x, which is a fictive formula containing the highest concentration of perfume and dye of the Meta SPC, since they are substances than which can imply some stability issues and have a very small impact on the phys-chem properties.
- The properties and stability of the products of Meta SPC 6 are covered by tests performed on the product 6-2. The acidity of product 6-1 was also assessed because it does not contain a co-formulant of product 6-2 that has an impact on the pH.
- The properties and stability of the products of Meta SPC 7 are covered by tests performed on several formulations:
 - The product 7-12 was fully tested (phys-chem parameters and stability) as it contains a specific co-formulant that is not present in the other mixtures of the Meta SPC.
 - The stability and properties of all other products (except for surface tension for some formulas) is covered by tests carried out on product 7-x, a fictive formulation containing the maximum concentration of co-formulants, including perfumes and dyes.
 - The surface tension of product 7-17, representative of the lowest concentration of surfactants of the Meta SPC, was assessed.
 - To evaluate the spray properties of the Meta SPC and their stability, formula 7-x was selected as it represents the worst-case in terms of stability and in terms of spray properties (especially the particles size) due to the presence of surfactants at the highest possible concentration of the Meta SPC.
- The properties and stability of the products of Meta SPC 8 are covered by tests performed on several formulations:

- Product 8-2 is tested to cover the products containing less thickening agent.
- Product 8-17 is tested to cover the product containing more thickening agent.
- Stability tests (accelerated and ambient storage) are performed on both products.
- The properties and stability of the products of Meta SPC 9 are covered by tests performed on several formulations:
 - Product 9-2 is tested to cover the properties of the products containing less thickening agent.
 - Product 9-10 is tested to cover the properties of the products containing more thickening agent.
 - Accelerated storage studies were performed on both products and showed that the active substance content decreased more for product 9-2. This mixture was thus selected to cover the whole Meta SPC in an ambient storage study.
- The properties and stability of the products of Meta SPC 10 are covered by tests performed on the product 10-2, which is the formulation of Meta SPC 10 containing the highest concentration of perfume.

The compositions of all the products and of the fictive formulations are reported in the BPF overview table in the confidential annex.

The products of Meta SPC 7 and Meta SPC 8 can be used by spraying in trigger spray packaging. 8 different trigger sprayers can be used. The all can be used for products of Meta SPC 7, while only one is used for Meta SPC 8.

The properties of all trigger sprayers were assessed before storage on product 7-x.

Regarding the stability of the trigger sprayers, since they are all made of plastic (mainly PP and PE), it can be expected that they are all going to be similarly stable when coming into contact with the biocidal products of the family. Accelerated storage studies were performed on some of the trigger sprayers and showed that they are all stable, as are the technical spray properties assessed (spray pattern, clogging, discharge rate, particles size distribution). Two long terms studies are ongoing, one on the product 7-x and the other on the product 8-2, with different trigger sprayers. The results will be able to cover all models of sprayers because of their similarity in terms of composing materials.

More specifically for the particles size distribution, the worst-case packaging in terms of results before storage was chosen for the accelerated and long term storage studies. This worst-case corresponds to the packaging that gave the smallest particles, focusing mainly on the D(0.5) value (the size below which half of the droplets, in volume, can be found).

With the test items selected as described above, all properties of all products of all Meta SPCs are covered.

Some storage studies are still ongoing. The available results (after 6 or 12 months of storage) are provided and summarised in the table.

| | Min in use concentration | Max in use concentration | Tested concentrations for dilution stability and persistent foaming |
|--|---------------------------------|---------------------------------|--|
| | | | |

| | | | |
|-------------|----------|---------|---|
| Meta SPC 1 | 2.5 %v/v | 9 %v/v | 0.5% – 20 % (considered worst case) |
| Meta SPC 2 | 4 %v/v | 8 %v/v | Covered by Meta SPC 1 (considered worst case) |
| Meta SPC 3 | 4 %v/v | 25 %v/v | 0.5% – 10 % |
| Meta SPC 4 | 4 %v/v | 20 %v/v | 4% – 20 % and 0.5% – 19 % |
| Meta SPC 5 | 3 %v/v | 15 %v/v | 0.1% – 18 % (considered worst case) |
| Meta SPC 6 | 4 %v/v | 9 %v/v | 0.5% – 9 % (considered worst case) |
| Meta SPC 10 | 4 %v/v | 20 %v/v | 4% – 20 % |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|---------------------------------------|---|---|--|------------|----------------|
| Physical state at 20 °C and 101.3 kPa | ECHA guidance on information requirements | Meta SPC 1, Product 1-3 (24% w/w lactic acid), Batch COM23 / Méta SPC 1-3 / 2020-01-21 | Homogeneous fluid liquid, without phase separation or precipitations | [REDACTED] | Acceptable |
| | | Meta SPC 3, Product 3-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 3-2 / 2019-10-07 | Homogeneous fluid, without phase separation or precipitations | [REDACTED] | Acceptable |
| | | Meta SPC 4, Product 4-1 (24% w/w lactic acid), | Homogeneous fluid liquid, without phase separation or precipitations | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|---|--|------------|----------------|
| | | Batch COM 23 / Méta SPC 4-1 / 2020-04-24 | | [REDACTED] | |
| | | Meta SPC 5, Product 5-x (28.8% w/w lactic acid), Batch COM 23 / MétaSPC 5-x / 2019-10-07 | Homogeneous fluid liquid, without phase separation or precipitations | [REDACTED] | Acceptable |
| | | Meta SPC 6, Product 6-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 6-2 / 2020-01-21 | Homogeneous fluid liquid, without phase separation or precipitations | [REDACTED] | Acceptable |
| | | Meta SPC 7, Product 7-12 (1.44% w/w lactic acid), Batch COM 23 / Méta SPC 7-12 / 2020-09-02 | Homogeneous fluid liquid, without phase separation or precipitations | [REDACTED] | Acceptable |
| | | Meta SPC 7, Product 7-x (1.44% w/w lactic acid), | Homogeneous fluid liquid without phase separation or precipitations | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|--|---|------------|----------------|
| | | Batch COM 23 / MétaSPC 7-x / 2019-10-28 / 1 | | | |
| | | Meta SPC 8, Product 8-2 (6% w/w lactic acid), Batch COM 23 / Méta SPC 8-2 / 2019-10-14 | Homogeneous fluid without phase separation or precipitations | [REDACTED] | Acceptable |
| | | Meta SPC 8, Product 8-17 (6% w/w lactic acid), Batch COM 23 / Méta SPC 8-17 / 2020-10-27 / 1 | Homogeneous fluid liquid without phase separation or precipitations | [REDACTED] | Acceptable |
| | | Meta SPC 9, Product 9-2 (2.9% w/w lactic acid), Batch COM 23 / Méta SPC 9-2 / 2019-10-10 | Homogeneous fluid without phase separation or precipitations | [REDACTED] | Acceptable |
| | | Meta SPC 9, Product 9-10 (2.9% w/w | Homogeneous liquid without phase separation or precipitations | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|-------------------------------|---|---|---|------------|----------------|
| | | lactic acid), Batch COM 23 / Méta SPC 9-10 / 2019-10-28 / 1 | | [REDACTED] | |
| | | Meta SPC 10, Product 10-2 (28.8% w/w lactic acid), Batch COM23 / Méta SPC 10-2 / 2020-05-27 | Homogeneous fluid liquid without phase separation or precipitations | [REDACTED] | Acceptable |
| Colour at 20 °C and 101.3 kPa | ECHA guidance on information requirements | Meta SPC 1, Product 1-3 (24% w/w lactic acid), Batch COM23 / Méta SPC 1-3 / 2020-01-21 | Colourless-yellow | [REDACTED] | Acceptable |
| | | Meta SPC 3, Product 3-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 3-2 / 2019-10-07 | Yellowish | [REDACTED] | Acceptable |
| | | Meta SPC 4, Product 4-1 | Dark green | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|---|------------------------|------------|----------------|
| | | (24% w/w lactic acid), Batch COM 23 / Méta SPC 4-1 / 2020-04-24 | | [REDACTED] | |
| | | Meta SPC 5, Product 5-x (28.8% w/w lactic acid), Batch COM 23 / MétaSPC 5-x / 2019-10-07 | Green | [REDACTED] | Acceptable |
| | | Meta SPC 6, Product 6-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 6-2 / 2020-01-21 | Transparent colourless | [REDACTED] | Acceptable |
| | | Meta SPC 7, Product 7-12 (1.44% w/w lactic acid), Batch COM 23 / Méta SPC 7-12 / 2020-09-02 | Slightly yellow | [REDACTED] | |
| | | Meta SPC 7, Product 7-x | Colourless-yellow | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|---|------------|------------|----------------|
| | | (1.44% w/w lactic acid), Batch COM 23 / MétaSPC 7-x / 2019-10-28 / 1 | | [REDACTED] | |
| | | Meta SPC 8, Product 8-2 (6% w/w lactic acid), Batch COM 23 / Méta SPC 8-2 / 2019-10-14 | Yellowish | [REDACTED] | Acceptable |
| | | Meta SPC 8, Product 8-17 (6% w/w lactic acid), Batch COM 23 / Méta SPC 8-17 / 2020-10-27 / 1 | Dark green | [REDACTED] | Acceptable |
| | | Meta SPC 9, Product 9-2 (2.9% w/w lactic acid), Batch COM 23 / Méta SPC 9-2 / 2019-10-10 | Colourless | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|------------------------------|---|--|------------------------------|------------|----------------|
| | | Meta SPC 9, Product 9-10 (2.9% w/w lactic acid), Batch COM 23 / Méta SPC 9-10 / 2019-10-28 / 1 | Colourless-yellowish | [REDACTED] | Acceptable |
| | | Meta SPC 10, Product 10-2 (28.8% w/w lactic acid), Batch COM23 / Méta SPC 10-2 / 2020-05-27 | Brown | [REDACTED] | Acceptable |
| Odour at 20 °C and 101.3 kPa | ECHA guidance on information requirements | Meta SPC 1, Product 1-3 (24% w/w lactic acid), Batch COM23 / Méta SPC 1-3 / 2020-01-21 | Citrusy characteristic odour | [REDACTED] | Acceptable |
| | | Meta SPC 3, Product 3-2 (24% w/w lactic acid), Batch COM 23 / Méta | Acidic characteristic odour | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|--|--|------------|----------------|
| | | SPC 3-2 / 2019-10-07 | | | |
| | | Meta SPC 4, Product 4-1 (24% w/w lactic acid), Batch COM 23 / Méta SPC 4-1 / 2020-04-24 | Characteristic odour | [REDACTED] | Acceptable |
| | | Meta SPC 5, Product 5-x (28.8% w/w lactic acid), Batch COM 23 / MétaSPC 5-x / 2019-10-07 | Mint characteristic odour | [REDACTED] | Acceptable |
| | | Meta SPC 6, Product 6-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 6-2 / 2020-01-21 | Acidic characteristic odour | [REDACTED] | Acceptable |
| | | Meta SPC 7, Product 7-12 (1.44% w/w lactic acid), Batch COM 23 / Méta | Strong citrusy-grassy characteristic odour | [REDACTED] | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|--|-----------------------------|------------|----------------|
| | | SPC 7-12 / 2020-09-02 | | | |
| | | Meta SPC 7, Product 7-x (1.44% w/w lactic acid), Batch COM 23 / MétaSPC 7-x / 2019-10-28 / 1 | Mint characteristic odour | [REDACTED] | Acceptable |
| | | Meta SPC 8, Product 8-2 (6% w/w lactic acid), Batch COM 23 / Méta SPC 8-2 / 2019-10-14 | Acidic characteristic odour | [REDACTED] | Acceptable |
| | | Meta SPC 8, Product 8-17 (6% w/w lactic acid), Batch COM 23 / Méta SPC 8-17 / 2020-10-27 / 1 | Mint characteristic odour | [REDACTED] | Acceptable |
| | | Meta SPC 9, Product 9-2 (2.9% w/w lactic acid), Batch COM | Acidic characteristic odour | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------------------|--|--|--|------------|----------------|
| | | 23 / Méta SPC 9-2 / 2019-10-10 | | | |
| | | Meta SPC 9, Product 9-10 (2.9% w/w lactic acid), Batch COM 23 / Méta SPC 9-10 / 2019-10-28 / 1 | Mint characteristic odour | [REDACTED] | Acceptable |
| | | Meta SPC 10, Product 10-2 (28.8% w/w lactic acid), Batch COM23 / Méta SPC 10-2 / 2020-05-27 | Acidic characteristic odour | [REDACTED] | Acceptable |
| Acidity / alkalinity | pH: CIPAC MT 75.3 Acidity: CIPAC MT 191 | Meta SPC 1, Product 1-3 (24% w/w lactic acid), Batch COM23 / Méta SPC 1-3 / 2020-01-21 | pH: 2.51 Acidity: 15.07 % w/w as H ₂ SO ₄ | [REDACTED] | Acceptable |
| | | Meta SPC 2, Product 2-1 (24 % w/w lactic acid), | pH: 1.72 Acidity: 15.24% w/w as H ₂ SO ₄ | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|--|--|------------|----------------|
| | | Batch COM23 / Méta SPC 2-1 / 2020-01-14 | | [REDACTED] | |
| | | Meta SPC 3, Product 3-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 3-2 / 2019-10-07 | pH: 1.58 Acidity: 14.83% w/w as H ₂ SO ₄ | [REDACTED] | Acceptable |
| | | Meta SPC 4, Product 4-1 (24% w/w lactic acid), Batch COM 23 / Méta SPC 4-1 / 2020-04-24 | pH: 2.21 Acidity: 15.64 % w/w as H ₂ SO ₄ | [REDACTED] | Acceptable |
| | | Meta SPC 5, Product 5-2 (28.8% w/w lactic acid), Batch COM 23 / MétaSPC 5-2 / 2019-10-01 | pH: 2.22 Acidity: 17.96% w/w as H ₂ SO ₄ | [REDACTED] | Acceptable |
| | | Meta SPC 5, Product 5-x (28.8% w/w lactic acid), | pH: 2.33 Acidity: 17.62% w/w as H ₂ SO ₄ | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|---|---|------------|----------------|
| | | Batch COM 23 / MétaSPC 5-x / 2019-10-07 | | | |
| | | Meta SPC 6, Product 6-1 (24% w/w lactic acid), Batch COM 23 / Méta SPC 6-1 / 2019-10-11 | pH: 1.45 Acidity: 14.51% w/w as H ₂ SO ₄ | [REDACTED] | Acceptable |
| | | Meta SPC 6, Product 6-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 6-2 / 2020-01-21 | pH: 2.18 Acidity: 14.59% w/w as H ₂ SO ₄ | [REDACTED] | Acceptable |
| | | Meta SPC 7, Product 7-12 (1.44% w/w lactic acid), Batch COM 23 / Méta SPC 7-12 / 2020-09-02 | pH: 2.70 Acidity: 0.91% w/w as H ₂ SO ₄ | [REDACTED] | |
| | | Meta SPC 7, Product 7-x (1.44% w/w lactic acid), | pH: 2.49 Acidity: 0.88% w/w as H ₂ SO ₄ | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|--|---|------------|----------------|
| | | Batch COM 23 / MétaSPC 7-x / 2019-10-28 / 1 | | | |
| | | Meta SPC 8, Product 8-2 (6% w/w lactic acid), Batch COM 23 / Méta SPC 8-2 / 2019-10-14 | pH: 2.05 Acidity: 3.62% w/w as H ₂ SO ₄ | [Redacted] | Acceptable |
| | | Meta SPC 8, Product 8-17 (6% w/w lactic acid), Batch COM 23 / Méta SPC 8-17 / 2020-10-27 / 1 | pH: 2.06 Acidity: 3.24% w/w as H ₂ SO ₄ | [Redacted] | Acceptable |
| | | Meta SPC 9, Product 9-2 (2.9% w/w lactic acid), Batch COM 23 / Méta SPC 9-2 / 2019-10-10 | pH: 2.24 Acidity: 1.86% w/w as H ₂ SO ₄ | [Redacted] | Acceptable |
| | | Meta SPC 9, Product 9-10 (2.9% w/w | pH: 2.20 Acidity: 1.61 % w/w as H ₂ SO ₄ | [Redacted] | Acceptable |


| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|---------------------------------|-----------------------------------|---|---|------------|----------------|
| | | lactic acid), Batch COM 23 / Méta SPC 9-10 / 2019-10-28 / 1 | | [REDACTED] | |
| | | Meta SPC 10, Product 10-2 (28.8% w/w lactic acid), Batch COM23 / Méta SPC 10-2 / 2020-05-27 | pH: 2.26 Acidity: 18.80% w/w as H ₂ SO ₄ | [REDACTED] | Acceptable |
| Relative density / bulk density | EC method A.3 (pycnometer method) | Meta SPC 1, Product 1-3 (24% w/w lactic acid), Batch COM23 / Méta SPC 1-3 / 2020-01-21 | 1.115 g/mL at 20°C | [REDACTED] | Acceptable |
| | | Meta SPC 3, Product 3-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 3-2 / 2019-10-07 | 1.0926 g/mL at 20°C | [REDACTED] | Acceptable |
| | | Meta SPC 4, Product 4-1 | 1.110 g/mL at 20°C | [REDACTED] | Acceptable |
| | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|---|---------------------|------------|----------------|
| | | (24% w/w lactic acid), Batch COM 23 / Méta SPC 4-1 / 2020-04-24 | | [REDACTED] | |
| | | Meta SPC 5, Product 5-x (28.8% w/w lactic acid), Batch COM 23 / MétaSPC 5-x / 2019-10-07 | 1.1408 g/mL at 20°C | [REDACTED] | Acceptable |
| | | Meta SPC 6, Product 6-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 6-2 / 2020-01-21 | 1.079 g/mL at 20°C | [REDACTED] | Acceptable |
| | | Meta SPC 7, Product 7-12 (1.44% w/w lactic acid), Batch COM 23 / Méta SPC 7-12 / 2020-09-02 | 1.010 g/mL at 20°C | [REDACTED] | |
| | | Meta SPC 7, Product 7-x | 1.005 g/mL at 20°C | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|--|--------------------|------------|----------------|
| | | (1.44% w/w lactic acid), Batch COM 23 / MétaSPC 7-x / 2019-10-28 / 1 | | [REDACTED] | |
| | | Meta SPC 8, Product 8-2 (6% w/w lactic acid), Batch COM 23 / Méta SPC 8-2 / 2019-10-14 | 1.017 g/mL at 20°C | [REDACTED] | Acceptable |
| | | Meta SPC 8, Product 8-17 (6% w/w lactic acid), Batch COM 23 / Méta SPC 8-17 / 2020-10-27 / 1 | 1.017 g/mL at 20°C | [REDACTED] | Acceptable |
| | | Meta SPC 9, Product 9-2 (2.9% w/w lactic acid), Batch COM 23 / Méta SPC 9-2 / 2019-10-10 | 1.007 g/mL at 20°C | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | | | | | | | |
|---|---|--|---|------------|----------------|-------------------------------------|-----------------------------------|---------------------|------------|---------------------|---------------------|------------|---|---|---|------------|---|
| | | Meta SPC 9, Product 9-10 (2.9% w/w lactic acid), Batch COM 23 / Méta SPC 9-10 / 2019-10-28 / 1 | 1.0098 g/mL at 20°C | [REDACTED] | Acceptable | | | | | | | | | | | | |
| | | Meta SPC 10, Product 10-2 (28.8% w/w lactic acid), Batch COM23 / Méta SPC 10-2 / 2020-05-27 | 1.141 g/mL at 20°C | [REDACTED] | Acceptable | | | | | | | | | | | | |
| Storage stability test – accelerated storage | CIPAC MT 46.3 Analytical method for active substance: SOPa-LABCHI-512 validated in 2.2.4 | Meta SPC 1, Product 1-3 (24% w/w lactic acid), Batch COM23 / Méta SPC 1-3 / 2020-01-21 | Two storage conditions were assessed: either at 54°C for two weeks or at 40°C for 8 weeks. <table border="1"> <thead> <tr> <th>Parameter</th> <th>Before storage</th> <th>After storage at 54°C for two weeks</th> <th>After storage at 40°C for 8 weeks</th> </tr> </thead> <tbody> <tr> <td>Lactic acid content</td> <td>23.26% w/w</td> <td>23.00% w/w (-1.12%)</td> <td>22.75% w/w (-2.19%)</td> </tr> <tr> <td>Appearance</td> <td>homogeneous transparent colourless-yellow fluid liquid of</td> <td>Homogeneous transparent light yellow fluid liquid</td> <td>homogeneous transparent light yellow fluid liquid</td> </tr> </tbody> </table> | Parameter | Before storage | After storage at 54°C for two weeks | After storage at 40°C for 8 weeks | Lactic acid content | 23.26% w/w | 23.00% w/w (-1.12%) | 22.75% w/w (-2.19%) | Appearance | homogeneous transparent colourless-yellow fluid liquid of | Homogeneous transparent light yellow fluid liquid | homogeneous transparent light yellow fluid liquid | [REDACTED] | Acceptable The biocide product was not found stable at 54°C The representative product of Meta SPC 1 and 2 (product 1-3) is considered stable after 8 weeks at 40°C. The products of Meta SPC 1 and 2 should |
| Parameter | Before storage | After storage at 54°C for two weeks | After storage at 40°C for 8 weeks | | | | | | | | | | | | | | |
| Lactic acid content | 23.26% w/w | 23.00% w/w (-1.12%) | 22.75% w/w (-2.19%) | | | | | | | | | | | | | | |
| Appearance | homogeneous transparent colourless-yellow fluid liquid of | Homogeneous transparent light yellow fluid liquid | homogeneous transparent light yellow fluid liquid | | | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | | Reference | eCA assessment |
|----------|----------------------|--|---------------------------------------|--|---|--|---|--|
| | | | | citrusy characteristic odour, without phase separation or precipitation | of a citrusy characteristic odour, without phase separation or precipitations | of a citrusy characteristic odour, without phase separation or precipitation | <p>██████████</p> <p>██████████</p> <p>██████████</p> | <p>not be stored above 40°C.</p> <p>A shelf-life of 2 years can be granted for products of Meta SPC 1 and 2.</p> |
| | | | Reactivity towards container material | white HDPE bottle containing about 1L of liquid; no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging | White HDPE bottle containing about 1L of liquid; no sample leaks or discolouration, foulings, spots; a bulge of 0.3 cm was detected on the bottom. One of the three bottles resulted deformed | white HDPE bottle containing about 1L of liquid; no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | | Reference | eCA assessment |
|----------|----------------------|---|--|--|--|--|---|--|
| | | | Weight loss | / | 0.07% | 0.03% | | |
| | | | pH | 2.51 | 2.42 | 2.51 | | |
| | | | Acidity | 15.07% w/w as H ₂ SO ₄ | 15.19% w/w as H ₂ SO ₄ | 15.20% w/w as H ₂ SO ₄ | | |
| | | | Dilution stability at 20% v/v in standard water D | No separated material | No separated material | No separated material | | |
| | | | <p>For both storage conditions, the loss of active substance is lower than the accepted threshold of 10%. Moreover, the physicochemical properties of the formulation were observed to be stable throughout the storage period of 8 weeks at 40°C. Considering the bulge observed and that one bottle resulted deformed after 14 days at 54°C, the packaging could not be considered stable after this storage period.</p> | | | | | |
| | | Meta SPC 3, Product 3-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 3-2 / 2019-10-07 | Storage at 54°C for two weeks, in a 1L commercial packaging (HDPE bottle). | | | |  | Acceptable The representative product of Meta SPC 3 (product 3-2) is considered stable after 2 weeks at 54°C. |
| | | | Parameter | Before storage | After storage | | | |
| | | | Lactic acid content | 22.67% w/w | 22.89% w/w (+ 1%) | | | |


| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|---|--|--|--|--|-----------|------------|--|
| | | | Appearance | homogeneous yellowish limpid fluid of an acidic characteristic odour, without phase separation or precipitations | No change | [REDACTED] | A shelf-life of 2 years can be granted for products of Meta SPC 3. |
| Reactivity towards container material | white bottles, no sample leak or signs of deformation, containing about 1L of sample | No change | [REDACTED] | | | | |
| Weight loss | / | 0.07-0.08% | [REDACTED] | | | | |
| pH | 1.58 | 1.39 | [REDACTED] | | | | |
| Acidity | 14.83% w/w as H ₂ SO ₄ | 15.19% w/w as H ₂ SO ₄ | [REDACTED] | | | | |
| Dilution stability at 10% v/v in standard water D | No separated material | No separated material | [REDACTED] | | | | |
| | | | The active substance content difference (+1%) is lower than the accepted threshold of 10%. Moreover, the physicochemical properties of the | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|----------|----------------------|---|--|--------------------|--|----------------------|--|
| | | | formulation were observed to be stable throughout the storage period. | | | | |
| | | Meta SPC 4, Product 4-1 (24% w/w lactic acid), Batch COM 23 / Méta SPC 4-1 / 2020-04-24 | Storage at 54°C for two weeks, in a 1L commercial packaging. | | | [Redacted Reference] | Acceptable The representative product of Meta SPC 4 (product 4-1) is considered stable after 2 weeks at 54°C. A shelf-life of 2 years can be granted for products of Meta SPC 4. |
| | | Parameter | Before storage | After storage | | | |
| | | Lactic acid content | 23.34% w/w | 22.92% w/w (-1.8%) | | | |
| | | Appearance | limpid homogeneous dark green fluid of a characteristic odour, without phase separation or precipitation | No change | | | |
| | | Reactivity towards container material | natural HDPE bottle containing about 1L of liquid; no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging | No change | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|----------|----------------------|--|--|---|--|---|---|
| | | | Weight loss | / | -0.22% | | |
| | | | pH | 2.21 | 2.21 | | |
| | | | Acidity | 15.64% w/w as H ₂ SO ₄ | 15.83% w/w as H ₂ SO ₄ | | |
| | | | Dilution stability at 19% v/v in standard water D | No separated material | No separated material | | |
| | | Meta SPC 5, Product 5-x (28.8% w/w lactic acid), Batch COM 23 / MétaSPC 5-x / 2019-10-07 | Storage at 54°C for two weeks, in a 1L commercial packaging (HDPE bottle). | | | <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> | <p>Acceptable</p> <p>The representative product of Meta SPC 5 (product 5-x) is considered stable after 2 weeks at 54°C.</p> <p>A shelf-life of 2 years can be granted for products of Meta SPC 5.</p> |
| | | | Parameter | Before storage | After storage | | |
| | | | Lactic acid content | 29.34% w/w | 28.06% w/w (-4%) | | |
| | | | Appearance | homogeneous green fluid liquid of a mint characteristic | No change | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|--|--|--|--|---|--|-----------|----------------|
| | | | | odour, without phase separation or precipitations | | | |
| Reactivity towards container material | white bottles, no sample leak or signs of deformation, containing about 1L of sample | No change | Weight loss | / | - 0.05% | | |
| pH | 2.33 | 2.41 | Acidity | 17.62% w/w as H ₂ SO ₄ | 18.08% w/w as H ₂ SO ₄ | | |
| Dilution stability (10% v/v) | No separated material | No separated material | The loss of active substance (4%) is lower than the accepted threshold of 10%. Moreover, the physicochemical properties of the formulation were observed to be stable throughout the storage period. | | | | |
| Meta SPC 6, Product 6-2 (24% w/w lactic acid), | Storage at 54°C for two weeks, in a 1L commercial packaging. | [REDACTED] | Acceptable The representative product of Meta SPC 6 | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|---------------------------------------|--|--|-------------|--|---------------|---|--|
| | | Batch COM 23 / Méta SPC 6-2 / 2020-01-21 | Parameter | Before storage | After storage | <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> | <p>(product 6-2) is considered stable after 2 weeks at 54°C.</p> <p>A shelf-life of 2 years can be granted for products of Meta SPC 6.</p> |
| Lactic acid content | 23.35% w/w | 23.36% w/w | Appearance | homogeneous transparent colourless fluid liquid of an acid characteristic odour, without phase separation or precipitation | No change | | |
| Reactivity towards container material | white HDPE bottle containing about 1L of liquid; no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging | white HDPE bottle containing about 1L of liquid; no sample leaks or discolouration, foulings, spots; a slight bulge of 0.1 cm was detected on the bottom | Weight loss | / | 0.07% | | |


| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|----------|----------------------|---|---|--|--|--|--|
| | | | pH | 2.18 | 2.18 | | |
| | | | Acidity | 14.59% w/w as H ₂ SO ₄ | 15.03% w/w as H ₂ SO ₄ | | |
| | | | Dilution stability at 9% v/v in standard water D | No separated material | No separated material | | |
| | | | No loss of active substance was observed. Moreover, the physicochemical properties of the formulation were observed to be stable throughout the storage period. | | | | |
| | | Meta SPC 7, Product 7-12 (1.44% w/w lactic acid), Batch COM 23 / Méta SPC 7-12 / 2020-09-02 | Storage at 54°C for two weeks, in a 1L commercial packaging. | | |  | Acceptable The product of Meta SPC 7 (product 7-12) is considered stable after 2 weeks at 54°C. A shelf-life of 2 years can be granted for products of Meta SPC 7. |
| | | | Parameter | Before storage | After storage | | |
| | | | Lactic acid content | 1.40% w/w | 1.36% w/w (-2.9%) | | |
| | | | Appearance | Limpid homogeneous slightly yellow fluid liquid of a strong citrusy-grassy characteristic odour, without phase | No change | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|----------|----------------------|--|--|--|---|-----------|----------------|
| | | | | separation or precipitations | | | |
| | | | Reactivity towards container material | White HDPE bottle containing about 1L of liquid; no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging | No change | | |
| | | | Weight loss | / | -0.05% | | |
| | | | pH | 2.70 | 2.81 | | |
| | | | Acidity | 0.91% w/w as H ₂ SO ₄ | 0.94% w/w as H ₂ SO ₄ | | |
| | | | The loss of active substance (2.9%) is lower than the accepted threshold of 10%. Moreover, the physicochemical properties of the formulation were observed to be stable throughout the storage period. | | | | |


| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|----------|----------------------|--|--|---|---|---|--|
| | | Meta SPC 7, Product 7-x (1.44% w/w lactic acid), Batch COM 23 / MétaSPC 7-x / 2019-10-28 / 1 | Storage at 54°C for two weeks, in a 1L commercial packaging (HDPE bottle). | | | <div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100px; height: 15px;"></div> | <p>Acceptable</p> <p>The product of Meta SPC 7 (product 7-x) is considered stable after 2 weeks at 54°C.</p> <p>A shelf-life of 2 years can be granted for products of Meta SPC 7.</p> |
| | | | Parameter | Before storage | After storage | | |
| | | | Lactic acid content | 1.48% w/w | 1.41% w/w (-5%) | | |
| | | | Appearance | homogeneous colourless-yellow fluid liquid of a mint characteristic odour, without phase separation or precipitations | No change | | |
| | | | Reactivity towards container material | white bottles, no sample leak or signs of deformation, containing about 1 L of sample | No change | | |
| | | | Weight loss | / | -0.13% | | |
| | | | pH | 2.49 | 2.42 | | |
| | | | Acidity | 0.88% w/w as H ₂ SO ₄ | 0.98% w/w as H ₂ SO ₄ | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | | | | | | | | | | | | | |
|----------------|--------------------------------------|--|---|-----------|----------------|---------------|-----------|---------------------------------|----------------------------------|-------------|---|------|---------------|-------------------------|-------------------------|----------|--------------------------------------|--------------------------------------|----------------|----------------|----------------|-------------------|---|
| | | | <p>The loss of active substance (5%) is lower than the accepted threshold of 10%. Moreover, the physicochemical properties of the formulation were observed to be stable throughout the storage period.</p> | | | | | | | | | | | | | | | | | | | | |
| | | <p>Meta SPC 7, Product 7-x (1.44% w/w lactic acid), Batch COM23/META SPC7-X/2020-07-29/1</p> | <p>Storage at 54°C for two weeks in the trigger spray packaging type GUALA TS1 Foam V3.</p> <table border="1" data-bbox="936 675 1576 1257"> <thead> <tr> <th data-bbox="936 675 1151 770">Parameter</th> <th data-bbox="1151 675 1368 770">Before storage</th> <th data-bbox="1368 675 1576 770">After storage</th> </tr> </thead> <tbody> <tr> <td data-bbox="936 770 1151 866">Packaging</td> <td data-bbox="1151 770 1368 866">Transparent HDPE sprayer of 1 L</td> <td data-bbox="1368 770 1576 866">Transparent HDPE sprayer of 1 L*</td> </tr> <tr> <td data-bbox="936 866 1151 962">Weight loss</td> <td data-bbox="1151 866 1368 962">/</td> <td data-bbox="1368 866 1576 962">0.2%</td> </tr> <tr> <td data-bbox="936 962 1151 1058">Spray pattern</td> <td data-bbox="1151 962 1368 1058">Circular, 17cm diameter</td> <td data-bbox="1368 962 1576 1058">Circular, 17cm diameter</td> </tr> <tr> <td data-bbox="936 1058 1151 1153">Clogging</td> <td data-bbox="1151 1058 1368 1153">No blocking of the pump was observed</td> <td data-bbox="1368 1058 1576 1153">No blocking of the pump was observed</td> </tr> <tr> <td data-bbox="936 1153 1151 1249">Discharge rate</td> <td data-bbox="1151 1153 1368 1249">0.616 mL/spray</td> <td data-bbox="1368 1153 1576 1249">0.635 mL/spray</td> </tr> </tbody> </table> <p>*No sign of degradation or leak was observed</p> | Parameter | Before storage | After storage | Packaging | Transparent HDPE sprayer of 1 L | Transparent HDPE sprayer of 1 L* | Weight loss | / | 0.2% | Spray pattern | Circular, 17cm diameter | Circular, 17cm diameter | Clogging | No blocking of the pump was observed | No blocking of the pump was observed | Discharge rate | 0.616 mL/spray | 0.635 mL/spray | <p>[REDACTED]</p> | <p>Acceptable</p> <p>The trigger sprayer GUALA TS1 Foam V3 is considered as stable after storage.</p> |
| Parameter | Before storage | After storage | | | | | | | | | | | | | | | | | | | | | |
| Packaging | Transparent HDPE sprayer of 1 L | Transparent HDPE sprayer of 1 L* | | | | | | | | | | | | | | | | | | | | | |
| Weight loss | / | 0.2% | | | | | | | | | | | | | | | | | | | | | |
| Spray pattern | Circular, 17cm diameter | Circular, 17cm diameter | | | | | | | | | | | | | | | | | | | | | |
| Clogging | No blocking of the pump was observed | No blocking of the pump was observed | | | | | | | | | | | | | | | | | | | | | |
| Discharge rate | 0.616 mL/spray | 0.635 mL/spray | | | | | | | | | | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | | | | | | | |
|----------------|---|--|---|-------------------|-------------------|---------------|---------------|---------------------------|---------------------------|----------|---|---|----------------|----------------|----------------|-------------------|--|
| | | | <p>The spray packaging was found to be stable after a storage procedure at 54°C for two weeks. The spray properties were also stable.</p> | | | | | | | | | | | | | | |
| | | <p>Meta SPC 7, Product 7-x (1.44% w/w lactic acid), Batch COM23/Meta SPC7-X/2020-10-21/1</p> | <p>Storage at 54°C for two weeks in the trigger spray packaging type GUALA TS3 SNAPON FOX STD SPRAY.</p> <table border="1" data-bbox="936 611 1597 1082"> <thead> <tr> <th data-bbox="936 611 1151 707">Parameter</th> <th data-bbox="1151 611 1368 707">Before storage</th> <th data-bbox="1368 611 1597 707">After storage</th> </tr> </thead> <tbody> <tr> <td data-bbox="936 707 1151 802">Spray pattern</td> <td data-bbox="1151 707 1368 802">Circular, 9.5 cm diameter</td> <td data-bbox="1368 707 1597 802">Circular, 9.9 cm diameter</td> </tr> <tr> <td data-bbox="936 802 1151 986">Clogging</td> <td data-bbox="1151 802 1368 986">No dysfunction such as spilling, nozzle or trigger blockage</td> <td data-bbox="1368 802 1597 986">No dysfunction such as spilling, nozzle or trigger blockage</td> </tr> <tr> <td data-bbox="936 986 1151 1082">Discharge rate</td> <td data-bbox="1151 986 1368 1082">1.276 mL/spray</td> <td data-bbox="1368 986 1597 1082">1.295 mL/spray</td> </tr> </tbody> </table> <p>The spray parameters were found to be stable after the storage procedure for two weeks at 54°C in the commercial spray packaging.</p> | Parameter | Before storage | After storage | Spray pattern | Circular, 9.5 cm diameter | Circular, 9.9 cm diameter | Clogging | No dysfunction such as spilling, nozzle or trigger blockage | No dysfunction such as spilling, nozzle or trigger blockage | Discharge rate | 1.276 mL/spray | 1.295 mL/spray | <p>[Redacted]</p> | <p>Acceptable</p> <p>The trigger sprayer GUALA TS3 SNAPON FOX STD SPRAY is considered as stable after storage.</p> <p>The particle size distribution has been reported separately.</p> |
| Parameter | Before storage | After storage | | | | | | | | | | | | | | | |
| Spray pattern | Circular, 9.5 cm diameter | Circular, 9.9 cm diameter | | | | | | | | | | | | | | | |
| Clogging | No dysfunction such as spilling, nozzle or trigger blockage | No dysfunction such as spilling, nozzle or trigger blockage | | | | | | | | | | | | | | | |
| Discharge rate | 1.276 mL/spray | 1.295 mL/spray | | | | | | | | | | | | | | | |
| | | <p>Meta SPC 7, Product 7-x (1.44% w/w lactic acid), Batch</p> | <p>Storage at 54°C for two weeks in the trigger spray type GUALA TS1 STD Spray.</p> <p>Spray droplet size distribution by laser diffraction</p> | <p>[Redacted]</p> | <p>Acceptable</p> | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | | | | |
|---------------------|-----------------------|---|---|-----------|----------------|---------------|---------------------|----------|------------------|------------|-----------------------|-----------|---|--|
| | | COM23/META SPC7-X/2020-09-23/1 | <p><u>Before storage:</u> 10% of the sprayed particles were found to be ≤ 67.87 µm. 50% of the sprayed particles were found to be ≤ 118.6 µm. 90% of the sprayed particles were found to be ≤ 218.3 µm. 0% of the sprayed particles were found to be smaller than 10 µm.</p> <p><u>After storage:</u> <u>Before storage:</u> 10% of the sprayed particles were found to be ≤ 58.93 µm. 50% of the sprayed particles were found to be ≤ 110.5 µm. 90% of the sprayed particles were found to be ≤ 221.1 µm. 0.113% of the sprayed particles were found to be smaller than 10 µm.</p> <p>A small decrease of the general particles size was observed during storage, but the sprayed particles remained of large size.</p> | | | | | | | | | | | |
| | | Meta SPC 8, Product 8-2 (6% w/w lactic acid), Batch COM 23 / Méta | <p>Storage at 40°C for 8 weeks, in a 1L commercial packaging (HDPE bottle).</p> <table border="1" data-bbox="936 1262 1576 1414"> <thead> <tr> <th>Parameter</th> <th>Before storage</th> <th>After storage</th> </tr> </thead> <tbody> <tr> <td>Lactic acid content</td> <td>6.4% w/w</td> <td>6.1% w/w (-4.7%)</td> </tr> <tr> <td>Appearance</td> <td>homogeneous yellowish</td> <td>No change</td> </tr> </tbody> </table> | Parameter | Before storage | After storage | Lactic acid content | 6.4% w/w | 6.1% w/w (-4.7%) | Appearance | homogeneous yellowish | No change |  | <p>Acceptable</p> <p>The product of Meta SPC 8 (product 8-2) is considered stable after 8 weeks at 40°C.</p> |
| Parameter | Before storage | After storage | | | | | | | | | | | | |
| Lactic acid content | 6.4% w/w | 6.1% w/w (-4.7%) | | | | | | | | | | | | |
| Appearance | homogeneous yellowish | No change | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|----------|----------------------|---|--|---|--|---|---|
| | | SPC 8-2 / 2019-10-14 | | limpid fluid of an acidic characteristic odour, without phase separation or precipitation | | | The products of Meta SPC 8 should not be stored above 40°C. A shelf-life of 2 years can be granted for products of Meta SPC 8. |
| | | | Reactivity towards container material | white bottles; no sample leak or signs of deformation, containing about 1L of sample | No change | | |
| | | | Weight loss | / | 0.042% | | |
| | | | pH | 2.05 | 2.07 | | |
| | | | Acidity | 3.62% w/w as H ₂ SO ₄ | 3.69% w/w as H ₂ SO ₄ | | |
| | | | Kinematic viscosity | 20°C: 20.89 mm ² /s 40°C: 12.73 mm ² /s | 20°C: 17.87 mm ² /s 40°C: 11.02 mm ² /s | | |
| | | | The loss of active substance (4.7%) is lower than the accepted threshold of 10%. Moreover, the physicochemical properties of the formulation were observed to be stable throughout the storage period. | | | | |
| | | Meta SPC 8, Product 8-2 (6% w/w lactic acid), Batch COM 23 / META | Storage at 54°C for two weeks in the trigger spray packaging type GUALA TS1 FOAM V2 | | | <div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 50px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 60px; height: 15px;"></div> | Acceptable The trigger sprayer GUALA TS1 FOAM V2 is considered as stable after storage. |
| | | | Parameter | Before storage | After storage | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|----------|----------------------|--|--|---|---|--|--|
| | | SPC 8-2 / 2020-11-23 | Spray pattern | Circular, 18.3 cm diameter | Circular, 22.0 cm diameter | | The particle size distribution has been reported separately. |
| | | | Clogging | No dysfunction such as spilling, nozzle or trigger blockage | No dysfunction such as spilling, nozzle or trigger blockage | | |
| | | | Discharge rate | 0.661 mL/spray | 0.642 mL/spray | | |
| | | | The spray parameters were found to be stable after the storage procedure for two weeks at 54°C in the commercial spray packaging. | | | | |
| | | Meta SPC 8, Product 8-2 (6% w/w lactic acid), Batch COM23/Meta SPC8-2/2020-11-20 | Storage at 54°C for two weeks in the trigger spray type GUALA TS1 FOAM V2. <u>Before storage:</u> 10% of the sprayed particles were found to be ≤ 339.5 µm. 50% of the sprayed particles were found to be ≤ 555.9 µm. 90% of the sprayed particles were found to be ≤ 808.7 µm. 0% of the sprayed particles were found to be smaller than 10 µm. <u>After storage:</u> <u>Before storage:</u> | | |  | Acceptable The trigger sprayer GUALA TS1 FOAM V2 is considered as stable after storage. |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | | | | | | | |
|---------------------------------------|--|---|---|-----------|----------------|---------------|---------------------|----------|------------------|------------|--|-----------|---------------------------------------|--|-----------|-------------------|--|
| | | | <p>10% of the sprayed particles were found to be ≤ 271.7 µm. 50% of the sprayed particles were found to be ≤ 509.9 µm. 90% of the sprayed particles were found to be ≤ 797.2 µm. 0.062% of the sprayed particles were found to be smaller than 10 µm.</p> <p>A small decrease of the general particles size was observed during storage, but the sprayed particles remained of large size.</p> | | | | | | | | | | | | | | |
| | | <p>Meta SPC 8, Product 8-17 (6% w/w lactic acid), Batch COM 23 / Méta SPC 8-17 / 2020-10-27 / 1</p> | <p>Storage at 40°C for 8 weeks, in a 1L commercial packaging.</p> <table border="1" data-bbox="936 869 1579 1396"> <thead> <tr> <th>Parameter</th> <th>Before storage</th> <th>After storage</th> </tr> </thead> <tbody> <tr> <td>Lactic acid content</td> <td>5.9% w/w</td> <td>5.6% w/w (-5.1%)</td> </tr> <tr> <td>Appearance</td> <td>homogeneous dark green fluid liquid of a mint characteristic odour, without phase separation or precipitations</td> <td>No change</td> </tr> <tr> <td>Reactivity towards container material</td> <td>HDPE white bottle containing about 1L of liquid; no sample leaks</td> <td>No change</td> </tr> </tbody> </table> | Parameter | Before storage | After storage | Lactic acid content | 5.9% w/w | 5.6% w/w (-5.1%) | Appearance | homogeneous dark green fluid liquid of a mint characteristic odour, without phase separation or precipitations | No change | Reactivity towards container material | HDPE white bottle containing about 1L of liquid; no sample leaks | No change | <p>[REDACTED]</p> | <p>Acceptable</p> <p>The product of Meta SPC 8 (product 8-17) is considered stable after 8 weeks at 40°C.</p> <p>The products of Meta SPC 8 should not be stored above 40°C.</p> <p>A shelf-life of 2 years can be granted for products of Meta SPC 8.</p> |
| Parameter | Before storage | After storage | | | | | | | | | | | | | | | |
| Lactic acid content | 5.9% w/w | 5.6% w/w (-5.1%) | | | | | | | | | | | | | | | |
| Appearance | homogeneous dark green fluid liquid of a mint characteristic odour, without phase separation or precipitations | No change | | | | | | | | | | | | | | | |
| Reactivity towards container material | HDPE white bottle containing about 1L of liquid; no sample leaks | No change | | | | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|----------|----------------------|--|--|--|--|------------|--|
| | | | | or signs of deformation, discolouration, foulings, bulges or spots on the packaging | | | |
| | | | Weight loss | / | 0.02% | | |
| | | | pH | 2.06 | 2.09 | | |
| | | | Acidity | 3.24% w/w as H ₂ SO ₄ | 3.49% w/w as H ₂ SO ₄ | | |
| | | | Kinematic viscosity | 20°C: 943.95 mm ² /s 40°C: 667.66 mm ² /s | 20°C: 694.58 mm ² /s 40°C: 450.05 mm ² /s | | |
| | | | The loss of active substance (5.1%) is lower than the accepted threshold of 10%. Moreover, the physicochemical properties of the formulation were observed to be stable throughout the storage period. | | | | |
| | | Meta SPC 9, Product 9-2 (2.9% w/w lactic acid), Batch COM 23 / Méta SPC 9-2 / 2019-10-10 | Storage at 40°C for 8 weeks, in a 1L commercial packaging (HDPE bottle). | | | [REDACTED] | Acceptable The product of Meta SPC 9 (product 9-2) is considered stable after 8 weeks at 40°C. The products of Meta SPC 9 should not be stored above 40°C. |
| | | | Parameter | Before storage | After storage | | |
| | | | Lactic acid content | 3.10% w/w | 2.90% w/w (-6.5%) | | |
| | | | Appearance | homogeneous colourless limpid fluid of an acidic characteristic odour, without phase | No change | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|----------|----------------------|--|--|---|--|------------|---|
| | | | Reactivity towards container material | separation or precipitation white bottles, no sample leak or signs of deformation, containing about 1L of sample | No change | | A shelf-life of 2 years can be granted for products of Meta SPC 9. |
| | | | Weight loss | / | -0.04% | | |
| | | | pH | 2.24 | 2.15 | | |
| | | | Acidity | 1.86% w/w as H ₂ SO ₄ | 1.94% w/w as H ₂ SO ₄ | | |
| | | | Kinematic viscosity | 20°C: 23.21 mm ² /s 40°C: 14.29 mm ² /s | 20°C: 20.38 mm ² /s 40°C: 12.73 mm ² /s | | |
| | | | The loss of active substance (4.7%) is lower than the accepted threshold of 10%. Moreover, the physicochemical properties of the formulation were observed to be stable throughout the storage period. | | | | |
| | | Meta SPC 9, Product 9-10 (2.9% w/w lactic acid), Batch COM 23 / Méta SPC 9-10 / 2019-10-28 / 1 | Storage at 40°C for 8 weeks, in a 1L commercial packaging. | | | [REDACTED] | Acceptable The product of Meta SPC 9 (product 9-10) is considered stable after 8 weeks at 40°C. The products of Meta SPC 9 should not be stored above 40°C. |
| | | | Parameter | Before storage | After storage | | |
| | | | Lactic acid content | 2.875% w/w | 2.996% w/w (-4%) | | |
| | | | Appearance | homogeneous colourless-yellowish limpid fluid of a mint | No change | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|---|--|---|--|---|--|------------|--|
| | | | | characteristic odour, without phase separation or precipitation | | | A shelf-life of 2 years can be granted for products of Meta SPC 9. |
| Reactivity towards container material | white bottles, no sample leak or signs of deformation, containing about 1L of liquid | No change | | | | | |
| Weight loss | / | -0.1 % | | | | | |
| pH | 2.20 | 2.13 | | | | | |
| Acidity | 1.61% w/w as H ₂ SO ₄ | 1.89% w/w as H ₂ SO ₄ | | | | | |
| Viscosity (capillary method) | 20°C: 69.23 mm ² /s 40°C: 40.29 mm ² /s | 20°C: 49.80 mm ² /s 40°C: 29.89 mm ² /s | | | | | |
| No loss of active substance was observed. Moreover, the physicochemical properties of the formulation were observed to be stable throughout the storage period. | | | | | | [REDACTED] | Acceptable |
| | | Meta SPC 9, Product 9-10 (2.9% w/w lactic acid), Batch COM 23 / Méta SPC 9-10 / | Storage at 40°C for 8 weeks, in a 1L commercial packaging. | | | | |
| Kinematic viscosity | Before storage | After storage | 20°C: 192.84 mm ² /s | 20°C: 169.60 mm ² /s | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|----------|----------------------|--|--|--|---------------------------------|---|--|
| | | 2020-06-01 / 1 | (rotational viscometer) | 40°C: 178.44 mm ² /s | 40°C: 147.21 mm ² /s | | |
| | | Meta SPC 10, Product 10-2 (28.8% w/w lactic acid), Batch COM 23 / Méta SPC 10-2 / 2020-05-27 | Storage at 40°C for 8 weeks, in a 1L commercial packaging. | | | <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> | <p>Acceptable</p> <p>The representative product of Meta SPC 10 (product 10-2) is considered stable after 8 weeks at 40°C.</p> <p>The products of Meta SPC 10 should not be stored above 40°C.</p> <p>A shelf-life of 2 years can be granted for products of Meta SPC 10.</p> |
| | | | Parameter | Before storage | After storage | | |
| | | | Lactic acid content | 27.75% w/w | 27.58% w/w (-0.6%) | | |
| | | | Appearance | Limpid homogeneous brown fluid liquid of an acidic characteristic odour, without phase separation or precipitations | No change | | |
| | | | Reactivity towards container material | Matt natural HDPE bottle containing about 1L of liquid; no sample leaks or signs of deformation, discolouration, foulings, bulges or spots | No change | | |


| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|--|--|---|---|--|--|------------|---|
| | | | | on the packaging | | | |
| | | | Weight loss | / | 0.02% | | |
| | | | pH | 2.26 | 2.47 | | |
| | | | Acidity | 18.80% w/w as H ₂ SO ₄ | 18.75% w/w as H ₂ SO ₄ | | |
| | | | Dilution stability at 20% v/v in standard water D | No separated material | No separated material | | |
| | | | No loss of active substance was observed. Moreover, the physicochemical properties of the formulation were observed to be stable throughout the storage period. | | | | |
| Storage stability test – long term storage at ambient temperature | Gifap monograph No.17 Analytical method for active substance: SOPa-LABCHI-512 | Meta SPC 1, Product 1-3 (24% w/w lactic acid), Batch COM 23 / Méta SPC 1-3 / 2020-01-21 | Storage at 25°C in a 1L commercial packaging. Only interim results after 6 months are currently available. The total study duration will be 2 years. | | | [REDACTED] | Intermediate results of the long term stability study are acceptable. The product is considered stable after 6 months. A shelf-life of 2 years can be granted for |
| | | | Parameter | Before storage | After storage at 25°C for 6 months | | |
| | | | Lactic acid content | 23.26% w/w | 23.36% w/w (+0,4%) | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|----------|----------------------|---|---|--|---|-----------|--|
| | validated in 2.2.4 | | Appearance | homogeneous transparent colourless-yellow fluid liquid of citrusy characteristic odour, without phase separation or precipitation | Homogeneous transparent light yellow fluid liquid of a citrusy characteristic odour, without phase separation or precipitations | | products of Meta SPC 1 and 2 based on the accelerated storage results. Final results of the long term storage study should be provided in post authorisation. |
| | | | Reactivity towards container material | white HDPE bottle containing about 1L of liquid; no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging | No change | | |
| | | | Weight loss | / | 0.03% | | |
| | | | The active substance content and appearance of the product and its packaging are stable during a storage of 6 months at ambient temperature. The pH, acidity, dilution stability and persistent foaming tests will be performed after 2 years at ambient temperature. | | | | |
| | | Meta SPC 3, Product 3-2 (24% w/w lactic acid) | Ongoing study: storage at 25°C for two years. | | | | A shelf-life of 2 years can be granted for products of Meta SPC 3 based on the |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | |
|---------------------|----------------------|---|--|-----------|--|-------------------------------------|---------------------|------------|--------------------|---|--|
| | | | | | <p>accelerated storage results.</p> <p>Final results of the long term storage study should be provided in post authorisation.</p> | | | | | | |
| | | Meta SPC 4, Product 4-1 (24% w/w lactic acid) | Ongoing study: storage at 25°C for two years. | | <p>A shelf-life of 2 years can be granted for products of Meta SPC 4 based on the accelerated storage results.</p> <p>Final results of the long term storage study should be provided in post authorisation.</p> | | | | | | |
| | | Meta SPC 5, Product 5-x (28.8% w/w lactic acid), Batch COM 23 / Méta SPC 5-x / 2019-10-07 | <p>Storage at 25°C in a 1L commercial packaging (HDPE bottle). Only interim results after 12 months are currently available. The total study duration will be 2 years.</p> <table border="1" data-bbox="936 1166 1603 1362"> <thead> <tr> <th>Parameter</th> <th>Before storage</th> <th>After storage at 25°C for 12 months</th> </tr> </thead> <tbody> <tr> <td>Lactic acid content</td> <td>29.34% w/w</td> <td>28.05% w/w (-4.4%)</td> </tr> </tbody> </table> | Parameter | Before storage | After storage at 25°C for 12 months | Lactic acid content | 29.34% w/w | 28.05% w/w (-4.4%) | <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> | <p>Intermediate results of the long term stability study are acceptable.</p> <p>The product is considered stable after 12 months.</p> <p>A shelf-life of 2 years can be granted for products of Meta SPC</p> |
| Parameter | Before storage | After storage at 25°C for 12 months | | | | | | | | | |
| Lactic acid content | 29.34% w/w | 28.05% w/w (-4.4%) | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|----------|----------------------|---|--|---|------------------------------------|------------|---|
| | | | Appearance | homogeneous green fluid liquid of a mint characteristic odour, without phase separation or precipitations | No change | | 5 based on the accelerated storage results. Final results of the long term storage study should be provided in post authorisation. |
| | | | Reactivity towards container material | white bottles, no sample leak or signs of deformation, containing about 1L of sample | No change | | |
| | | | Weight loss | / | 0.04% | | |
| | | | The active substance content and appearance of the product and its packaging are stable during a storage of 12 months at ambient temperature. The pH, acidity, dilution stability and persistent foaming tests will be performed after 2 years at ambient temperature. | | | | |
| | | Meta SPC 6, Product 6-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 6-2 / 2020-01-21 | Storage at 25°C in a 1L commercial packaging. Only interim results after 6 months are currently available. The total study duration will be 2 years. | | | [REDACTED] | Intermediate results of the long term stability study are acceptable. The product is considered stable after 6 months. |
| | | | Parameter | Before storage | After storage at 25°C for 6 months | | |
| | | | Lactic acid content | 23.35% w/w | 23.45% w/w (+0.4%) | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|----------|----------------------|--|--|--|-----------|-----------|--|
| | | | Appearance | homogeneous transparent colourless fluid liquid of an acid characteristic odour, without phase separation or precipitation | No change | | <p>A shelf-life of 2 years can be granted for products of Meta SPC 6 based on the accelerated storage results.</p> <p>Final results of the long term storage study should be provided in post authorisation.</p> |
| | | | Reactivity towards container material | white HDPE bottle containing about 1L of liquid; no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging | No change | | |
| | | | Weight loss | / | 0.04% | | |
| | | | <p>The active substance content and appearance of the product and its packaging are stable during a storage of 6 months at ambient temperature. The pH, acidity, dilution stability and persistent foaming tests will be performed after 2 years at ambient temperature.</p> | | | | |
| | | Meta SPC 7, Product 7-12 (1.44% w/w lactic acid) | Ongoing study: storage at 25°C for two years. | | | | A shelf-life of 2 years can be granted for products of Meta SPC 7 based on the accelerated storage results. |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|----------|----------------------|---|--|---|-------------------------------------|---|--|
| | | Meta SPC 7, Product 7-x (1.44% w/w lactic acid), Batch COM 23 / Méta SPC 7-x / 2019-10-28 | Storage at 25°C in a 1L commercial packaging (HDPE bottle). Only interim results after 12 months are currently available. The total study duration will be 2 years. | | |  | <p>Final results of the long term storage study should be provided in post authorisation.</p> <p>Intermediate results of the long term stability study are acceptable.</p> <p>The product is considered stable after 12 months.</p> <p>A shelf-life of 2 years can be granted for products of Meta SPC 7 based on the accelerated storage results.</p> <p>Final results of the long term storage study should be provided in post authorisation.</p> |
| | | | Parameter | Before storage | After storage at 25°C for 12 months | | |
| | | | Lactic acid content | 1.48% w/w | 1.41% w/w (-4.7%) | | |
| | | | Appearance | homogeneous colourless-yellow fluid liquid of a mint characteristic odour, without phase separation or precipitations | No change | | |
| | | | Reactivity towards container material | white bottles, no sample leak or signs of deformation, containing about 1L of sample | No change | | |
| | | | Weight loss | / | 0.11% | | |


| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | | | | | | | |
|---------------------------------------|---|--|---|-----------|---|-------------------------------------|---------------------|----------|----------------|------------|---|-----------|---------------------------------------|---|-----------|---|--|
| | | | The active substance content and appearance of the product and its packaging are stable during a storage of 12 months at ambient temperature. The pH and acidity tests will be performed after 2 years at ambient temperature. | | | | | | | | | | | | | | |
| | | Meta SPC 7, Product 7-x (1.44% w/w lactic acid) | Ongoing studies at 20°C for two years in commercial spray packaging to cover the stability of the spray properties (spray pattern, discharge rate, clogging, particles size distribution). | | The spray properties after 2 years at ambient temperature should be provided in post authorisation. | | | | | | | | | | | | |
| | | Meta SPC 8, Product 8-2 (6% w/w lactic acid), Batch COM 23 / Méta SPC 8-2 / 2019-10-14 | <p>Storage at 25°C in a 1L commercial packaging (HDPE bottle). Only interim results after 12 months are currently available. The total study duration will be 2 years.</p> <table border="1" data-bbox="936 874 1608 1393"> <thead> <tr> <th data-bbox="936 874 1106 970">Parameter</th> <th data-bbox="1106 874 1357 970">Before storage</th> <th data-bbox="1357 874 1608 970">After storage at 25°C for 12 months</th> </tr> </thead> <tbody> <tr> <td data-bbox="936 970 1106 1066">Lactic acid content</td> <td data-bbox="1106 970 1357 1066">6.4% w/w</td> <td data-bbox="1357 970 1608 1066">6.2% w/w (-3%)</td> </tr> <tr> <td data-bbox="936 1066 1106 1278">Appearance</td> <td data-bbox="1106 1066 1357 1278">homogeneous yellowish limpid fluid of an acidic characteristic odour, without phase separation or precipitation</td> <td data-bbox="1357 1066 1608 1278">No change</td> </tr> <tr> <td data-bbox="936 1278 1106 1393">Reactivity towards container material</td> <td data-bbox="1106 1278 1357 1393">transparent bottles containing about 1L of sample; no</td> <td data-bbox="1357 1278 1608 1393">No change</td> </tr> </tbody> </table> | Parameter | Before storage | After storage at 25°C for 12 months | Lactic acid content | 6.4% w/w | 6.2% w/w (-3%) | Appearance | homogeneous yellowish limpid fluid of an acidic characteristic odour, without phase separation or precipitation | No change | Reactivity towards container material | transparent bottles containing about 1L of sample; no | No change | <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> | <p>Intermediate results of the long term stability study are acceptable.</p> <p>The product is considered stable after 12 months.</p> <p>A shelf-life of 2 years can be granted for products of Meta SPC 8 based on the accelerated storage results.</p> <p>Final results of the long term storage study should be provided in post authorisation.</p> |
| Parameter | Before storage | After storage at 25°C for 12 months | | | | | | | | | | | | | | | |
| Lactic acid content | 6.4% w/w | 6.2% w/w (-3%) | | | | | | | | | | | | | | | |
| Appearance | homogeneous yellowish limpid fluid of an acidic characteristic odour, without phase separation or precipitation | No change | | | | | | | | | | | | | | | |
| Reactivity towards container material | transparent bottles containing about 1L of sample; no | No change | | | | | | | | | | | | | | | |



| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | eCA assessment |
|----------|----------------------|---|--|---|-------|-----------|---|
| | | | | sample leak or signs of deformation, discolouration, foulings, bulges or spots on the packaging | | | |
| | | | Weight loss | / | 0.09% | | |
| | | | The active substance content and appearance of the product and its packaging are stable during a storage of 12 months at ambient temperature. The pH and acidity tests will be performed after 2 years at ambient temperature. | | | | |
| | | Meta SPC 8, Product 8-2 (6% w/w lactic acid) | Ongoing studies at 20°C for two years in commercial spray packaging to cover the stability of the spray properties (spray pattern, discharge rate, clogging, particles size distribution). | | | | The spray properties after 2 years at ambient temperature should be provided in post authorisation. |
| | | Meta SPC 8, Product 8-17 (6% w/w lactic acid) | Ongoing study: storage at 25°C for two years. | | | | A shelf-life of 2 years can be granted for products of Meta SPC 8 based on the accelerated storage results. Final results of the long term storage study should be provided in post authorisation. |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | | | | | | | | | | | | | |
|---------------------------------------|---|---|--|-----------|----------------|-------------------------------------|---------------------|-----------|-------------------|------------|--|-----------|---------------------------------------|---|-----------|-------------|---|-------|-----------|--------------------------------|--------------------------------|-------------------|--|
| | | Meta SPC 9, Product 9-2 (2.9% w/w lactic acid), Batch COM 23 /Méta SPC 9-2 / 2019-10-10 | <p>Storage at 25°C in a 1L commercial packaging (HDPE bottle). Only interim results after 12 months are currently available. The total study duration will be 2 years.</p> <table border="1" data-bbox="938 512 1603 1401"> <thead> <tr> <th data-bbox="938 512 1126 608">Parameter</th> <th data-bbox="1126 512 1370 608">Before storage</th> <th data-bbox="1370 512 1603 608">After storage at 25°C for 12 months</th> </tr> </thead> <tbody> <tr> <td data-bbox="938 608 1126 703">Lactic acid content</td> <td data-bbox="1126 608 1370 703">3.10% w/w</td> <td data-bbox="1370 608 1603 703">2.93% w/w (-5.5%)</td> </tr> <tr> <td data-bbox="938 703 1126 911">Appearance</td> <td data-bbox="1126 703 1370 911">homogeneous colourless limpid fluid of an acidic characteristic odour, without phase separation or precipitation</td> <td data-bbox="1370 703 1603 911">No change</td> </tr> <tr> <td data-bbox="938 911 1126 1206">Reactivity towards container material</td> <td data-bbox="1126 911 1370 1206">white bottles containing about 1L of sample, no sample leak or signs of deformation, discolouration, foulings, bulges or spots on the packaging</td> <td data-bbox="1370 911 1603 1206">No change</td> </tr> <tr> <td data-bbox="938 1206 1126 1302">Weight loss</td> <td data-bbox="1126 1206 1370 1302">/</td> <td data-bbox="1370 1206 1603 1302">0.06%</td> </tr> <tr> <td data-bbox="938 1302 1126 1401">Viscosity</td> <td data-bbox="1126 1302 1370 1401">20°C: 23.21 mm²/s</td> <td data-bbox="1370 1302 1603 1401">20°C: 20.82 mm²/s</td> </tr> </tbody> </table> | Parameter | Before storage | After storage at 25°C for 12 months | Lactic acid content | 3.10% w/w | 2.93% w/w (-5.5%) | Appearance | homogeneous colourless limpid fluid of an acidic characteristic odour, without phase separation or precipitation | No change | Reactivity towards container material | white bottles containing about 1L of sample, no sample leak or signs of deformation, discolouration, foulings, bulges or spots on the packaging | No change | Weight loss | / | 0.06% | Viscosity | 20°C: 23.21 mm ² /s | 20°C: 20.82 mm ² /s | <p>[REDACTED]</p> | <p>Intermediate results of the long term stability study are acceptable.</p> <p>The product is considered stable after 12 months.</p> <p>A shelf-life of 2 years can be granted for products of Meta SPC 9 based on the accelerated storage results.</p> <p>Final results of the long term storage study should be provided in post authorisation.</p> |
| Parameter | Before storage | After storage at 25°C for 12 months | | | | | | | | | | | | | | | | | | | | | |
| Lactic acid content | 3.10% w/w | 2.93% w/w (-5.5%) | | | | | | | | | | | | | | | | | | | | | |
| Appearance | homogeneous colourless limpid fluid of an acidic characteristic odour, without phase separation or precipitation | No change | | | | | | | | | | | | | | | | | | | | | |
| Reactivity towards container material | white bottles containing about 1L of sample, no sample leak or signs of deformation, discolouration, foulings, bulges or spots on the packaging | No change | | | | | | | | | | | | | | | | | | | | | |
| Weight loss | / | 0.06% | | | | | | | | | | | | | | | | | | | | | |
| Viscosity | 20°C: 23.21 mm ² /s | 20°C: 20.82 mm ² /s | | | | | | | | | | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | Reference | eCA assessment | | | |
|--|---|---|---|--|-----------|---|--------------------------------|--|--|
| | | | <table border="1"> <tr> <td data-bbox="936 352 1122 443"></td> <td data-bbox="1122 352 1368 443">40°C: 14.29 mm²/s</td> <td data-bbox="1368 352 1615 443">40°C: 13.11 mm²/s</td> </tr> </table> | | | 40°C: 14.29 mm ² /s | 40°C: 13.11 mm ² /s | | |
| | 40°C: 14.29 mm ² /s | 40°C: 13.11 mm ² /s | | | | | | | |
| | | Meta SPC 10, Product 10-2 (28.8% w/w lactic acid) | Ongoing study: storage at 25°C for two years. | | | <p>A shelf-life of 2 years can be granted for products of Meta SPC 10 based on the accelerated storage results.</p> <p>Final results of the long term storage study should be provided in post authorisation.</p> | | | |
| Storage stability test – low temperature stability test for liquids | The products labels state that the formulations should be protected from frost during storage. Therefore, testing for the products stability to low temperatures is not required. | | | | | <p>Acceptable</p> <p>The labels of the products state: "Protect from frost."</p> | | | |
| Effects on content of the active substance and technical characteristics | The products labels state that the formulations should be kept out of the direct sunlight during storage. Moreover, the active substance is known not to undergo photolysis. Hence, the consideration of the effect of light is not relevant. | | | | | <p>Acceptable</p> <p>The labels of the products state: "Keep away from direct sunlight."</p> | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|---|--|--|--|-----------|----------------|
| of the biocidal product - light | | | | | |
| Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity | Effect of temperature higher than normal were assessed during the accelerated storage studies. The results indicate that temperature has no adverse effect on the products. Effect of humidity is not relevant based on the formulation types (water-based AL and SL formulations). | | | | Acceptable |
| Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material | The ambient storage studies are ongoing. Some results are available, as are results from accelerated storage studies. All results show that no reactivity between the products and their container material occurs. | | | | Acceptable |
| Wettability | Waiver | | Not relevant for the formulation types (AL, SL). | | Not relevant |
| Suspensibility, spontaneity and dispersion stability | Waiver | | Not relevant for the formulation types (AL, SL). | | Not relevant |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | | | | | | | | | | | | | | | | |
|--|--|--|---|------------------------------|-------------------------------|---|------------|-------------------------------|-------------|-------------|-------------|-------------------|-------|-------|-------|-------|-------|--------------------------------|-----|-----|-------|-------|-------|--|--|--|
| Wet sieve analysis and dry sieve test | Waiver | Not relevant for the formulation types (AL, SL). | | | Not relevant | | | | | | | | | | | | | | | | | | | | | |
| Emulsifiability, re-emulsifiability and emulsion stability | Waiver | Not relevant for the formulation types (AL, SL). | | | Not relevant | | | | | | | | | | | | | | | | | | | | | |
| Disintegration time | Waiver | Not relevant for the formulation types (AL, SL). | | | Not relevant | | | | | | | | | | | | | | | | | | | | | |
| Particle size distribution, content of dust/fines, attrition, friability | content of dust/fines, attrition, friability | Not relevant for the formulation types (AL, SL). | | | Not relevant | | | | | | | | | | | | | | | | | | | | | |
| Particle size distribution, content of dust/fines, attrition, friability | Particle size distribution – CIPAC MT 187 | Meta SPC 7, Product 7-x (1.44% w/w lactic acid), Batch COM 23/METASPC 7-X/2020-07-29/1 | Spray droplet size distribution by laser diffraction | | |  | Acceptable | | | | | | | | | | | | | | | | | | | |
| | | | <table border="1"> <thead> <tr> <th>Sprayer type</th> <th>Mean diameter in volume (µm)</th> <th>Mean diameter in surface (µm)</th> <th>D(0.1) (µm)</th> <th>D(0.5) (µm)</th> <th>D(0.9) (µm)</th> </tr> </thead> <tbody> <tr> <td>Guala TS1 Foam v3</td> <td>273.3</td> <td>167.1</td> <td>88.07</td> <td>218.9</td> <td>547.6</td> </tr> <tr> <td>Guala TS3 Snapon fox std spray</td> <td>257</td> <td>146</td> <td>84.58</td> <td>187.8</td> <td>553.3</td> </tr> </tbody> </table> | Sprayer type | Mean diameter in volume (µm) | | | Mean diameter in surface (µm) | D(0.1) (µm) | D(0.5) (µm) | D(0.9) (µm) | Guala TS1 Foam v3 | 273.3 | 167.1 | 88.07 | 218.9 | 547.6 | Guala TS3 Snapon fox std spray | 257 | 146 | 84.58 | 187.8 | 553.3 | | | |
| | | | Sprayer type | Mean diameter in volume (µm) | Mean diameter in surface (µm) | | | D(0.1) (µm) | D(0.5) (µm) | D(0.9) (µm) | | | | | | | | | | | | | | | | |
| Guala TS1 Foam v3 | 273.3 | 167.1 | 88.07 | 218.9 | 547.6 | | | | | | | | | | | | | | | | | | | | | |
| Guala TS3 Snapon fox std spray | 257 | 146 | 84.58 | 187.8 | 553.3 | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------|-------------------------------------|---|---|---|----------------|-------|-------|-------|-----|------------------|-------|-------|------|-------|-------|------------|-------|-------|-------|-------|-----|--------------|-------|-----|-------|-------|-------|---------------------|-------|-------|-------|-------|-------|--|--|
| | | | <table border="1"> <tr> <td data-bbox="958 357 1084 459">Guala TS1 Foam v2</td> <td data-bbox="1084 357 1189 459">444.8</td> <td data-bbox="1189 357 1294 459">269.3</td> <td data-bbox="1294 357 1400 459">141.9</td> <td data-bbox="1400 357 1505 459">433.6</td> <td data-bbox="1505 357 1610 459">762</td> </tr> <tr> <td data-bbox="958 459 1084 561">Eproplast ST1204</td> <td data-bbox="1084 459 1189 561">208.2</td> <td data-bbox="1189 459 1294 561">95.01</td> <td data-bbox="1294 459 1400 561">54.7</td> <td data-bbox="1400 459 1505 561">134.8</td> <td data-bbox="1505 459 1610 561">483.9</td> </tr> <tr> <td data-bbox="958 561 1084 651">OpUs FO vi</td> <td data-bbox="1084 561 1189 651">496.7</td> <td data-bbox="1189 561 1294 651">392.2</td> <td data-bbox="1294 561 1400 651">245.9</td> <td data-bbox="1400 561 1505 651">481.7</td> <td data-bbox="1505 561 1610 651">448</td> </tr> <tr> <td data-bbox="958 651 1084 740">TR343 28-410</td> <td data-bbox="1084 651 1189 740">538.8</td> <td data-bbox="1189 651 1294 740">453</td> <td data-bbox="1294 651 1400 740">339.1</td> <td data-bbox="1400 651 1505 740">523.6</td> <td data-bbox="1505 651 1610 740">765.2</td> </tr> <tr> <td data-bbox="958 740 1084 842">Guala TS1 STD Spray</td> <td data-bbox="1084 740 1189 842">139.3</td> <td data-bbox="1189 740 1294 842">99.71</td> <td data-bbox="1294 740 1400 842">69.29</td> <td data-bbox="1400 740 1505 842">119.2</td> <td data-bbox="1505 740 1610 842">233.7</td> </tr> </table> | Guala TS1 Foam v2 | 444.8 | 269.3 | 141.9 | 433.6 | 762 | Eproplast ST1204 | 208.2 | 95.01 | 54.7 | 134.8 | 483.9 | OpUs FO vi | 496.7 | 392.2 | 245.9 | 481.7 | 448 | TR343 28-410 | 538.8 | 453 | 339.1 | 523.6 | 765.2 | Guala TS1 STD Spray | 139.3 | 99.71 | 69.29 | 119.2 | 233.7 | | |
| Guala TS1 Foam v2 | 444.8 | 269.3 | 141.9 | 433.6 | 762 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eproplast ST1204 | 208.2 | 95.01 | 54.7 | 134.8 | 483.9 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| OpUs FO vi | 496.7 | 392.2 | 245.9 | 481.7 | 448 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| TR343 28-410 | 538.8 | 453 | 339.1 | 523.6 | 765.2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Guala TS1 STD Spray | 139.3 | 99.71 | 69.29 | 119.2 | 233.7 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | Meta SPC 7, Product 7-x (1.44% w/w lactic acid), Batch COM23/META SPC7-X/2020-09-23/1 | Test with the spray packaging type GUALA TS1 STD Spray. 10% of the sprayed particles were found to be ≤ 67.87 µm. 50% of the sprayed particles were found to be ≤ 118.6 µm. 90% of the sprayed particles were found to be ≤ 218.3 µm. 0% of the sprayed particles were found to be smaller than 10 µm. |  | Acceptable | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Test performed by the trigger spray | Meta SPC 7, Product 7-x (1.44% w/w lactic acid), | Test with the spray packaging type SILGAN E23081 |  | Acceptable | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|--------------------|---|--|---|--|---|
| | packaging supplier | Batch 2020-01-14 | 10% of the sprayed particles were found to be ≤ 71.57 µm. 50% of the sprayed particles were found to be ≤ 131.19 µm. 90% of the sprayed particles were found to be ≤ 277.44 µm. 0.01% of the sprayed particles were found to be smaller than 10 µm. | | |
| | Particle size distribution – CIPAC MT 187 | Meta SPC 8, Product 8-2 (6% w/w lactic acid), Batch COM23/Meta SPC8-2/2020-11-20 | Test with the trigger spray type GUALA TS1 FOAM V2. 10% of the sprayed particles were found to be ≤ 339.5 µm. 50% of the sprayed particles were found to be ≤ 555.9 µm. 90% of the sprayed particles were found to be ≤ 808.7 µm. 0% of the sprayed particles were found to be smaller than 10 µm. | [REDACTED] [REDACTED] [REDACTED] | Acceptable |
| Persistent foaming | CIPAC MT 47.3 | Meta SPC 1, Product 1-3 (24% w/w lactic acid), Batch COM23 / Méta SPC 1-3 / 2020-01-21 | 0.5 % v/v: 700 mL of foam after 1 min and 12 min 20% v/v: out of limit, not measurable after 1 min and 12 min The foam production exceeds 60 mL. This is completely normal since the production of foam during use is a wanted trait of the product. On the products labels, a recommendation has been added for the product dilution step, | [REDACTED] [REDACTED] [REDACTED] | Acceptable The product is a foaming product and the recommendation on the labels of the products: "During the product dilution, pour almost all water first, then the product, then the |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|--|--|-------------------|---|
| | | | <p>according to which almost all water should be added first, then the product, then the remaining of the water. Videos were performed following this protocol and show that the production of foam is very limited in that case. Taking the above elements into account, the production of foam during the dilution step is deemed acceptable.</p> | | <p>remaining of the water." allow to avoid any overflow of the foam</p> |
| | | <p>Meta SPC 3, Product 3-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 3-2 / 2019-10-07</p> | <p>0.5% v/v: out of limit, not measurable 10% v/v: out of limit, not measurable</p> <p>The foam production exceeds 60 mL. This is completely normal since the production of foam during use is a wanted trait of the product. On the products labels, a recommendation has been added for the product dilution step, according to which almost all water should be added first, then the product, then the remaining of the water. Videos were performed following this protocol and show that the production of foam is very limited in that case. Taking the above elements into account, the production of foam during the dilution step is deemed acceptable. The max in use concentration (20%) has not been tested. However, considered the results at 10%, the persistent foaming at 20% is not expected to be different.</p> | <p>[Redacted]</p> | <p>Acceptable The product is a foaming product and the recommendation on the labels of the products state: "During the product dilution, pour almost all water first, then the product, then the remaining of the water." allow to avoid any overflow of the foam</p> |
| | | <p>Meta SPC 4, Product 4-1 (24% w/w</p> | <p>0.5% v/v: 84mL after 1min and 30 mL of foam after 12 min</p> | <p>[Redacted]</p> | <p>The product is a foaming product and</p> |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|---|--|-------------------|--|
| | | lactic acid), Batch COM 23 / Méta SPC 4-1 / 2020-04-24 | <p>19% v/v: out of limit, not measurable after 1 min and 12 min</p> <p>The foam production exceeds 60 mL. This is completely normal since the production of foam during use is a wanted trait of the product. On the products labels, a recommendation has been added for the product dilution step, according to which almost all water should be added first, then the product, then the remaining of the water. Videos were performed following this protocol and show that the production of foam is very limited in that case.</p> <p>Taking the above elements into account, the production of foam during the dilution step is deemed acceptable.</p> | <p>[REDACTED]</p> | <p>the recommendation on the labels of the products state: "During the product dilution, pour almost all water first, then the product, then the remaining of the water." allow to avoid any overflow of the foam</p> |
| | | Meta SPC 4, Product 4-1 (24% w/w lactic acid), Batch COM 23 / Méta SPC 4-1 / 2020-10-23 | <p>4% v/v: out of limit, not measurable</p> <p>20% v/v: out of limit, not measurable</p> <p>The foam production exceeds 60 mL. This is completely normal since the production of foam during use is a wanted trait of the product. On the products labels, a recommendation has been added for the product dilution step, according to which almost all water should be added first, then the product, then the remaining of the water. Videos were performed following this protocol and show that the production of foam is very limited in that case.</p> | <p>[REDACTED]</p> | <p>The product is a foaming product and the recommendation on the labels of the products state: "During the product dilution, pour almost all water first, then the product, then the remaining of the water." allow to avoid any overflow of the foam</p> |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|--|---|------------|---|
| | | | Taking the above elements into account, the production of foam during the dilution step is deemed acceptable. | | |
| | | Meta SPC 5, Product 5-x (28.8% w/w lactic acid), Batch COM 23 / MétaSPC 5-x / 2019-10-07 | 0.1% v/v: 50 mL of foam after 12 min 10% v/v: out of limit, not measurable The max in use concentration (18%) has not been tested. However, considered the results at 10%, the persistent foaming at 18% is not expected to be different. | [Redacted] | The product is a foaming product and the recommendation on the labels of the products state: "During the product dilution, pour almost all water first, then the product, then the remaining of the water." allow to avoid any overflow of the foam |
| | | Meta SPC 6, Product 6-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 6-2 / 2020-01-21 | 0.5% v/v: 0 mL of foam after 1min and 12 min 9% v/v: 6mL after 1min and 0 mL of foam after 12 min | [Redacted] | Acceptable |
| | | Meta SPC 10, Product 10-2 (28.8% w/w lactic acid), Batch COM23 / Méta SPC | 4% v/v: out of limit, not measurable after 1min and 12min 20% v/v: out of limit, not measurable after 1min and 12min | [Redacted] | The product is a foaming product and the recommendation on the labels of the products state: |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|---|----------------------|--|--|-----------|--|
| | | 10-2 / 2020-05-27 | The foam production exceeds 60 mL. This is completely normal since the production of foam during use is a wanted trait of the product. On the products labels, a recommendation has been added for the product dilution step, according to which almost all water should be added first, then the product, then the remaining of the water. Videos were performed following this protocol and show that the production of foam is very limited in that case. Taking the above elements into account, the production of foam during the dilution step is deemed acceptable. | | "During the product dilution, pour almost all water first, then the product, then the remaining of the water." allow to avoid any overflow of the foam |
| | | AL formulations | Not relevant for the formulation type. | | |
| Flowability/Pourability/Dustability | Waiver | Not relevant for the formulation types (AL, SL). | | | Not relevant |
| Burning rate – smoke generators | Waiver | Not relevant for the formulation types (AL, SL). | | | Not relevant |
| Burning completeness – smoke generators | Waiver | Not relevant for the formulation types (AL, SL). | | | Not relevant |
| Composition of smoke – smoke generators | Waiver | Not relevant for the formulation types (AL, SL). | | | Not relevant |
| Spraying pattern – aerosols | Waiver | Not relevant for the formulation types (AL, SL). | | | Not relevant |
| | | SL formulations | Not relevant for the formulation type. | | Not relevant |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|---|--|---|---|------------|----------------|
| Spraying properties of trigger sprayers | Spray pattern: Adapted FEA 644 Discharge rate and clogging: Internal method | Meta SPC 7, Product 7-x (1.44% w/w lactic acid), Batch COM23/META SPC7-X/2020-07-29/1 | Spray type GUALA TS1 Foam V3 <ul style="list-style-type: none"> Discharge rate = 0.616 mL/spray No blocking of the pump was observed Spray pattern: circular with a mean diameter of 17 cm | [REDACTED] | Acceptable |
| | Internal method | Meta SPC 7, Product 7-x (1.44% w/w lactic acid), Batch COM23/Meta SPC7-X/2020-10-21/1 | Spray type GUALA TS3 SNAPON FOX STD SPRAY <ul style="list-style-type: none"> Discharge rate = 1.276 mL/spray No dysfunction such as spilling, nozzle or trigger blockage was observed Spray pattern: circular with a mean diameter of 9.5 cm | [REDACTED] | Acceptable |
| | | | Spray type GUALA TS1 FOAM V2 <ul style="list-style-type: none"> Discharge rate = 0.63 mL/spray No dysfunction such as spilling, nozzle or trigger blockage was observed Spray pattern: circular with a mean diameter of 13.74 cm | [REDACTED] | Acceptable |
| | | | Spray type EPROPLAST ST1204 <ul style="list-style-type: none"> Discharge rate = 0.20 mL/spray No dysfunction such as spilling, nozzle or trigger blockage was observed Spray pattern: circular with a mean diameter of 7.7 cm | [REDACTED] | Acceptable |
| | | | Spray type OpUs FO vi <ul style="list-style-type: none"> Discharge rate = 1.42 mL/spray No dysfunction such as spilling, nozzle or trigger blockage was observed | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|---|---|------------|----------------|
| | | | <ul style="list-style-type: none"> Spray pattern: circular with a mean diameter of 6.75 cm | | |
| | | | Spray type TR343 28-410 <ul style="list-style-type: none"> Discharge rate = 1.496 mL/spray No dysfunction such as spilling, nozzle or trigger blockage was observed Spray pattern: circular with a mean diameter of 33.13 cm | [REDACTED] | Acceptable |
| | | | Spray type GUALA TS1 STD Spray <ul style="list-style-type: none"> Discharge rate = 0.636 mL/spray No dysfunction such as spilling, nozzle or trigger blockage was observed Spray pattern: circular with a mean diameter of 4.76 cm | [REDACTED] | Acceptable |
| | | Meta SPC 7, Product 7-x (1.44% w/w lactic acid), Batch 2020-01-14 | Spray type SILGAN E23081 <ul style="list-style-type: none"> Discharge rate = 1.25 mL/spray Spray patter: Circular with a mean diameter of 18 cm | [REDACTED] | Acceptable |
| | | Meta SPC 8, Product 8-2 (6% w/w lactic acid), Batch COM 23 / META | Spray type GUALA TS1 FOAM V2 <ul style="list-style-type: none"> Discharge rate = 0.661 mL/spray No dysfunction such as spilling, nozzle or trigger blockage was observed Spray pattern: circular with a mean diameter of 18.3 cm | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|--|------------------------------------|---|--|------------|----------------|
| | | SPC 8-2 / 2020-11-23 | | | |
| Physical compatibility | Waiver | No combined uses with other products is foreseen for the formulations of the family. Therefore, there is no need to prove physical or chemical compatibility. | | | Not relevant |
| Chemical compatibility | | | | | Not relevant |
| Degree of dissolution and dilution stability | CIPAC MT 41.1 (dilution stability) | Meta SPC 1, Product 1-3 (24% w/w lactic acid), Batch COM23 / Méta SPC 1-3 / 2020-01-21 | 20% v/v: no separated material | [REDACTED] | Acceptable |
| | | Meta SPC 3, Product 3-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 3-2 / 2019-10-07 | 10% v/v: no separated material The max in use concentration (20%) has not been tested. However, considered the results at 10%, the dilution stability at 20% is not expected to be different. | [REDACTED] | Acceptable |
| | | Meta SPC 4, Product 4-1 (24% w/w lactic acid), Batch COM 23 / Méta SPC 4-1 / 2020-10-23 | 20% v/v: no separated material | [REDACTED] | Acceptable |
| | | Meta SPC 5, Product 5-x | 10% v/v: no separated material | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|-----------------|------------------------|---|--|------------|----------------|
| | | (28.8% w/w lactic acid), Batch COM 23 / MétaSPC 5-x / 2019-10-07 | The max in use concentration (18%) has not been tested. However, considered the results at 10%, the dilution stability at 18% is not expected to be different. | [REDACTED] | |
| | | Meta SPC 6, Product 6-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 6-2 / 2020-01-21 | 9% v/v: no separated material | [REDACTED] | Acceptable |
| | | Meta SPC 10, Product 10-2 (28.8% w/w lactic acid), Batch COM23 / Méta SPC 10-2 / 2020-05-27 | 20% v/v: no separated material | [REDACTED] | Acceptable |
| | | AL formulations | Not relevant for the formulation type. | | Not relevant |
| Surface tension | OECD 115 (ring method) | Meta SPC 1, Product 1-3 (24% w/w lactic acid), Batch COM23 / Méta SPC 1-3 / 2020-01-21 | 30.38 mN/m at 20% v/v (20°C) | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|--|------------------------------|------------|----------------|
| | | Meta SPC 3, Product 3-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 3-2 / 2019-10-07 | 31.82 mN/m at 20% v/v (20°C) | [REDACTED] | Acceptable |
| | | Meta SPC 4, Product 4-1 (24% w/w lactic acid), Batch COM 23 / Méta SPC 4-1 / 2020-04-24 | 30.91 mN/m at 19% v/v (20°C) | [REDACTED] | Acceptable |
| | | Meta SPC 5, Product 5-x (28.8% w/w lactic acid), Batch COM 23 / MétaSPC 5-x / 2019-10-07 | 30.44 mN/m at 18% v/v (20°C) | [REDACTED] | Acceptable |
| | | Meta SPC 6, Product 6-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 6-2 / 2020-01-21 | 29.00 mN/m at 9% v/v (20°C) | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|---|--|------------|----------------|
| | | Meta SPC 7, Product 7-12 (1.44% w/w lactic acid), Batch COM 23 / Méta SPC 7-12 / 2020-09-02 | 29.65 mN/m for the neat product (20°C) | [REDACTED] | |
| | | Meta SPC 7, Product 7-17 (1.44% w/w lactic acid), Batch COM 23 / Méta SPC 7-17 / 2019-10-28 / 1 | 29.58 mN/m for the neat product (20°C) | [REDACTED] | Acceptable |
| | | Meta SPC 7, Product 7-x (1.44% w/w lactic acid), Batch COM 23 / MétaSPC 7-x / 2019-10-28 / 1 | 30.01 mN/m for the neat product (20°C) | [REDACTED] | Acceptable |
| | | Meta SPC 8, Product 8-2 (6% w/w lactic acid), Batch COM 23 / Méta | 28.44 mN/m for the neat product (20°C) | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|--|--|------------|----------------|
| | | SPC 8-2 / 2019-10-14 | | | |
| | | Meta SPC 8, Product 8-17 (6% w/w lactic acid), Batch COM 23 / Méta SPC 8-17 / 2020-10-27 / 1 | 29.42 mN/m for the neat product (20°C) | [REDACTED] | Acceptable |
| | | Meta SPC 9, Product 9-2 (2.9% w/w lactic acid), Batch COM 23 / Méta SPC 9-2 / 2019-10-10 | 30.60 mN/m for the neat product (20°C) | [REDACTED] | Acceptable |
| | | Meta SPC 9, Product 9-10 (2.9% w/w lactic acid), Batch COM 23 / Méta SPC 9-10 / 2019-10-28 / 1 | 28.58 mN/m for the neat product (20°C) | [REDACTED] | Acceptable |
| | | Meta SPC 10, Product 10-2 (28.8% w/w lactic acid), | 30.54 mN/m at 20% v/v (20°C) | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|-----------|---------------------------------|---|---|------------|----------------|
| | | Batch COM23 / Méta SPC 10-2 / 2020-05-27 | | [REDACTED] | |
| Viscosity | OECD 114 (capillary viscometer) | Meta SPC 1, Product 1-3 (24% w/w lactic acid), Batch COM23 / Méta SPC 1-3 / 2020-01-21 | 20°C: 7.65 mm ² /s 40°C: 4.20 mm ² /s | [REDACTED] | Acceptable |
| | | Meta SPC 3, Product 3-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 3-2 / 2019-10-07 | 20°C: 5.40 mm ² /s 40°C: 3.13 mm ² /s | [REDACTED] | Acceptable |
| | | Meta SPC 4, Product 4-1 (24% w/w lactic acid), Batch COM 23 / Méta SPC 4-1 / 2020-04-24 | 20°C: 6.00 mm ² /s 40°C: 3.37 mm ² /s | [REDACTED] | Acceptable |
| | | Meta SPC 5, Product 5-x (28.8% w/w lactic acid), | 20°C: 15.14 mm ² /s 40°C: 7.77 mm ² /s | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------|--|--|------------|----------------|
| | | Batch COM 23 / MétaSPC 5-x / 2019-10-07 | | | |
| | | Meta SPC 6, Product 6-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 6-2 / 2020-01-21 | 20°C: 3.03 mm ² /s 40°C: 1.75 mm ² /s | [REDACTED] | Acceptable |
| | | Meta SPC 7, Product 7-12 (1.44% w/w lactic acid), Batch COM 23 / Méta SPC 7-12 / 2020-09-02 | 20°C: 1.15 mm ² /s 40°C: 0.76 mm ² /s | [REDACTED] | |
| | | Meta SPC 7, Product 7-x (1.44% w/w lactic acid), Batch COM 23 / MétaSPC 7-x / 2019-10-28 / 1 | 20°C: 1.18 mm ² /s 40°C: 0.77 mm ² /s | [REDACTED] | Acceptable |
| | | Meta SPC 8, Product 8-2 (6% w/w lactic acid), | 20°C: 20.89 mm ² /s 40°C: 12.73 mm ² /s | [REDACTED] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------------------|--|--|------------|----------------|
| | | Batch COM 23 / Méta SPC 8-2 / 2019-10-14 | | [Redacted] | |
| | OECD 114 (rotational viscometer) | Meta SPC 8, Product 8-17 (6% w/w lactic acid), Batch COM 23 / Méta SPC 8-17 / 2020-10-27 / 1 | 20°C: 943.95 mm ² /s 40°C: 667.66 mm ² /s | [Redacted] | Acceptable |
| | OECD 114 (capillary viscometer) | Meta SPC 9, Product 9-2 (2.9% w/w lactic acid), Batch COM 23 / Méta SPC 9-2 / 2019-10-10 | 20°C: 23.21 mm ² /s 40°C: 14.29 mm ² /s | [Redacted] | Acceptable |
| | | Meta SPC 9, Product 9-10 (2.9% w/w lactic acid), Batch COM 23 / Méta SPC 9-10 / 2019-10-28 / 1 | 20°C: 69.23 mm ² /s 40°C: 40.29 mm ² /s | [Redacted] | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|----------|----------------------------------|--|--|------------|----------------|
| | OECD 114 (rotational viscometer) | Meta SPC 9, Product 9-10 (2.9% w/w lactic acid), Batch COM 23 / Méta SPC 9-10 / 2020-06-01 / 1 | 20°C: 192.84 mm ² /s 40°C: 178.44 mm ² /s | [REDACTED] | Acceptable |
| | OECD 114 (capillary viscometer) | Meta SPC 10, Product 10-2 (28.8% w/w lactic acid), Batch COM23 / Méta SPC 10-2 / 2020-05-27 | 20°C: 95.35 mm ² /s 40°C: 64.16 mm ² /s | [REDACTED] | Acceptable |

Conclusion on the physical, chemical and technical properties of the product

The products of the family are SL and AL formulations. The physical, chemical and technical properties of the products of the family were determined and found to be in compliance with the intended uses.

Accelerated storage studies are available to cover all Meta SPCs. After 8 weeks at 40°C or 2 weeks at 54°C, the active ingredient content was not changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging material (HDPE). Considering the types of formulation of the products (SL and AL) these results can be extrapolated to other claimed packaging material. The long term storage stability studies (24 months) are on-going. Interim results after 12 months or 6 months of storage show that the products are stable. The final reports of the long term storage studies should be provided in post authorisation. These reports should include technical properties after storage.

The labels of the products of Meta SPCs 1, 2, 3, 4, 5 and 10 state: "During the product dilution, pour almost all water first, then the product, then the remaining of the water." Indeed, the persistent foaming measured is out of limit for several Meta SPCs. However, additional data have been provided to show that the production of foam is very limited using this recommendation. The products of Meta SPC 1, 2, 8, 9 and 10 should not be stored above 40°C.

No cold storage studies were performed on the products of the family. It should be reported on the label: "Protect from frost" and "Keep away from direct sunlight".

The following sentences are required :

- Protect from frost.
 - Applicable to all products of the family.
- Keep away from direct sunlight.
 - Applicable to all products of the family.
- Do not store above 40°C.
 - Applicable to Meta SPCs 1, 2, 8, 9 and 10.
- During the product dilution, pour almost all water first, then the product, then the remaining of the water.
 - Applicable to Meta SPCs 1, 2, 3, 4, 5 and 10.
- Shelf-life = two years.
 - Applicable to all products of the family.

2.2.3 Physical hazards and respective characteristics

The product 5-x (from Meta SPC 5) has been tested for explosive properties, flammable liquids, self-reactive substances and mixtures and auto-ignition temperatures of products. This product has been considered representative of the worst-case of the family, as other products do not contain co-formulants at concentrations high enough to have an impact on tested properties. For each property, how the tested product(s) has/have been selected is detailed in each respective section.


| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|------------|-----------------------------------|--|---|------------|--|
| Explosives | Differential Scanning Calorimetry | Meta SPC 5, Product 5-x (28.8% w/w lactic acid), Batch COM23/REPRESNTATIVE PRODUCT FOR PHYSICHEM HAZARD/5-x/2020-07-13 | <p>Differential Scanning Calorimetry was used to determine the endothermic and exothermic reactions in test item during heating.</p> <p>Conditions: Crucibles with crimped lids Isotherm at about 25 °C for 5 min Heating phase from 25 °C to 600 °C at 5 °C/min</p> <p>No exothermic peak was observed up to 600 °C under the experimental conditions used. One endothermic peak was observed around 100°C probably associated to the water evaporation. Hence, according to the Guidance on the Application of the CLP Criteria, it can be concluded that the test item presents no potential for explosive properties. The test item has been considered representative of the worst-case of the family, since it contains the greatest concentration of co-formulants that might be associated with explosive properties in the family. Therefore, explosive properties are not anticipated for the products of the family.</p> | [REDACTED] | <p>Acceptable Products in BPF are not considered as explosive.</p> <p>Demonstration that this test cover the whole family is performed in confidential annex</p> |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|---------------------------------------|-----------------------------------|---|--|-----------|---|
| Flammable gases | Waiver | | | | Not relevant |
| Flammable aerosols | Waiver | | | | Not relevant |
| Oxidising gases | Waiver | | | | Not relevant |
| Gases under pressure | Waiver | | | | Not relevant |
| Flammable liquids | EC A.9 | Meta SPC 5, Product 5-x (28.8% w/w lactic acid), Batch COM23/REPRESENATIVE PRODUCT FOR PHYSCHEM HAZARD/5-x/2020-07-13 | No flash point was observed up to 150°C (boiling point). Therefore, the test item is not classified as a flammable liquid. Since the test item is a representative worst-case of the family (it contains the highest possible concentration of potentially flammable substances, mainly perfumes), it can be concluded that none of the products is a flammable liquid. | | Acceptable Products in BPF are not considered as flammable. |
| Flammable solids | Waiver | Not relevant because the products are liquid formulations. | | | Not relevant |
| Self-reactive substances and mixtures | Differential Scanning Calorimetry | Meta SPC 5, Product 5-x (28.8% w/w lactic acid), Batch COM23/REPRESENATIVE PRODUCT FOR PHYSCHEM HAZARD/5-x/2020-07-13 | Differential Scanning Calorimetry was used to determine the endothermic and exothermic reactions in test item during heating. Endothermic peaks will be characterized melting or boiling points, whereas exothermic peak will be characterized decomposition. No exothermic peak was observed up to 600 °C under the experimental conditions used. One endothermic peak was observed around 100°C probably associated to the water evaporation. Hence, according to the Guidance on the Application of the CLP Criteria, it can be | | Acceptable Products in BPF are not considered to have self-reactive properties. |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|--|----------------------|---|---|-----------|--|
| | | | concluded that the test item presents no potential for self-reactive properties. The test item is representative of the worst-case of the family, since it contains the greatest concentration of co-formulants that might be associated with self-reactive properties in the family. Therefore, self-reactive properties are not anticipated for the products of the family. | | |
| Pyrophoric liquids | Waiver | Experience in manufacture and has shown that the products are stable in air at room temperature for prolonged periods of time. Hence, the classification procedure does not need to be applied. | | | Acceptable Products in BPF are aqueous solutions. |
| Pyrophoric solids | Waiver | Not relevant because the products are liquid formulations. | | | Not relevant |
| Self-heating substances and mixtures | Waiver | Not relevant because the products are liquid at room temperature (i.e. their melting point is below 160 °C). | | | Acceptable |
| Substances and mixtures which in contact with water emit flammable gases | Waiver | The products are water-based formulations known to be stable in water. Hence, the classification procedure does not need to be applied. | | | Acceptable |
| Oxidising liquids | Waiver | No experimental study is available. Consideration of the structure indicates that L-(+)-lactic acid does not have oxidising properties. Moreover, the products are water-based formulations in which none of the co-formulants is classified as oxidising. According to CLP criteria (Annex I §2.14.4), "For organic substances or mixtures, the classification procedure for this class shall not apply if: (a) the substance or mixture does not contain oxygen, fluorine or chlorine; or | | | Acceptable Products of the BPF are not considered as oxidising liquids. |


| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | | | | | | | |
|---------------------|-------------------------|--|--|-----------|-------------------------|-----------|------|--------------------|-----|---------------|------|--|-------------------------|-----------|------|---------------|---|
| | | (b) the substance or mixture contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen. None of the components contain halogen atoms. Some components contain oxygen atoms, but those are only linked to carbon or hydrogen. It is therefore concluded that the products cannot be oxidising, and that this classification can be waived without testing. | | | | | | | | | | | | | | | |
| Oxidising solids | Waiver | Not relevant because the products are liquid formulations. | | | Not relevant | | | | | | | | | | | | |
| Organic peroxides | Waiver | The classification procedure does not need to be applied because the products do not fall under the definition of organic peroxides. | | | Not relevant | | | | | | | | | | | | |
| Corrosive to metals | UN C.1 | Meta SPC 1, 2 and 3 Product 2-1 (24% w/w lactic acid), Batch COM23/MetaSPC2 /Product2-1/2021-11-15 | 2 mm thickness aluminium and steel plates (50mm length, 20mm width) were exposed to the test item in defined conditions for 7 days at 55 °C ± 1 °C. For each material, one specimen was immersed, one was half way immersed and one was placed in the gaseous phase. The loss of mass for steel plates is summarized below: <table border="1"> <thead> <tr> <th></th> <th>Loss of mass (%)</th> </tr> </thead> <tbody> <tr> <td>Immersion</td> <td>16.7</td> </tr> <tr> <td>Half way immersion</td> <td>8.4</td> </tr> <tr> <td>Gaseous phase</td> <td>0.22</td> </tr> </tbody> </table> The loss of mass for aluminium plates is summarized below: <table border="1"> <thead> <tr> <th></th> <th>Loss of mass (%)</th> </tr> </thead> <tbody> <tr> <td>Immersion</td> <td>0.23</td> </tr> </tbody> </table> | | Loss of mass (%) | Immersion | 16.7 | Half way immersion | 8.4 | Gaseous phase | 0.22 | | Loss of mass (%) | Immersion | 0.23 | 21-907022-001 | Acceptable meta SPCs 1, 2 and 3 need to be classified as corrosive to metals H290. |
| | Loss of mass (%) | | | | | | | | | | | | | | | | |
| Immersion | 16.7 | | | | | | | | | | | | | | | | |
| Half way immersion | 8.4 | | | | | | | | | | | | | | | | |
| Gaseous phase | 0.22 | | | | | | | | | | | | | | | | |
| | Loss of mass (%) | | | | | | | | | | | | | | | | |
| Immersion | 0.23 | | | | | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | |
|--------------------|---------------------------------------|--|--|--------------------|---------------------------------------|---------------|------|--------------------|------|---------------|--|
| | | | <table border="1" data-bbox="1032 309 1379 429"> <tr> <td>Half way immersion</td> <td>0.14</td> </tr> <tr> <td>Gaseous phase</td> <td>0.17</td> </tr> </table> <p>Uniform corrosion was observed after the test, with a maximum mass loss of 16.7%, exceeding the classification threshold of 13.5%.</p> <p>Conclusion: product 2.1 is corrosive to metals and must be classified H290</p> <p>MetaSPC1, 2 and 3 can be considered to be covered by this test. See detail of read across in confidential part.</p> <p>meta SPCs 1, 2 and 3 need to be classified as corrosive to metals H290.</p> | Half way immersion | 0.14 | Gaseous phase | 0.17 | | | | |
| Half way immersion | 0.14 | | | | | | | | | | |
| Gaseous phase | 0.17 | | | | | | | | | | |
| | | Meta SPC 4 | <p>2 mm thickness aluminium and steel plates (50mm length, 20mm width) were exposed to the test item in defined conditions for 28 days at 55 °C ± 1 °C. For each material, one specimen was immersed, one was half way immersed and one was placed in the gaseous phase.</p> <p>The loss of mass for steel plates is summarized below:</p> <table border="1" data-bbox="1032 1246 1485 1406"> <thead> <tr> <th></th> <th>Loss of mass (%) after 28 days</th> </tr> </thead> <tbody> <tr> <td>Immersion</td> <td>15%</td> </tr> <tr> <td>Half way immersion</td> <td>8.8%</td> </tr> </tbody> </table> | | Loss of mass (%) after 28 days | Immersion | 15% | Half way immersion | 8.8% | 21-907022-005 | <p>Acceptable</p> <p>meta SPC 4 do not need to be classified as corrosive to metals.</p> |
| | Loss of mass (%) after 28 days | | | | | | | | | | |
| Immersion | 15% | | | | | | | | | | |
| Half way immersion | 8.8% | | | | | | | | | | |


| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | | | | | |
|--------------------|---------------------------------------|---|--|---|---|--|---------------------------------------|-----------|-----|--------------------|-----|---------------|-----|--|--|
| | | | <table border="1" data-bbox="1032 309 1485 368"> <tr> <td>Gaseous phase</td> <td>0.6%</td> </tr> </table> <p data-bbox="1032 405 1574 464">The loss of mass for aluminium plates is summarized below:</p> <table border="1" data-bbox="1032 469 1485 676"> <thead> <tr> <th></th> <th>Loss of mass (%) after 28 days</th> </tr> </thead> <tbody> <tr> <td>Immersion</td> <td>0.6</td> </tr> <tr> <td>Half way immersion</td> <td>0.3</td> </tr> <tr> <td>Gaseous phase</td> <td>0.1</td> </tr> </tbody> </table> <p data-bbox="1032 713 1536 772">Uniform corrosion was observed after the test.</p> <p data-bbox="1032 809 1547 938">Conclusion: loss of mass is below 51.5%, product 4.1 is not corrosive to metals and must not be classified corrosive to metal</p> <p data-bbox="1032 975 1507 1034">MetaSPC 4 can be considered to be covered by this test.</p> | Gaseous phase | 0.6% | | Loss of mass (%) after 28 days | Immersion | 0.6 | Half way immersion | 0.3 | Gaseous phase | 0.1 | | |
| Gaseous phase | 0.6% | | | | | | | | | | | | | | |
| | Loss of mass (%) after 28 days | | | | | | | | | | | | | | |
| Immersion | 0.6 | | | | | | | | | | | | | | |
| Half way immersion | 0.3 | | | | | | | | | | | | | | |
| Gaseous phase | 0.1 | | | | | | | | | | | | | | |
| | | Meta SPC 5-7-10 CONCENTRATED PRODUCT 28.8% LACTIC ACID, Batch COM23/CONCENTRATED PRODUCT | The test item is a fictive product representative of the highest concentration of lactic acid, without alkaline substance (as it brings the pH closer to neutrality) and without sequestering agent (as they also increase the pH). It covers products of meta SPCs 5, 7 and 10 without |  | Acceptable Meta SPCs 5, 7 and 10 without sequestering agent do not need to be classified as corrosive to metals. | | | | | | | | | | |


| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | | | | | | | | | | | |
|--------------------|-------------------------|--|--|-----------|-------------------------|-----------|-----|--------------------|-----|---------------|-----|--|-------------------------|-----------|-----|--------------------|-----|---------------|-----|--|--|
| | | 28.8% LACTIC ACID /2020-07-27/1 | <p>sequestering agent. See details of read across in confidential part.</p> <p>2 mm thickness aluminium and steel plates (50mm length, 20mm width) were exposed to the test item in defined conditions for 7 days at 55 °C ± 1 °C. For each material, one specimen was immersed, one was half way immersed and one was placed in the gaseous phase.</p> <p>The loss of mass for steel plates is summarized below:</p> <table border="1" data-bbox="1032 796 1382 1019"> <thead> <tr> <th></th> <th>Loss of mass (%)</th> </tr> </thead> <tbody> <tr> <td>Immersion</td> <td>3.6</td> </tr> <tr> <td>Half way immersion</td> <td>3.1</td> </tr> <tr> <td>Gaseous phase</td> <td>0.0</td> </tr> </tbody> </table> <p>The loss of mass for aluminium plates is summarized below:</p> <table border="1" data-bbox="1032 1117 1382 1329"> <thead> <tr> <th></th> <th>Loss of mass (%)</th> </tr> </thead> <tbody> <tr> <td>Immersion</td> <td>0.4</td> </tr> <tr> <td>Half way immersion</td> <td>0.3</td> </tr> <tr> <td>Gaseous phase</td> <td>0.1</td> </tr> </tbody> </table> | | Loss of mass (%) | Immersion | 3.6 | Half way immersion | 3.1 | Gaseous phase | 0.0 | | Loss of mass (%) | Immersion | 0.4 | Half way immersion | 0.3 | Gaseous phase | 0.1 | | |
| | Loss of mass (%) | | | | | | | | | | | | | | | | | | | | |
| Immersion | 3.6 | | | | | | | | | | | | | | | | | | | | |
| Half way immersion | 3.1 | | | | | | | | | | | | | | | | | | | | |
| Gaseous phase | 0.0 | | | | | | | | | | | | | | | | | | | | |
| | Loss of mass (%) | | | | | | | | | | | | | | | | | | | | |
| Immersion | 0.4 | | | | | | | | | | | | | | | | | | | | |
| Half way immersion | 0.3 | | | | | | | | | | | | | | | | | | | | |
| Gaseous phase | 0.1 | | | | | | | | | | | | | | | | | | | | |


| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | |
|----------|-------------------------|---|--|-----------|-------------------------|---|---|
| | | | <p>The maximum weight loss of the metal plates after 7 days was 3.6%, which is lower than the 13.5% limit. No localised corrosion was observed. Therefore, the test item does not need to be classified as corrosive to metals.</p> <p>In addition with results of study 20-907022-004 (below) Meta SPCs 5, 7 and 10 do not need to be classified as corrosive to metals.</p> | | | | |
| | | <p>Meta SPC 5-7-10</p> <p>CONCENTRATED PRODUCT 28.8% LACTIC ACID + SEQUESTERING AGENT, Batch COM23/CONCENTRATED PRODUCT 28.8% LACTIC ACID + SEQUESTERING AGENT/2020-07-28/1</p> | <p>The test item is a fictive product representative of the highest concentration of lactic acid, without alkaline substance (as it brings the pH closer to neutrality) and with sequestering agent.</p> <p>It covers products of meta SPC 5, 7 and 10 with sequestering agent. See details of read across in confidential part.</p> <p>2 mm thickness aluminium and steel plates (50mm length, 20mm width) were exposed to the test item in defined conditions for 7 days at 55 °C ± 1 °C. For each material, one specimen was immersed, one was half way immersed and one was placed in the gaseous phase.</p> <p>The loss of mass for steel plates is summarized below:</p> <table border="1" data-bbox="1028 1353 1379 1410"> <tr> <td data-bbox="1028 1353 1205 1410"></td> <td data-bbox="1205 1353 1379 1410">Loss of mass (%)</td> </tr> </table> | | Loss of mass (%) | <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> | <p>Acceptable</p> <p>Meta SPCs 5, 7 and 10 do not need to be classified as corrosive to metals.</p> |
| | Loss of mass (%) | | | | | | |


| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | | | | | | | | | |
|--------------------|-------------------------|---|--|---|---|--------------------|-----|---------------|-----|--|-------------------------|-----------|-----|--------------------|-----|---------------|-----|--|--|
| | | | <table border="1" data-bbox="1032 312 1384 469"> <tr> <td>Immersion</td> <td>4.2</td> </tr> <tr> <td>Half way immersion</td> <td>2.3</td> </tr> <tr> <td>Gaseous phase</td> <td>0.0</td> </tr> </table> <p data-bbox="1032 507 1574 564">The loss of mass for aluminium plates is summarized below:</p> <table border="1" data-bbox="1032 568 1384 778"> <thead> <tr> <th></th> <th>Loss of mass (%)</th> </tr> </thead> <tbody> <tr> <td>Immersion</td> <td>0.2</td> </tr> <tr> <td>Half way immersion</td> <td>0.1</td> </tr> <tr> <td>Gaseous phase</td> <td>0.1</td> </tr> </tbody> </table> <p data-bbox="1032 817 1574 1005">The maximum weight loss of the metal plates after 7 days was 4.2%, which is lower than the 13.5% limit. No localised corrosion was observed. Therefore, the test item does not need to be classified as corrosive to metals.</p> <p data-bbox="1032 1043 1574 1171">In addition with results of study 20-907022-003 (see study above) Meta SPCs 5, 7 and 10 do not need to be classified as corrosive to metals.</p> | Immersion | 4.2 | Half way immersion | 2.3 | Gaseous phase | 0.0 | | Loss of mass (%) | Immersion | 0.2 | Half way immersion | 0.1 | Gaseous phase | 0.1 | | |
| Immersion | 4.2 | | | | | | | | | | | | | | | | | | |
| Half way immersion | 2.3 | | | | | | | | | | | | | | | | | | |
| Gaseous phase | 0.0 | | | | | | | | | | | | | | | | | | |
| | Loss of mass (%) | | | | | | | | | | | | | | | | | | |
| Immersion | 0.2 | | | | | | | | | | | | | | | | | | |
| Half way immersion | 0.1 | | | | | | | | | | | | | | | | | | |
| Gaseous phase | 0.1 | | | | | | | | | | | | | | | | | | |
| | | Meta SPC 6, Product 6-1 (24% w/w lactic acid), Batch COM23/MétaSPC6 -1/2020-03-25 | The tested product is considered to cover meta SPC 6. see details of read across in confidential part. 2 mm thickness aluminium and steel plates (50mm length, 20mm width) |  | Acceptable Based on available data, the product is not classified for steel. | | | | | | | | | | | | | | |




| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | | | | | | | | | | | |
|--------------------|-------------------------|--|--|-----------|-------------------------|-----------|-----|--------------------|-----|---------------|-----|--|-------------------------|-----------|------|--------------------|-----|---------------|-----|--|--|
| | | | <p>were exposed to the test item in defined conditions for 7 days at 55 °C ± 1 °C. For each material, one specimen was immersed, one was half way immersed and one was placed in the gaseous phase.</p> <p>The loss of mass for steel plates is summarized below:</p> <table border="1" data-bbox="1032 600 1382 823"> <thead> <tr> <th></th> <th>Loss of mass (%)</th> </tr> </thead> <tbody> <tr> <td>Immersion</td> <td>4.3</td> </tr> <tr> <td>Half way immersion</td> <td>2.5</td> </tr> <tr> <td>Gaseous phase</td> <td>0.4</td> </tr> </tbody> </table> <p>The loss of mass for aluminium plates is summarized below:</p> <table border="1" data-bbox="1032 922 1382 1134"> <thead> <tr> <th></th> <th>Loss of mass (%)</th> </tr> </thead> <tbody> <tr> <td>Immersion</td> <td>11.2</td> </tr> <tr> <td>Half way immersion</td> <td>7.7</td> </tr> <tr> <td>Gaseous phase</td> <td>0.1</td> </tr> </tbody> </table> <p>The maximum weight loss of the metal plates after 7 days was 11.2%, which is lower than the 13.5% limit. The report states that no localised corrosion was observed. However, localised corrosion can be seen on the half way immersed plate of aluminium</p> | | Loss of mass (%) | Immersion | 4.3 | Half way immersion | 2.5 | Gaseous phase | 0.4 | | Loss of mass (%) | Immersion | 11.2 | Half way immersion | 7.7 | Gaseous phase | 0.1 | | <p>However, For aluminium, results obtained do not allow to conclude on the classification A new study was performed during 28 days(see below)</p> |
| | Loss of mass (%) | | | | | | | | | | | | | | | | | | | | |
| Immersion | 4.3 | | | | | | | | | | | | | | | | | | | | |
| Half way immersion | 2.5 | | | | | | | | | | | | | | | | | | | | |
| Gaseous phase | 0.4 | | | | | | | | | | | | | | | | | | | | |
| | Loss of mass (%) | | | | | | | | | | | | | | | | | | | | |
| Immersion | 11.2 | | | | | | | | | | | | | | | | | | | | |
| Half way immersion | 7.7 | | | | | | | | | | | | | | | | | | | | |
| Gaseous phase | 0.1 | | | | | | | | | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | |
|----------|-------------------------|---|---|-----------|-------------------------|---|--|
| | | | <p>after treatment (see below).</p>  <p>As the intrusion depth has not been measured, it is not possible to conclude on corrosive to metals properties of the product 6-1. The test was started over in a longer version of the test for aluminium (see below)</p> | | | | |
| | | <p>Meta SPC 6, Product 6-1 (24% w/w lactic acid), Batch COM23/MetaSPC6 /Product6-1/2021-11-15</p> | <p>The tested product is considered to cover meta SPC 6. see details of read across in confidential part.</p> <p>2 mm thickness aluminium plates (50mm length, 20mm width) were exposed to the test item in defined conditions for 28 days at 55 °C ± 1 °C. One specimen was immersed, one was half way immersed and one was placed in the gaseous phase.</p> <p>The loss of mass for aluminium plates is summarized below:</p> <table border="1" data-bbox="1032 1331 1382 1391"> <tr> <td data-bbox="1032 1331 1205 1391"></td> <td data-bbox="1205 1331 1382 1391">Loss of mass (%)</td> </tr> </table> | | Loss of mass (%) | <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> | <p>Acceptable</p> <p>Meta SPC 6 is classified H290</p> |
| | Loss of mass (%) | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | |
|--------------------|-------------------------|---|--|-----------|-------------------------|--------------------|------|---|---|--|--|
| | | | <table border="1" data-bbox="1032 312 1384 459"> <tr> <td>Immersion</td> <td>79.1</td> </tr> <tr> <td>Half way immersion</td> <td>47.4</td> </tr> <tr> <td>Gaseous phase</td> <td>0.12</td> </tr> </table> <p data-bbox="1032 496 1574 751">The maximal loss of mass recorded was 79.1% for the immersed steel plate which is higher than 51.5% for an exposure time of 28 days. Therefore, the test item is classified as corrosive to metals H290. Meta SPC 6 is therefore classified as corrosive to metals.</p> | Immersion | 79.1 | Half way immersion | 47.4 | Gaseous phase | 0.12 | | |
| Immersion | 79.1 | | | | | | | | | | |
| Half way immersion | 47.4 | | | | | | | | | | |
| Gaseous phase | 0.12 | | | | | | | | | | |
| | | <p data-bbox="770 823 1010 1110">Meta SPC 8, 9 Product 8-17 (6% w/w lactic acid), Batch COM23/RTU GEL PRODUCT 6% LACTIC ACID/2020-07-28/1</p> | <p data-bbox="1032 823 1554 919">The tested product is considered to cover meta SPC 8 and 9. see details of read across in confidential part.</p> <p data-bbox="1032 956 1574 1211">2 mm thickness aluminium and steel plates (50mm length, 20mm width) were exposed to the test item in defined conditions for 7 days at 55 °C ± 1 °C. For each material, one specimen was immersed, one was half way immersed and one was placed in the gaseous phase.</p> <p data-bbox="1032 1248 1496 1307">The loss of mass for steel plates is summarized below:</p> <table border="1" data-bbox="1032 1310 1384 1409"> <tr> <td></td> <td>Loss of mass (%)</td> </tr> <tr> <td>Immersion</td> <td>13.3</td> </tr> </table> | | Loss of mass (%) | Immersion | 13.3 |  | <p data-bbox="1823 823 2040 919">Acceptable for aluminium : not classified</p> <p data-bbox="1823 956 2063 1110">Not sufficient to conclude for steel A new study was performed (see below)</p> | | |
| | Loss of mass (%) | | | | | | | | | | |
| Immersion | 13.3 | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | | | | | | | |
|--------------------|-------------------------|---|---|---|--|---------------|-----|--|-------------------------|-----------|-----|--------------------|-----|---------------|-----|--|--|
| | | | <table border="1" data-bbox="1032 309 1384 427"> <tr> <td>Half way immersion</td> <td>6.5</td> </tr> <tr> <td>Gaseous phase</td> <td>0.0</td> </tr> </table> <p data-bbox="1032 464 1574 523">The loss of mass for aluminium plates is summarized below:</p> <table border="1" data-bbox="1032 523 1384 735"> <thead> <tr> <th></th> <th>Loss of mass (%)</th> </tr> </thead> <tbody> <tr> <td>Immersion</td> <td>0.4</td> </tr> <tr> <td>Half way immersion</td> <td>0.3</td> </tr> <tr> <td>Gaseous phase</td> <td>0.0</td> </tr> </tbody> </table> <p data-bbox="1032 807 1574 930">After the test, a maximum mass loss of 13.3% was observed, which is below the classification threshold of 13.5%. No localised corrosion was observed.</p> <p data-bbox="1032 970 1574 1129">However, due to the closeness of the mass loss compared to the classification threshold, a new study was carried out on the most sensitive metal (steel) with a longer test duration.</p> | Half way immersion | 6.5 | Gaseous phase | 0.0 | | Loss of mass (%) | Immersion | 0.4 | Half way immersion | 0.3 | Gaseous phase | 0.0 | | |
| Half way immersion | 6.5 | | | | | | | | | | | | | | | | |
| Gaseous phase | 0.0 | | | | | | | | | | | | | | | | |
| | Loss of mass (%) | | | | | | | | | | | | | | | | |
| Immersion | 0.4 | | | | | | | | | | | | | | | | |
| Half way immersion | 0.3 | | | | | | | | | | | | | | | | |
| Gaseous phase | 0.0 | | | | | | | | | | | | | | | | |
| | | Meta SPC 8, 9 Product 8-17 (6% w/w lactic acid), Batch COM23/MetaSPC8-17/2021-11-15/2 | 2 mm thickness aluminium and steel plates (50mm length, 20mm width) were exposed to the test item in defined conditions for 28 days at 55 °C ± 1 °C. For each material, one specimen was immersed, one was half way immersed |  | Acceptable Meta SPC 8 and 9 are not classified H290 | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment | | | | | | | | |
|--------------------|-------------------------|--|---|-------------------|-------------------------|-----------|------|--------------------|------|---------------|-----|--|--|
| | | | <p>and one was placed in the gaseous phase.</p> <p>The loss of mass for steel plates is summarized below:</p> <table border="1" data-bbox="1032 472 1384 692"><thead><tr><th data-bbox="1032 472 1205 533">Conditions</th><th data-bbox="1205 472 1384 533">Loss of mass (%)</th></tr></thead><tbody><tr><td data-bbox="1032 533 1205 571">Immersion</td><td data-bbox="1205 533 1384 571">27.8</td></tr><tr><td data-bbox="1032 571 1205 632">Half way immersion</td><td data-bbox="1205 571 1384 632">13.9</td></tr><tr><td data-bbox="1032 632 1205 692">Gaseous phase</td><td data-bbox="1205 632 1384 692">0.8</td></tr></tbody></table> <p>Localised corrosion: for the 3 plates, a few spot appear after 28 days but no localised corrosion was detected</p> <p>Immersion:</p>  <p>Half way immersion:</p> | Conditions | Loss of mass (%) | Immersion | 27.8 | Half way immersion | 13.9 | Gaseous phase | 0.8 | | |
| Conditions | Loss of mass (%) | | | | | | | | | | | | |
| Immersion | 27.8 | | | | | | | | | | | | |
| Half way immersion | 13.9 | | | | | | | | | | | | |
| Gaseous phase | 0.8 | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|--|----------------------|---|---|---|----------------|
| | | |  <p>Gaseous phase:</p>  <p>After the test, a maximum mass loss of 27.8% was observed, which is below the classification threshold of 51.5%. No localised corrosion was observed.</p> <p>Therefore, meta SPCs 8 and 9, both covered by the test item, should not be classified as corrosive to metals.</p> | | |
| Auto-ignition temperatures of products (liquids and gases) | | Meta SPC 5, Product 5-x (28.8% w/w lactic acid), Batch COM23/REPRES NTATIVE PRODUCT FOR | The auto-ignition temperature of the test item was 526 °C. Since the test item is a representative worst-case of the family (it contains the highest possible concentration of potentially flammable substances, mainly perfumes), it can be concluded that none of the products will have an |  | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | eCA assessment |
|---|----------------------|--|--|-----------|----------------|
| | | PHYSICHEM HAZARD/5-x/2020-07-13 | auto-ignition temperature (significantly) lower than 526°C and no hazard in terms of auto-ignition is expected for the products of the family. | | |
| Relative self-ignition temperature for solids | Waiver | Not relevant because the products are liquid formulations. | | | Not relevant |
| Dust explosion hazard | Waiver | Not relevant because the products are liquid formulations. | | | Not relevant |

Conclusion on the physical hazards and respective characteristics of the product

The products of the family are neither flammable nor auto-flammable. They have no explosive and no oxidizing properties.
 Products of meta SPC 1, 2, 3 and 6 are classified corrosive to metals (H290)
 Products of other meta SPC 4, 5, 7, 8, 9 and 10 are not classified as corrosive to metals (H290).

2.2.4 Methods for detection and identification

Active substance L-(+)-lactic acid – Method SOPa-LABCHI-512

The same method for the determination of lactic acid is used for all products. Only the dilution factor differs in order to reach the same range on concentrations in the samples injected into the HPLC system.

A validation of the analytical method was not performed on every formulation of the family, since the co-formulants are similar between many products. The following validations were performed:

- Complete validation (linearity, precision, accuracy, specificity) on the product 5-x of Meta SPC 5.
- Complete validation on the product 6-2 of Meta SPC 6.
- Complete validation on the product 7-x of Meta SPC 7.
- Complete validation on the product 8-17 of Meta SPC 8.
- Complementary validation (accuracy, specificity) on the product 1-3 of Meta SPC 1.
 - Covers Meta SPC 2 (identical composition except for an alkaline substance) and Meta SPC 3 (same coformulants but less concentrated in Meta SPC 3 than in Meta SPC 1).
- Complementary validation on the product 4-1 of Meta SPC 4.
- Complementary validation on the product 7-12 of Meta SPC 7. This product has been tested because of an additional coformulant.
 - Because it contains a specific co-formulant not found in the other formulations.
- Complementary validation on product 9-10 of Meta SPC 9.
- Complementary validation on product 10-2 of Meta SPC 10.

Moreover, since some co-formulants (mainly perfumes and dyes) were not covered by the above test items, 5 further complementary validations were performed on fictive mixtures containing the active substance and some of the previously uncovered co-formulants (so that all co-formulants are now covered).

The compositions of all tested products for the analytical quantification of L-(+) lactic acid are reported in a specific tab “analytical details” in the BPF overview table in the confidential annex.

Overview of the method

L-(+)-Lactic acid is determined by HPLC-UV using external calibration.

Column settings:


| | |
|--------------------|--|
| Column | AMINEX HPX-87H, 300 mm x 7.8 mm x 9 µm |
| Column temperature | 25°C |


| | |
|----------------------------------|--|
| Mobile phase | 4mM Sulphuric acid solution |
| Flow | 0.6 mL/min |
| Elution | Isocratic |
| Injection volume | 20 µL |
| Detector | 214 nm ± 4 nm |
| Run time | 20 min |
| L-(+)-Lactic acid retention time | Peak 1 about 11 min, Peak 2 about 12 min |


Sample preparation: see "Analytical method" column below.


Method validation


| 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 (%) | | | Limit of quantification (LOQ) or other limits | Reference |
| | | | | | Range | Mean | RSD | | |
| <i>L-(+)-lactic acid (active substance) in Meta SPC 5, Product 5-X (28.8% w/w lactic acid), Batch COM 23 / MétaSPC 5-x / 2019-10-07</i> | HPLC-UV. About 300 mg of test item were accurately (± 0.1 mg) weighed into a 50 ml volumetric flask and diluted to volume with milliQ water. 2.5 ml of this solution were diluted to | 14.35% w/w 28.99% w/w 42.7% w/w | 5 concentration levels, 1 reference solution per level. The response of the method was found to be linear between 199 and 607 mg/L L-(+)-Lactic acid (eq to 14.33% to 43.7%) – corresponding to 50% - 152% of the | In the Blank solution and in the Placebo solution no interferences were present at retention time of L-(+)-Lactic acid peaks. Two peaks belong to L-(+)-Lactic acid, peak 1 at about 11.17 minutes and peak 2 at about 11.95 minutes. They are both detected in the Reference and in the Test Solutions. The | 102 101 99 | 102 101 99 | 1.2 (< 1.62) for a mean concentration of 29.34% w/w in the product samples (based on 5 independent preparations of product samples) | Not required for active substances | |

| | | | | | | | | | |
|---|---|--|--|--|---------------------------|---------------------------|--|------------------------------------|---|
| | 10 ml with milliQ water. | | target concentration r = 1 y = 1379*x + 0 (the intercept was set to 0 because the confidence interval of the intercept includes 0). | retention times of the analyte peaks in the Reference Solution correspond to those of the analyte in the Test Solution. UV-vis spectra of L-(+)-Lactic acid peaks in the Reference and Test solutions are equivalent. Chromatograms of the blank solution, the placebo solution, the reference solution and the test solution were provided. | | | | | |
| L-(+)-lactic acid (active substance) in Meta SPC 6, Product 6-2 (24% w/w lactic acid), Batch COM 23 / Méta SPC 6-2 / 2020-01-21 | HPLC-UV. About 300 mg of test item were accurately (± 0.1 mg) weighed into a 50 ml volumetric flask and diluted to volume with milliQ water. 5.5 ml of this solution | 12.00% w/w 24.29% w/w 36.05% w/w | 5 concentration levels, 1 reference solution per level. The response of the method was found to be linear between 200 and 610 mg/L L-(+)-Lactic acid (eq to 12% to 37%) – corresponding | In the Blank solution and in the Placebo solution no interferences were present at retention time of L-(+)-Lactic acid peaks. Two peaks belong to L-(+)-Lactic acid, peak 1 at about 10.76 minutes and peak 2 at about 11.64 minutes. They are both detected in | 102 102 101 | 102 102 101 | 1.31 (< 1.66) for a mean concentration of 24.01% w/w in the product samples (based on 5 independent preparations of product samples) | Not required for active substances |  |


| | | | | | | | | | |
|---|---|---|--|---|--------------------------|--------------------------|--|------------------------------------|--|
| | were diluted to 20 ml with milliQ water. | | to 50% - 152% of the target concentration r = 1 y = 1375*x + 0 (the intercept was set to 0 because the confidence interval of the intercept includes 0). | the Reference and in the Test Solutions. The retention times of the analyte peaks in the Reference Solution correspond to those of the analyte in the Test Solution. UV-vis spectra of L-(+)-Lactic acid peaks in the Reference and Test solutions are equivalent. Chromatograms of the blank solution, the placebo solution, the reference solution and the test solution were provided. | | | | | |
| <i>L-(+)-lactic acid (active substance) in Meta SPC 7, Product 7-X (1.44% w/w lactic acid), Batch COM 23 / MétaSPC 7-x / 2019-10-28 / 1</i> | HPLC-UV. About 2750 mg of test item were accurately (± 0.01 mg) weighed into a 20 ml volumetric flask and diluted to | 0.74% w/w 1.48% w/w 2.18% w/w | 5 concentration levels, 1 reference solution per level. The response of the method was found to be linear between 193 and 608 mg/L L-(+)-Lactic | In the Blank solution and in the Placebo solution no interferences were present at retention time of L-(+)-Lactic acid peaks. Two peaks belong to L-(+)-Lactic acid, peak 1 at about 11.04 minutes and peak | 99 100 101 | 99 100 101 | 0.42 (< 2.54) for a mean concentration of 1.48% w/w measured in the product samples (based on 5 independent preparations of product samples) | Not required for active substances |  |


| | | | | | | | | | |
|---|---|---------------------------|--|--|-------------|-----|--|------------------------------------|---|
| | volume with milliQ water. 1 ml of this solution was diluted to 5 ml with milliQ water. | | acid- (eq to 0.69% to 2.19%) corresponding to 48% - 152% of the target concentration. r = 1 y = 1366*x + 0 (the intercept was set to 0 because the confidence interval of the intercept includes 0). | 2 at about 11.89 minutes. They are both detected in the Reference and in the Test Solutions. The retention times of the analyte peaks in the Reference Solution correspond to that of the analyte in the Test Solution. UV-vis spectra of L-(+)-Lactic acid peaks in the Reference and Test solutions are equivalent. Chromatograms of the blank solution, the placebo solution, the reference solution and the test solution were provided. | | | | | |
| <i>L-(+)-lactic acid (active substance) in Meta SPC 8, Product 8-17 (6% w/w lactic acid), Batch COM 23 / Méta SPC 8-17 / 2020-06-01 / 1</i> | HPLC-UV. About 650 mg of test item were accurately (± 0.01 mg) weighed into a 20 ml volumetric | 6.06% w/w (3 repetitions) | 5 concentration levels, 1 reference solution per level. The response of the method was found to be linear | In the Blank solution and in the Placebo solution no interferences were present at retention time of L-(+)-Lactic acid peaks. Two peaks belong to L-(+)-Lactic | 100-100-101 | 100 | 0.34 (< 2.05) for a mean concentration of 6.08% w/w measured in the product samples (based on 5 independent preparations | Not required for active substances |  |


| | | | | | | | | | |
|--|---|---|--|--|-----|-----|---|------------------------------------|---|
| | flask and diluted to volume with milliQ water. 4 ml of this solution were diluted to 20 ml with milliQ water. | | <p>between 201 and 602 mg/L L-(+)-Lactic acid (eq to 3.01% to 9.02%) corresponding to 50% - 150% of the target concentration.</p> <p>$r = 1$</p> <p>$y = 1376*x + 0$ (the intercept was set to 0 because the confidence interval of the intercept includes 0).</p> | <p>acid, peak 1 at about 10.76 minutes and peak 2 at about 11.62 minutes. They are both detected in the Reference and in the Test Solutions. The retention times of the analyte peaks in the Reference Solution correspond to that of the analyte in the Test Solution.</p> <p>UV-vis spectra of L-(+)-Lactic acid peaks in the Reference and Test solutions are equivalent.</p> <p>Chromatograms of the blank solution, the placebo solution, the reference solution and the test solution were provided.</p> | | | of product samples) | | |
| <i>L-(+)-lactic acid (active substance) in Meta SPC 1, Product 1-3 (24% w/w lactic acid), Batch COM 23 / Méta SPC 1-3 / 2020-01-21</i> | HPLC-UV. About 300 mg of test item were accurately (± 0.01 mg) weighed | <p>12.24% w/w</p> <p>24.31% w/w</p> <p>36.11% w/w</p> | Covered by product 6-2 | <p>In the Blank solution and in the Placebo solution no interferences were present at retention time of</p> | 102 | 102 | 0.84 (<1.66) for a mean concentration of 24.53% w/w measured in the product samples (based on 3 | Not required for active substances |  |


| | | | | | | | | | |
|---|---|--------------------------|------------------------|---|------------|------------|---|------------------------------------|---|
| | into a 50 ml volumetric flask and diluted to volume with milliQ water. 5.5 ml of this solution were diluted to 20 ml with milliQ water. | | | <p>L-(+)-Lactic acid peaks.</p> <p>Two peaks belong to L-(+)-Lactic acid, peak 1 at about 10.77 minutes and peak 2 at about 11.64 minutes. They are both detected in the Reference and in the Test Solutions. The retention times of the analyte peaks in the Reference Solution correspond to that of the analyte in the Test Solution.</p> <p>UV-vis spectra of L-(+)-Lactic acid peaks in the Reference and Test solutions are equivalent.</p> <p>Chromatograms of the blank solution, the placebo solution, the reference solution and the test solution were provided.</p> | | | independent preparations of product samples) | | |
| <i>L-(+)-lactic acid (active substance) in Meta SPC 4, Product 4-1 (24%</i> | HPLC-UV. About 300 mg of test item were | 12.41% w/w 23.97% w/w | Covered by product 6-2 | In the Blank solution and in the Placebo solution no | 102 101 | 102 101 | 1.07 (<1.66) for a mean concentration of 25.74% | Not required for active substances |  |



| | | | | | | | | | |
|---|---|-------------------|--|--|------------|------------|---|--|--|
| <p>w/w lactic acid), Batch COM 23 / Méta SPC 4-1 / 2020-02-17</p> | <p>accurately (± 0.01 mg) weighed into a 50 ml volumetric flask and diluted to volume with milliQ water. 5.5 ml of this solution were diluted to 20 ml with milliQ water.</p> | <p>36.18% w/w</p> | | <p>interferences were present at retention time of L-(+)-Lactic acid peaks. Two peaks belong to L-(+)-Lactic acid, peak 1 at about 10.81 minutes and peak 2 at about 11.67 minutes. They are both detected in the Reference and in the Test Solutions. The retention times of the analyte peaks in the Reference Solution correspond to that of the analyte in the Test Solution. UV-vis spectra of L-(+)-Lactic acid peaks in the Reference and Test solutions are equivalent. Chromatograms of the blank solution, the placebo solution, the reference solution and the test solution were provided.</p> | <p>101</p> | <p>101</p> | <p>w/w measured in the product samples (based on 3 independent preparations of product samples)</p> | | |
|---|---|-------------------|--|--|------------|------------|---|--|--|


| | | | | | | | | | |
|--|--|------------------------|-------------------------------|---|------------|------------|-------------------------------|---|---|
| <p><i>L-(+)-lactic acid (active substance) in Meta SPC 7, Product 7-12 (1.44% w/w lactic acid)</i></p> | <p>HPLC-UV. About 275 mg of test item were accurately (± 0.01 mg) weighed into a 20 ml volumetric flask and diluted to volume with milliQ water. 2 ml of this solution were diluted to 10 ml with milliQ water.</p> | <p>1.47% w/w (n=1)</p> | <p>Covered by product 7-x</p> | <p>In the Blank solution and in the Placebo solution no interferences were present at retention time of L-(+)-Lactic acid peaks. Two peaks belong to L-(+)-Lactic acid, peak 1 at about 10.6 minutes and peak 2 at about 11.5 minutes. They are both detected in the Reference and in the Test Solutions. The retention times of the analyte peaks in the Reference Solution correspond to that of the analyte in the Test Solution. UV-vis spectra of L-(+)-Lactic acid peaks in the Reference and Test solutions are equivalent. Chromatograms of the placebo solution, the reference solution and the test</p> | <p>100</p> | <p>100</p> | <p>Covered by product 7-x</p> | <p>Not required for active substances</p> |  |
|--|--|------------------------|-------------------------------|---|------------|------------|-------------------------------|---|---|


| | | | | | | | | |
|--|---|--|--|---|---|--|---|---|
| <p><i>L-(+)-lactic acid (active substance) in Meta SPC 9, Product 9-10 (2.9% w/w lactic acid), Batch COM 23 / Méta SPC 9-10 / 2019-10-28</i></p> | <p>HPLC-UV. / About 280 mg of test item were accurately (\pm 0.01 mg) weighed into a 20 ml volumetric flask and diluted to volume with milliQ water.</p> | | <p>Could be covered by products 7-x and 8-17</p> | <p>solution were provided. In the Blank solution and in the Placebo solution no interferences were present at retention time of L-(+)-Lactic acid peaks. Two peaks belong to L-(+)-Lactic acid, peak 1 at about 11.1 minutes and peak 2 at about 11.9 minutes. They are both detected in the Reference and in the Test Solutions. The retention times of the analyte peaks in the Reference Solution correspond to that of the analyte in the Test Solution. UV-vis spectra of L-(+)-Lactic acid peaks in the Reference and Test solutions are equivalent. Chromatograms of the blank solution, the</p> | <p>Covered by products 7-x and 8-17</p> | <p>2.03 (<2.28) for a mean concentration of 2.875% w/w measured in the product samples (based on 3 independent preparations of product samples)</p> | <p>Not required for active substances</p> |  |
|--|---|--|--|---|---|--|---|---|

| | | | | | | | | | |
|---|---|---------------------------|------------------------|---|-----------------------|-----|---|------------------------------------|---|
| | | | | placebo solution, the reference solution and the test solution were provided.. | | | | | |
| <i>L-(+)-lactic acid (active substance) in Meta SPC 10, Product 10-2 (28.8% w/w lactic acid), Batch COM 23 / Méta SPC 10-2 / 2020-05-27</i> | HPLC-UV. About 280 mg of test item were accurately (± 0.01 mg) weighed into a 50 ml volumetric flask and diluted to volume with milliQ water. 2.5 ml of this solution were diluted to 10 ml with milliQ water. | 28.9% w/w (3 repetitions) | Covered by product 5-x | In the Blank solution and in the Placebo solution no interferences were present at retention time of L-(+)-Lactic acid peaks. Two peaks belong to L-(+)-Lactic acid, peak 1 at about 10.77 minutes and peak 2 at about 11.62 minutes. They are both detected in the Reference and in the Test Solutions. The retention times of the analyte peaks in the Reference Solution correspond to that of the analyte in the Test Solution. UV-vis spectra of L-(+)-Lactic acid peaks in the Reference and Test solutions are equivalent. | 102 - 102 - 102 | 102 | 1.05 (<1.62) for a mean concentration of 28.6% w/w measured in the product samples (based on 3 independent preparations of product samples) | Not required for active substances |  |

| | | | | | | | | | |
|--|---|--|---------------------------------|--|-----------|-------|---------------------------------|------------------------------------|---|
| | | | | Chromatograms of the blank solution, the placebo solution, the reference solution and the test solution were provided. | | | | | |
| <i>L-(+)-lactic acid (active substance) in Mixture 1 (28.8% w/w lactic acid), Batch COM23/MétaSPC6-Mélange1/2020-10-16</i> | HPLC-UV. About 400 mg of test item were accurately (± 0.01 mg) weighed into a 50 ml volumetric flask and diluted to volume with water for HPLC. The solution was manually stirred then diluted 5 times with water. | 28.3% w/w (2 repetitions, 2 measurements per repetition) | Covered by the other test items | No peak appears in the solvent blank and in the formulation blank near the peaks of lactic acid. In the reference item and in the test item, the peaks at the retention times at about 11.1 min and 12.0 represent respectively lactic acid I and lactic acid II. No additional peak appears in the reference item and in the test item near the peaks of lactic acid. Chromatograms of the solvent blank, the formulation blank, the reference item and the test | 99.1-99.9 | 99.55 | Covered by the other test items | Not required for active substances |  |

| | | | | | | | | | |
|--|---|--|---------------------------------|--|-------------|--------|---------------------------------|------------------------------------|---|
| | | | | item were provided. | | | | | |
| <i>L-(+)-lactic acid (active substance) in Mixture 2 (28.8% w/w lactic acid), Batch COM23/MétaSPC6-Mélange2/2020-10-01</i> | HPLC-UV. About 400 mg of test item were accurately (± 0.01 mg) weighed into a 50 ml volumetric flask and diluted to volume with water for HPLC. The solution was manually stirred then diluted 5 times with water. | 28.3% w/w (2 repetitions, 2 measurements per repetition) | Covered by the other test items | No peak appears in the solvent blank and in the formulation blank near the peaks of lactic acid. In the reference item and in the test item, the peaks at the retention times at about 11.1 min and 12.0 represent respectively lactic acid I and lactic acid II. No additional peak appears in the reference item and in the test item near the peaks of lactic acid. Chromatograms of the solvent blank, the formulation blank, the reference item and the test item were provided. | 101.2-102.4 | 101.8 | Covered by the other test items | Not required for active substances |  |
| <i>L-(+)-lactic acid (active substance) in Mixture 3 (28.8% w/w lactic acid), Batch</i> | HPLC-UV. About 400 mg of test item were | 28.2% w/w (2 repetitions, 2 measurements per repetition) | Covered by the other test items | No peak appears in the solvent blank and in the formulation blank | 99.6-101.3 | 100.45 | Covered by the other test items | Not required for active substances |  |

| | | | | | | | | | |
|--|--|---|--|--|------------------|--------------|--|---|---|
| <p>COM23/MétaSPC6-mélange3</p> | <p>accurately (\pm 0.01 mg) weighed into a 50 ml volumetric flask and diluted to volume with water for HPLC. The solution was manually stirred then diluted 5 times with water.</p> | | | <p>near the peaks of lactic acid. In the reference item and in the test item, the peaks at the retention times at about 10.7 min and 11.9 represent respectively lactic acid I and lactic acid II. No additional peak appears in the reference item and in the test item near the peaks of lactic acid. Chromatograms of the solvent blank, the formulation blank, the reference item and the test item were provided.</p> | | | | | |
| <p>L-(+)-lactic acid (active substance) in Mixture 4 (28.8% w/w lactic acid), Batch COM23/MétaSPC6-mélange4/2020-10-02</p> | <p>HPLC-UV. About 400 mg of test item were accurately (\pm 0.01 mg) weighed into a 50 ml volumetric</p> | <p>27.9% w/w (2 repetitions, 2 measurements per repetition)</p> | <p>Covered by the other test items</p> | <p>No peak appears in the solvent blank and in the formulation blank near the peaks of lactic acid. In the reference item and in the test item, the peaks at the retention times at</p> | <p>99.7-99.6</p> | <p>99.65</p> | <p>Covered by the other test items</p> | <p>Not required for active substances</p> |  |

| | | | | | | | | | |
|--|---|--|---------------------------------|--|-----------|------|---------------------------------|------------------------------------|---|
| | flask and diluted to volume with water for HPLC. The solution was manually stirred then diluted 5 times with water. | | | about 11.1 min and 12.0 represent respectively lactic acid I and lactic acid II. No additional peak appears in the reference item and in the test item near the peaks of lactic acid. Chromatograms of the solvent blank, the formulation blank, the reference item and the test item were provided. | | | | | |
| <i>L-(+)-lactic acid (active substance) in Mixture 5 (28.8% w/w lactic acid), Batch COM23/MétaSPC6-mélange5/2020-10-05/1</i> | HPLC-UV. About 400 mg of test item were accurately (± 0.01 mg) weighed into a 50 ml volumetric flask and diluted to volume with water for HPLC. The solution | 28.3% w/w (2 repetitions, 2 measurements per repetition) | Covered by the other test items | No peak appears in the solvent blank and in the formulation blank near the peaks of lactic acid. In the reference item and in the test item, the peaks at the retention times at about 11.2 min and 12.0 represent respectively lactic acid I and lactic acid II. | 97.2-97.6 | 97.4 | Covered by the other test items | Not required for active substances |  |

| | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|
| | was manually stirred then diluted 5 times with water. | | | No additional peak appears in the reference item and in the test item near the peaks of lactic acid. Chromatograms of the solvent blank, the formulation blank, the reference item and the test item were provided. | | | | | |
|--|---|--|--|--|--|--|--|--|--|

| 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 | | |
| Not required because relevant residues arising from the application of L(+) lactic acid are not expected. | | | | | | | | | |

| 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 | | |
| Not required because relevant residues arising from the application of L(+) lactic acid are not expected. | | | | | | | | | |

| 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 | | |
| | | | | | | | | | |

| active substance) | measurements | other limits |
|---|--------------|--------------|
| Not required because relevant residues arising from the application of L(+) lactic acid are not expected. | | |

| 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 because L(+) lactic acid is not classified as toxic or very toxic. | | | | | | | | | |

| 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 because relevant residues arising from the application of L(+) lactic acid are not expected. | | | | | | | | | |

| Conclusion on the methods for detection and identification of the product |
|--|
| <p>An analytical method was developed and validated for the determination of the active substance L-(+)-lactic acid in the formulations of the family. It was shown to possess sufficient analytical qualities in terms of linearity, precision, accuracy and specificity.</p> <p>Residue analytical methods for L(+) lactic acid in food of plant and animal origin, in soil, air, drinking and surface water are not required. Since L(+)lactic acid is not classified as toxic or very toxic, analytical methods in body fluids and tissues are not required.</p> |

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

MG 01: Disinfectants

PT2: Disinfectants and algacides not intended for direct application to humans or animals

PT4: Food and feed area.

The biocidal family FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS is a PT2 and PT4 biocidal family for both professional and non-professional users. The family includes several products, and related uses, which were separated in ten Meta SPCs:

- Meta SPC 1, 2, 3, 4 and 6 include soluble concentrate liquid products at 24 % w/w L(+) lactic acid.
- Meta SPC 5, 10 include soluble concentrate liquid products at 28.8 % w/w L(+) lactic acid.
- Meta SPC 7 includes ready-to use products at 1.44 % w/w L(+) lactic acid.
- Meta SPC 8 includes ready-to use products at 6 % w/w L(+) lactic acid.
- Meta SPC 9 includes ready-to use products at 2.9 % w/w L(+) lactic acid.

The uses claimed by the applicant are:

- Use #1: Disinfection of hard surfaces and equipment by manual liquid spraying (PT2) - Meta SPC 1, Meta SPC 2, Meta SPC 3, Meta SPC 4, Meta SPC 5 and Meta SPC 6
- Use #2: Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) (PT2) - Meta SPC 1, Meta SPC 2, Meta SPC 3, Meta SPC 4, Meta SPC 5 and Meta SPC 6
- Use #3: Disinfection of equipment by manual dipping/soaking (PT2) - Meta SPC 1, Meta SPC 2, Meta SPC 3, Meta SPC 4, Meta SPC 5 and Meta SPC 6
- Use #4: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT2) - Meta SPC 1, Meta SPC 2, Meta SPC 3, Meta SPC 4, Meta SPC 5 and Meta SPC 6
- Use #5: Disinfection of equipment by automatic application in cleaning washer (PT2) - Meta SPC 6
- Use #6: Disinfection of cleaning washer by automatic application (PT2) - Meta SPC 6
- Use #7: Disinfection of inner surfaces by CIP (PT2) - Meta SPC 6
- Use #8: Not claimed anymore.
- Use #9: Disinfection of hard surfaces and equipment by manual liquid spraying (PT4) - Meta SPC 1, Meta SPC 2, Meta SPC 3, Meta SPC 4, Meta SPC 5 and Meta SPC 6
- Use #10: Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) (PT4) - Meta SPC 1, Meta SPC 2, Meta SPC 3, Meta SPC 4, Meta SPC 5 and Meta SPC 6
- Use #11: Disinfection of equipment by manual dipping/soaking (PT4) - Meta SPC 1, Meta SPC 2, Meta SPC 3, Meta SPC 4, Meta SPC 5, Meta SPC 6 and Meta SPC 10
- Use #12: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT4) - Meta SPC 1, Meta SPC 2, Meta SPC 3, Meta SPC 4, Meta SPC 5 and Meta SPC 6

- Use #13: Disinfection of equipment by dish washing machine and crate washer (PT4) - Meta SPC 6
- Use #14: Disinfection of dish washing machine and crate washer (PT4) - Meta SPC 6
- Use #15: Disinfection of inner surfaces by CIP (PT4) - Meta SPC 6
- Use #16: Not claimed anymore.
- Use #17: - Disinfection of hard surfaces and equipment by manual liquid spraying (PT2) - Meta SPC 7
- Use #18: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT2) - Meta SPC 7 and Meta SPC 8
- Use #19: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT2) - Meta SPC 7, Meta SPC 8 and Meta SPC 9
- Use #20: Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding (PT2) - Meta SPC 7, Meta SPC 8 and Meta SPC 9
- Use #21: Disinfection of hard surfaces and equipment by manual liquid spraying (PT4) - Meta SPC 7
- Use #22: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT4) - Meta SPC 7
- Use #23: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT4) - Meta SPC 7, Meta SPC 8 and Meta SPC 9
- Use #24: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT2) - Meta SPC 7
- Use #25: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT2) - Meta SPC 7, Meta SPC 8 and Meta SPC 9
- Use #26: Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding (PT2) - Meta SPC 7, Meta SPC 8 and Meta SPC 9
- Use #27: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT4) - Meta SPC 7
- Use #28: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT4) - Meta SPC 7, Meta SPC 8 and Meta SPC 9
- Use #29: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT2) - Meta SPC 1, Meta SPC 4 and Meta SPC 5
- Use #30: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT2) - Meta SPC 1, Meta SPC 4 and Meta SPC 5
- Use #31: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT4) - Meta SPC 1, Meta SPC 4 and Meta SPC 5
- Use #32: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT4) - Meta SPC 1, Meta SPC 4 and Meta SPC 5
- Use #33: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT2) - Meta SPC 1, Meta SPC 4 and Meta SPC 5
- Use #34: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT4) - Meta SPC 1, Meta SPC 4 and Meta SPC 5
- Use #35: Disinfection of the inner surfaces of small kitchen appliances without circulation (PT4) - Meta SPC 6
- Use #36: Disinfection of the inner surfaces of small kitchen appliances by CIP (PT4) - Meta SPC 6

All uses are claimed without mechanical action.

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

The biocidal product family is used to disinfect hard surfaces and/or equipments and furnitures. They are intended to be used against bacteria and yeasts for all the Meta SPCs, as well as viruses for the Meta SPCs 4, 5 and 7.

2.2.5.3 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 viral particles (virucidal activity) of relevant test organisms under defined conditions.

2.2.5.4 Mode of action, including time delay

The dissociation degree of Lactic acid in solution depends on pH value. In contact of undissociated form of Lactic acid with biological materials, such as micro-organisms, the Lactic acid is able to pass the cells membrane. At a relatively low pH, the Lactic acid inhibits the pathogens through the penetration of the undissociated form across the membrane, which interferes with the metabolic functions of the pathogen. The decrease in the intracellular pH causes dissipation of the membrane and leads to membrane disruption.

Therefore, the mode of action for this product is inhibiting of cells growth and biomass producing and finally cells are destroyed.

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

2.2.5.5 Efficacy data

1- Inactivity of co-formulants (see composition of the family in the confidential PAR)

Efficacy tests have been provided to demonstrate the non-activity of one co-formulant present in the composition of the family.

The results and conclusions of these tests are presented in the confidential section of the PAR.

2- Efficacy of the product family "FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS"

Laboratory studies were conducted with representative products of "FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS" according to the Guidance on BPR, Volume II Efficacy – Assessment and Evaluation (Parts B+C).

Efficacy studies are provided for assessing the efficacy of the "FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS" products and are summarised Meta SPC by Meta SPC for more readability.

These studies are:

- quantitative suspension tests (phase 2, step 1) for bactericidal, yeasticidal and virucidal efficacy,

- quantitative non-porous surface tests (phase 2, step 2) for bactericidal and yeasticidal efficacy (no P2S2 test is available for virus at the time of the submission of the dossier).

Please note that in some phase 2 step 1 efficacy studies on bacteria and yeasts, flocs appeared when mixing the microorganisms inoculum with the product. In such a case, the actual effective concentration was considered to be the lowest effective concentration without any floc upon mixing with the product.

However, in cases where flocs appeared at all effective concentrations in P2S1 tests (but all controls are validated), the effective concentration determined in the corresponding phase 2 step 2 tests have been used. Indeed, as indicated in these norms "counting microorganisms embedded in a precipitate or flocculant is difficult and unreliable".

Also, for the EN 14476 tests performed on product 5-1 (LSN 5-1) and product 7-1 (LSN 7-1) on rotavirus, small precipitation occurred. Based on the EN14476 norm, this minor deviation should be reported but does not invalidate the tests.

For the concentrate products and for the fields of use involving professionals in agrifood industries (PT4), all the activities are individually detailed by the applicant. Indeed, according to the applicant for these uses "the user can select the relevant concentration and contact time depending on the target organism, as stated in the Technical agreements for biocides EFF V2.2 (entry 14)".

However, it is clearly indicated in the TAB entry 14 that "contact time and dose can be differentiated for bacteria and yeast for professional users, if sufficiently justified in the PAR.". Considering that the claimed PT4 uses are general surface disinfection and that no specific justification was provided, eCA considered that the validated application rate and contact time for these uses should cover all mandatory organisms (bacteria and yeasts).

- **Meta SPC 1**

For META-SPC1, no variation occurs, except minor variations of perfumes and sequestering agent. Efficacy tests have been performed with the representative product 1-x (without perfumes and sequestering agent).

The composition of this test item is presented in the confidential section of the PAR with a justification regarding its representativeness of the Meta SPC 1.

Taking into account the variations of the co-formulants presented in this META-SPC, it can be assumed that they have no impact on efficacy and the efficacy results of this representative product is representative of products within this META-SPC.

The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

| 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 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC1 – Product 1-x (24% w/w lactic acid) Batch: COM23-1-x-2020-02-19 | <u>Bacteria</u> <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 4% v/v. Remarks: - Presence of small flocs at 3, 2 and 1% dilutions. - Homogeneous at 0.5% and 4%. The lowest effective concentration without flocculation was retained for each target organism. | COM23/METASPC1 /PRODUCT1-X – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20 °C Report No 20/000159213 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC1 – Product 1-x (24% w/w lactic acid) Batch: COM23/META SPC1-X/2020-07-17/1 | <u>Bacteria</u> <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>E. coli</i> , <i>S. Typhimurium</i> , <i>E. cloacae</i> , <i>L. brevis</i> and <i>L. monocytogenes</i> demonstrated at 3% v/v. Activity against <i>C. jejuni</i> demonstrated at 0.5% v/v. | COM23/METASPC1 -X – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Report No 20/000447272 R.I.: 2 (no inactive dilution for <i>C. jejuni</i>) |

| | | | | | | | |
|-----------------------|--|---|--|-----------------------------|--|--|--|
| | | | <i>L. monocytogenes</i> ATCC 19115 <i>C. jejuni</i> ATCC 33560 | | | | |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC1 – Product 1-x (24% w/w lactic acid) Batch: COM23/META SPC1-X/2020-07-17/1 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <i>E. coli</i> ATCC 10536 <i>E. faecium</i> ATCC 6057 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 <i>L. monocytogenes</i> ATCC 19115 <i>C. jejuni</i> ATCC 33560 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> , <i>E. coli</i> , <i>S. Typhimurium</i> , <i>E. cloacae</i> , <i>L. brevis</i> and <i>L. monocytogenes</i> demonstrated at 4% v/v. Activity against <i>C. jejuni</i> demonstrated at 0.5% v/v. Remarks: - Presence of small flocs at 3% dilution. - Homogeneous at 0.5 and 4%. The lowest effective concentration without flocculation was retained for each target organism. | COM23/METASPC1-X – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Report No 20/000447272 R.I.: 2 (no inactive dilution for <i>E. coli</i> and <i>C. jejuni</i>) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC1 – Product 1-x (24% w/w lactic acid) | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (surface test) Concentration tested: 4%, 5%, 6%, 8% and 10% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 6% v/v. | COM23/METASPC1/PRODUCT1-X – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C |

| | | | | | | | |
|-----------------------|---|---|---|--------------------------------------|--|---|--|
| | | Batch: COM23-1-x- 2020-02-19 | <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | | Contact time: 15 min Criteria: at least a 4 log reduction | | Report No 20/000159213 R.I.: 2 (no inactive dilution for <i>E. coli</i> <i>K12</i> , <i>P. aeruginosa</i> and <i>E. hirae</i>) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC1 – Product 1-x (24% w/w lactic acid) Batch: COM23/META SPC1- X/2020-07- 17/1 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC <i>10536</i> <u>Additional strains</u> <i>S. Typhimurium</i> <i>ATCC 13311</i> <i>E. cloacae</i> DSM <i>6234</i> <i>L. brevis</i> DSM <i>6235</i> <i>L.</i> <i>monocytogenes</i> <i>ATCC 19115</i> <i>C. jejuni</i> ATCC <i>33560</i> | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (surface test) Concentration tested: 0.5%, 5% and 6% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>E.</i> <i>coli</i> , <i>C. jejuni</i> , <i>E.</i> <i>cloacae</i> , and <i>L.</i> <i>monocytogenes</i> demonstrated at 5% v/v. Activity against <i>S.</i> <i>Typhimurium</i> demonstrated at 0.5% v/v. Activity against <i>L.</i> <i>brevis</i> is not demonstrated. | COM23/METASPC1 -X – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C Report No 20/000447272 R.I.: 2 (no inactive dilution for <i>S.</i> <i>Typhimurium</i>) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC1 – Product 1-x (24% w/w lactic acid) Batch: COM23/META SPC1- X/2020-07- 17/1 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <i>E. faecium</i> ATCC 6057 <u>Additional strains</u> | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (surface test) Concentration tested: 0.5%, 1%, 1.5%, 2% and 2.5% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>P.</i> <i>aeruginosa</i> , <i>S.</i> <i>aureus</i> , <i>E. hirae</i> , <i>E.</i> <i>coli</i> K12 and <i>E.</i> <i>faecium</i> demonstrated at 2.5% v/v. | COM23/METASPC1 /PRODUCT1-X – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Report No 20/000159213 R.I.: 2 (no inactive dilution for <i>P.</i> <i>aeruginosa</i> and <i>E.</i> <i>coli</i> K12) |

| | | | | | | | |
|-----------------------|--|---|---|-----------------------------|---|---|---|
| | | | <i>E. coli</i> K12 NCTC 10538 | | | | |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC1 – Product 1-x (24% w/w lactic acid) Batch: COM23/META SPC1-X/2020-07-17/1 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 <i>L. monocytogenes</i> ATCC 19115 <i>C. jejuni</i> ATCC 33560 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (surface test) Concentration tested: 0.5%, 2% and 2.5% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>L. brevis</i> and <i>L. monocytogenes</i> demonstrated at 2% v/v. Activity against <i>E. coli</i> , <i>C. jejuni</i> , <i>S. Typhimurium</i> , and <i>E. cloacae</i> demonstrated at 0.5% v/v. | COM23/METASPC1-X – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Report No 20/000447272 R.I.: 2 (no inactive dilution for <i>E. coli</i> , <i>C. jejuni</i> , <i>S. Typhimurium</i> , and <i>E. cloacae</i>) |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC1 – Product 1-x (24% w/w lactic acid) Batch: COM23-1-x-2020-02-19 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 1650:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 6%, 7%, 8%, 9% and 10% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 10% v/v. | COM23/METASPC1/PRODUCT1-X – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 20°C Report No 20/000159213 R.I.: 1 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC1 – Product 1-x (24% w/w lactic acid) | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 1650:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 2%, 3%, 3.5% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C | Yeasticidal activity demonstrated at 4% v/v. Remarks: - Presence of small flocs at 3.5%, 3% and 2% dilutions. | COM23/METASPC1/PRODUCT1-X – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 40°C Report No |

| | | | | | | | |
|----------------------|--|--|---|-----------------------------|--|--|---|
| | | Batch: COM23-1-x- 2020-02-19 | | | Contact time: 15 min Criteria: at least a 4 log reduction | - Homogeneous at 1 and 4%. The lowest effective concentration without flocculation was retained for each target organism. | 20/000159213 R.I.: 2 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC1 – Product 1-x (24% w/w lactic acid) Batch: COM23/Méta SPC1/Product 1-x/2020-10-06 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 14%, 16%, 18% and 19% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 18% v/v. | Yeasticidal activity of product Com 23 – Product 1-X in accordance with the European standard EN 13697 (July 2019) Dirty conditions – 20°C Report No R20201022-EN13697 20°C 15min Product 1-X R.I.: 1 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC1 – Product 1-x (24% w/w lactic acid) Batch: COM23/Méta SPC1/Product 1-x/2020-10-06 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 6%, 7% and 8% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 8% v/v. | Yeasticidal activity of product Com 23 – Product 1-X in accordance with the European standard EN 13697 (July 2019) Dirty conditions – 40°C Report No R20201022-EN13697 40°C 15min Product 1-X R.I.: 1 |

General disinfection PT2/PT4 (20°C):

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 6% v/v.
- additional bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
 - o 5% v/v for *Enterobacter cloacae*
 - o 3% v/v for *Salmonella* Typhimurium
 - o 5% v/v for *Campylobacter jejuni*
 - o 5% v/v for *Listeria monocytogenes*
- Activity against *L. brevis* is not demonstrated in phase 2, step 2 test (EN 13697) at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin).
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 18% v/v.

General disinfection PT2/PT4 (40°C):

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 4% v/v.
- additional bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
 - o 4% v/v for *Enterobacter cloacae*
 - o 4% v/v for *Salmonella* Typhimurium
 - o 4% v/v for *Lactobacillus brevis*
 - o 0.5% v/v for *Campylobacter jejuni*
 - o 4% v/v for *Listeria monocytogenes*
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 8% v/v.

Conclusion on the efficacy of the product – Meta SPC 1

The products of the family "FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS", have shown a sufficient efficacy in accordance with the Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 for the following uses:

META-SPC 1

- o Use 1: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 02) – except health care facilities

- Use 2: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 02) – except health care facilities
- Use 3: Disinfection of equipment by manual dipping/soaking (PT 02) (without mechanical action) – except health care facilities
- Use 4: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) – except health care facilities
- Use 9: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 04)
- Use 10: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 04)
- Use 11: Disinfection of equipment by manual dipping/soaking (PT 04)
- Use 12: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 04)
- Use 29: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 02)
- Use 30: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02)
- Use 31: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 04)
- Use 32: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 04)
- Use 33: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 02) – except health care facilities
- Use 34: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 04)
 - Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 18% v/v, 15 min, 20°C, clean and dirty conditions, without mechanical action
 - Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Lactobacillus brevis*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 8% v/v, 15 min, 40°C, clean and dirty conditions, without mechanical action

The use in veterinary health care is not demonstrated as efficacy data have not been provided against *Proteus vulgaris* and only clean conditions have been validated for health care facilities (dirty conditions of medical areas (3.0 g/L BSA + 3.0 mL/L sheep erythrocytes have not been tested for bacteria and yeasts). Therefore, only clean conditions have been proven for the following uses:

- Use 1: Disinfection of hard surfaces and equipment by manual liquid sprayin(PT 02) – health care facilities (excluding the hospitals)
- Use 2: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 02) – health care facilities (excluding the hospitals)
- Use 3: Disinfection of equipment by manual dipping/soaking (PT 02) (without mechanical action) – health care facilities (excluding the hospitals)
- Use 4: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) – health care facilities (excluding the hospitals)
- Use 33: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 02) – health care facilities (excluding the hospitals)
 - Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes*)

and yeasts: 18% v/v, 15 min, 20°C, clean conditions, without mechanical action

- Bacteria (including *Enterobacter cloacae*, *Salmonella Typhimurium*, *Lactobacillus brevis*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 8% v/v, 15 min, 40°C, clean conditions, without mechanical action

- **Meta SPC 2**

For META-SPC 2, no variation occurs, except minor variations of perfumes and sequestering agent. Efficacy tests have been performed with the representative product 2-x (without perfumes and sequestering agent).

The composition of this test item is presented in the confidential section of the PAR with a justification regarding its representativeness of the Meta SPC 2.

Taking into account the variations of the co-formulants presented in this META-SPC, it can be assumed that they have no impact on efficacy and the efficacy results of this representative product is representative of products within this META-SPC.

The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

| 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 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC2 – Product 2-x (24% w/w lactic acid) Batch: COM23-2-x-2020-02-19 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strains</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 3% v/v. Remarks: - Presence of small flocs at 1% and 2% dilutions. - Homogeneous at 0.5, 3 and 4%. The lowest effective concentration without flocculation was retained for each target organism. | COM23/METASPC2 /PRODUCT2-X – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Report No 20/000159247 R.I.: 2 (no inactive dilution for <i>P. aeruginosa</i>) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC2 – Product 2-x (24% w/w lactic acid) Batch: COM23/META SPC2-X/2020-07-08 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>E. coli</i> , <i>S. Typhimurium</i> , <i>E. cloacae</i> , <i>L. brevis</i> and <i>L. monocytogenes</i> demonstrated at 4% v/v. Activity against <i>C. jejuni</i> demonstrated at 0.5% v/v. Remarks: - Presence of small flocs at 3% dilution. - Homogeneous at 0.5 and 4%. | COM23/METASPC2 -X – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Report No 20/000447261 R.I.: 2 (no inactive dilution for <i>C. jejuni</i>) |

| | | | | | | | |
|-----------------------|--|---|--|-----------------|--|--|--|
| | | | <i>L. monocytogenes</i> ATCC 19115 <i>C. jejuni</i> ATCC 33560 | | | The lowest effective concentration without flocculation was retained for each target organism. | |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC2 – Product 2-x (24% w/w lactic acid) Batch: COM23-2-x-2020-02-19 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <i>E. faecium</i> ATCC 6057 <u>Additional strains</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> , <i>E. coli</i> K12 and <i>E. faecium</i> demonstrated at 4% v/v. Remarks: - Presence of small flocs at 3, 2 and 1% dilutions. - Homogeneous at 0.5 and 4%. The lowest effective concentration without flocculation was retained for each target organism. | COM23/METASPC2 /PRODUCT2-X – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Report No 20/000159247 R.I.: 2 (no inactive dilution for <i>P. aeruginosa</i>) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC2 – Product 2-x (24% w/w lactic acid) Batch: COM23/META SPC2-X/2020-07-08 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | The lowest effective concentration without flocculation was retained for each target organism. As no effective concentration without flocculation is observed, the effective concentration determined in the corresponding phase 2 step 2 tests against <i>E. cloacae</i> , <i>L. brevis</i> and | COM23/METASPC2 -X – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Report No 20/000447261 R.I.: 2 (no inactive dilution for <i>E. coli</i> , <i>S. Typhimurium</i> and <i>C. jejuni</i>) |

| | | | | | | | |
|-----------------------|--|---|---|-----------------------------|--|--|---|
| | | | <i>L. monocytogenes</i> ATCC 19115 <i>C. jejuni</i> ATCC 33560 | | | <i>L. monocytogenes</i> are used. Activity against <i>E. coli</i> , <i>S. Typhimurium</i> and <i>C. jejuni</i> demonstrated at 0.5% v/v. Remarks: - Presence of small flocs at 4% and 3% dilutions. - Homogeneous at 0.5%. | |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC2 – Product 2-x (24% w/w lactic acid) Batch: COM23-2-x-2020-02-19 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strains</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (surface test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 4% v/v. | COM23/METASPC2 /PRODUCT2-X – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C Report No 20/000159247 R.I.: 2 (no inactive dilution for <i>E. coli</i> K12 and <i>P. aeruginosa</i>) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC2 – Product 2-x (24% w/w lactic acid) Batch: COM23/META SPC2-X/2020-07-08 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (surface test) Concentration tested: 0.5%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>E. coli</i> , <i>E. cloacae</i> , and <i>L. monocytogenes</i> demonstrated at 3% v/v. Activity against <i>S. Typhimurium</i> and <i>C. jejuni</i> demonstrated at 0.5% v/v. | COM23/METASPC2 -X – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C Report No 20/000447261 R.I.: 2 (no inactive dilution for <i>S.</i> |

| | | | | | | | |
|-----------------------|--|---|--|-----------------------------|---|---|--|
| | | | <i>L. brevis</i> DSM 6235 <i>L. monocytogenes</i> ATCC 19115 <i>C. jejuni</i> ATCC 33560 | | | Activity against <i>L. brevis</i> is not demonstrated. | Typhimurium and <i>C. jejuni</i>) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC2 – Product 2-x (24% w/w lactic acid) Batch: COM23-2-x-2020-02-19 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <i>E. faecium</i> ATCC 6057 <u>Additional strains</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (surface test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> , <i>E. faecium</i> and <i>E. coli</i> K12 demonstrated at 3% v/v. | COM23/METASPC2 /PRODUCT2-X – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Report No 20/000159247 R.I.: 2 (no inactive dilution for <i>E. coli</i> K12 and <i>P. aeruginosa</i>) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC2 – Product 2-x (24% w/w lactic acid) Batch: COM23/META SPC2-X/2020-07-08 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 <i>L. monocytogenes</i> ATCC 19115 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (surface test) Concentration tested: 0.5%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>E. coli</i> , <i>S. Typhimurium</i> , <i>E. cloacae</i> and <i>C. jejuni</i> demonstrated at 0.5% v/v. Activity against <i>L. monocytogenes</i> demonstrated at 3% v/v. Activity against <i>L. brevis</i> demonstrated at 4% v/v. | COM23/METASPC2 -X – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Report No 20/000447261 R.I.: 2 (no inactive dilution for <i>E. coli</i> , <i>S. Typhimurium</i> , <i>E. cloacae</i> and <i>C. jejuni</i>) |

| | | | | | | | |
|----------------------|--|---|---|-----------------------------|--|--|---|
| | | | <i>C. jejuni</i> ATCC 33560 | | | | |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC2 – Product 2-x (24% w/w lactic acid) Batch: COM23-2-x-2020-02-19 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 1650:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 4%, 5%, 6%, 7% and 8% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 7% v/v. | COM23/METASPC2 /PRODUCT2-X – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 20°C Report No 20/000159247 R.I.: 1 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC2 – Product 2-x (24% w/w lactic acid) Batch: COM23-2-x-2020-02-19 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 1650:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 3% v/v. Remarks: - Flocculate at 2% and 1% concentrations. - Homogeneous at 4%, 3% and 0.5%. The lowest effective concentration without flocculation was retained for each target organism. | COM23/METASPC2 /PRODUCT2-X – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 40°C Report No 20/000159247 R.I.: 2 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC2– Product 2-x (24% w/w lactic acid) Batch: COM23/META SPC2-X/2020-07-08 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 12%, 14%, 16%, 18% and 20% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 30 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 20% v/v. | COM23/METASPC2 -X – Evaluation of yeasticidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C Report No 20/000447261 R.I.: 1 |

| | | | | | | | |
|----------------------|--|--|---|-----------------------------|--|--|--|
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC2-Product 2-x (24% w/w lactic acid) Batch: COM23-2-x- 2020-02-19 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 5%, 6%, 7%, 8% and 9% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 8% v/v. | COM23/METASPC2 /PRODUCT2-X – Evaluation of yeasticidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Report No 20/000159247 R.I.: 1 |
|----------------------|--|--|---|-----------------------------|--|--|--|

General disinfection PT2/PT4 (20°C):

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 4% v/v.
- additional bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
 - o 4% v/v for *Enterobacter cloacae*
 - o 4% v/v for *Salmonella* Typhimurium
 - o 0.5% v/v for *Campylobacter jejuni*
 - o 4% v/v for *Listeria monocytogenes*
- activity against *L. brevis* is not demonstrated in phase 2, step 2 test (EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin).
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 30 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 20% v/v.

General disinfection PT2/PT4 (40°C):

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 4% v/v.
- additional bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
 - o 0.5% v/v for *Salmonella typhimurium*
 - o 0.5% v/v for *Campylobacter jejuni*
- additional bactericidal activity is also demonstrated in phase 2 step 2 tests (EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). As no effective concentration without flocculation is observed in P2S1 tests, the effective concentration determined in the corresponding phase 2 step 2 tests. In these conditions, activity is shown at the in-use concentration of:
 - o 0.5% v/v for *Enterobacter cloacae*
 - o 4% v/v for *Lactobacillus brevis*
 - o 3% v/v for *Listeria monocytogenes*
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 8% v/v.

Conclusion on the efficacy of the product – Meta SPC 2

The products of the family "FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS", have shown a sufficient efficacy in accordance with the requirements of the guidance II Efficacy – Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 for the following uses:

META-SPC 2

- Use 1: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 02) – except health care facilities
- Use 2: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 02) – except health care facilities
- Use 3: Disinfection of equipment by manual dipping/soaking (PT 02) – except health care facilities
- Use 4: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) – except health care facilities
- Use 9: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 04)
- Use 10: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 04)
- Use 11: Disinfection of equipment by manual dipping/soaking (PT 04)
- Use 12: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 04)
 - Bacteria (including *Enterobacter cloacae*, *Salmonella Typhimurium*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 20% v/v, 30 min, 20°C, clean and dirty conditions, without mechanical action
 - Bacteria (including *Enterobacter cloacae*, *Salmonella Typhimurium*, *Lactobacillus brevis*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 8% v/v, 15 min, 40°C, clean and dirty conditions, without mechanical action

The use in veterinary health care is not demonstrated as efficacy data have not been provided against *Proteus vulgaris* and only clean conditions have been validated for health care facilities (dirty conditions of medical areas (3.0 g/L BSA + 3.0 mL/L sheep erythrocytes) have not been tested for bacteria and yeasts). Therefore, only clean conditions have been proven for the following uses:

- Use 1: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 02) – health care facilities (excluding the hospitals)
- Use 2: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 02) – health care facilities (excluding the hospitals)
- Use 3: Disinfection of equipment by manual dipping/soaking (PT 02) – health care facilities (excluding the hospitals)
- Use 4: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) – health care facilities (excluding the hospitals)
 - Bacteria (including *Enterobacter cloacae*, *Salmonella Typhimurium*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 20% v/v, 30 min, 20°C, clean conditions, without mechanical action
 - Bacteria (including *Enterobacter cloacae*, *Salmonella Typhimurium*, *Lactobacillus brevis*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 8% v/v, 15 min, 40°C, clean conditions, without mechanical action

- **Meta SPC 3**

For META-SPC3, no variation occurs, except minor variations of perfumes. Efficacy tests have been performed with the representative product 3-1 without perfume.

The composition of this test item is presented in the confidential section of the PAR with a justification regarding its representativeness of the Meta SPC 3.

Taking into account the variations of the co-formulants presented in this META-SPC, it can be assumed that they have no impact on efficacy and the efficacy results of this representative product is representative of products within this META-SPC.

The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

| 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 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC3 – Product 3-1 (24% w/w lactic acid) Batch: COM23/META SPC3-1/2019-09-26/1 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 4% v/v. Remarks: - Presence of flocs in the dilutions: 3%, 2%, 1%, 0.5%. - Homogeneous at 4%. The lowest effective concentration without flocculation was retained. | COM23/METASPC3-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Report No 20/000022074 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC3 – Product 3-1 (24% w/w lactic acid) Batch: COM23/META SPC3-1/2020-07-07/1 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 <i>L. monocytogenes</i> ATCC 19115 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.1%, 3.5% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>L. brevis</i> , <i>L. monocytogenes</i> , <i>E. coli</i> , <i>S. Typhimurium</i> , <i>E. cloacae</i> and <i>C. jejuni</i> demonstrated at 4% v/v. Remarks: - Presence of flocs in the 3.5% dilution. - Homogeneous at 0.1 and 4%. The lowest effective concentration without flocculation was retained. | COM23/METASPC3-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Report No 20/000447225 R.I.: 2 |

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|-----------------------|--|---|---|-----------------|--|--|---|
| | | | <i>C. jejuni</i> ATCC 33560 | | | | |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC3 – Product 3-1 (24% w/w lactic acid) Batch: COM23/META SPC3-1/2019-09-26/1 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strains</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 4% v/v. Remarks: - Presence of flocs in the 3, 2, 1 and 0.5% dilutions. - Homogeneous at 4%. The lowest effective concentration without flocculation was retained. | COM23/METASPC3 -1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Report No 20/000022074 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC3 – Product 3-1 (24% w/w lactic acid) Batch: COM23/META SPC3-1/2020-02-17 | Bacteria <u>Mandatory strain</u> <i>E. faecium</i> ATCC 6057 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>E. faecium</i> demonstrated at 1% v/v. | COM23/METASPC3 -1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Report No 20/000159182 R.I.: 1 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC3 – Product 3-1 (24% w/w lactic acid) Batch: COM23/META SPC3-1/2020-07-07/1 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.1%, 3.5% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | The lowest effective concentration without flocculation was retained for each target organism. As no effective concentration without flocculation is observed, the effective concentration determined in the | COM23/METASPC3 -1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Report No 20/000447225 R.I.: 2 (no inactive dilution against <i>C. jejuni</i>) |

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| | | | <i>L. brevis</i> DSM 6235 <i>L. monocytogenes</i> ATCC 19115 <i>C. jejuni</i> ATCC 33560 | | | corresponding phase 2 step 2 tests against <i>L. brevis</i> , <i>L. monocytogenes</i> , <i>E. coli</i> , <i>S. Typhimurium</i> and <i>E. cloacae</i> are used. Activity against <i>C. jejuni</i> demonstrated at 0.1% v/v. Remarks: - Presence of small flocs in the 4 and 3.5% dilutions. - Homogeneous at 0.1%. | |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC3 – Product 3-1 (24% w/w lactic acid) Batch: COM23/METAS PC3-1/2019-09-26/1 | <u>Bacteria</u> <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 4% v/v. | COM23/METASPC3 -1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C Report No 20/000022074 R.I.: 2 (no inactive dilution against <i>E. coli</i> K12) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC3 – Product 3-1 (24% w/w lactic acid) Batch: COM23/META SPC3- | <u>Bacteria</u> <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.1%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 15 min | Activity against <i>L. monocytogenes</i> , <i>E. coli</i> , <i>S. Typhimurium</i> , <i>E. cloacae</i> and <i>C. jejuni</i> demonstrated at 3% v/v. Activity against <i>L. brevis</i> is not demonstrated. | COM23/METASPC3 -1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C Report No 20/000447225 |

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|-----------------------|--|---|--|-----------------------------|---|---|---|
| | | 1/2020-07-07/1 | <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 <i>L. monocytogenes</i> ATCC 19115 <i>C. jejuni</i> ATCC 33560 | | Criteria: at least a 4 log reduction | | R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC3 – Product 3-1 (24% w/w lactic acid) Batch: COM23/META SPC3-1/2019-09-26/1 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 2% v/v. | COM23/METASPC3 -1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Report No 20/000022074 R.I.: 2 (no inactive dilution <i>P. aeruginosa</i> and <i>E. coli</i> K12) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC3 – Product 3-1 (24% w/w lactic acid) Batch: COM23/META SPC 3-1/2020-02-17 | Bacteria <u>Mandatory strain</u> <i>E. faecium</i> ATCC 6057 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.1%, 0.5%, 1%, 2%, and 3% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>E. faecium</i> demonstrated at 1% v/v. | COM23/METASPC3 -1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Report No 20/000159182 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC3 – Product 3-1 (24% w/w lactic acid) | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.1%, 2%, and 3% v/v | Activity against <i>L. brevis</i> , <i>L. monocytogenes</i> , <i>E. coli</i> , <i>S. Typhimurium</i> , <i>E. cloacae</i> and <i>C. jejuni</i> | COM23/METASPC3 -1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C |

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| | | Batch: COM23/META SPC3- 1/2020-07- 07/1 | <u>Additional strains</u> <i>S. Typhimurium</i> <i>ATCC 13311</i> <i>E. cloacae DSM</i> <i>6234</i> <i>L. brevis DSM</i> <i>6235</i> <i>L.</i> <i>monocytogenes</i> <i>ATCC 19115</i> <i>C. jejuni ATCC</i> <i>33560</i> | | Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | <i>K12</i> demonstrated at 2% v/v. | Report No 20/000447225 R.I.: 2 |
| Yeasticidal activity | Food, industrial, domestic and institution al areas | Meta SPC3 – Product 3-1 (24% w/w lactic acid) Batch: COM23/META SPC 3- 1/2020-02-17 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 1650:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 6%, 7%, 8%, 9% and 10% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 6% v/v. | COM23/METASPC3 -1 – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 20°C Report No 20/000159182 R.I.: 2 (no inactive dilution) |
| Yeasticidal activity | Food, industrial, domestic and institution al areas | Meta SPC3 – Product 3-1 (24% w/w lactic acid) Batch: COM23/META SPC 3- 1/2020-02-17 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 1650:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 4%, 5%, 6%, 7% and 8% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 4% v/v. | COM23/METASPC3 -1 – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 40°C Report No 20/000159182 R.I.: 1 |
| Yeasticidal activity | Food, industrial, domestic and institution al areas | Meta SPC3 – Product 3-1 (24% w/w lactic acid) | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 20%, 22.5%, 25%, 27.5% and 30% v/v | Yeasticidal activity demonstrated at 25% v/v. | COM23/METASPC3 -1 – Evaluation of yeasticidal activity according to BS EN 13697: 2015 + |

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| | | Batch: COM23/META SPC3- 1/2020-07- 07/1 | | | Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 15 min Criteria: at least a 3 log reduction | | A1:2019 – 20°C – 15 min Report No 20/000386217 R.I.: 1 |
| Yeasticidal activity | Food, industrial, domestic and institution al areas | Meta SPC3 – Product 3-1 (24% w/w lactic acid) Batch: COM23/META SPC3- 1/2020-07- 07/1 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 12%, 14%, 16%, 18% and 20% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 30 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 20% v/v. | COM23/METASPC3 -1 – Evaluation of yeasticidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C – 30 min Report No 20/000447225 R.I.: 1 |
| Yeasticidal activity | Food, industrial, domestic and institution al areas | Meta SPC3 – Product 3-1 (24% w/w lactic acid) Batch: COM23/META SPC3- 1/2019-09- 26/1 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 3%, 4%, 5%, 6% and 7% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 6% v/v. | COM23/METASPC3 -1 – Evaluation of yeasticidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Report No 20/000022074 R.I.: 1 |

General disinfection PT2/PT4 (20°C):

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 4% v/v.
- additional bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
 - o 4% v/v for *Enterobacter cloacae*
 - o 4% v/v for *Salmonella* Typhimurium
 - o 4% v/v for *Campylobacter jejuni*
 - o 4% v/v for *Listeria monocytogenes*
- activity against *L. brevis* is not demonstrated in phase 2, step 2 test (EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin).
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 25% v/v.
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 30 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 20% v/v.

General disinfection PT2/PT4 (40°C):

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). Please note that for *E. coli*, as no effective concentration without flocculation is observed in P2S1 test, the effective concentration is determined in the corresponding phase 2 step 2 test. In these conditions, bactericidal activity is shown at the in-use concentration of 4% v/v.
- additional bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
 - o 2% v/v for *Campylobacter jejuni*
- additional bactericidal activity is also demonstrated in phase 2 step 2 tests (EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). As no effective concentration without flocculation is observed in P2S1 tests, the effective concentration are determined in the corresponding phase 2 step 2 tests. In these conditions, activity is shown at the in-use concentration of:
 - o 2% v/v for *Enterobacter cloacae*
 - o 2% v/v for *Salmonella* Typhimurium
 - o 2% v/v for *Lactobacillus brevis*
 - o 2% v/v for *Listeria monocytogenes*

- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 6% v/v.

Conclusion on the efficacy of the product – Meta SPC 3

The products of the biocidal family FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS have shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 for the following uses:

META-SPC 3

- Use 1: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 02) – except health care facilities
- Use 2: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 02) – except health care facilities
- Use 3: Disinfection of equipment by manual dipping/soaking (PT 02) – except health care facilities
- Use 4: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) – except health care facilities
- Use 9: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 04)
- Use 10: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 04)
- Use 11: Disinfection of equipment by manual dipping/soaking (PT 04)
- Use 12: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 04)
 - Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 25% v/v, 15 min, 20°C, clean and dirty conditions, without mechanical action
 - Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 20% v/v, 30 min, 20°C, clean and dirty conditions, without mechanical action
 - Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Lactobacillus brevis*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 6% v/v, 15 min, 40°C, clean and dirty conditions, without mechanical action

The use in veterinary health care is not demonstrated as efficacy data have not been provided against *Proteus vulgaris* and only clean conditions have been validated for health care facilities (dirty conditions of medical areas (3.0 g/L BSA + 3.0 mL/L sheep erythrocytes) have not been tested for bacteria and yeasts). Therefore, only clean conditions have been proven for the following uses:

- Use 1: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 02) – health care facilities (excluding the hospitals)
- Use 2: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 02) – health care facilities (excluding the hospitals)
- Use 3: Disinfection of equipment by manual dipping/soaking (PT 02) - health care facilities (excluding the hospitals)
- Use 4: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) – health care facilities (excluding the hospitals)

- Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 25% v/v, 15 min, 20°C, clean conditions, without mechanical action
- Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 20% v/v, 30 min, 20°C, clean conditions, without mechanical action
- Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Lactobacillus brevis*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 6% v/v, 15 min, 40°C, clean conditions, without mechanical action

- **Meta SPC 4**

For META-SPC4, no variation occurs, except minor variations of perfumes. Efficacy tests have been performed with the representative product 4-1.

The composition of this test item is presented in the confidential section of the PAR with a justification regarding its representativeness of the Meta SPC 4. Additional efficacy data with a product without perfume have also been provided to support the non efficacy of these co-formulants (see confidential section of the PAR).

Taking into account the variations of the co-formulants presented in this META-SPC and the efficacy data provided, the efficacy results of this representative product is considered as representative of products within this META-SPC.

The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

| 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 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product tested not specified in the report but being the Product 4-1 (24% w/w lactic acid) Batch: COM23/META SCP 4-1/2019-10-17 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 2%, 3%, 4% and 5% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 5% v/v. Remarks: - Presence of flocs in the 4, 3, 2 and 1% dilutions. - Homogeneous at 5%. The lowest effective concentration without flocculation was retained. | COM23/METASPC4 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Report No 20/000214030 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Product 4-1 (24% w/w lactic acid) Batch: COM23/META SPC4-1/2020-07-09 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 <i>L. monocytogenes</i> ATCC 19115 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 4% and 5% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 5 log reduction | The lowest effective concentration without flocculation was retained for each target organism. As no effective concentration without flocculation is observed, the effective concentration determined in the corresponding phase 2 step 2 tests against <i>E. coli</i> , <i>E. cloacae</i> , <i>L. brevis</i> , <i>S. Typhimurium</i> and <i>L. monocytogenes</i> are used. | COM23/METASPC4 -1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Report No 20/000447157 R.I.: 2 (no inactive dilution for <i>C. jejuni</i>) |

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| | | | <i>C. jejuni</i> ATCC 33560 | | | Activity against <i>C. jejuni</i> demonstrated at 0.5% v/v. Remarks: - Presence of small flocs in the 5 and 4% dilutions. - Homogeneous at 0.5%. | |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product tested not specified in the report but being the Product 4-1 (24% w/w lactic acid) Batch: COM23/META SCP 4-1/2019-10-17 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442. <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 4% v/v. Remarks: - Presence of flocs in the 3, 2, 1 and 0.5% dilutions. - Homogeneous at 4%. The lowest effective concentration without flocculation was retained. | COM23/METASPC4 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Report No 20/000214030 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product tested not specified in the report but being the Product 4-1 (24% w/w lactic acid) Batch: COM 23/METASPC 4-1/2020-02-20 | Bacteria <u>Mandatory strain</u> <i>E. faecium</i> ATCC 6057 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>E. faecium</i> demonstrated at 3% v/v. Remarks: - Presence of flocs in the 2, 1 and 0.5% dilutions. - Homogeneous at 3 and 4%. The lowest effective concentration without flocculation was retained. | COM23/METASPC4 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Report No 20/000159100 R.I.: 2 |

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| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product tested not specified in the report but being the Product 4-1 (24% w/w lactic acid) Batch: COM23/META SPC4-1/2020-07-09 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 <i>L. monocytogenes</i> ATCC 19115 <i>C. jejuni</i> ATCC 33560 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | The lowest effective concentration without flocculation was retained for each target organism. As no effective concentration without flocculation is observed, the effective concentration determined in the corresponding phase 2 step 2 tests against <i>E. cloacae</i> , <i>L. brevis</i> , <i>S. Typhimurium</i> and <i>L. monocytogenes</i> are used. Activity against <i>C. jejuni</i> and <i>E. coli</i> demonstrated at 0.5% v/v. Remarks: - Presence of small flocs in the 4 and 3% dilutions. - Homogeneous at 0.5%. | COM23/METASPC4 -1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Report No 20/000447157 R.I.: 2 (no inactive dilution for <i>C. jejuni</i> and <i>E. coli</i> K12) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product tested not specified in the report but being the Product 4-1 (24% w/w lactic acid) Batch: | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 1%, 2%, 3%, 4% and 5% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 5% v/v. | COM23/METASPC4 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C Report No 20/000214030 R.I.: 2 (no inactive dilution for <i>P.</i> |

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| | | COM23/METAS CP 4-1/2019-10- 17 | <i>E. coli</i> K12 NCTC 10538 | | | | <i>aeruginosa</i> and <i>E. coli</i> K12) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product tested not specified in the report but being the Product 4-1 (24% w/w lactic acid) Batch: COM23/META SPC4-1/2020-07-09 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 <i>L. monocytogenes</i> ATCC 19115 <i>C. jejuni</i> ATCC 33560 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.1%, 4% and 5% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>E. coli</i> , <i>C. jejuni</i> , <i>L. monocytogenes</i> , <i>S. Typhimurium</i> and <i>E. cloacae</i> demonstrated at 4% v/v. Activity against <i>L. brevis</i> is not demonstrated. | COM23/METASPC4 -1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C Report No 20/000447157 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product tested not specified in the report but being the Product 4-1 (24% w/w lactic acid) Batch: COM23/METAS CP 4-1/2019-10-17 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 2% v/v. | COM23/METASPC4 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Report No 20/000214030 R.I.: 2 (no inactive dilution for <i>P. aeruginosa</i> and <i>E. coli</i> K12) |
| Bactericidal activity | Food, industrial, domestic and | Meta SPC4 – Product tested not specified in | Bacteria <u>Mandatory strain</u> | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) | Activity against <i>E. faecium</i> demonstrated at 2% v/v. | COM23/METASPC4 – Evaluation of bactericidal activity according to BS EN |

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| | institutional areas | the report but being the Product 4-1 (24% w/w lactic acid) Batch: COM 23/METASPC 4-1/2020-02-20 | <i>E. faecium</i> ATCC 6057 | | Concentration tested: 0.1%, 0.5%, 1%, 2% and 3% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | | 13697: 2015 + A1:2019 – 40°C Report No 20/000159100 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product tested not specified in the report but being the Product 4-1 (24% w/w lactic acid) Batch: COM23/META SPC4-1/2020-07-09 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 <i>L. monocytogenes</i> ATCC 19115 <i>C. jejuni</i> ATCC 33560 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.1% 2% and 3% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>E. coli</i> , <i>L. brevis</i> , <i>C. jejuni</i> , <i>L. monocytogenes</i> , <i>S. Typhimurium</i> and <i>E. cloacae</i> demonstrated at 2% v/v. | COM23/METASPC4 -1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Report No 20/000447157 R.I.: 2 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product 4-1 (24% w/w lactic acid) Batch: COM 23/METASPC 4-1/2020-02-20 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 1650:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 5%, 6%, 7%, 8% and 9% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min | Yeasticidal activity demonstrated at 7% v/v. | COM23/METASPC4 -1 – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 20°C Report No 20/000159100 R.I.: 1 |

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| | | | | | Criteria: at least a 4 log reduction | | |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product tested not specified in the report but being the Product 4-1 (24% w/w lactic acid) Batch: COM23/METASPC 4-1/2019-10-17 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 1650:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 4% v/v. Remarks: - Presence of flocs in the 3, 2, 1 and 0.5% dilutions. - Homogeneous at 4%. The lowest effective concentration without flocculation was retained. | COM23/METASPC4 – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 40°C Report No 20/000214030 R.I.: 2 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product 4-1 (24% w/w lactic acid) Batch: COM23/METASPC4-1/2020-07-09 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 20%, 22.5%, 25%, 27.5% and 30% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 15 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 20% v/v. | COM23/METASPC4 -1 – Evaluation of yeasticidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C – 15 min Report No 20/000386201 R.I.: 2 (no inactive dilution) |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product 4-1 (24% w/w lactic acid) Batch: COM23/METASPC4-1/2020-07-09 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 12%, 14%, 16%, 18% and 20% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 30 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 12% v/v. | COM23/METASPC4 -1 – Evaluation of yeasticidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C – 30 min Report No 20/000386201 R.I.: 2 |

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| | | | | | | | (no inactive dilution) |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product 4-1 (24% w/w lactic acid) Batch: COM23/METASPC4-1/2020-02-20 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 5%, 6%, 7%, 8% and 9% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 5% v/v. | COM23/METASPC4-1 – Evaluation of yeasticidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Report No 20/000159100 R.I.: 2 (no inactive dilution) |
| Virucidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product 4-1 (24% w/w lactic acid) Batch: COM23/META SPC4-1/2020-07-09 | Virus <i>Adenovirus type 5</i> (strain <i>Adenoid</i> , ATCC VR-5) <i>Murine norovirus</i> (strain <i>S99 Berlin</i>), <i>Poliovirus type 1</i> (<i>Sc-2ab</i>) | NF EN 14476+A2: 2019 | Phase 2 step 1 test (suspension test) Concentration tested: 7.5%, 15% and 17.5% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 60 min Criteria: at least a 4 log reduction | Virucidal efficacy demonstrated at 17.5% v/v. | Report No R2012LVGFB001 R.I.: 1 |
| Virucidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product 4-1 (24% w/w lactic acid) Batch: COM23/META SPC4-1/2020-07-09 | Virus <i>Adenovirus type 5</i> (strain <i>Adenoid</i> , ATCC VR-5) <i>Murine norovirus</i> (strain <i>S99 Berlin</i>), <i>Poliovirus type 1</i> (<i>Sc-2ab</i>) | NF EN 14476+A2: 2019 | Phase 2 step 1 test (suspension test) Concentration tested: 7.5%, 15% and 17.5% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 30 min Criteria: at least a 4 log reduction | Virucidal efficacy demonstrated at 17.5% v/v. | Report No R2012LVGFB007 R.I.: 1 |

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| Virucidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product 4-1 (24% w/w lactic acid) Batch: COM23/META SPC4-1/2020-07-09 | Virus <u>Additional virus</u> <i>Murine parvovirus, strain Crawford, ATCC VR-1346</i> | NF EN 14476+A2: 2019 | Phase 2 step 1 test (suspension test) Concentration tested: 7.5%, 15% and 17.5% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 30 min Criteria: at least a 4 log reduction | Activity against <i>Murine parvovirus</i> demonstrated at 15% v/v. | Report No R2012LVGFB010 R.I.: 1 |
| Virucidal activity | Food, industrial, domestic and institutional areas | Meta SPC4 – Product 4-1 (24% w/w lactic acid) Batch: COM23/META SPC4-1/2020-07-09 | <u>Virus</u> <u>Additional virus</u> <i>Bovine coronavirus strain L9</i> | NF EN 14476+A2: 2019 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 2% and 3% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 5 min Criteria: at least a 4 log reduction | Activity against <i>Bovine coronavirus</i> demonstrated at 2% v/v. | Report No R2012LVGFB002 R.I.: 1 |

General disinfection PT2/PT4 (20°C):

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). Please note that for *E. coli*, as no effective concentration without flocculation is observed in P2S1 test, the effective concentration is determined in the corresponding phase 2 step 2 test. In these conditions, bactericidal activity is shown at the in-use concentration of 5% v/v.
- additional bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
 - o 4% v/v for *Campylobacter jejuni*
- additional bactericidal activity is also demonstrated in phase 2 step 2 tests (EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). As no effective concentration without flocculation is observed on P2S1 tests, the effective concentration is determined in the corresponding phase 2 step 2 tests. In these conditions, activity is shown at the in-use concentration of:
 - o 4% v/v for *Enterobacter cloacae*
 - o 4% v/v for *Salmonella Typhimurium*
 - o 4% v/v for *Listeria monocytogenes*
- activity against *L. brevis* is not demonstrated in phase 2, step 2 test (EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin).
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 20% v/v.
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 30 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 12% v/v.
- virucidal activity is demonstrated in phase 2 step 1 tests (EN 14476), at 20°C, with a contact time of 60 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, virucidal activity is shown at the in-use concentration of 17.5% v/v.
- additional activity against bovine coronavirus is demonstrated in phase 2, step 1 test (EN 14476), at 20°C, with a contact time of 5 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of 2% v/v.

General disinfection PT2/PT4 (40°C):

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 4% v/v.

- additional bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
 - o 2% v/v for *Campylobacter jejuni*
- additional bactericidal activity is also demonstrated in phase 2 step 2 tests (EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). As no effective concentration without flocculation is observed on P2S1 test, the effective concentration is determined in the corresponding phase 2 step 2 tests. In these conditions, activity is shown at the in-use concentration of:
 - o 2% v/v for *Enterobacter cloacae*
 - o 2% v/v for *Salmonella* Typhimurium
 - o 2% v/v for *Lactobacillus brevis*
 - o 2% v/v for *Listeria monocytogenes*
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 5% v/v.
- virucidal activity is demonstrated in phase 2 step 1 tests (EN 14476), at 40°C, with a contact time of 30 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, virucidal activity is shown at the in-use concentration of 17.5% v/v.
- Additional activity against murine parvovirus is demonstrated in phase 2, step 1 test (EN 14476), at 40°C, with a contact time of 30 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of 15% v/v.

Conclusion on the efficacy of the product – Meta SPC 4

The products of the biocidal family FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS have shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 for the following uses:

META-SPC 4

- o Use 1: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 02) – except health care facilities
- o Use 2: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 02) – except health care facilities
- o Use 3: Disinfection of equipment by manual dipping/soaking (PT 02) – except health care facilities
- o Use 4: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) – except health care facilities
- o Use 9: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 04)
- o Use 10: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 04)
- o Use 11: Disinfection of equipment by manual dipping/soaking (PT 04)
- o Use 12: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 04)

- Use 29: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 02)
- Use 30: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02)
- Use 31: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 04)
- Use 32: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 04)
- Use 33: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 02) – except health care facilities
- Use 34: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 04)
 - Bacteria (including *Enterobacter cloacae*, *Salmonella Typhimurium*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 20% v/v, 15 min, 20°C, clean and dirty conditions, without mechanical action
 - Bacteria (including *Enterobacter cloacae*, *Salmonella Typhimurium*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 12% v/v, 30 min, 20°C, clean and dirty conditions, without mechanical action
 - Virus (including bovine coronavirus): 17.5% v/v, 60 min, 20°C, clean and dirty conditions, without mechanical action
 - Bacteria (including *Enterobacter cloacae*, *Salmonella Typhimurium*, *Lactobacillus brevis*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 5% v/v, 15 min, 40°C, clean and dirty conditions, without mechanical action
 - Virus (including Murine parvovirus): 17.5% v/v, 30 min, 40°C, clean and dirty conditions, without mechanical action

The use in veterinary health care is not demonstrated as efficacy data have not been provided against *Proteus vulgaris* and only clean conditions have been validated for health care facilities (dirty conditions of medical areas (3.0 g/L BSA + 3.0 mL/L sheep erythrocytes) have not been tested for bacteria and yeasts). Therefore, only clean conditions have been proven for the following uses:

- Use 1: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 02) – health care facilities (excluding the hospitals)
- Use 2: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 02) – health care facilities (excluding the hospitals)
- Use 3: Disinfection of equipment by manual dipping/soaking (PT 02) – health care facilities (excluding the hospitals)
- Use 4: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) – health care facilities (excluding the hospitals)
- Use 33: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 02) – health care facilities (excluding the hospitals)
 - Bacteria (including *Enterobacter cloacae*, *Salmonella Typhimurium*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 20% v/v, 15 min, 20°C, clean conditions, without mechanical action
 - Bacteria (including *Enterobacter cloacae*, *Salmonella Typhimurium*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 12% v/v, 30 min, 20°C, clean conditions, without mechanical action

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| <ul style="list-style-type: none">• Virus (including bovine coronavirus): 17.5% v/v, 60 min, 20°C, clean conditions, without mechanical action• Bacteria (including <i>Enterobacter cloacae</i>, <i>Salmonella</i> Typhimurium, <i>Lactobacillus brevis</i>, <i>Campylobacter jejuni</i> and <i>Listeria monocytogenes</i>) and yeasts: 5% v/v, 15 min, 40°C, clean conditions, without mechanical action• Virus (including Murine parvovirus): 17.5% v/v, 30 min, 40°C, clean conditions, without mechanical action |
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- **Meta SPC 5**

For META-SPC5, efficacy tests have been performed with the representative product 5-1.

The composition of this test item is presented in the confidential section of the PAR with a justification regarding its representativeness of the Meta SPC 5.

Taking into account the variations of the co-formulants presented in this META-SPC and the efficacy data provided, the efficacy results of this representative product is considered as representative of products within this META-SPC.

The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

| 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 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5-1/2019-10-1/1 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 2% v/v. Remarks: - Presence of flocs in the 0.5 and 1% dilutions. - Homogeneous at 2%, 3% and 4%. | Report No 20/000025008 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5-1/2020-07-21-1 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. monocytogenes</i> ATCC 19115 | NF EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.1%, 2% and 3% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>E. coli</i> , <i>L. monocytogenes</i> , <i>S. Typhimurium</i> and <i>E. cloacae</i> demonstrated at 3% v/v. Remarks: - Unclear suspension for the 2% dilution. - Homogeneous at 3 and 0.1%. The lowest effective concentration without flocculation was retained. | Report No RE20-1010-2 R.I.: 2 |
| Bactericidal activity | Food, industrial, | Meta SPC5 – Product 5-1 | Bacteria | NF EN 1276:2019 | Phase 2 step 1 test (suspension test) | Activity against <i>L. brevis</i> and <i>C. jejuni</i> | Report No RE20-1010-3 |

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| | domestic and institutional areas | (28.8% w/w lactic acid) Batch: COM23/META SPC5-1/2020-07-21-1 | <u>Additional strains</u> <i>L. brevis</i> DSM 6235 <i>C. jejuni</i> ATCC 33560 | | Concentration tested: 0.1%, 2% and 3% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 5 log reduction | demonstrated at 3% v/v. Remarks: - Unclear suspension for the 2% dilution. - Homogeneous at 3 and 0.1%. The lowest effective concentration without flocculation was retained. | R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5-1/2019-10-1/1 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 2% v/v. Remarks: - Presence of flocs in the 0.5 and 1% dilutions. - Homogeneous at 2%, 3% and 4%. | Report No 20/000025008 R.I.: 2 (no inactive dilution for <i>P. aeruginosa</i> and <i>E. coli</i> K12) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5-1/2020-07-21-1 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 | NF EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.1%, 2% and 3% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>E. coli</i> , <i>L. monocytogenes</i> , <i>S. Typhimurium</i> and <i>E. cloacae</i> demonstrated at 3% v/v. Remarks: - Unclear suspension for the 2% dilution. - Homogeneous at 3 and 0.1%. | Report No RE20-1025-2 R.I.: 2 |

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| | | | <i>L. monocytogenes</i> ATCC 19115 | | | The lowest effective concentration without flocculation was retained. | |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5-1/2020-07-21-1 | Bacteria <u>Additional strains</u> <i>L. brevis</i> DSM 6235 <i>C. jejuni</i> ATCC 33560 | NF EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.1%, 2% and 3% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>L. brevis</i> , and <i>C. jejuni</i> demonstrated at 3% v/v. Remarks: - Unclear suspension for the 2% dilution. - Homogeneous at 3 and 0.1%. The lowest effective concentration without flocculation was retained. | Report No RE20-1025-3 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5-1/2020-03-05/1 | Bacteria <u>Mandatory strain</u> <i>E. faecium</i> ATCC 6057 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>E. faecium</i> demonstrated at 3% v/v. Remarks: - Presence of flocs in the 2, 1 and 0.5% dilutions. - Homogeneous at 3 and 4%. The lowest effective concentration without flocculation was retained. | Report No 20/000461956 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) | Bacteria <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v | Activity against <i>E. coli</i> K12 demonstrated at 2% v/v. | Report No 20/000025008 R.I.: 2 |

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| | | Batch: COM23/META SPC5- 1/2019-10- 1/1 | | | Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 15 min Criteria: at least a 4 log reduction | | |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5- 1/2020-07- 21-1 | <u>Bacteria</u> <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>E. coli</i> ATCC 10536 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 | NF EN 13697 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.1%, 3%, 4%, 5% and 6% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 4 log reduction | Bactericidal efficacy demonstrated at 3% v/v. | Report No RE20-1011-1 R.I.: 1 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5- 1/2020-07- 21-1 | <u>Bacteria</u> <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 <i>L. monocytogenes</i> ATCC 19115 <i>C. jejuni</i> ATCC 33560 | NF EN 13697 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.1%, 3%, 4%, 5% and 6% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>L. brevis</i> , <i>L. monocytogenes</i> , <i>S. Typhimurium</i> and <i>E. cloacae</i> demonstrated at 5% v/v. Activity against <i>C. jejuni</i> demonstrated at 3% v/v. | Report No RE20-1012-1 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META | <u>Bacteria</u> <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 2% v/v. | Report No 20/000025008 R.I.: 2 (no inactive dilution for <i>P. aeruginosa</i> and <i>E. coli</i> K12) |

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| | | SPC5-1/2019-10-1/1 | <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | | Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | | |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5-1/2020-07-21-1 | <u>Bacteria</u> <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>E. coli</i> ATCC 10536 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 | NF EN 13697 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.1%, 0.5%, 1%, 2% and 3% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Bactericidal efficacy demonstrated at 3% v/v. | Report No RE20-1014-1 R.I.: 1 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5-1/2020-07-21-1 | <u>Bacteria</u> <u>Mandatory strain</u> <i>E. faecium</i> ATCC 6057 | NF EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.1%, 4%, 5%, 6% and 7% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>E. faecium</i> demonstrated at 4% v/v. | Report No RE20-1013-1 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5-1/2020-07-21-1 | <u>Bacteria</u> <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 | NF EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.1%, 0.5%, 1%, 2% and 3% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min | Activity against <i>L. monocytogenes</i> and <i>S. Typhimurium</i> demonstrated at 3% v/v. Activity against <i>L. brevis</i> and <i>E. cloacae</i> demonstrated at 2% v/v. | Report No RE20-1015-1 R.I.: 2 (no inactive dilution for <i>C. jejuni</i>) |

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| | | | <i>L. monocytogenes</i> ATCC 19115 <i>C. jejuni</i> ATCC 33560 | | Criteria: at least a 4 log reduction | Activity against <i>C. jejuni</i> demonstrated at 0.1% v/v. | |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5-1/2019-10-1/1 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 1650:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 2%, 3%, 4% and 5% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 30 min Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 3% v/v. | Report No 20/000025008 R.I.: 1 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5-1/2019-10-1/1 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 1650:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.1%, 0.5%, 1%, 2% and 3% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 2% /v. | Report No 20/000025008 R.I.: 1 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5-1/2020-07-21-1 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 10%, 15%, 20%, 25% and 30% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 15% v/v. | Report No RE20-1016-2 R.I.: 1 |

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| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5-1/2020-07-21-1 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 10%, 12.5%, 15%, 17.5% and 20% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 30 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 12.5% v/v. | Report No RE20-1017-2 R.I.: 1 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5-1/2020-07-21-1 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 10%, 12%, 14%, 16% and 18% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 10% v/v. | Report No RE20-1018-2 R.I.: 2 (no inactive dilution) |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/META SPC5-1/2020-07-21-1 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 4%, 6%, 8%, 10% and 12% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 30 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 4% v/v. | Report No RE20-1019-2 R.I.: 2 (no inactive dilution) |
| Virucidal activity | Food, industrial, domestic and | Meta SPC5 – Product 5-1 (named "LSN 5-1" in the report) | Virus <i>Murine norovirus</i> (S99; FLI | EN 14476:2013 +A2:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 2%, 3% and 4% v/v | Activity against Murine norovirus demonstrated at 3% v/v. | Report No L19/0627M.2 R.I.: 1 |

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| | institutional areas | (28.8% w/w lactic acid) Batch: E430.01 | registration no. RVB-0651) | | Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 4 log reduction | | |
| Virucidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/Meta SPC5-1/2020-08-26/1 | Virus <i>Type 5 adenovirus</i> | EN 14476:2013 +A2:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 3% and 5% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against adenovirus type 5 demonstrated at 3% v/v. | Report No R2012LVGFB006 R.I.: 1 |
| Virucidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/Meta SPC5-1/2020-08-26/1 | Virus <i>Type 1 poliovirus</i> | EN 14476:2013 +A2:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 11%, 12% and 13% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 60 min Criteria: at least a 4 log reduction | Activity against poliovirus demonstrated at 13% v/v. | Report No R2012LVGFB008 R.I.: 1 |
| Virucidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (28.8% w/w lactic acid) Batch: COM23/Meta SPC5-1/2020-08-26/1 | Virus <i>Type 1 poliovirus</i> | EN 14476:2013 +A2:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 4%, 6%, 8%, 10%, 12.5%, 15%, 17.5%, 20%, 25% and 30% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 60 min Criteria: at least a 4 log reduction | Activity against poliovirus demonstrated at 12.5% v/v. | Report No PR2010LVGFB001-3 R.I.: 1 |

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| Virucidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (named "LSN 5-1" in the report) (28.8% w/w lactic acid) Batch: E430.01 | <u>Virus</u> <u>Additional virus</u> <i>Bovine coronavirus strain L9</i> | EN 14476:2013 +A2:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.3%, 0.75%, 1%, 1.5% and 3% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 5 and 30 min Criteria: at least a 4 log reduction | Activity against bovine coronavirus demonstrated at 1% v/v (CT: 5 min). | Report No L20/0262BC.1 R.I.: 1 |
| Virucidal activity | Food, industrial, domestic and institutional areas | Meta SPC5 – Product 5-1 (named "LSN 5-1" in the report) (28.8% w/w lactic acid) Batch: E430.01 | <u>Virus</u> <u>Additional virus</u> <i>human rotavirus strain Wa</i> | EN 14476:2013 +A1:2015 | Phase 2 step 1 test (suspension test) Concentration tested: 0.1%, 1% and 2% v/v Medical dirty conditions: 3 g/L BSA + 3mL/L erythrocytes Temperature: 20°C Contact time: 5, 15 and 30 min Criteria: at least a 4 log reduction | Activity against human rotavirus demonstrated at 2% v/v (CT: 5 min). Remark: - small precipitation occurred | Report No L19/0627R.2 R.I.: 2 |

General disinfection PT2/PT4 (20°C):

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 3% v/v.
- additional bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
 - o 5% v/v for *Enterobacter cloacae*
 - o 5% v/v for *Salmonella* Typhimurium
 - o 5% v/v for *Lactobacillus brevis*
 - o 3% v/v for *Campylobacter jejuni*
 - o 5% v/v for *Listeria monocytogenes*
- yeasticidal activity is not demonstrated with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin) as no P2S1 tests with a contact time of 15 minutes were provided.
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 30 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 12.5% v/v.
- For PT2 uses: virucidal activity (adenovirus, norovirus and poliovirus) is demonstrated in phase 2 step 1 tests (EN 14476), at 20°C, with a contact time of 60 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, virucidal activity is shown at the in-use concentration of 12.5% v/v
- For PT4 uses: virucidal activity (adenovirus and norovirus) is demonstrated in phase 2 step 1 tests (EN 14476), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, virucidal activity is shown at the in-use concentration of 3% v/v
- additional virucidal activity is demonstrated in phase 2, step 1 tests (EN 14476), at 20°C, with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
 - o 1% v/v for bovine coronavirus (CT: 5 minutes)
 - o 2% v/v for human rotavirus (CT: 5 minutes)

General disinfection PT2/PT4 (40°C):

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 4% v/v.
- additional bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
 - o 3% v/v for *Enterobacter cloacae*
 - o 3% v/v for *Salmonella* Typhimurium
 - o 3% v/v for *Lactobacillus brevis*

- 3% v/v for *Campylobacter jejuni*
 - 3% v/v for *Listeria monocytogenes*
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 10% v/v.
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 40°C, with a contact time of 30 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 4% v/v.

Conclusion on the efficacy of the product – Meta SPC 5

The products of the biocidal family FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS have shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 for the following uses:

META-SPC 5

- Use 1: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 02) – except health care facilities
- Use 2: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 02) – except health care facilities
- Use 3: Disinfection of equipment by manual dipping/soaking (PT 02) – except health care facilities
- Use 4: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) – except health care facilities
- Use 9: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 04)
- Use 10: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 04)
- Use 11: Disinfection of equipment by manual dipping/soaking (PT 04)
- Use 12: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 04)
- Use 29: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 02)
- Use 30: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02)
- Use 31: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 04)
- Use 32: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 04)
- Use 33: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 02) – except health care facilities
- Use 34: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 04)
 - Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 12.5% v/v, 30 min, 20°C, clean and dirty conditions, without mechanical action
 - PT2 uses: virus (including bovine coronavirus and human rotavirus): 12.5% v/v, 60 min, 20°C, clean and dirty conditions, without mechanical action

- PT4 uses: virus (including bovine coronavirus and human rotavirus): 3% v/v, 15 min, 20°C, clean and dirty conditions, without mechanical action
- Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Lactobacillus brevis*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 10% v/v, 15 min, 40°C, clean and dirty conditions, without mechanical action
- Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Lactobacillus brevis*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 4% v/v, 30 min, 40°C, clean and dirty conditions, without mechanical action

However:

- As no P2S1 tests against yeasts with a contact time of 15 minutes have been provided, yeasticidal activity is not demonstrated at 20°C, with a contact time of 15 minutes. Therefore, as both bacteria and yeasts are mandatory target organisms, efficacy with a contact time of 15 minutes (20°C) is not demonstrated and only efficacy with a contact time of 30 minutes (20°C) is validated.
- Additional virucidal activity against poliovirus for PT4 has been rejected as this target organisms is clearly identified as not relevant for PT4 uses in the efficacy guidance.

Moreover, the use in veterinary health care is not demonstrated as efficacy data have not been provided against *Proteus vulgaris* and only clean conditions have been validated for health care facilities (dirty conditions of medical areas (3.0 g/L BSA + 3.0 mL/L sheep erythrocytes) have not been tested for bacteria and yeasts). Therefore only clean conditions have been proven for the following uses:

- Use 1: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 02) – health care facilities (excluding the hospitals)
 - Use 2: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 02) – health care facilities (excluding the hospitals)
 - Use 3: Disinfection of equipment by manual dipping/soaking (PT 02) – health care facilities (excluding the hospitals)
 - Use 4: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) – health care facilities (excluding the hospitals)
 - Use 33: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 02) – health care facilities (excluding the hospitals)
- Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 12.5% v/v, 30 min, 20°C, clean conditions, without mechanical action
 - Virus (including bovine coronavirus and human rotavirus): 12.5% v/v, 60 min, 20°C, clean conditions, without mechanical action
 - Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Lactobacillus brevis*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 10% v/v, 15 min, 40°C, clean conditions, without mechanical action
 - Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Lactobacillus brevis*, *Campylobacter jejuni* and

Listeria monocytogenes) and yeasts: 4% v/v, 30 min, 40°C, clean conditions, without mechanical action

However:

- As no P2S1 tests against yeasts with a contact time of 15 minutes have been provided, yeasticidal activity is not demonstrated at 20°C, with a contact time of 15 minutes. Therefore, as both bacteria and yeasts are mandatory target organisms, efficacy with a contact time of 15 minutes (20°C) is not demonstrated and only efficacy with a contact time of 30 minutes (20°C) is validated.

- **Meta SPC 6**

For META-SPC6, efficacy tests have been performed with the representative product 6-1.

The composition of this test item is presented in the confidential section of the PAR with a justification regarding its representativeness of the Meta SPC 6.

Taking into account the variations of the co-formulants presented in this META-SPC and the efficacy data provided, the efficacy results of this representative product is considered as representative of products within this META-SPC.

The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

| 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 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC6 – Product 6-1 (24% w/w lactic acid) Batch: COM23/META SPC 6-1/2020-02-17 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 5%, 6%, 7%, 8% and 9% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 6% v/v. | COM23/METASPC6-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Report No 20/000212177 R.I.: 2 (no inactive dilution for <i>P. aeruginosa</i> , <i>S. aureus</i> and <i>E. coli</i> K12) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC6 – Product 6-1 (24% w/w lactic acid) Batch: COM23/META SPC6-1/2020-07-15 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 <i>L. monocytogenes</i> ATCC 19115 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 5% and 6% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>E. coli</i> , <i>L. monocytogenes</i> , <i>S. Typhimurium</i> , <i>E. cloacae</i> and <i>C. jejuni</i> demonstrated at 5% v/v. Activity against <i>L. brevis</i> is not demonstrated. | COM23/METASPC6-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Report No 20/000447288 R.I.: 2 |

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|-----------------------|--|--|---|-----------------|--|--|---|
| | | | <i>C. jejuni</i> ATCC 33560 | | | | |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC6 – Product 6-1 (24% w/w lactic acid) Batch: COM23/META SPC 6-1/2020-02-17 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <i>E. faecium</i> ATCC 6057 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 4%, 5%, 6%, 7% and 8% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 4% v/v. | COM23/METASPC6 -1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Report No 20/000212177 R.I.: 2 (no inactive dilution) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC6 – Product 6-1 (24% w/w lactic acid) Batch: COM23/META SPC6-1/2020-07-15 | <u>Bacteria</u> <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>E. coli</i> ATCC 10536 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <i>E. faecium</i> ATCC 6057 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.1%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | Bactericidal activity (<i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> , <i>E. coli</i> and <i>E. faecium</i>) demonstrated at 4% v/v. Activity against <i>L. brevis</i> demonstrated at 4% v/v. Activity against <i>E. cloacae</i> demonstrated at 2% v/v. Activity against <i>L. monocytogenes</i> , <i>S. Typhimurium</i> and <i>C. jejuni</i> demonstrated at 1% v/v. | COM23/METASPC6 -1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Report No 20/000447288 R.I.: 1 |

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|-----------------------|--|--|---|-----------------------------|---|---|---|
| | | | <i>L. brevis</i> DSM 6235 <i>L. monocytogenes</i> ATCC 19115 <i>C. jejuni</i> ATCC 33560 | | | | |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC6 – Product 6-1 (24% w/w lactic acid) Batch: COM23/META SPC 6-1/2020-02-17 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 5%, 6%, 7%, 8% and 9% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 6% v/v. | COM23/METASPC6 -1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C Report No 20/000212177 R.I.: 2 (no inactive dilution for <i>P. aeruginosa</i> , <i>E. hirae</i> and <i>E. coli</i> K12) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC6 – Product 6-1 (24% w/w lactic acid) Batch: COM23/META SPC6-1/2020-07-15 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 <i>L. monocytogenes</i> ATCC 19115 <i>C. jejuni</i> ATCC 33560 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.5%, 6% and 7% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>E. coli</i> , <i>L. brevis</i> , <i>L. monocytogenes</i> , <i>S. Typhimurium</i> and <i>E. cloacae</i> demonstrated at 6% v/v. Activity against <i>C. jejuni</i> demonstrated at 0.5% v/v. | COM23/METASPC6 -1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C Report No 20/000447288 R.I.: 2 (no inactive dilution for <i>C. jejuni</i>) |

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|-----------------------|--|---|--|-----------------------------|--|---|--|
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC6 – Product 6-1 (24% w/w lactic acid) Batch: COM23/META SPC6-1/2019-09-26/2 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 4% v/v. | COM23/METASPC6 -1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Report No 20/000022154 R.I.: 2 (no inactive dilution for <i>P. aeruginosa</i> and <i>E. hirae</i>) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC6 – Product 6-1 (24% w/w lactic acid) Batch: COM23/META SPC 6-1/2020-02-17 | Bacteria <u>Mandatory strain</u> <i>E. faecium</i> ATCC 6057 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>E. faecium</i> demonstrated at 3% v/v. | COM23/METASPC6 -1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Report No 20/000212177 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC6 – Product 6-1 (24% w/w lactic acid) Batch: COM23/META SPC6-1/2020-07-15 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>S. Typhimurium</i> ATCC 13311 <i>E. cloacae</i> DSM 6234 <i>L. brevis</i> DSM 6235 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.5%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>L. brevis</i> and <i>L. monocytogenes</i> demonstrated at 3% v/v. Activity against <i>E. coli</i> , <i>E. cloacae</i> , <i>S. Typhimurium</i> and <i>C. jejuni</i> demonstrated at 0.5% v/v. | COM23/METASPC6 -1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Report No 20/000447288 R.I.: 2 (no inactive dilution for <i>E. coli</i> , <i>E. cloacae</i> , <i>S. Typhimurium</i> and <i>C. jejuni</i>) |

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| | | | <i>L. monocytogenes</i> ATCC 19115 <i>C. jejuni</i> ATCC 33560 | | | | |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC6 – Product 6-1 (24% w/w lactic acid) Batch: COM23/META SPC6-1/2019-09-26/2 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 1650:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 5%, 6%, 7%, 8% and 9% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 30 min Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 9% v/v. | COM23/METASPC6 -1 – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 20°C Report No 20/000022154 R.I.: 1 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC6 – Product 6-1 (named "Formule 2-2 bis" in the report) (24% w/w lactic acid) Batch: 20181228/lab o1 | Yeasts <i>C. albicans</i> ATCC 10231 | UNI EN 1650:2013 | Phase 2 step 1 test (suspension test) Concentration tested: 2%, 3%, 4%, 5% and 7% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 5% v/v. | COM23 - Formule 2-2 bis – Evaluation of yeasticidal activity according to UNI EN 1650:2013 – 40°C Report No 19/000046002 R.I.: 1 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC6 – Product 6-1 (24% w/w lactic acid) Batch: COM23/META SPC6-1/2019-09-26/2 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 6%, 7%, 8%, 9% and 10% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 30 min | Yeasticidal activity demonstrated at 6% v/v. | COM23/METASPC6 -1 – Evaluation of yeasticidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C Report No 20/000022154 |

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|----------------------|--|--|---|-----------------------------|--|--|---|
| | | | | | Criteria: at least a 3 log reduction | | R.I.: 2 (no inactive dilution) |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC6 – Product 6-1 (24% w/w lactic acid) Batch: COM23/META SPC6-1/2019-09-26/2 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 2%, 3%, 4%, 5% and 6% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 4% v/v. | COM23/METASPC6 -1 – Evaluation of yeasticidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Report No 20/000022154 R.I.: 1 |

Disinfection by CIP PT2/PT4 (20°C):

- bactericidal activity is demonstrated in phase 2, step 1 tests (EN 1276), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 6% v/v.
- additional bactericidal activity is demonstrated in phase 2, step 1 tests (EN 1276), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
 - o 5% v/v for *Enterobacter cloacae*
 - o 5% v/v for *Salmonella* Typhimurium
 - o 5% v/v for *Campylobacter jejuni*
 - o 5% v/v for *Listeria monocytogenes*
- activity against *L. brevis* is not demonstrated in phase 2, step 1 test (EN 1276), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin).
- yeasticidal activity is demonstrated in phase 2, step 1 tests (EN 1650), at 20°C, with a contact time of 30 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 9% v/v.

Disinfection by CIP PT2/PT4 (40°C):

- bactericidal activity is demonstrated in phase 2, step 1 tests (EN 1276), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 4% v/v.
- additional bactericidal activity is demonstrated in phase 2, step 1 tests (EN 1276), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
 - o 2% v/v for *Enterobacter cloacae*
 - o 1% v/v for *Salmonella* Typhimurium
 - o 4% v/v for *Lactobacillus brevis*
 - o 1% v/v for *Campylobacter jejuni*
 - o 1% v/v for *Listeria monocytogenes*
- yeasticidal activity is demonstrated in phase 2, step 1 tests (EN 1650), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 5% v/v.

General disinfection PT2/PT4 (20°C):

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 6% v/v.
- additional bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
 - o 6% v/v for *Enterobacter cloacae*

- 6% v/v for *Salmonella* Typhimurium
 - 5% v/v for *Campylobacter jejuni*
 - 6% v/v for *Listeria monocytogenes*
- activity against *L. brevis* is not demonstrated in phase 2, step 1 test (EN 1276), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin).
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 30 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 9% v/v.

General disinfection PT2/PT4 (40°C):

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 4% v/v.
- additional bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
- 2% v/v for *Enterobacter cloacae*
 - 1% v/v for *Salmonella* Typhimurium
 - 4% v/v for *Lactobacillus brevis*
 - 1% v/v for *Campylobacter jejuni*
 - 3% v/v for *Listeria monocytogenes*
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 5% v/v.

Conclusion on the efficacy of the product – Meta SPC 6

The products of the biocidal family FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS have shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 for the following uses:

META-SPC 6

- Use 7: Disinfection of inner surfaces by CIP (PT 02)
- Use 15: Disinfection of inner surfaces by CIP (PT 04)
- Use 36: Disinfection of the inner surfaces of small kitchen appliances by CIP (PT 04)
 - Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 9% v/v, 30 min, 20°C, clean and dirty conditions
 - Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Lactobacillus brevis*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 5% v/v, 15 min, 40°C, clean and dirty conditions

- Use 1: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 02) – except health care facilities
- Use 2: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 02) – except health care facilities
- Use 3: Disinfection of equipment by manual dipping/soaking (PT 02) – except health care facilities
- Use 4: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) – except health care facilities
- Use 9: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 04)
- Use 10: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 04)
- Use 11: Disinfection of equipment by manual dipping/soaking (PT 04)
- Use 12: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 04)
- Use 35: Disinfection of the inner surfaces of small kitchen appliances without circulation (PT 04)
 - Bacteria (including *Enterobacter cloacae*, *Salmonella Typhimurium*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 9% v/v, 30 min, 20°C, clean and dirty conditions, without mechanical action
 - Bacteria (including *Enterobacter cloacae*, *Salmonella Typhimurium*, *Lactobacillus brevis*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 5% v/v, 15 min, 40°C, clean and dirty conditions, without mechanical action

The use in veterinary health care is not demonstrated as efficacy data have not been provided against *Proteus vulgaris* and only clean conditions have been validated for health care facilities (dirty conditions of medical areas (3.0 g/L BSA + 3.0 mL/L sheep erythrocytes) have not been tested for bacteria and yeasts). Therefore, only clean conditions have been proven for the following uses:

- Use 1: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 02) – health care facilities (excluding the hospitals)
- Use 2: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 02) – health care facilities (excluding the hospitals)
- Use 3: Disinfection of equipment by manual dipping/soaking (PT 02) – health care facilities (excluding the hospitals)
- Use 4: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) – health care facilities (excluding the hospitals)
 - Bacteria (including *Enterobacter cloacae*, *Salmonella Typhimurium*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 9% v/v, 30 min, 20°C, clean conditions, without mechanical action
 - Bacteria (including *Enterobacter cloacae*, *Salmonella Typhimurium*, *Lactobacillus brevis*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 5% v/v, 15 min, 40°C, clean conditions, without mechanical action
- Use 5: Disinfection of equipment by automatic application in cleaning washer (PT 02)
- Use 6: Disinfection of cleaning washer by automatic application (PT 02)
- Use 13: Disinfection of equipment by dish washing machine and crate washer (PT 04)

- Use 14: Disinfection of dish washing machine and crate washer (PT 04)
As efficacy data (SU or field test) have not been provided, the uses of disinfection by dish washing machine and crate washer are not demonstrated.

- **Meta SPC 7**

For META-SPC7, efficacy tests have been performed with the representative product 7-1. The composition of this test item is presented in the confidential section of the PAR with a justification regarding its representativeness of the Meta SPC 7.

Taking into account the variations of the co-formulants presented in this META-SPC and the efficacy data provided, the efficacy results of this representative product is considered as representative of products within this META-SPC.

The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

| 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 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC7 – Product 7-1 (1.44% w/w lactic acid) Batch: COM23/Meta SPC7-1/2019_10_01/1 | Bacteria <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 50% and 80% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 5 log reduction | Activity against <i>E. coli</i> K12 demonstrated at 80% v/v. Remarks: - Presence of flocs in the 50 and 1% dilutions. - Homogeneous at 80%. The lowest effective concentration without flocculation was retained. | COM23/METASPC7-1 – Evaluation of bactericidal activity against <i>E. coli</i> K12 according to BS EN 1276:2019 – 20°C Report No 20/000025084 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC7 – Named Formule 3-7 in the report, corresponding to the Product 7-1 (1.44% w/w lactic acid) Batch: HYC-3-7-1827 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>E. coli</i> ATCC 10536 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 | UNI EN 1276:2009 / EC1:2011 | Phase 2 step 1 test (suspension test) Concentration tested: 5%, 50% and 80% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 5 log reduction | Bactericidal efficacy demonstrated at 50% v/v. | FORMULE 3-7 - Evaluation of bactericidal activity according to UNI EN 1276:2009 / EC1:2011– 20°C TEST REPORT N. 18/000530536 R.I.: 2 (no inactive dilution for <i>E. coli</i> and <i>P. aeruginosa</i>) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC7 – Product 7-1 (1.44% w/w lactic acid) | Bacteria <u>Additional strains</u> | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 50% and 80% v/v Dirty conditions: 3 g/L BSA | Activity against <i>E. cloacae</i> , <i>S. Typhimurium</i> , <i>L. brevis</i> , <i>L. monocytogenes</i> and <i>C. jejuni</i> demonstrated at 50% v/v. | COM23/META SPC7-1 - Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C |

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| | | Batch: COM23 / MetaSPC7-1 / 2020-02-25 / 1 | <i>Enterobacter cloacae</i> DSM 6234 <i>Salmonella</i> Typhimurium ATCC 13311 <i>Lactobacillus brevis</i> DSM 6235 <i>Listeria monocytogenes</i> ATCC 19115 <i>Campylobacter jejuni</i> ATCC 29428 | | Temperature: 20°C Contact time: 15 min Criteria: at least a 5 log reduction | | Report No 20/000367130 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC7 – Named Formule 3-7 in the report, corresponding to the Product 7-1 (1.44% w/w lactic acid) Batch: HYC- 3-7-1827 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>E.coli</i> ATCC 10536 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 | UNI EN 13697: 2015 | Phase 2 step 2 test (non porous surface test) Concentration tested: 5%, 50% and 100% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 15 min Criteria: at least a 4 log reduction | Bactericidal efficacy demonstrated at 50% v/v. | FORMULE 3-7 - Evaluation of bactericidal activity according to UNI EN 13697: 2015– 20°C Report No 18/000530536 R.I.: 2 (no inactive dilution for <i>E. coli</i> , and <i>P. aeruginosa</i>) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC7 – Product 7-1 (1.44% w/w lactic acid) Batch: COM23/Meta SPC7- 1/2019_10_0 1/1 | Bacteria <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | UNI EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 1%, 50% and 100% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>E. coli</i> K12 demonstrated at 50% v/v. | Draft – COM23/METASPC7 -1 – Evaluation of bactericidal activity according to UNI EN 13697: 2015 + A1:2019 – 20°C Report No 20/000025084 R.I.: 2 |
| Bactericidal activity | Food, industrial, | Meta SPC7 – Product 7-1 | Bacteria | UNI EN 13697: | Phase 2 step 2 test (non porous surface test) | Activity against <i>E. cloacae</i> , <i>S.</i> | COM23/METASPC7 -1 – Evaluation of |

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| | domestic and institutional areas | (1.44% w/w lactic acid) Batch: COM23 / MetaSPC7-1 / 2020-02-25 / 1 | <u>Additional strains</u> <i>Enterobacter cloacae</i> DSM 6234 <i>Salmonella</i> Typhimurium ATCC 13311 <i>Lactobacillus brevis</i> DSM 6235 <i>Listeria monocytogenes</i> ATCC 19115 <i>Campylobacter jejuni</i> ATCC 29428 | 2015 + A1:2019 | Concentration tested: 1%, 50% and 100% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 15 min Criteria: at least a 4 log reduction | Typhimurium, <i>L. brevis</i> and <i>L. monocytogenes</i> demonstrated at 50% v/v. Activity against <i>C. jejuni</i> demonstrated at 1% v/v. | bactericidal activity according to UNI EN 13697: 2015 + A1:2019 – 20°C Report No 20/000367130 R.I.: 2 (no inactive dilution for <i>C. jejuni</i>) |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC7 – Named Formule 3-7 in the report, corresponding to the Product 7-1 (1.44% w/w lactic acid) Batch: HYC-3-7-1827 | Yeasts <i>C. albicans</i> ATCC 10231 | UNI EN 1650:2013 | Phase 2 step 1 test (suspension test) Concentration tested: 5%, 50% and 80% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 15 min Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 80% v/v. | FORMULE 3-7 - Evaluation of yeasticidal activity according to UNI EN 1650:2013 – 20°C Report No 18/000530536 R.I.: 1 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC7 – Named Formule 3-7 in the report, corresponding to the Product 7-1 (1.44% w/w lactic acid) | Yeasts <i>C. albicans</i> ATCC 10231 | UNI EN 13697: 2015 | Phase 2 step 2 test (non porous surface test) Concentration tested: 5%, 50% and 100% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 15 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 100% v/v. | FORMULE 3-7 – Evaluation of yeasticidal activity according to UNI EN 13697: 2015 – 20°C Report No 18/000530536 R.I.: 1 |

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| | | Batch: HYC-3-7-1827 | | | | | |
| Virucidal activity | Food, industrial, domestic and institutional areas | Meta SPC7 – Product 7-1 (1.44% w/w lactic acid) Batch: COM23/META SPC 7-1/2020.02.25 /1 | Virus <i>Adenovirus type 5</i> <i>Murine norovirus</i> | UNI EN 14476+A2:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 50% and 80% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 60 min Criteria: at least a 4 log reduction | Activity against Adenovirus and norovirus demonstrated at 50% v/v. | UNI EN 14476+A2:2019 Chemical disinfectants and antiseptics Quantitative suspension test for the evaluation of virucidal activity in the medical area (phase 2, step 1) – COM23/Meta SPC 7-1 - 20°C Report No 20/000367130 R.I.: 1 |
| Virucidal activity | Food, industrial, domestic and institutional areas | Meta SPC7 – Product 7-1 (1.44% w/w lactic acid) Batch: COM23/Meta SPC7-1/2020-08-26/ | Virus <i>Type 1 poliovirus (LSc-2ab)</i> | NF EN 14476+A2:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 50%, 80% and 97% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 60 min Criteria: at least a 4 log reduction | Activity against poliovirus demonstrated at 97% v/v. | Report No R2010LVGFB002-3 R.I.: 1 |
| Virucidal activity | Food, industrial, domestic and institutional areas | Meta SPC7 – Product 7-1 (named "LSN 7-1 in the report) (1.44% w/w lactic acid) | Virus <i>Additional virus Human rotavirus strain Wa</i> | EN 14476:2013 +A1:2015 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 5%, 20% and 50% v/v Medical dirty conditions: 3 g/L BSA + 3mL/L erythrocytes Temperature: 20°C Contact time: 5, 15 and 30 min | Activity against <i>Human rotavirus</i> demonstrated at 50% v/v (CT: 5 min). Remark: - small precipitation occurred | Report No L19/0626R.2 R.I.: 2 |

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| | | Batch: E754.01 | | | Criteria: at least a 4 log reduction | | |
| Virucidal activity | Food, industrial, domestic and institutional areas | Meta SPC7 – Product 7-1 (1.44% w/w lactic acid) Batch: COM23/Meta SPC7-1/2020-08-26/1 | Virus <u>Additional virus</u> <i>Bovine coronavirus strain L9</i> | NF EN 14476+A2: 2019 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 50% and 80% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 5 min Criteria: at least a 4 log reduction | Activity against bovine coronavirus demonstrated at 50% v/v. | Report No R2012LVGFB003 R.I.: 1 |
| Virucidal activity | Food, industrial, domestic and institutional areas | Meta SPC7 – Product 7-1 (1.44% w/w lactic acid) Batch: COM23/Meta SPC7-1/2020-08-26/1 | Virus <u>Additional virus</u> <i>Influenza virus H1N1</i> | NF EN 14476+A2: 2019 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 50% and 80% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 5 min Criteria: at least a 4 log reduction | Activity against <i>Influenza virus</i> demonstrated at 50% v/v. | Report No R2012LVGFB004 R.I.: 1 |
| Virucidal activity | Food, industrial, domestic and institutional areas | Meta SPC7 – Product 7-1 (1.44% w/w lactic acid) Batch: COM23/Meta SPC7-1/2020-08-26/1 | Virus <u>Additional virus</u> <i>Vaccinia virus Ankara</i> | NF EN 14476+A2: 2019 | Phase 2 step 1 test (suspension test) Concentration tested: 50%, 80% and 97% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 5 min Criteria: at least a 4 log reduction | Activity against <i>Vaccinia virus Ankara</i> demonstrated at 80% v/v. | Report No R2012LVGFB005-1 R.I.: 1 |

General disinfection PT2/PT4 (20°C):

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 50% v/v.
- additional bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
 - o 50% v/v for *Enterobacter cloacae*
 - o 50% v/v for *Salmonella* Typhimurium
 - o 50% v/v for *Lactobacillus brevis*
 - o 50% v/v for *Campylobacter jejuni*
 - o 50% v/v for *Listeria monocytogenes*
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 100% v/v.
- virucidal activity is demonstrated in phase 2 step 1 tests (EN 14476), at 20°C, with a contact time of 60 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, virucidal activity is shown at the in-use concentration of 97% v/v.
- Additional virucidal activity is also demonstrated in phase 2 step 1 test (EN 14476), at 20°C, with a contact time of 5 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, virucidal activity is shown at the in-use concentration of:
 - o 97% v/v for human rotavirus
 - o 50% v/v for bovine coronavirus
 - o 50% v/v for influenza virus
 - o 80% v/v for vaccinia virus Ankara

Conclusion on the efficacy of the product – Meta SPC7

The products of the biocidal family FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS, have shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 for the following uses:

META-SPC 7

- o Use 17: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 02) - except health care facilities
- o Use 18: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 02) - except health care facilities
- o Use 19: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) - except health care facilities
- o Use 20: Disinfection of toilet bowls and sanitary facilities by direct spreading /flooding (PT 02) - except health care facilities
- o Use 21: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 04)
- o Use 22: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 04)

- Use 23: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 04)
- Use 24: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 02)
- Use 25: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02)
- Use 26: Disinfection of toilet bowls and sanitary facilities by direct spreading /flooding (PT 02)
- Use 27: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 04)
- Use 28: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 04)
 - Bacteria (including *Enterobacter cloacae*, *Lactobacillus brevis*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 100% v/v, 15 min, 20°C, clean and dirty conditions, without mechanical action
 - Enveloped viruses: 100% v/v, 15 min, 20°C, clean and dirty conditions, without mechanical action
 - Virus (including bovine coronavirus, rotavirus, influenza virus): 100% v/v, 60 min, 20°C, clean and dirty conditions, without mechanical action

The use in veterinary health care is not demonstrated as efficacy data have not been provided against *Proteus vulgaris* and only clean conditions have been validated for health care facilities (dirty conditions of medical areas (3.0 g/L BSA + 3.0 mL/L sheep erythrocytes) have not been tested for bacteria and yeasts). Therefore, only clean conditions have been proven for the following uses:

- Use 17: Disinfection of hard surfaces and equipment by manual liquid spraying (PT 02) - health care facilities (excluding the hospitals)
- Use 18: Disinfection of hard surfaces by manual spraying using mural cleaning station (PT 02) - health care facilities (excluding the hospitals)
- Use 19: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) - health care facilities (excluding the hospitals)
- Use 20: Disinfection of toilet bowls and sanitary facilities by direct spreading /flooding (PT 02) - health care facilities (excluding the hospitals)
 - Bacteria (including *Enterobacter cloacae*, *Lactobacillus brevis*, *Salmonella* Typhimurium, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 100% v/v, 15 min, 20°C, clean conditions, without mechanical action
 - Enveloped viruses: 100% v/v, 15 min, 20°C, clean conditions, without mechanical action
 - Virus (including bovine coronavirus, rotavirus, influenza virus): 100% v/v, 60 min, 20°C, clean conditions, without mechanical action

- **Meta SPC 8**

For META-SPC8, efficacy tests have been performed with the representative product 8-2.

The composition of this test item is presented in the confidential section of the PAR with a justification regarding its representativeness of the Meta SPC 8.

Taking into account the variations of the co-formulants presented in this META-SPC and the efficacy data provided, the efficacy results of this representative product is considered as representative of products within this META-SPC.

The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

| 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 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC8 – Product 8-2 (6% w/w lactic acid) Batch: COM23/META SPC8-2/2020-03-05/1 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 50% and 80% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 60 min Criteria: at least a 5 log reduction | The lowest effective concentration without flocculation was retained for each target organism. As no effective concentration without flocculation is observed, the effective concentration determined in the corresponding phase 2 step 2 tests against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 are used. Remarks: - Presence of flocs in the 50% and 80% dilution. - Homogeneous at 1%. | COM23/METASP C8-2 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Report No 20/000175182 R.I.: 2 (no inactive dilution for <i>P. aeruginosa</i>) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC8 – Product 8-2 (6% w/w lactic acid) Batch: COM23/Méta SPC8/Product 8-2/2020-10-06 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 | EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 50% and 80% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 60 min Criteria: at least a 5 log reduction | Activity against <i>E. coli</i> demonstrated at 80% v/v. Remarks: - Presence of flocs in the 50% dilution. - Homogeneous at 80 and 1%. The lowest effective concentration without flocculation was retained. | Bactericidal activity of product Com 23 – Product 8-2 in accordance with the European standard EN 1276 (August 2019) Report No |

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| | | | | | | | R20201023- EN1276 20°C 60 min R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC8 – Product 8-2 (6% w/w lactic acid) Batch: COM23/Meta SPC8-2/2019_09_26 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 1%, 50% and 100% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 30 min Criteria: at least a 4 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 50% v/v. | COM23/METASP C8-2 – Evaluation of bactericidal activity according to UNI EN 13697: 2015 + A1:2019 – 20°C Report No 20/000025068 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC8 – Product 8-2 (6% w/w lactic acid) Batch: COM23/Méta SPC8/Product 8-2/2020-10-06 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 | EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 1%, 50% and 100% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 30 min Criteria: at least a 4 log reduction | Activity against <i>E. coli</i> demonstrated at 50% v/v. | Bactericidal activity of product Com 23 – Product 8-2 in accordance with the European standard EN 13697 (July 2019) Report No R20201023-EN13697 20°C 30 min R.I.: 2 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC8 – Product 8-2 (6% w/w lactic acid) | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 1650:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 50% and 80% v/v Dirty conditions: 3 g/L BSA | The lowest effective concentration without flocculation was retained for each target organism. | COM23/METASP C8-2 – Evaluation of yeasticidal activity according to BS |

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| | | Batch: COM23/META SPC8- 2/2020-03- 05/1 | | | Temperature: 20°C Contact time: 60 min Criteria: at least a 4 log reduction | As no effective concentration without flocculation is observed, the effective concentration determined in the corresponding phase 2 step 2 tests against <i>C. albicans</i> is used. Remarks: - Presence of flocs in the 50% and 80% dilution. - Homogeneous at 1%. | EN 1650:2019 – 20°C Report No 20/000175182 R.I.: 2 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC8 – Product 8-2 (6% w/w lactic acid) Batch: COM23/META SPC8- 2/2020-03- 05/1 | Yeasts <i>C. albicans</i> ATCC 10231 | UNI EN 13697: 2015 | Phase 2 step 2 test (non porous surface test) Concentration tested: 1%, 50% and 100% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 60 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 100% v/v. | COM23/METASP C8-2 – Evaluation of yeasticidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C Report No 20/000175182 R.I.: 1 |

General disinfection PT2/PT4 (20°C):

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 60 minutes with dirty conditions (3 g/L bovine albumin). Please note that for *P. aeruginosa*, *S. aureus*, and *E. hirae*, as no effective concentration without flocculation is observed in P2S1 test, the effective concentration is determined in the corresponding phase 2 step 2 tests. In these conditions, bactericidal activity is shown at the in-use concentration of 80% v/v.
- yeasticidal activity is demonstrated in phase 2, step 2 tests (EN 13697), at 20°C, with a contact time of 60 minutes with dirty conditions (3 g/L bovine albumin). Please note that, as no effective concentration without flocculation is observed in P2S1 test (EN1650), the effective concentration is determined in the corresponding phase 2 step 2 tests. In these conditions, yeasticidal activity is shown at the in-use concentration of 100% v/v.

Conclusion on the efficacy of the product – Meat SPC 8

The products of the biocidal family FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS, have shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 for the following uses:

META-SPC 8

- Use 18: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 02) – except health care facilities
- Use 19: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) – except health care facilities
- Use 20: Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding (PT 02) – except health care facilities
- Use 23: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 04)
- Use 25: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02)
- Use 26: Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding (PT 02)
- Use 28: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 04)
 - Bacteria and yeasts: 100% v/v, 60 min, 20°C, clean and dirty conditions, without mechanical action

The use in veterinary health care is not demonstrated as efficacy data have not been provided against *Proteus vulgaris* and only clean conditions have been validated for health care facilities (dirty conditions of medical areas (3.0 g/L BSA + 3.0 mL/L sheep erythrocytes) have not been tested for bacteria and yeasts). Therefore, only clean conditions have been proven for the following uses:

- Use 18: Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (PT 02) – health care facilities (excluding the hospitals)
- Use 19: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) – health care facilities (excluding the hospitals)

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| <ul style="list-style-type: none">○ Use 20: Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding (PT 02) – health care facilities (excluding the hospitals)<ul style="list-style-type: none">• Bacteria and yeasts: 100% v/v, 60 min, 20°C, clean conditions, without mechanical action |
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- **Meta SPC 9**

For META-SPC9, efficacy tests have been performed with the representative product 9-2.

The composition of this test item is presented in the confidential section of the PAR with a justification regarding its representativeness of the Meta SPC 9.

Taking into account the variations of the co-formulants presented in this META-SPC and the efficacy data provided, the efficacy results of this representative product is considered as representative of products within this META-SPC.

The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

| 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 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC9 – Named PAE GEL PRO/GP SURFACES in the report, corresponding to the Product 9-2 (2.9% w/w lactic acid) Batch: 02102019/2 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 50% and 80% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 60 min Criteria: at least a 5 log reduction | The lowest effective concentration without flocculation was retained for each target organism. As no effective concentration without flocculation is observed, the effective concentration determined in the corresponding phase 2 step 2 tests against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 are used. Remarks: - Presence of flocs in the 50% and 80% dilutions. - Homogeneous at 1%. | PAE GEL PRO/GP SURFACES – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Report No 20/000033180 R.I.: 2 (no inactive dilution for <i>P. aeruginosa</i>) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC9 – Named PAE GEL PRO/GP SURFACES in the report, corresponding to the Product 9-2 (2.96% w/w lactic acid) | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 | EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 50% and 80% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 60 min Criteria: at least a 5 log reduction | Activity against <i>E. coli</i> demonstrated at 50% v/v. | Bactericidal activity of product Com 23 – Product 9-2 in accordance with the European standard EN 1276 (August 2019) Report No R20201027-EN1276 20°C 60 min |

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| | | Batch: COM23/Méta SPC9/Product 9-2/2020-10- 06 | | | | | R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC9 – Named PAE GEL PRO/GP SURFACES in the report, corresponding to the Product 9-2 (2.9% w/w lactic acid) Batch: 02102019/2 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <u>Additional strain</u> <i>E. coli</i> K12 NCTC 10538 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 1%, 50% and 100% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 60 min Criteria: at least a 4 log reduction | Activity against <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>E. hirae</i> and <i>E. coli</i> K12 demonstrated at 50% v/v. | PAE GEL PRO/GP SURFACES – Evaluation of bactericidal activity according to UNI EN 13697: 2015 + A1:2019 – 20°C Report No 20/000033180 R.I.: 2 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC9 – Named PAE GEL PRO/GP SURFACES in the report, corresponding to the Product 9-2 (2.9% w/w lactic acid) Batch: COM23/Méta SPC9/Product 9-2/2020-10- 06 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 | EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 1%, 50% and 100% v/v Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 60 min Criteria: at least a 4 log reduction | Activity against <i>E. coli</i> demonstrated at 50% v/v. | Bactericidal activity of product Com 23 – Product 9-2 in accordance with the European standard EN 13697 (July 2019) Report No R20201027-EN13697 20°C 60 min R.I.: 2 |
| Yeasticidal activity | Food, industrial, domestic and | Meta SPC9 – Named PAE GEL PRO/GP SURFACES in the report, | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 1650:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 1%, 50% and 80% v/v | The lowest effective concentration without flocculation was retained for each target organism. | PAE GEL PRO/GP SURFACES – Evaluation of yeasticidal activity according to BS |

| | | | | | | | |
|----------------------|--|--|---|-----------------------------|--|---|---|
| | institutional areas | corresponding to the Product 9-2 (2.9% w/w lactic acid) Batch: 02102019/2 | | | Dirty conditions: 3 g/L BSA Temperature: 20°C Contact time: 60 min Criteria: at least a 4 log reduction | As no effective concentration without flocculation is observed, the effective concentration determined in the corresponding phase 2 step 2 tests against <i>C. albicans</i> is used. Remarks: - Presence of flocs in the 50% and 80% dilutions. - Homogeneous at 1%. | EN 1650:2019 – 20°C Report No 20/000033180 R.I.: 2 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC9 – Named PAE GEL PRO/GP SURFACES in the report, corresponding to the Product 9-2 (2.9% w/w lactic acid) Batch: 02102019/2 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 1%, 50% and 100% v/v Dirty conditions: 3 g/L BSA Temperature: 18-25°C Contact time: 60 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 100% v/v. | PAE GEL PRO/GP SURFACES – Evaluation of yeasticidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C Report No 20/000033180 R.I.: 1 |

General disinfection PT2/PT4 (20°C):

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 60 minutes with dirty conditions (3 g/L bovine albumin). Please note that for *P. aeruginosa*, *S. aureus* and *E. hirae*, as no effective concentration without flocculation is observed in P2S1 tests, the effective concentration is determined in the corresponding phase 2 step 2 tests. In these conditions, bactericidal activity is shown at the in-use concentration of 80% v/v.
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 60 minutes with dirty conditions (3 g/L bovine albumin). Please note that for *C. albicans*, as no effective concentration without flocculation is observed in P2S1 test, the effective concentration is determined in the corresponding phase 2 step 2 test. In these conditions, yeasticidal activity is shown at the in-use concentration of 100% v/v.

Conclusion on the efficacy of the product – Meta SPC 9

The products of the biocidal family FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS have shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 for the following uses:

META-SPC 9

- Use 19: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) – except health care facilities
- Use 20: Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding (PT 02) – except health care facilities
- Use 23: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 04)
- Use 25: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02)
- Use 26: Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding (PT 02)
- Use 28: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 04)
 - Bacteria and yeasts: 100% v/v, 60 min, 20°C, clean and dirty conditions, without mechanical action

The use in veterinary health care is not demonstrated as efficacy data have not been provided against *Proteus vulgaris* and only clean conditions have been validated for health care facilities (dirty conditions of medical areas (3.0 g/L BSA + 3.0 mL/L sheep erythrocytes) have not been tested for bacteria and yeasts). Therefore, only clean conditions have been proven for the following uses:

- Use 19: Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (PT 02) – except health care facilities
- Use 20: Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding (PT 02) – except health care facilities
 - Bacteria and yeasts: 100% v/v, 60 min, 20°C, clean conditions, without mechanical action

- **Meta SPC 10**

For META-SPC10, efficacy tests have been performed with the representative product 10-1.

The composition of this test item is presented in the confidential section of the PAR with a justification regarding its representativeness of the Meta SPC 10.

Taking into account the variations of the co-formulants presented in this META-SPC and the efficacy data provided, the efficacy results of this representative product is considered as representative of products within this META-SPC.

The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

| 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 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC10 – Product 10-1 (28.8% w/w lactic acid) Batch: COM23/META SPC10-1/2020-03-05/1 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>E. coli</i> ATCC 10536 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <i>E. faecium</i> ATCC 6057 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 1%, 2%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | Bactericidal efficacy demonstrated at 4% v/v. Remarks: - Presence of flocs in the 3, 2, 1 and 0.5% dilutions. - Homogeneous at 4%. The lowest effective concentration without flocculation was retained. | COM23/METASP C10-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Report No 20/000159147 R.I.: 2 (no inactive dilution for <i>P. aeruginosa</i>) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC10 – Product 10-1 (28.8% w/w lactic acid) Batch: COM23/META SPC10-1/2020-07-10/2 | Bacteria <u>Additional strains</u> <i>Enterobacter cloacae</i> DSM 6234 <i>Salmonella</i> Typhimurium ATCC 13311 <i>Lactobacillus brevis</i> DSM 6235 <i>Listeria monocytogenes</i> ATCC 19115 <i>Campylobacter jejuni</i> ATCC 29428 | BS EN 1276:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 0.5%, 4% and 5% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 5 log reduction | The lowest effective concentration without flocculation was retained for each target organism. As no effective concentration without flocculation is observed, the effective concentration determined in the corresponding phase 2 step 2 tests against <i>E. cloacae</i> , <i>L. brevis</i> and <i>L. monocytogenes</i> are used. | COM23/METASP C10-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Report No 20/000398595 R.I.: 2 (no inactive dilution for <i>S.</i> |

| | | | | | | | |
|-----------------------|--|--|---|-----------------------------|--|--|--|
| | | | | | | Activity against <i>S. Typhimurium</i> and <i>C. jejuni</i> demonstrated at 0.5%. Remarks: - Presence of small flocs in the 5 and 4% dilutions. - Homogeneous at 0.5%. The lowest effective concentration was retained for each target organism. | Typhimurium and <i>C. jejuni</i>) |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC10 – Product 10-1 (28.8% w/w lactic acid) Batch: COM23/META SPC10-1/2020-03-05/1 | Bacteria <u>Mandatory strains</u> <i>P. aeruginosa</i> ATCC 15442 <i>E. coli</i> ATCC 10536 <i>S. aureus</i> ATCC 6538 <i>E. hirae</i> ATCC 10541 <i>E. faecium</i> ATCC 6057 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.1%, 0.5%, 1%, 2% and 3% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Bactericidal efficacy demonstrated at 3% v/v. | COM23/METASP C10-1 – Evaluation of bactericidal activity according to UNI EN 13697: 2015 + A1:2019 – 40°C Report No 20/000159147 R.I.: 1 |
| Bactericidal activity | Food, industrial, domestic and institutional areas | Meta SPC10 – Product 10-1 (28.8% w/w lactic acid) Batch: COM23/META SPC10-1/2020-07-10/2 | Bacteria <u>Mandatory strain</u> <i>E. coli</i> ATCC 10536 <u>Additional strains</u> <i>Enterobacter cloacae</i> DSM 6234 <i>Salmonella</i> Typhimurium ATCC 13311 <i>Lactobacillus brevis</i> DSM 6235 | BS EN 13697: 2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 0.1%, 3% and 4% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Activity against <i>E. coli</i> , <i>S. Typhimurium</i> , <i>C. jejuni</i> , <i>L. brevis</i> , <i>L. monocytogenes</i> and <i>E. cloacae</i> demonstrated at 3% v/v. | COM23/METASP C10-1 – Evaluation of bactericidal activity according to UNI EN 13697: 2015 + A1:2019 – 40°C Report No 20/000398595 R.I.: 2 |

| | | | | | | | |
|----------------------|--|--|---|----------------------------|---|---|---|
| | | | <i>Listeria monocytogenes</i> ATCC 19115 <i>Campylobacter jejuni</i> ATCC 29428 | | | | |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC10 – Product 10-1 (28.8% w/w lactic acid) Batch: COM23/META SPC10-1/2019-09-30/1 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 1650:2019 | Phase 2 step 1 test (suspension test) Concentration tested: 3%, 4%, 5%, 6% and 7% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 4% v/v. | COM23/METASP C10-1 – PRODUCT 10-1 – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 40°C Report No 20/000024947 R.I.: 1 |
| Yeasticidal activity | Food, industrial, domestic and institutional areas | Meta SPC10 – Product 10-1 (28.8% w/w lactic acid) Batch: COM23/META SPC10-1/2020-03-05/1 | Yeasts <i>C. albicans</i> ATCC 10231 | BS EN 13697:2015 + A1:2019 | Phase 2 step 2 test (non porous surface test) Concentration tested: 12%, 14%, 16%, 18% and 20% v/v Dirty conditions: 3 g/L BSA Temperature: 40°C Contact time: 15 min Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 20% v/v. | COM23/METASP C10-1 – Evaluation of yeasticidal activity according to BS EN 13697:2015 + A1:2019 – 40°C Report No 20/000159147 R.I.: 1 |

General disinfection PT2/PT4 (40°C):

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 4% v/v.
- additional bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, activity is shown at the in-use concentration of:
 - o 3% v/v for *Salmonella* Typhimurium
 - o 3% v/v for *Campylobacter jejuni*
- additional bactericidal activity is also demonstrated in phase 2 step 2 tests (EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). As no effective concentration without flocculation is observed in P2S1 tests, the effective concentration is determined in the corresponding phase 2 step 2 tests. In these conditions, activity is shown at the in-use concentration of:
 - o 3% v/v for *Enterobacter cloacae*
 - o 3% v/v for *Lactobacillus brevis*
 - o 3% v/v for *Listeria monocytogenes*
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 40°C, with a contact time of 15 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 20% v/v.

Conclusion on the efficacy of the product – Meta SPC10

The products of the biocidal family FAMILLE DE PRODUITS ACIDE LACTIQUE TP2-TP4 – SOPRODIS have shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 for the following uses:

META-SPC 10

- o Use 11: Disinfection of equipment by manual dipping/soaking (PT 04)
 - Bacteria (including *Enterobacter cloacae*, *Salmonella* Typhimurium, *Lactobacillus brevis*, *Campylobacter jejuni* and *Listeria monocytogenes*) and yeasts: 20% v/v, 15 min, 40°C, clean and dirty conditions, without mechanical action

2.2.5.6 Occurrence of resistance and resistance management

No resistance phenomenon has been reported with lactic acid in the scientific literature.

No incidence of resistance to Lactic acid has been recorded until now. (Source: Assessment Report. L (+) Lactic Product types 2, 3 and 4. June 2017. RMS, Germany).

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

2.2.5.7 Known limitations

None.

2.2.5.8 Evaluation of the label claims

The uses assessed in this dossier belong to the Product Type 2 and the Product Type 4.

The products are used by professional and non-professional users.

Please refer to conclusion on efficacy regarding the accordance of the label claimed with the submitted efficacy data and uses claimed.

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

The "Famille de produits Acide lactique TP2-4" is not intended to be used with another biocidal product.

2.2.6 Risk assessment for human health


2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation


In vitro studies are available for skin corrosion.


No study was conducted for sensitisation, acute toxicity effects and eye irritation. Classification is determined by using the calculation method described in the Guidance on the Application of the CLP Criteria Version 5.0 (July 2017), based on the available data on each component.

| Summary table of <i>in vitro</i> studies on skin corrosion | | | | | |
|--|--|--|---|------------------------------|--|
| Method, Guideline, GLP status, Reliability | Test substance, Doses | Relevant information about the study | Results | Remarks | Reference |
| <p><i>In vitro</i> Membrane Barrier Test Method for Skin Corrosion, OECD Guideline 435 (July 2015), GLP compliance, Reliability level: 1</p> | <p>Test item: PH-20/0674</p> <p>In compatibility test: 150 µL</p> <p>In timescale category test: 150 µL</p> <p>In classification assay: 500 µL tested neat (without dilution)</p> <p>Positive control: sodium hydroxide (110 mg)</p> <p>Negative control: 6% propionic acid (500 µL)</p> | <p>Performed according to the Corrositex® Method</p> | <p>The test was performed following 3 steps.</p> <p>Step 1 – Compatibility test: confirmed by a color change (red coloration) within 5 minutes of observation</p> <p>Step 2 – Timescale Category test: strong color change of the liquids (bright pink coloration) → assignment to category 1</p> <p>Step 3 – endpoint measured = time to corrosion 4 replicates: disruption of the membrane after 27 min 38 sec.</p> <p>Negative control: no disruption of the membrane</p> <p>Positive control: disruption of the membrane after 09 min 57 sec.</p> <p><u>Conclusion:</u> According to the OECD 435 guideline and GHS criteria, the test item is corrosive to the skin and classified Skin Corr. 1B (H314 1B).</p> | <p>No deviation recorded</p> | <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>COM 23/META SPC 5-25</p> |

| Summary table of <i>in vitro</i> studies on skin corrosion | | | | | |
|--|---|--|--|-----------------------------|---|
| <i>In vitro</i> Membrane Barrier Test Method for Skin Corrosion, OECD Guideline 435 (July 2015), GLP compliance, Reliability level: 1 | Test item: PH-20/0672 In compatibility test: 150 µL In timescale category test: 150 µL In classification assay: 500 µL tested neat (without dilution) Positive control: sodium hydroxide (115.50 mg) Negative control: 6% propionic acid (500 µL) | Performed according to the Corrositex ® Method | The test was performed following 3 steps. Step 1 – Compatibility test: confirmed by a color change (red coloration) within 5 minutes of observation Step 2 – Timescale Category test: strong color change of the liquids (bright pink coloration) → assignment to category 1 Step 3 – endpoint measured = time to corrosion 4 replicates: disruption of the membrane after 30 min 16 sec. Negative control: no disruption of the membrane Positive control: disruption of the membrane after 09 min 57 sec. <u>Conclusion:</u> According to the OECD 435 guideline and GHS criteria, the test item is corrosive to the skin and classified Skin Corr. 1B (H314 1B). | No deviation recorded |  COM 23/META SPC 1-3 |

| Summary table of <i>in vitro</i> studies on skin corrosion | | | | | |
|---|---|---|---|--------------------------------------|--|
| <p><i>In vitro</i> Membrane Barrier Test Method for Skin Corrosion, OECD Guideline 435 (July 2015), GLP compliance, Reliability level: 1</p> | <p>Test item: PH-20/0673 In timescale category test: 150 µL In classification assay: 500 µL tested neat (without dilution) Positive control: sodium hydroxide (115.50 mg) Negative control: 6% propionic acid (500 µL)</p> | <p>Performed according to the Corrositex ® Method</p> | <p>The test was performed following 3 steps.</p> <p>Step 1 – Compatibility test: confirmed by a color change (red coloration) within 5 minutes of observation</p> <p>Step 2 – Timescale Category test: strong color change of the liquids (bright pink coloration) → assignment to category 1</p> <p>Step 3 – endpoint measured = time to corrosion 4 replicates: disruption of the membrane after 29 min 12 sec.</p> <p>Negative control: no disruption of the membrane</p> <p>Positive control: disruption of the membrane after 09 min 57 sec.</p> <p><u>Conclusion:</u> According to the OECD 435 guideline and GHS criteria, the test item is corrosive to the skin and classified Skin Corr. 1B (H314 1B).</p> | <p>No deviation recorded</p> | <p>[REDACTED] [REDACTED] [REDACTED] [REDACTED]</p> <p>COM 23/META SPC 4-2</p> |

| Summary table of <i>in vitro</i> studies on skin corrosion | | | | | |
|---|---|---|---|-------------|---|
| <p><i>In vitro</i> Membrane Barrier Test Method for Skin Corrosion, OECD Guideline 435 (July 2015), GLP compliance, Reliability level: 1</p> | <p>Test item: PH-20/0675 In timescale category test: 150 µL In classification assay: 500 µL tested neat (without dilution) Positive control: sodium hydroxide (115.50 mg) Negative control: 6% propionic acid (500 µL)</p> | <p>Performed according to the Corrositex ® Method</p> | <p>The test was performed following 3 steps.</p> <p>Step 1 – Compatibility test: confirmed by a color change (red coloration) within 5 minutes of observation</p> <p>Step 2 – Timescale Category test: strong color change of the liquids (bright pink coloration) → assignment to category 1</p> <p>Step 3 – endpoint measured = time to corrosion 4 replicates: disruption of the membrane after 27min.</p> <p>Negative control: no disruption of the membrane</p> <p>Positive control: disruption of the membrane after 09 min 57 sec.</p> <p><u>Conclusion:</u> According to the OECD 435 guideline and GHS criteria, the test item is corrosive to the skin and classified Skin Corr. 1B (H314 1B).</p> | <p>None</p> |  <p>COM 23/META SPC 6-1</p> |

| Summary table of <i>in vitro</i> studies on skin corrosion | | | | | |
|---|--|--|---|-------------|---|
| <p><i>In vitro</i> Membrane Barrier Test Method for Skin Corrosion, OECD Guideline 435 (July 2015), GLP compliance, Reliability level: 1</p> | <p>Test item: PH-20/0676 In timescale category test: 150 µL In classification assay: 500 µL tested neat (without dilution) Positive control: sodium hydroxide (112.70mg) Negative control: 6% propionic acid (500 µL)</p> | <p>Performed according to the Corrositex® Method</p> | <p>The test was performed following 3 steps. Step 1 – Compatibility test: confirmed by a color change (red coloration) within 5 minutes of observation Step 2 – Timescale Category test: strong color change of the liquids (bright pink coloration) → assignment to category 1 Step 3 – endpoint measured = time to corrosion 4 replicates: disruption of the membrane after 1h 02min and 22 sec. Negative control: no disruption of the membrane Positive control: disruption of the membrane after 12 min 41 sec. <u>Conclusion:</u> According to the OECD 435 guideline and GHS criteria, the test item is corrosive to the skin and classified Skin Corr. 1C (H314 1C).</p> | <p>None</p> |  <p>COM 23/META SPC 6-2</p> |

In vitro studies on the skin corrosion has been provided on representative products pertaining to the meta- SPC 1, 4, 5 and 6.
Based on the read-across approach, a classification Skin corr 1B- H314 is proposed for products pertaining to the meta-SPC 2, 3, 8, 10.
Please refer to confidential annex for further details.

META SPC 1, 2, 3, 4, 5, 6, 8, 10

| Conclusion used in Risk Assessment – Skin corrosion | |
|--|--|
| Value/conclusion | The products of the Meta SPC 1 to 6, 8 and 10 are considered to cause corrosion to the skin. |
| Justification for the value/conclusion | Based on the results of the provided studies and on the read-across approach (please see confidential annex), a classification Skin corr 1B- H314 is proposed for products pertaining to the meta-SPC 1, 2, 3, 4, 5, 6, 8, 10. |
| Classification of the product according to CLP and DSD | Classification Skin corrosion, category 1B, H314 : Causes skin corrosion is required |

META SPC 7 - 9

| Conclusion used in Risk Assessment – Skin irritation | |
|---|---|
| Value/conclusion | The products of meta SPC 7 and 9 are considered to cause skin irritation |
| Justification for the value/conclusion | No study on skin irritation was performed. The classification is determined using the calculation method of CLP Regulation. Considering the content of active substance and co-formulants in the products, a classification Skin Irrit.2 H315 (in accordance with Regulation EC/1272/2008) is needed. |
| Classification of the product according to CLP and DSD | Classification Skin irritant, category 2, H315: Causes skin irritation is required. |

Eye irritation

No in vitro, in vivo or human data on the eye irritation potential of products pertaining to meta-SPC 1 to 10 are available.

Meta SPC 1, 2, 3, 4, 5, 6, 7, 8, 9, 10

| Conclusion used in Risk Assessment – Eye irritation | |
|--|--|
| Value/conclusion | The products of meta 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 are considered to cause serious eye damage. |
| Justification for the value/conclusion | No study on eye irritation was performed. The classification is determined using the calculation method of CLP Regulation. Considering the content of active substance and co-formulants in the products, a classification Eye Dam.1 H318 (in accordance with Regulation EC/1272/2008) is needed. Calculation details in Confidential annex. |
| Classification of the product according to CLP and DSD | Classification Serious eye damage category 1, H318: Causes serious eye damage is required. |

Respiratory tract irritation

| Conclusion used in the Risk Assessment – Respiratory tract irritation | |
|--|---|
| Justification for the conclusion | Corrosive to the respiratory tract |
| Classification of the product according to CLP and DSD | <p>A co-formulant is classified H335 but is present in the formulation at a content below the concentration of 20%. Therefore, no classification is required for irritation to the respiratory tract.</p> <p>However, several products from the BPF required a classification Skin corr1B – H314 and inhaled exposure during use of the products is occurring. In this context and according to the CLP regulation, a supplementary hazard statement EUH 071 “Corrosive to the respiratory tract” is required for products pertaining to the following Meta SPCs:</p> <ul style="list-style-type: none"> - Meta SPC 1; - Meta SPC 2; - Meta SPC 3; - Meta SPC 4; - Meta SPC 5; - Meta SPC 6; - Meta SPC 8; - Meta SPC 10; |

Skin sensitization**META SPC 1, 2, 3, 5 and 10**

| Conclusion used in Risk Assessment – Skin sensitisation | |
|--|---|
| Value/conclusion | Sensitising to the skin |
| Justification for the value/conclusion | Based on the provided MSDS, CMIT/MIT is present as a minor ingredient in one co-formulant at a content ranging from 0.08 to 0.09%. Based on the content of the co-formulant in the META SPC 1, 2, 3, 5 and 10, the concentration of CMIT/MIT in the final products has been calculated (please see confidential annex). The specific limit concentration of the CMIT/MIT being of 15ppm, its presence leads to the classification H317 of the products from the meta-SPC 1, 2, 3, 5 and 10. |
| Classification of the product according to CLP and DSD | Classification skin sensitisation, category 1A, H317: May cause an allergic reaction is required for products of the meta-SPC 1, 2, 3, 5 and 10. |

Respiratory sensitization (ADS)

| Conclusion used in Risk Assessment – Respiratory sensitisation | |
|---|--|
| Value/conclusion | Not sensitive to the respiratory tract |
| Justification for the value/conclusion | One ingredient is classified sensitive to the respiratory tract, H334 Cat1. Regarding its maximal content in the relevant meta-SPC, no classification is required. |
| Classification of the product according to CLP and DSD | No classification is required. |

Acute toxicityAcute toxicity by oral route

| Value used in the Risk Assessment – Acute oral toxicity | |
|--|--|
| Value | Not toxic via oral route |
| Justification for the selected value | Some ingredients are classified Acute toxicity cat.4, H302. According to the additivity approach, none of meta SPC is classified for acute oral toxicity. See confidential annex for further details on the ATE mix calculation. |
| Classification of the product according to CLP and DSD | No classification is required. |

Acute toxicity by inhalation

| Value used in the Risk Assessment – Acute inhalation toxicity | |
|--|---|
| Value | Not toxic via inhalation |
| Justification for the selected value | According to the composition, none of the component is identified as toxicologically relevant via inhalation. |
| Classification of the product according to CLP and DSD | No classification is required. |

Acute toxicity by dermal route

| Value used in the Risk Assessment – Acute dermal toxicity | |
|--|---|
| Value | Not toxic via dermal route. |
| Justification for the selected value | According to the composition, none of the component is identified as toxicologically relevant via dermal route. |
| Classification of the product according to CLP and DSD | Not toxic via inhalation |

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

As mentioned in the hazard assessment part (2.2.6.1), the following substance contributes to the classification skin sensitisation, category 1A, H317:

- CMIT/MIT (Meta SPC 1-2-3-5 and 10)

According to the "Guidance on the BPR, volume III Human Health- Assessment & Evaluation (Parts B+C)" this classified ingredient that led to classification of products to the BPF should be considered as substance of concern (SoC). For this SoC, a banding evaluation is done according the scheme described in the "Guidance on the BPR, volume III Human Health- Assessment & Evaluation (Parts B+C)", p356.

2.2.6.2 Exposure assessment**Introductory remarks**

The products are part of the Disinfectants, PT2: Disinfectants and algeacides not intended for direct application to humans or animals and PT4: Disinfectants for surfaces which come into contact with foodstuffs and animal fodder.

The biocidal product family "SOPRODIS" is a water-based family composed of 10 meta-SPC used by professionals and non-professionals for:

- Disinfection of hard surfaces and equipment by manual liquid spraying (**Uses #1, 9, 17, 21**) → PROFESSIONALS
- Disinfection of hard surfaces by manual spraying using mural cleaning station (**Uses #2 and 10**) → PROFESSIONALS
- Disinfection of hard surfaces and equipment by manual dipping/ soaking (**Uses #3, 11**) → PROFESSIONALS
- Disinfection of hard surfaces by mopping, wiping, brushing, scrubbing (**Uses #4, 12, 19, 23**) → PROFESSIONALS and (**Uses #25, 28, 30, 32**) → NON PROFESSIONALS
- Disinfection by dish washing and cleaning washers (**Use #5, 6, 13, 14**) → PROFESSIONALS
- Disinfection of inner surfaces without circulation and by CIP (**Use #7, 15, 35, 36**) → PROFESSIONALS

-
- Disinfection of hard surfaces (small surfaces) and equipment by manual spraying via a trigger sprayer (**Use #18, 22, 33, 34**) → PROFESSIONALS and (**Use #24, 27, 29 and 31**) → NON PROFESSIONALS
 - Disinfection of toilets bowls and sanitary facilities by direct spreading/flooding (**Use 20#**) → PROFESSIONALS and (**Use 26#**) → NON PROFESSIONALS

All the uses of the biocidal product family are summarized for each META SPC in the table below.

Table 1: Summary of Uses developed in the exposure assessment

| | META SPC 1 | META SPC 2 | META SPC 3 | META SPC 4 | META SPC 5 | META SPC 6 | META SPC 7 | META SPC 8 | META SPC 9 | META SPC 10 |
|---------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|--------------------|
| Use 1 | x | x | x | x | x | x | | | | |
| Use 2 | x | x | x | x | x | x | | | | |
| Use 3 | x | x | x | x | x | x | | | | |
| Use 4 | x | x | x | x | x | x | | | | |
| Use 5 | | | | | | x | | | | |
| Use 6 | | | | | | x | | | | |
| Use 7 | | | | | | x | | | | |
| Use 9 | x | x | x | x | x | x | | | | |
| Use 10 | x | x | x | x | x | x | | | | |
| Use 11 | x | x | x | x | x | x | | | | x |
| Use 12 | x | x | x | x | x | x | | | | |
| Use 13 | | | | | | x | | | | |
| Use 14 | | | | | | x | | | | |
| Use 15 | | | | | | x | | | | |
| Use 17 | | | | | | | x | | | |
| Use 18 | | | | | | | x | x | | |
| Use 19 | | | | | | | x | x | x | |
| Use 20 | | | | | | | x | x | x | |
| Use 21 | | | | | | | x | | | |
| Use 22 | | | | | | | x | | | |
| Use 23 | | | | | | | x | x | x | |
| Use 24 | | | | | | | x | | | |
| Use 25 | | | | | | | x | x | x | |
| Use 26 | | | | | | | x | x | x | |
| Use 27 | | | | | | | x | | | |
| Use 28 | | | | | | | x | x | x | |
| Use 29 | x | | | x | x | | | | | |
| Use 30 | x | | | x | x | | | | | |
| Use 31 | x | | | x | x | | | | | |
| Use 32 | x | | | x | x | | | | | |
| Use 33 | x | | | x | x | | | | | |
| Use 34 | x | | | x | x | | | | | |
| Use 35 | | | | | | x | | | | |
| Use 36 | | | | | | x | | | | |

All disinfectants products of all the META SPC are liquid formulations to be diluted before application or RTU (Ready To Use) liquid formulations.

Following the WG TOX I - 2021 that was held on March 2021 and in the frame of the discussion of the CAR of Lactic Acid TP6, it has been agreed not to perform the comparison of endogenous L-(+)-lactic acid with systemic exposure levels at product authorization. Consequently, no calculation regarding the estimation of level of exposure of lactic acid is necessary.

Therefore, based on the classification of all the concentrated and diluted products of the BPF family (please see confidential annex fore more details about the classification), only a qualitative local risk assessment has been performed according to the Guidance on the Biocidal Products Regulation - Volume III Human health - Assessment and Evaluation (Parts B + C).

For classification of diluted products, please refer to the Excel file embedded in the Confidential Annex.

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

| Summary table: main paths of human exposure | | | | | |
|--|--|-------------------------------|--|--|-----------------|
| Exposure path | Primary (direct) exposure | | Secondary (indirect) exposure | | |
| | Professional users (including industrial users and trained professional users) | Non-professional users | Professional users (including industrial users and trained professional users) | Non-professional bystanders/ General public | Via food |
| Oral | No | No | No | Yes | Yes |
| Dermal | Yes | Yes | Yes | Yes | n.a. |
| Inhalation | Yes | Yes | Yes | Yes | n.a. |

Summary table: List of exposure scenarios

| Summary table: exposure scenarios | | |
|--|--|-------------------------------|
| Scenario and task number | Description of scenario and tasks | Exposed group |
| Professionals | | |
| Primary exposure | | |
| Use # 1, 2, 9, 10, 17, 21 : Disinfection of hard surfaces and equipment by manual liquid/foaming spraying | | |
| [Scenario 1] | Application by manual spraying using a compression sprayer | |
| Task [1.1] | Mixing and Loading | Professionals/ Industrials |
| Task [1.2] | Application by spraying using a compression sprayer | |
| Task [1.3] | Post application – Rinsing of the treated surfaces and cleaning of the sprayer | |
| Use # 3, 11 : Disinfection of hard surfaces and equipment by manual dipping / soaking | | |
| [Scenario 2] | Application by dipping/ soaking | |
| Task [2.1] | Mixing and loading | Professionals/ Industrials |
| Task [2.2] | Application by dipping in an immersion bath | |
| Task [2.3] | Post application – Rinsing of the treated surfaces/material/furniture with water | |
| Uses #4, #12, #19, #23- Disinfection of hard surfaces by wiping/mopping/brushing/scrubbing | | |
| [Scenario 3] | Application by wiping/mopping/scrubbing/brushing | |
| Task [3.1] | Mixing and Loading | Professionals/ Industrials |
| Task [3.2] | Application by mopping/wiping/scrubbing | |
| Task [3.3] | Post application - Rinsing of the treated surfaces with a mop/ cloth | |
| Uses #5, 6, 13, 14 – Disinfection of equipment by automatic application in cleaning washer/dish washing machine | | |
| [Scenario 4] | Treatment in cleaning washer/dish washing machine | |
| Task [4.1] | Mixing and Loading | Professionals/ Industrials |
| Task [4.2] | Application by automatic spraying in a closed system | |
| Task [4.3] | Post application – rinsing of the treated equipment and opening of the washer | |
| Use # 18, 22, 33, 34 : Disinfection of hard surfaces and equipment by trigger spray | | |
| [Scenario 5] | Application by manual spraying using a trigger spray | |
| Task [5.1] | Mixing and Loading | Professionals/ Industrials |
| Task [5.2] | Application by spraying using a trigger spray | |
| Task [5.3] | Post application – Rinsing of the treated surfaces with a cloth | |

| | | |
|---|--|-------------------------------|
| Uses #7, 15, 35, 36 - Disinfection by CIP and without circulation | | |
| [Scenario 6] | Application by CIP and without circulation | |
| Task [6.1] | Mixing and loading | Professionals/ Industrials |
| Task [6.2] | Application | |
| Task [6.3] | Post application – Rinsing of the treated surfaces | |
| Task [6.4] | Post application – cleaning/maintenance of the dosing pumps | |
| Task [6.5] | Post application – cleaning/maintenance of the circuit system | |
| Uses #20 - Disinfection of toilet bowls by direct spreading/flooding | | |
| [Scenario 7] | Application by flooding | |
| Task [7.1] | Application by pouring | Professionals/ Industrials |
| Task [7.2] | Post application – Brush/wipe of the toilet bowl | |
| Task [7.3] | Post application – Rinsing by flushing | |
| Secondary exposure | | |
| [Scenario 8] | Exposure of bystander during spray application | Professionals bystander |
| [Scenario 9] | Dermal contact with freshly treated surfaces | |
| Non professionals | | |
| Primary exposure | | |
| Uses #25, #28, #30, #32- Disinfection of hard surfaces by wiping/mopping/brushing/scrubbing | | |
| [Scenario 10] | Application by wiping/mopping/scrubbing/brushing | |
| Task [10.1] | Mixing and Loading | Non professionals |
| Task [10.2] | Application by mopping/wiping/scrubbing | |
| Task [10.3] | Post application - Rinsing of the treated surfaces with a mop/ cloth | |
| Use # 24, 27, 29, 31 : Disinfection of hard surfaces and equipment by trigger spray | | |
| Task [11.1] | Mixing and Loading | Non professionals |
| Task [11.2] | Application by spraying using a trigger spray | |
| Task [11.3] | Post application – Rinsing of the treated surfaces with a cloth | |
| Uses #26 - Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding | | |
| [Scenario 12] | Application by flooding | |
| Task [12.1] | Application by pouring | Non professionals |

| | | |
|---------------------------|--|---------------------------------------|
| Task [12.2] | Post application – Brush of the toilet bowl | |
| Task [12.3] | Post application – Rinsing by flushing | |
| Secondary exposure | | |
| Scenario 13 | Exposure of a bystander | Bystander / General public |
| Scenario 14 | Contact with wet treated surfaces and oral exposure due to hand-to-mouth transfer | General public |

Professional users (including industrial users)

Use #1, 2, 9, 10, 17, 21- Disinfection of hard surfaces and equipment by manual liquid spraying- PT 2 & 4 (META SPC 1, 2, 3, 4, 5, 6, 7)

Primary exposure

As the same tasks are performed with products of the META SPC 1, 2, 3, 4, 5, 6, 7 for the Uses #1, 2, 9, 10, 17, 21 the same exposure and risk assessment can be considered for these uses.

The product is diluted manually or (semi) automatically in water according to the claimed doses.

Then the professional user applies the diluted product/ RTU products on hard surfaces by manual liquid/foaming spraying using a compression sprayer.

According to the applicant, after the required contact time, the treated surfaces are rinsed with water and then wiped off or left to dry in open air.

Considering the spraying with a compression sprayer, it is considered that the product is rinsed with water using the same apparatus as for the application.

The cleaning of the compression sprayer is also taken into account in the assessment.

To be noted that for those uses, in first instance, the classification of the dilutions has been determined by calculation considering the worst-case dilution factor.

In a second step of the assessment, when an unacceptable risk has been observed considering the worst case content of a.s after dilution, the classification has been re-calculated taking into account a lowest dilution factor claimed by the applicant in the SPC for these specific uses (Please refer to the Confidential Annex for further details).

It regards the uses #1, 2, 9 and 10.

Scenario 1: Disinfection of hard surfaces by manual liquid spraying

Task [1.1] – Mixing and loading

| Description of Task [1.1]: Mixing and loading |
|--|
| <p>Before use, soluble concentrate products of the META SPC 1, 2, 3, 4, 6 are diluted into water at the claimed doses. The dilution step either is done manually if the packaging is less than 20L, or automatically if the packaging is more than 20L.</p> <p>For RTU products from the meta-SPC 7, a loading step in the sprayer is needed before the application by spraying.</p> <p>As concentrated products are classified, a qualitative risk assessment for local effects during the mixing and loading is performed.</p> |

Task [1.2]: Application by spraying using a compression sprayer

Description of Task [1.2] – Application by spraying with a compression sprayer

Products of meta-SPC 1, 2, 3, 4, 5, 6 are diluted in water according to the claimed doses, then the professional user applies the diluted products/ RTU products (meta-SPC 7) on hard surfaces by spraying/foaming using a compression sprayer.

As RTU and diluted products are classified, a qualitative risk assessment for local effects during the application by spraying is performed.

Task [1.3]: Post application –Rinsing of the treated surfaces and cleaning of the equipment

Description of Task [1.3] – Post-application - Rinsing of treated surfaces

After the required contact time, the products applied with a compression sprayer is rinsed off with water by the professional user, also using a compression sprayer. Then, the compression sprayer is manually cleaned.

Despite the dilution provided by the rinsing, it is difficult to consider that solution remaining on the surfaces is no more classified for dermal route. As a worst-case, a qualitative risk assessment is performed taking into account the classification of the in-use dilution and the RTU products.

Combined scenarios

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

Outcome of qualitative local risk assessment

Summary of the classification for Meta SPC 1, 2, 3, 4, 5, 6, 7: Concentrated and diluted products (worst case)

| Classification | Meta SPC1 | | Meta SPC2 | | Meta SPC3 | | Meta SPC4 | | Meta SPC5 | | Meta SPC6 | | Meta SPC7 |
|-------------------------------|-----------|---|-----------|---|-----------|---|-----------|---|-----------|---|-----------|---|-----------|
| | C | D | C | D | C | D | C | D | C | D | C | D | |
| H314 Cat 1 H317 1A H318 | X | | X | | X | | | | | X | | | |
| H314 Cat 1 H318 | | X | | X | | X | X | X | | X | X | | |
| H315 H318 | | | | | | | | | | | | | X |
| H315 H319 | | | | | | | | | | | | X | |

C: Concentrated product; D: Diluted product (worst case)
EUH071 if classification H314 and exposure by inhalation

Summary of the classification for Meta SPC 1, 2, 3, 4 and 5: Diluted products after refinement

| Meta SPC 1 | Meta SPC 2 | Meta SPC 3 | Meta SPC 4 | Meta SPC 5 |
|------------|------------|------------|------------|------------|
| H315, H318 | H315, H318 | H315, H318 | H315, H318 | H315, H318 |

The professional is using the product for the mixing & loading task for a low duration per day and with PPE. Considering this, the risk is deemed acceptable.

For application by compression sprayer, the professional is using the product for more than few minutes per day and no high level of containment is expected even with the use of PPE. Therefore, the risk is not considered acceptable for diluted products classified H314/H317 1A/ H318.

After refinement, for diluted products of Meta SPCs 1 to 5 classified H315/H318, the risk is deemed acceptable considering appropriate PPE.

For diluted products from the meta-SPC 6 classified H315/H319 and RTU product from meta-SPC 7 classified H315/H318, the risk is deemed acceptable considering appropriate PPE.

Outcome of qualitative local risk assessment – Handling of products classified for skin, inhalation and eye damages during treatment with a compression sprayer - Professionals

| Hazard | | Exposure information | | | | | Risk | | | |
|--|--|----------------------|----------------------------------|--------------------------|--|--|--|--|--------------------------|---|
| Hazard category | Effects in terms of C&L | PT | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant PPE | Relevant RMMs | Conclusion on local risk | Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓) |
| Meta SPC 1, 2, 3, 4, 5, 6 (soluble concentrate) | | | | | | | | | | |
| HIGH | Skin Corr, Cat 1 (H314) - Skin sens Cat 1A (H317) Eye Dam. Cat 1 (H318) | 2 4 | M&L (manual or (semi)-automated) | Skin Eye | Frequency : 1/day_ Duration : no data but 10 min expected | Direct dermal contact and potential splashes or spills Hand-to-eye transfer | Use of appropriate personal protective equipment: - <u>Hand protection</u> : gloves <u>Eye protection</u> : goggles <u>Body protection</u> : Protective overall | <u>Labelling</u> : - Labelling according to CLP <u>Professionals</u> : - Professional workers Instructions for use minimizing exposure for professionals | Acceptable | (↑) High hazard category (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low frequency and exposure duration (few minutes per day) |
| Meta SPC 1, 2, 3, 4, 5, 6 (diluted products – Worst case) and 7 (RTU) | | | | | | | | | | |

| | | | | | | | | | |
|-------------|---|----------------|--|------------|---|---|---|-----------------------|---|
| HIGH | Skin Corr, Cat 1 (H314) - Skin sens Cat 1A (H317) | 2 4 | Application by compression spraying/foaming Rinsing | Skin | Frequency : 1/day Duration : no data but potentially high exposure duration (2h) | Dermal contact with treated surfaces Deposit of aerosols on skin | - | Not acceptable | (↑) High hazard category (↑) High exposure duration (↑) <u>Spray application</u> (high level of exposure) (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE |
| | EUH 071 | | | Inhalation | | Aerosols generated | | | |
| | Eye Dam. Cat 1 (H318) | | | Eye | | Eye exposure through potential splashes or hand to eye transfer during task | | | |
| | LOW | | | Skin | | Dermal contact with treated surfaces Deposit of aerosols on skin | | | Gloves Skin coverall Eye protection Optional face shield |

| | | | | | | |
|-------------|-------------------------------|-----|---|------------------|--|---|
| HIGH | Eye Irrit. Cat 2 (H319) | Eye | Eye exposure through potential splashes or hand to eye transfer during task | Chemical goggles | Instructions for use minimizing exposure for professionals | (↑) <u>Spray application</u> (high level of exposure) (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE |
| | Eye Dam. Cat 1 (H318) | | | | | |

Meta SPC 1, 2, 3, 4, 5 (diluted products after refinement)

| | | | | | | | |
|------------|--------------------------------|------|---|---|--|------------|--|
| LOW | Skin Irrit. Cat 2 (H315) | Skin | Dermal contact with treated surfaces Deposit of aerosols on skin | Gloves Skin coverall Eye protection Optional face shield | <u>Labelling:</u> - Labelling according to CLP <u>Professionals:</u> - Professional workers | Acceptable | (↑) High exposure duration (↑) <u>Spray application</u> (high level of exposure) (↓) Professionals following instructions for use and RMM on the label |
| | HIGH | | | | | | |

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SOPRODIS >

<PT2, 4>

| | | | | | | | | | |
|--|--|--|--|--|----------------------|--|--|--|-----------------------------|
| | | | | | transfer during task | | | | (↓) Professionals using PPE |
|--|--|--|--|--|----------------------|--|--|--|-----------------------------|

Conclusion: Disinfection by manual spraying – Uses 1, 2, 9, 10, 17, 21**META SPC 1, 2, 3, 4, 5, 6, 7**

For products pertaining to the Meta-SPC 6 and RTU products pertaining to the meta-SPC 7, the risk is considered acceptable taking into account the qualitative risk assessment for local effects with the application of personal protective equipment (PPE) listed below:

- * For mixing and loading task: gloves, protective coverall and chemical goggles.
- * For application and rinsing by compression sprayer: gloves, protective coverall and chemical goggles

After refinement, for products pertaining to the Meta-SPC 1, 2, 3, 4 and 5, the risk is considered acceptable in the conditions described in the SPC (dose and temperature) and taking into account the qualitative risk assessment for local effects with the application of personal protective equipment (PPE) listed below:

- * For mixing and loading task: gloves, protective coverall and chemical goggles.
- * For application and rinsing by compression sprayer: gloves, protective coverall and chemical goggles

Uses # 3 & 11- Disinfection of hard surfaces and equipment by manual dipping/soaking- PT 2 & 4 (META SPC 1, 2, 3, 4, 5, 6, 10)**Scenario 2: Disinfection by dipping**

Primary exposure

As the same tasks are performed with products of META SPC 1, 2, 3, 4, 5, 6 and 10 for the Uses #3 and #11, it has been considered that the same exposure and risk assessment can be done for these uses.

The concentrated products of the META SPC 1, 2, 3, 4, 5, 6 and 10 are diluted into water prior to their application.

The professional user is disinfecting the equipments or the materials using an immersion bath containing the diluted product.

The products are diluted manually or (semi) automatically in water according to the claimed doses.

After immersion, the equipments or the materials are rinsed using an immersion bath containing water.

It is considered that the exposure during the cleaning of the equipment (immersion bath) is covered by the exposure during the application.

Task [2.1] – Mixing and loading

Description of Task [2.1]: Mixing and loading

Before use, products of the meta-SPC 1, 2, 3, 4, 5, 6 and 10 are diluted into water at the claimed doses. The dilution step either is done manually if the packaging is less than 20L, or automatically if the packaging is more than 20L.

As concentrated products are classified, a qualitative risk assessment for local effects during the mixing and loading is performed.

Task [2.2] – Application by dipping in an immersion bath

Description of Task [2.2]: Application by dipping in an immersion bath

After dilution, the professional user disinfects the instruments or equipments by dipping them in an immersion bath containing the diluted product. Then the user removes the treated equipments from the bath and leave them to dry.

As diluted products are classified, a qualitative risk assessment for local effects is performed.

Task [2.3] – Rinsing of the treated equipment with water

Description of Task [2.3]: Post application - Rinsing of treated equipment with water

After the treatment by immersion, the professional user rinses the equipment and materials by dipping them into a bath filled water.

As the diluted products are classified for human health, a qualitative risk assessment is performed.

Combined scenarios

Not relevant.

Risk characterisation for primary exposure for Uses : 3/11 (Hard surfaces disinfection) - professionals

Outcome of qualitative local risk assessment

Summary of the classification for Meta SPC 1, 2, 3, 4, 5, 6, 10

| | | | | | | | |
|----------------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| Classification | Meta SPC1 | Meta SPC2 | Meta SPC3 | Meta SPC4 | Meta SPC5 | Meta SPC6 | Meta SPC10 |
|----------------|-----------|-----------|-----------|-----------|-----------|-----------|------------|

| | C | D | C | D | C | D | C | D | C | D | C | D | C | D |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| H314 Cat 1 H317 1A H318 | X | | X | | X | | | | X | X | | | X | X |
| H314 Cat 1 H318 | | X | | X | | X | X | X | | | X | | | |
| H315 H319 | | | | | | | | | | | | X | | |

C: Concentrated product; D: Diluted product
EUH071 if classification H314 and exposure by inhalation

All the products are intended to be applied by professional users.

Considering that, a qualitative risk assessment is performed. Please refer to the tables below.

The professional is using the product for the mixing & loading task for a low duration per day and with PPE. Considering this, the risk is deemed acceptable during M&L task considering appropriate PPE.

The professional will be exposed few minutes per day during the dipping tasks considering the use of PPE and the RMM to prevent direct contact with the in-use dilution "Let the equipment soak for the necessary time in the bath of cleaning/disinfectant solution, then empty the bath, and finish by rinsing without touching the equipment that has remained in the tank"and "do not immerse hands in the bath" the risk is deemed acceptable. Products classified H315 are used in the same conditions (frequency, duration of exposure) as the products classified H314. Hence, the same PPE are required for the use of all these products (gloves, coverall and chemical goggles).

Outcome of qualitative local risk assessment for professional users –

| Hazard | | Exposure information | | | | | Risk | | | |
|--|--|----------------------|----------------------------------|--------------------------|--|--|--|--|--------------------------|---|
| Hazard category | Effects in terms of C&L | PT | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant PPE | Relevant RMMs | Conclusion on local risk | Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓) |
| Meta SPC 1, 2, 3, 4, 5, 6, 10 (soluble concentrate) | | | | | | | | | | |
| HIGH | Skin Corr, Cat 1 (H314) - Skin sens Cat 1A (H317) Eye Dam. Cat 1 (H318) | 2 4 | M&L (manual or (semi)-automated) | Skin Eye | Frequency :_1/day_ Duration : no data but 10 min expected | Direct dermal contact and potential splashes or spills Hand-to-eye transfer | Use of appropriate personal protective equipment: - <u>Hand protection</u> : gloves <u>Eye protection</u> : goggles <u>Body protection</u> : Protective overall | <u>Labelling</u> : - Labelling according to CLP <u>Professionals</u> : - Professional workers Instructions for use minimizing exposure for professionals | Acceptable | (↑) High hazard category (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low frequency and exposure duration (few minutes per day) |
| Meta SPC 1, 2, 3, 4, 5, 6, 10 (only diluted products) | | | | | | | | | | |

| | | | | | | | | | | |
|-------------|---|-----------|---------------------------------------|------|---|---|---|--|------------|--|
| HIGH | Skin Corr, Cat 1 (H314) - Skin sens Cat 1A (H317) | 24 | Application by dipping Rinsing | Skin | Frequency: no data Duration: few minutes | Dermal contact through hand dipping | Gloves Skin coverall Eye protection Optional face shield | Labelling: - Labelling according to CLP | Acceptable | (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low exposure duration (few minutes per day) (↓) Exposure limited with the use of a basket or another appropriate device (↑) Potentially high frequency |
| | Eye Dam. Cat 1 (H318) | | | Eye | | Eye exposure through potential splashes or hand to eye transfer during task | Chemical goggles | Professionals: - Professional workers - Instructions for use minimizing exposure for professionals RMM: - Do not immerse hands in the bath - Let the equipment soak for the necessary time in the bath of cleaning/disinfectant solution, then empty the bath, and finish by rinsing without touching the equipment | | |

| | | | | | | | | |
|------------|--------------------------|--|------|---|---|--|--|--|
| LOW | | | | | | that has remained in the tank | | |
| | Skin Irrit. Cat 2 (H315) | | Skin | Dermal contact through hand dipping | Gloves Skin coverall Eye protection Optional face shield | Labelling: - Labelling according to CLP | | |
| | Eye Irrit. Cat 2 (H319) | | Eye | Eye exposure through potential splashes or hand to eye transfer during task | Chemical goggles | Professionals: - Professional workers - Instructions for use minimizing exposure for professionals | | |

Conclusion: Disinfection by manual dipping – Uses 3 and 11**META SPC 1, 2, 3, 4, 5, 6, 10**

For diluted products pertaining to the Meta-SPC 1, 2, 3, 4, 5, 6, 10 the risk is considered acceptable taking into account the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

PPE:

- * For mixing and loading task: gloves, protective coverall and chemical goggles.
- * For application and rinsing: gloves, protective coverall and chemical goggles

RMM (only for meta-SPC 1, 2, 3, 4, 5, 10)

“Do not immerse hands in the bath”.

“Let the equipment soak for the necessary time in the bath of cleaning/disinfectant solution, then empty the bath, and finish by rinsing without touching the equipment that has remained in the tank” **Uses # 4, 12, 19, 23 - Disinfection of hard surfaces by wiping/scrubbing/mopping/brushing - PT 2 & 4 (META SPC 1, 2, 3, 4, 5, 6, 7, 8, 9)**

Primary exposure

As the same tasks are performed with products of the meta-SPC 1, 2, 3, 4, 5, 6, 7, 8, 9 for these claimed uses, it has been considered that the same exposure and risk assessment can be done for these uses.

The concentrated products of the META SPC 1, 2, 3, 4, 5, 6 are diluted into water prior to their application.

The diluted and RTU products are manually applied (e.g. with a sponge, a cloth, a brush or a mop) onto surfaces to be treated without a mechanical action, as claimed by the applicant.

After the disinfection treatment, the treated surfaces are thoroughly rinsed with water and then wiped off or left to dry in open air.

A qualitative local risk assessment is performed when the product or the dilution is classified for human health.

Scenario 3: Disinfection by wiping/mopping/brushing/scrubbing**Task [3.1] – Mixing and loading**

Description of Task [3.1] – Mixing and Loading

Before the application by wiping / mopping / scrubbing, the products of the meta-SPC 1, 2, 3, 4, 5, 6 are diluted in water according to the claimed doses. The dilution step is either done manually if the packaging is less than 20L, or (semi-)automatically if the packaging is more than 20L.

For RTU products, a loading task is required before the application.

As all the products of the meta-SPC 1, 2, 3, 4, 5, 6, 7, 8, 9 are classified for human health, a qualitative risk assesment is performed.

Task [3.2] – Application by mopping / wiping / scrubbing/brushing

Description of Task [3.2] – Application by mopping / wiping / scrubbing

The professional user applies the dilution/RTU products on surfaces by wiping using a mop, brush or a cloth and bucket.

A qualitative local risk assessment during the application task is performed as the in-use dilutions and RTU products are classified for human health.

Task [3.3]: Post-application – Rinsing with a mop or a wet cloth

Description of Task [3.3]: Post-application –Rinsing with a mop or a cloth

After the required contact time, the product applied by mopping / wiping / scrubbing is rinsed off with water using a mop or a wet cloth.

Despite the dilution provided by the rinsing, it is difficult to consider that solution remaining on the surfaces is no more classified for dermal route. As a worst-case, a qualitative risk assessment is performed taking into account the classification of the RTU and diluted products.

Combined scenarios

Not relevant.

Risk characterisation for primary exposure for Uses : 4/12/19/23 (Hard surfaces disinfection) - professionals

Outcome of qualitative local risk assessment (dermal)

All the claimed products are intended to be used by professionals.

Summary of the classification for Meta SPC 1, 2, 3, 4, 5, 6, 7, 8, 9

| Classification | Meta SPC1 | Meta SPC2 | Meta SPC3 | Meta SPC4 | Meta SPC5 | Meta SPC6 | Meta SPC7 | Meta SPC8 | Meta SPC9 |
|----------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| | | | | | | | | | |

| | C | D | C | D | C | D | C | D | C | D | C | D | RTU | RTU | RTU |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|-----|-----|-----|
| H314 Cat 1 H317 1A H318 | X | | X | | X | | | | X | | | | | | |
| H314 Cat 1 H318 | | X | | X | | X | X | X | | X | X | | | X | |
| H315 H318 | | | | | | | | | | | | | X | | X |
| H315 H319 | | | | | | | | | | | | X | | | |

C: Concentrated product; D: Diluted product

EUH071 if classification H314 and exposure by inhalation

Considering that, a qualitative risk assessment is performed. Please refer to the table below.

For the mixing and loading task, the professional is using the product for a low duration per day and with PPE. Considering this, the risk is deemed acceptable.

The diluted products of the Meta-SPC 1, 2, 3, 4, 5 are classified Skin corrosive cat 1 (H314) Skin sensitive cat 1A (only meta-SPC 5) and severe eye damage (H318). Diluted products of the meta-SPC 6 are classified Skin irritant cat 2 (H315) and eye irritant (H319).

For application by mopping / scrubbing and rinsing, the professional will be exposed to the dilution few minutes per day considering the use of PPE and the RMM to prevent direct contact with the in-use dilution: "A mop/brush with a handle has to be used to apply the diluted solution" and "do not immerse hands in the diluted solution". Considering this, the risk is deemed acceptable.

For application by wiping/scrubbing, the professional will be exposed to the dilution few minutes per day. Considering the use of PPE and the RMM to prevent direct contact with the in-use dilution: "Pour the solution direct on the surface and wipe with a cloth / brush". Considering this, the risk is deemed acceptable. The risk is also considered acceptable during rinsing with wet cloth considering the use of PPE, the rinsing with water and the cloth, no direct contact is expected with the dilution.

Outcome of qualitative local risk assessment for disinfection surfaces– by professional users: Products from meta-SPC1, 2, 3, 4, 5, 6, 7.

| Hazard | | Exposure information | | | | | | | Risk | |
|-----------------|--|----------------------|------------------------|---|---|---|---|--|--------------------|---|
| Hazard category | Effects in terms of C&L | PT | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant PPE | Relevant RMM | Conclusion on risk | Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓) |
| HIGH | Skin Corr, Cat 1 (H314) - Skin sens Cat 1A (H317) | 2, 4 | Mixing and loading | Skin | Frequency: no data Duration: Mixing and loading: 10min | Dermal contact | Gloves Skin coverage Eye protection Optional face shield | Labelling: - Labelling according to CLP Professionals: - Professional workers - Instructions for use minimizing exposure for professionals | Acceptable | (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low exposure duration (few minutes per day) (↑) Potentially high frequency (↑) High hazard category |
| | Eye | | | Eye exposure through potential splashes or hand to eye transfer during task | | Chemical goggles | | | | |
| LOW | Skin Irrit. Cat 2 (H315) | | | Skin | Dermal contact | Gloves Skin coverage Eye protection Optional face shield | | | | |
| | Eye Irrit. | | | Eye | Eye exposure through | Chemical goggles | | | | |

| | | | | | | | |
|--|-----------------|--|--|--|--|--|--|
| | Cat 2 (H319) | | | potential splashes or hand to eye transfer during task | | | (↓) Professionals using PPE (↓) Low exposure duration (few minutes per day) (↑) Potentially high frequency (↓) Low hazard category |
|--|-----------------|--|--|--|--|--|--|

Outcome of qualitative local risk assessment for disinfection of surfaces- application by wiping, mopping, brushing, scrubbing - by professional users: Diluted products of meta-SPC 1, 2, 3, 4, 5, 6 and RTU products of meta-SPC 7, 8, 9.

| Hazard | | Exposure information | | | | | | | Risk | |
|-----------------|---|----------------------|---|--------------------------|--|---|---|---|--------------------|---|
| Hazard category | Effects in terms of C&L | PT | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant PPE | Relevant RMM | Conclusion on risk | Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓) |
| HIGH | Skin Corr, Cat 1 (H314) - Skin sens Cat 1A (H317) | | Application by mopping / scrubbing Rinsing | Skin | Frequency: everyday Duration: few minutes | Dermal contact with in-use product and treated surfaces | Gloves Skin coverall Eye protection Optional face shield | <u>Labelling</u> <ul style="list-style-type: none"> Labelling according to CLP <u>Trained personnel</u> <ul style="list-style-type: none"> Professional workers Instructions for use minimizing exposure for professionals <u>RMM</u> <ul style="list-style-type: none"> A mop/brush with a handle has to be used to apply the solution do not immerse hands in the diluted solution | Acceptable | (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low duration of exposure considering the proposed RMM (↑) High frequency |
| | Eye Dam Cat 1 (H318) | | | Eye | | Hand-to-eye transfer | Chemical goggles | | | |
| LOW | Skin Irrit. Cat 2 (H315) | | | Skin | | Dermal contact with in-use product and treated surfaces | Gloves Skin coverall Eye protection Optional face shield | <u>Labelling</u> <ul style="list-style-type: none"> Labelling according to CLP <u>Trained personnel</u> | | Acceptable |

| | | | | | | | | | | |
|-------------|---|--------------------------------------|------|--|--|---|---|--|---|--|
| | Eye Irrit. Cat 2 (H319) | | | | | | | <ul style="list-style-type: none"> Professional workers Instructions for use minimizing exposure for professionals | | (↓) Professionals using PPE |
| HIGH | Eye Dam Cat 1 (H318) | | Eye | | Hand-to-eye transfer | Chemical goggles | | | | (↑) High frequency |
| HIGH | Skin Corr, Cat 1 (H314) - Skin sens Cat 1A (H317) | Application by wiping Rinsing | Skin | Frequency: everyday Duration: few minutes | Dermal contact with in-use solution and treated surfaces | Gloves Skin coverall Eye protection Optional face shield | <u>Labelling</u> <ul style="list-style-type: none"> Labelling according to CLP <u>Trained personnel</u> <ul style="list-style-type: none"> Professional workers Instructions for use minimizing exposure for professionals | Acceptable | (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low duration of exposure considering the proposed RMM (↑) High frequency | |
| | Eye Dam Cat 1 (H318) | | Eye | | Hand-to-eye transfer | Chemical goggles | | | | <u>RMM</u> Pour the solution direct on the surface and wipe with a cloth / brush solution |
| LOW | Skin Irrit. Cat 2 (H315) | | Skin | | | Dermal contact with in-use solution and treated surfaces | Gloves Skin coverall Eye protection Optional face shield | | | <u>Labelling</u> <ul style="list-style-type: none"> Labelling according to CLP <u>Trained personnel</u> <ul style="list-style-type: none"> Professional workers Instructions for use minimizing |
| | Eye Irrit. Cat 2 (H319) | | Eye | | | Hand-to-eye transfer | Chemical goggles | | | |

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|-------------|-------------------------------|--|--|--|--|--|--|-------------------------------|--|-----------------------|
| HIGH | Eye Dam Cat 1 (H318) | | | | | | | exposure for professionals | | (↑) High frequency |
|-------------|-------------------------------|--|--|--|--|--|--|-------------------------------|--|-----------------------|

**Conclusion: Disinfection by wiping, mopping, brushing, scrubbing– Uses
4/12/19/23****META SPC 1, 2, 3, 4, 5, 6, 7, 8 and 9**

- For products pertaining to the Meta-SPC 1, 2, 3, 4, 5, 8 the risk is considered acceptable taking into account the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

PPE:

- * For mixing and loading task: gloves, protective coverall and chemical goggles.
- * For application by wiping/mopping/brushing/scrubbing and rinsing: gloves, protective coverall and chemical goggles

RMM:

"Pour the solution direct on the surface and wipe with a cloth / brush solution"
"A mop/brush with a handle has to be used to apply the solution"
"Do not immerse hands in the diluted solution"

- For products pertaining to the Meta-SPC 6, 7 and 9 the risk is considered acceptable taking into account the qualitative risk assessment for local effects with the personal protective equipment (PPE) listed below:

- * For mixing and loading task: gloves, protective coverall and chemical goggles.
- * For application by wiping/mopping/brushing/scrubbing and rinsing with a cloth: gloves, protective coverall and chemical goggles.

Uses #5, #6, #13 and #14 - Disinfection of equipment by automatic application in cleaning washer– Professionals - PT2 & 4 (META SPC 6)**Scenario 4: Disinfection by dish washing/cleaning washer**

Primary exposure

As the cleaning and disinfection of equipment and cleaning washer/dish washing machine is done by automatic application in a closed system, it has been considered that the uses #5, #6, #13 and #14 can be grouped and that the same exposure and risk assessment can be done for these uses.

As claimed by the applicant, the concentrated product is automatically connected to the cleaning washer/dish washing through a built-in pump connected to water arrival or to a conductometer for concentration control.

As the treatment is performed automatically, the exposure of the professional during the application is considered negligible.

After disinfection treatment, the treated equipment is automatically rinsed with drinking water and then wiped off or left to dry in open air. Therefore the exposure of the professional during rinsing is considered negligible.

A qualitative local risk assessment is performed during the mixing and loading task are concentrated products are classified for skin and eyes hazard.

Task [4.1]: Mixing and loading

Description of Task [4.1]: Mixing and loading

Before automated application, products of meta-SPC 6 are automatically diluted in water by a built-in pump of the cleaning machine according to the applicant.

As the concentrated products of the meta-SPC 6 are classified, a qualitative risk assessment is performed.

Task [4.2]: Application by automatic process in a closed system

Description of Task [4.2] : Application by spraying in a closed system

The disinfection process (application) is automated and takes place in a closed system.

As the treatment occurs in a closed system without any contact with the product, no qualitative risk assesment has been performed for the application task.

Task [4.3]: Post application – Rinsing of the equipment and opening of the washers

Description of Task [4.3] – Post-application- Rinsing

After the application of the products, the treated equipment is rinsed with water and then wiped off or left to dry in open air.

It is considered that the rinsing task with water is performed automatically therefore exposure during the rinsing is considered as negligible.

After the rinsing task and considering the number of cycles, the solution remaining on the material is not considered classified for human health. That is the reason why a qualitative risk assessment is not required.

Risk characterisation for primary exposure for Uses #5, #6, #13 and #14

Outcome of qualitative local risk assessment (dermal)

The products of Meta SPC 6 are classified Skin corrosive category 1 (H314) and Severe eye damage (H318).

All the products are intended to be applied by professionals.

Considering that, a qualitative risk assessment is performed. Please refer to the table below:

Outcome of qualitative local risk assessment – Products of meta SPC 6 which are classified H314/H318 used by professionals.

| Hazard | | Exposure information | | | | | Risk | | | |
|------------------------------|--------------------------|----------------------|------------------------|--------------------------|--|--|---|--|--------------------|---|
| Hazard category | Effects in terms of C&L | PT | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant PPE | Relevant RMMs | Conclusion on risk | Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓) |
| Concentrated products | | | | | | | | | | |
| High | Skin Corr. 1 H314 | 2 4 | Mixing and loading | Dermal | Frequency: once a day, everyday | Potential splashes and spills | Gloves Skin coverage Eye protection Optional face shield | Labelling: - Labelling according to CLP Professionals: - Professional workers Instructions for use minimizing exposure for professionals | Acceptable | (↑) High hazard category (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low frequency (↓) Low exposure duration expected (few minutes per day) |
| | Eye Dam.1, H318 | | | Ocular | Duration : no data but 10 min expected | Eye exposure through potential splashes and spills or hand-to-eye transfer | Chemical goggles | | | |

Disinfection by dish washing/cleaning washer – Uses #5, #6, #13 and #14

META SPC 6

For products pertaining to the Meta-SPC 6 the risk is considered acceptable taking into account the qualitative risk assessment for local effects with the personal protective equipment (PPE) listed below:

* For mixing and loading task: gloves, protective coverall and chemical goggles.

Uses #18, #22, #33 and #34 - Disinfection of hard surfaces and equipment by trigger spray– Professionals - PT2 & 4 (META SPC 1, 4, 5, 7 and 8)

Scenario 5: Application by manual spraying using a trigger spray

As the same tasks are performed with products from the META SPC 1, 4, 5, 7 and 8 for these claimed uses, it has been considered that the same exposure and risk assessment can be done for these uses.

The product is manually diluted by screwing the cartridge to the bottle of the trigger sprayer filled with water. Then the in-use solution is applied by manual spraying on the surfaces to be treated at an application rate of 60 ml/m².

After the required contact time, the treated surfaces are rinsed with water. Treated surfaces are then wiped off or left to dry in open air.

Task [5.1] – Mixing and loading

Description of Task [5.1]: Mixing and loading

Before use, concentrated products from the meta-SPC 1, 4 and 5 are manually diluted by screwing the cartridge to the bottle of the trigger sprayer filled with water.

Professionals can be exposed dermally to the product during the mixing a loading task. As the products are classified, a qualitative risk assessment is performed.

Task [5.2]: Application by spraying using a trigger spray

Description of Task [5.2] – Application by spraying with a trigger spray

After the dilution of the products, the professional user applies the diluted/ RTU products on hard surfaces using a trigger spray.

As the diluted and RTU products from the meta-SPC 1, 4, 5, 7, 8 are classified, a qualitative risk assessment is performed for the application task by spraying.

Task [5.3]: Post application –Rinsing of the treated surfaces with a cloth

Description of Task [5.3] – Post-application - Rinsing with a cloth

After the application by trigger spray, the products are rinsed off with a wet cloth by the professional user. The professional can be exposed dermally to the classified products during the rinsing. Therefore, a qualitative risk assessment is performed for the post-application task.

Combined scenarios

Not relevant.

Outcome of qualitative local risk assessment

Summary of the classification for Meta SPC 1, 4, 5, 7, 8

| Classification | Meta SPC1 | | Meta SPC4 | | Meta SPC5 | | Meta SPC7 | Meta SPC8 |
|-------------------------------|-----------|---|-----------|---|-----------|---|-----------|-----------|
| | C | D | C | D | C | D | RTU | RTU |
| H314 Cat 1 H317 1A H318 | X | | | | X | | | |
| H315 H318 | | | | | | | X | |
| H314 Cat 1 H318 | | X | X | X | | X | | X |
| H315 H319 | | | | | | | | |

C: Concentrated product; D: Diluted product

Moreover, as they are applied by spraying, the mention EUH071 is required.

All the products are intended to be applied by professionals.

Considering that, a qualitative risk assessment is performed. Please refer to the tables below:

Outcome of qualitative local risk assessment – Handling of products classified for skin and eye damage during disinfection with a trigger spray - Professionals

| Hazard | | Exposure information | | | | | Risk | | | |
|--|---|----------------------|------------------------|--------------------------|---|--|---|--|--------------------------|---|
| Hazard category | Effects in terms of C&L | PT | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant PPE | Relevant RMMs | Conclusion on local risk | Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓) |
| Meta SPC 1, 4, 5 (soluble concentrate) | | | | | | | | | | |
| HIGH | Skin Corr, Cat 1 (H314) - Skin sens Cat 1A (H317) | 2 4 | M&L manual | Skin | Frequency : 1/day Duration : no data but 10 min expected | Direct dermal contact and potential splashes or spills Hand-to-eye transfer | Use of appropriate personal protective equipment: <u>Hand protection:</u> gloves <u>Eye protection:</u> goggles <u>Body protection:</u> Protective overall | <u>Labelling:</u> - Labelling according to CLP <u>Professionals:</u> - Professional workers Instructions for use minimizing exposure for professionals | Acceptable | (↑) High hazard category |
| | Eye Dam. Cat 1 (H318) | | | Eye | | | | | | (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low frequency and exposure duration (few minutes per day) |
| Meta SPC 1, 4, 5, 7, 8 (RTU and diluted products) | | | | | | | | | | |

| | | | | | | | | | | |
|-------------|---|----------------|---|------------|---|---|--|-------------------|---|--|
| HIGH | Skin Corr, Cat 1 (H314) - Skin sens Cat 1A (H317) | 2 4 | Application by trigger spray Rinsing | Skin | Frequency : 1/day Duration : no data but potentially 10 – 30 min | Dermal contact with treated surfaces | <u>Hand protection</u> : gloves | Acceptable | (↑) High hazard category (↑) <u>Spray application</u> (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low exposure duration | |
| | EUH 071 | | | Inhalation | | Aerosols generated | <u>Body protection</u> : Protective overall RPE : Substance/task appropriate respirator (only for application) | | | Labelling: - Labelling according to CLP |
| | Eye Dam. Cat 1 (H318) | | | Eye | | Eye exposure through potential splashes or hand to eye transfer during task | Chemical goggles | | | Professionals: - Professional workers |
| | Skin Irrit. Cat 2 (H315) | | | Skin | | Dermal contact with treated surfaces | Gloves Skin overall Eye protection Optional face shield | | | Instructions for use minimizing exposure for professionals |
| LOW | Eye Irrit. Cat 2 (H319) | | | Eye | | Eye exposure through potential splashes or hand to eye | Chemical goggles | | (↑) <u>Spray application</u> (high level of exposure) (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE | |

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|--|-----------------------------|--|--|-------------------------|--|--|------------------------------|
| | Eye Dam. Cat 1 (H318) | | | transfer during task | | | (↓) Low exposure duration |
|--|-----------------------------|--|--|-------------------------|--|--|------------------------------|

Conclusion: Disinfection of hard surfaces by trigger spray – Uses 18, 22, 33 & 34**META SPC 1, 4, 5, 7, 8**

-For products pertaining to the Meta-SPC 1, 4, 5 the risk is considered acceptable taking into account the qualitative risk assessment for local effects with the application of personal protective equipment (PPE) listed below:

PPE:

- * For mixing and loading and rinsing: gloves, protective coverall and chemical goggles.
- * For application by trigger spray: gloves, protective coverall, chemical goggles and a respiratory protective equipment

-For RTU products pertaining to the Meta-SPC 8 the risk is considered acceptable taking into account the qualitative risk assessment for local effects with personal protective equipment (PPE) listed below:

PPE:

- * For application by trigger spray and rinsing: gloves, protective coverall, chemical goggles and a respiratory protective equipment only during application

-For RTU products pertaining to the Meta-SPC 7 the risk is considered acceptable taking into account the qualitative risk assessment for local effects with personal protective equipment (PPE) listed below:

PPE:

- * For application by trigger spray and rinsing: gloves, protective coverall and chemical goggles

Uses #7, 15, 35, 36- Disinfection of inner surfaces by CIP and without circulation - PT 2 & 4 (META SPC 6)**Primary exposure**

In the claimed uses, pipe, vessels, process equipment, filters and associated fitting, milking system (PT 4 specifically) are disinfected by a cleaning in place (CIP) process. Inner surfaces of small kitchen appliances (PT4) are disinfected without circulation. As the same tasks are performed with products of META SPC 6 for the Uses #7, #15, #35, #36, it has been considered that the same exposure and risk assessment can be done for these uses.

The product is automatically pumped into the machine which is connected to the product container.

As the treatment is performed automatically, the dermal and inhalation exposure during the application is considered as negligible.

It is considered that the rinsing is also performed automatically in CIP. Therefore the dermal and inhalation exposure during rinsing is considered negligible.

The post-application phases include the cleaning or repair of dosing pumps and circuit system.

Task [6.1]: Mixing and loading

Description of Task [6.1]: Mixing and loading

For the coffee maker and percolator, the mixing and loading can be performed either via a manual loading directly into the machine or via an automated dosing system. For other machines, the dosing to obtain the intended dilution with water is performed by the built-in system of the machine. Indeed, the concentrate product is inserted (pumped) automatically into the machine once the product container has been connected to the machine via lines. In brief, the product is transferred into a CIP product mixing/storage tank via automatic dosing control pumps but the connecting lines step is performed by the worker.

As the products of the meta-SPC 6 are classified, a qualitative risk assessment is performed for the M&L task.

Task [6.2]: Application by CIP/ without circulation

Description of Task [6.2] : Application

The disinfection process (application) is automated and takes place in a closed system.

Therefore, exposure of the worker is considered as negligible.

Task [6.3] – Post Application – Rinsing

Description of Task [6.3] – Post-application – Rinsing

It is considered that the rinsing is also performed automatically, therefore exposure of the professional during the rinsing task is considered as negligible.

Task [6.4]: Post-application - Cleaning/maintenance of dosing pumps (concentrated product)

Description of Task [6.4] – Post-application – Repair or cleaning of dosing pump

The professional user can be exposed to the concentrated product during maintenance/cleaning of dosing pumps, considering there is still some concentrated product left under pressure in the dosing system.

As products from the meta-SPC 6 are classified for human health, a qualitative risk assessment is performed.

Task [6.5]: Post-application - Cleaning/repair of the circuit system (diluted products)**Description of Task [6.5] – Post-application – Repair or cleaning of the circuit system**

The user can be in contact with the diluted product during the repair or cleaning of the circuit system.

A qualitative local risk assessment is needed as the diluted products pertaining to the meta-SPC 6 are classified.

Combined exposure

Not relevant.

Risk characterisation for primary exposure for uses 7, 15, 35, 36 (Disinfection of inner surfaces by CIP and Disinfection of inner surfaces without circulation) - professionalsOutcome of qualitative local risk assessment (dermal/inhalation)

The products of Meta SPC **6** are classified Skin corrosive category 1 (H314) and Severe eye damage (H318). All the products are intended to be applied by professionals. Considering that, a qualitative risk assessment is performed. Please refer to the table below.

The professional is using the product for a low duration per day and with PPE. Considering this, the risk is deemed acceptable.

RPE is only required for Meta SPC 6 during maintenance of the dosing pump.

The diluted products of meta-SPC **6** for all uses are classified Skin irritant (H315) and classified Eye irritant (H319).

The professionals will be in contact with diluted products during maintenance of circuit system. Considering that, a qualitative risk assessment is performed. Please refer to the table below.

The professional is expected to be in contact with the dilution for a low duration per day and low frequency and with PPE. Considering this, the risk is deemed acceptable.

Outcome of qualitative local risk assessment – Handling of products classified for skin and eye damages during treatment by CIP and without circulation- Professionals

| Hazard | | Exposure information | | | | | Risk | | | |
|-----------------|-------------------------|----------------------|--|--|--|------------------------------|--|--|--------------------|--|
| Hazard category | Effects in terms of C&L | PT | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant PPE | Relevant RMMs | Conclusion on risk | Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓) |
| HIGH | Skin Corr. 1 H314 | 2, 4 | Mixing and loading Post application – Maintenance/Cleaning of dosing pumps | Dermal | Frequency: no data Duration : 10 min | Dermal contact | Gloves Skin coverage Eye protection Optional face shield | Labelling: - Labelling according to CLP Professionals: - Professional workers Instructions for use minimizing exposure for professionals | Acceptable | (↑) High hazard category |
| | Inhalation | | | Inhalation exposure through aerosol (only maintenance dosing pump) | | RPE | (↓) Professionals following instructions for use and RMM on the label | | | |
| | Ocular | | | Eye exposure through potential splashes and spills or hand-to-eye transfer | | Chemical goggles | (↓) Professionals using PPE (↓) Low exposure duration (few minutes per day) (↑) Potentially high frequency | | | |
| | Eye Dam.1, H318 | | | | | | | | | |

| | | | | | | | | | |
|-----|-----------------------|---------|---|--------|--|---|--|--|--|
| LOW | Skin Irrit. 2 H315 | 2, 4 | Post application - Maintenance / Cleaning circuit system | Dermal | Frequency: no data Duration : no data | Dermal contact | Gloves Skin coverage Eye protection Optional face shield | | |
| | Eye Irrit. 2 H319 | | | Ocular | | Eye exposure through potential splashes and spills or hand-to- eye transfer | Chemical goggles | | |

(↓) Low hazard category

(↓) Professionals following instructions for use and RMM on the label

(↓) Professionals using PPE

(↑↓) few minutes per day expected

(↓) Low frequency expected

Conclusion: Disinfection by CIP and without circulation– Uses 7/15/35/36

META SPC 6

- For products pertaining to the Meta-SPC 6 the risk is considered acceptable taking into account the qualitative risk assessment for local effects with the personal protective equipment (PPE) listed below:

PPE:

- * For mixing and loading task: gloves, protective coverall and chemical goggles.
- * For maintenance/cleaning of dosing pumps: gloves, protective coverall, chemical goggles and respiratory protective equipment
- * For maintenance/ cleaning circuit system: gloves, protective coverall and chemical goggles

Use #20- Disinfection of surfaces in sanitary areas, toilet bowls and drains by spreading/flooding- PT 2 (META SPC 7, 8, 9)

Primary exposure

Scenario 7: Application by direct pouring/spreading

As the products are RTU, no mixing and loading task is needed before the application.

The professional user applies the products on surfaces in sanitary area, toilet bowl and drains. The products are applied either in the interior of toilets (referred as toilet bowls) or on horizontal and vertical sanitary facilities surfaces (sink, washbasin, shower tray, bath tub, earthenware and all other sanitary surfaces to disinfect). In all cases, the application method is the same, the product is poured on the surface to be treat, brushed/wiped once the required contact time is over and then as a post-application step, the toilet is flushed.

A qualitative local risk assessment is performed as the RTU product are classified for human health.

Task [7.1] – Application by pouring

Description of Task [7.1]: Application by pouring

The products of the META SPC 7, 8, 9 are manually poured into sanitary installations such as toilet bowls, drains, sinks.

As the RTU products are classified, a qualitative risk assessment is performed for the application task.

Task [7.2] – Post-application by brushing/wiping

Description of Task [7.2]: Post-application by brushing/wiping

According to the applicant, after the required contact time, the product is brushed/wiped. During this post-application task, the professional can be exposed to the classified product. Therefore, a qualitative risk assesment is requied during this task.

Task [7.3] – Post-application- Rinsing of the treated surfaces

Description of Task [7.3]: Post-application - Flush

The rinsing step is performed by flushing the toilet. Therefore, there is no contact between the professional user and the rinsing solution. As exposure is considered negligible, no qualitative risk assessment is undertaken.

Combined exposure

Not relevant.

Risk characterisation for primary exposure for Use 20 (Toilet bowl disinfection by direct flooding) - Professionals

Summary of the classification for Meta SPC 7, 8, 9

| Classification | Meta SPC7 | Meta SPC8 | Meta SPC9 |
|--------------------|-----------|-----------|-----------|
| | RTU | RTU | RTU |
| H314 Cat 1 H318 | | X | |
| H315 H318 | X | | X |
| H315 H319 | | | |

EUH071 if classification H314 and exposure by inhalation

All the RTU products are intended to be applied by professionals. Considering that, a qualitative risk assessment is performed. Please refer to tables below.

For the pouring and the brushing/wiping, the professional is using the product for a low duration per day and with PPE. Considering this, the risk is deemed acceptable. Products classified H315 and/or H319 are used in the same conditions (frequency, duration of exposure) as the products classified H314 and/or H318. Hence, the same PPE are required for the use of all these products (gloves, coverall and chemical goggles).

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<PT2, 4>

Outcome of qualitative local risk assessment for Toilet bowl disinfection by professional users –

Products from meta-SPC 7, 8, 9

| Hazard | | Exposure information | | | | | | Risk | | | | | | |
|-----------------|--------------------------|----------------------|--|--------------------------|---|---|---|---|--------------------|---|--|--|--|---|
| Hazard category | Effects in terms of C&L | PT | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant PPE | Relevant RMM | Conclusion on risk | Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓) | | | | |
| HIGH | Skin Corr. Cat 1 (H314) | 2 | Application by pouring (RTU products) Post application by brush/wipe | Skin | Frequency: no data Duration: 10min Application: 10min | Dermal contact | Gloves Skin coverage Eye protection Optional face shield | Labelling: - Labelling according to CLP | Acceptable | (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low exposure duration (few minutes per day) (↑) Potentially high frequency | | | | |
| | Eye Dam. Cat 1 (H318) | | | Eye | | Eye exposure through potential splashes or hand to eye transfer | Chemical goggles | | | | Professionals: - Professional workers - Instructions for use minimizing exposure for professionals | | | |
| LOW | Skin Irrit. Cat 2 (H315) | | | Skin | | Dermal contact | Gloves Skin coverage Eye protection Optional face shield | Packaging: - With fixed directional nozzle (RTU) | | | | | | (↓) Packaging with fixed directional nozzle for RTU application |
| | Eye Irrit. Cat 2 (H319) | | | Eye | | Eye exposure through potential splashes or | Chemical goggles | | | | | | | |

| | | | | | | | | | | |
|------|-----------------------|--|--|--|--|----------------------|--|---|--|--|
| HIGH | Eye Dam. Cat 1 (H318) | | | | | hand to eye transfer | | Labelling: <ul style="list-style-type: none">- Labelling according to CLP Professionals: <ul style="list-style-type: none">- Professional workers- Instructions for use minimizing exposure for professionals Packaging: <ul style="list-style-type: none">- With fixed directional nozzle (RTU) | | |
|------|-----------------------|--|--|--|--|----------------------|--|---|--|--|

Conclusion: Disinfection by direct spreading– Use 20**META SPC 7, 8 and 9**

- For products pertaining to the Meta-SPC 7, 8, 9 the risk is considered acceptable taking into account the qualitative risk assessment for local effects with the personal protective equipment (PPE) listed below:

PPE:

- * For application task (pouring): gloves, protective coverall and chemical goggles.
- * For brushing/wiping after the required contact time: gloves, protective coverall and chemical goggles

Secondary exposure of professional bystander**Scenario [8]: Exposure of bystanders during spray application (Uses 1, 2, 9, 10, 17, 18, 21, 22, 33, 34)****Description of Scenario [8] : Exposure of bystander during spray application**

Bystanders present during the application by spraying can be exposed to aerosols generated by the spray equipment.

It is assumed that exposure of bystanders is equal or of less than the exposure of the professional performing the task.

Scenario [9]: Dermal contact with wet treated surface**Description of Scenario [9]**

Bystanders re-entering a room freshly treated can touch the treated surfaces.
As a worst-case approach, a direct contact with a treated surface before the rinsing step is assumed.
A qualitative risk assessment is performed.

Risk characterisation for secondary exposure

As a worst-case approach, inhalation exposure of bystanders during spray application is considered to be the same than inhalation exposure of the professional performing the task. In this context, an additional RMM is required for products for which a RPE is required for professional users (see qualitative risk assessment).

The following RMM is proposed:

“Do not be present in the treatment area during disinfection process by spraying. If it is necessary to be present, wear same RPE and PPE as the professional user”.

After application, diluted/RTU products remaining on the freshly treated surface are classified for skin corrosion/irritation, therefore the following risk mitigation measure is required for professional bystander:

- Do not touch the surface until it is completely dried

Non-professional users

Uses #25, 28, 30, 32 - Disinfection of hard surfaces by mopping/wiping/scrubbing/brushing - PT 2 & 4 (META SPC 1, 4, 5, 7, 8 and 9)

Primary exposure

Scenario 10 – Disinfection of hard surfaces by mopping/wiping/scrubbing

Task [10.1]: Mixing and loading

Description of Task [10.1]: Mixing and loading

Before the application by wiping/mopping/scrubbing, the products of the relevant Meta-SPC are diluted in water according to the claimed doses. The soluble concentrate is manually diluted in water via a measuring cap, a pump cap or a tap for packaging of nominal content above 5L.

For the cartridge packaging, the product is manually diluted by screwing the cartridge to a bottle filled with water.

As all the concentrate products are classified, a qualitative risk assessment is performed.

Task [10.2] – Application by mopping/wiping/scrubbing/brushing

Description of Task [10.2]: Application by mopping/wiping/scrubbing

The non-professional user applies the dilution/RTU products on the surfaces to be treated by wiping using a mop, brush or a cloth and bucket without mechanical action.

According to the ConsExpo Disinfectant Products Factsheet, during mopping / wiping / scrubbing, dermal exposure can occur due to hands and forearms that come into contact with the solution when using a cloth or dipping the mop/brush/scrub in the bucket.

For dermal route exposure, a qualitative local risk assessment is required as the in-use dilutions and RTU are classified for human health.

Task [10.3] – Rinsing with a mop or wet cloth

Description of Task [10.3]: Post application- Rinsing with a mop or a wet cloth

After the required contact time, the consumer rinses off the treated surfaces with a clean cloth/mop/brush/scrub soaked in water. The surface is thus treated with water.

As the in-use dilutions and RTU products from the meta-SPC 1, 4, 5, 7, 8 and 9 are classified for human health, a qualitative risk assessment is required.

Combined exposure

Not relevant.

Risk characterisation for primary exposure for Uses #25, 28, 30, 32_ (Hard surface disinfection by wiping/mopping/brushing/scrubbing) – Non professionals**Outcome of qualitative local risk assessment**

The products of meta-SPC 1, 4, 5 are classified Skin corrosive category 1 (H314), skin sensitizer (H317 1A) and Severe eye damage (H318). The products of meta-SPC 7 & 9 are classified Skin irritant cat 2 (H315) and Severe eye damage (H318).

The diluted products of the Meta-SPC 1, 4, 5 are classified Skin corrosive cat 1 (H314), Skin sensitizer (H317 1A, only meta-SPC 5) and severe eye damage (H318).

All the dilutions are intended to be applied by non-professionals.

Considering that, a qualitative risk assessment is performed. Please refer to the table below.

For products pertaining to the meta-SPC 1, 4, 5 classified as severe eye damage (H318) / Skin corrosive category 1 (H314)/ Skin sens (H3171A) considering the absence of a protection offered by the packaging to limit exposure, the risk is not considered acceptable for non-professional users during M&L task.

For application by mopping /wiping/ brushing and scrubbing, RTU and dilutions classified as severe eye damage (H318) and Skin corrosive category 1 (H314) are used by non-professionals for a moderate frequency . Considering that the user is in direct contact with corrosive products, the risk is deemed not acceptable for the meta-SPC 1, 4, 5, 8.

For RTU products classified for severe eye damage (H318) and skin irritant (H315), the risk is deemed acceptable for meta-SPC 7 & 9 considering the additional RMM:

“Wash hands after use”

“Avoid contact with eyes”

“Avoid splashes and spills”

“The packaging must be adapted with a child proof closure”

Outcome of qualitative local risk assessment for disinfection surfaces by wiping/mopping/brushing/scrubbing– by non-professional users:

| Hazard | | Exposure information | | | | | | Risk | |
|-----------------|--|----------------------|--|--------------------------|--|---|--------------|-----------------------|--|
| Hazard category | Effects in terms of C&L | PT | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant RMM | Conclusion on risk | Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓) |
| HIGH | Skin Corr. Cat 1 (H314)/Skin sens Cat 1 (H317) | 2 4 | Mixing and loading | Skin | Frequency: no data Duration: Mixing and loading = few minutes or less | Skin exposure through potential liquid spills around the opening of the bottle and/or due to splashes of the liquid concentrate | none | Not acceptable | (↑) Exposure to corrosive substance (↑) Formulation (liquid formulation to be diluted, no viscious formulation limiting splashes) (↑) No PPE |
| | Eye Dam. Cat 1 (H318) | | | Eye | | Eye exposure through potential splashes or hand to eye transfer | | | |
| HIGH | Skin Corr. Cat 1 (H314)/Skin sens Cat 1 (H317) | | Application by mopping /wiping/brushing scrubbing Rinsing | Skin | Frequency: everyday Duration: few minutes | Direct dermal contact and potential splashes or spills during dipping of a mop into a bucket. | none | Not acceptable | (↓) instruction of use and RMM on the label (wash hands after use) (↑) Moderate exposure duration |

| | | | | | | | | | |
|------|--------------------------|--|--|------|--|---|---|------------|---|
| | Eye Dam. Cat 1 (H318) | | | Eye | | Hand-to-eye transfer | | | (less than few minutes per day cannot be ensure) (↑) moderate frequency (equal to or less than once per week cannot be ensure) (↑) Exposure to corrosive substance (↑) Mode of application (the user is in direct contact with the diluted/RTU product) (↓) child-proof closure |
| LOW | Skin Irrit. Cat 2 (H315) | | | Skin | | Dermal contact with in-use product and treated surfaces | <u>No PPE</u> <u>Labelling</u> | | (↓) RMM to avoid dermal and ocular long term exposure |
| HIGH | Eye Dam Cat 1 (H318) | | | Eye | | Hand-to-eye transfer | <ul style="list-style-type: none"> • Labelling according to CLP • Instructions for use and storage • "Wash hands after use" • "Avoid contact with eyes" | Acceptable | (↑) Potentially high exposure duration and frequency |

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|--|--|--|--|--|--|--|---|--|--|
| | | | | | | | <ul style="list-style-type: none">• "Avoid splashes and spills• The packaging must be adapted with a child proof closure | | |
|--|--|--|--|--|--|--|---|--|--|

Conclusion for Uses #25, 28, 30, 32: Disinfection of hard surfaces by wiping/mopping/brushing/scrubbing (non-medical professional users) - PT2 and 4 (Meta-SPC 1, 4, 5, 7, 8 and 9)

For products pertaining to **Meta SPC 7 and 9**, risk is acceptable **for application by mopping/ wiping/ scrubbing/brushing** considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM):

- Wash hands after use
- Avoid contact with eyes
- Avoid splashes and spills
- The packaging must be adapted with a child proof closure

For products pertaining to **Meta SPC 1, 4, 5, 8**, risk is not acceptable considering the qualitative risk assessment for local effects.

Uses #24, 27, 29, 31 - Disinfection of hard surfaces and equipment by trigger spray - PT 2 & 4 (META SPC 1, 4, 5, 7)

Primary exposure

Scenario 11: Disinfection of hard surfaces by trigger spray

Task [11.1] – Mixing and loading

Description of Task [11.1]: Mixing and loading

For the ready-to-use products, there is no mixing and loading step. For the concentrate products, the mixing and loading with cartridge or with specific dosing bottle is designed so that no contact can occur.

Indeed, according to the description of the packaging provided by the applicant, the non-professional user fills the bottle with water, inserts the cartridge and screws on the trigger. As the trigger is screwed on to the bottle, it releases the concentrate, ensuring the correct mix of concentrate to water. For the dosing bottle, the bottle with the cap on it is gently squeezed to raise the product into the dispenser. The cap is then unscrewed and the quantity of product present is emptied in the spray bottle previously filled with water. It is performed without any possible splashes or exposition of the consumer.

Considering that, it is considered that exposure of non-professional during M&L task is negligible. No qualitative risk assessment is required.

Task [11.2] – Application by spraying with a trigger spray**Description of Task [11.2] – Application by spraying with a trigger spray**

After the mixing and loading task, the non-professional user applies the diluted/RTU products on surfaces using a trigger spray at an application rate of 60 mL/m². Dermal and inhalation exposure is expected during the spray application.

As RTU and diluted products from meta-SPC 1, 4, 5, 7 are classified for human health, a qualitative local risk assessment is performed for the application task by spraying.

Task [11.2] – Post-application - Rinsing of the treated surfaces with a wet cloth**Description of Task [11.3]: Post application – Rinsing with a wet cloth**

According to the applicant, after the application by spraying, the dilution applied with a trigger spray is rinsed off with a wet cloth by the non-professional user.

According to the ConsExpo Disinfectant Products Factsheet (4.2.2.3), during rinsing, dermal exposure can occur.

A qualitative local risk assessment is required as the in-use dilutions/RTU are classified for human health.

Combined scenarios

Not relevant.

Risk characterisation for primary exposure for Uses #24, 27, 29, 31 (Hard surface disinfection by trigger spray) – non professionals**Outcome of qualitative local risk assessment**

Diluted products from the meta-SPC 1, 4, 5 are classified Skin corrosive category 1 (H314), Skin sensitize Cat 1A (H317 1A, only meta spc 5) and Severe eye damage (H318). RTU products from the meta-SPC 7 are classified skin irritant (H315) and Severe eye damage (H318).

All the products are intended to be applied by non-professionals.

Considering that, a qualitative risk assessment is performed. Please refer to the tables below:

Outcome of qualitative local risk assessment for disinfection of surfaces by trigger spray - by non-professional users:

| Hazard | | Exposure information | | | | Risk | | | |
|-----------------|---------------------------|----------------------|------------------------------|--------------------------|--|---|--------------|-----------------------|--|
| Hazard category | Effects in terms of C&L | PT | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant RMM | Conclusion on risk | Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓) |
| HIGH | Skin Corr. Cat 1/2 (H314) | 2, 4 | Application by trigger spray | Skin | Frequency: no data | Dermal contact with treated surfaces Deposit of aerosols on skin | none | Not acceptable | (↑) High hazard category (↑) Spraying application |
| | EUH071 | | Rinsing with a wet cloth | Inhalation | Duration: Application: 30 min | Aerosols generated | | | (↑) High exposure duration (more than few minutes per day) (↑) Potentially high frequency |

| | | | | | | | | | |
|------------|--------------------------------|--|--|------|--|---|--|--|--|
| | Eye Dam. Cat 1 (H318) | | | Eye | | Eye exposure through potential splashes or hand to eye transfer during task | | | |
| LOW | Skin Irrit. Cat 2 (H315) | | | Skin | | Dermal contact with treated surfaces Deposit of aerosols on skin | | | |
| HIGH | Eye Dam. Cat 1 (H318) | | | Eye | | Eye exposure through potential splashes or hand to eye transfer during task | | | |

Conclusions for Uses 24, 27, 29, 31 (Hard surface disinfection by trigger spray) – non professionals

For products pertaining to the Meta-SPC **1, 4, 5** and **7** the risk is deemed not acceptable considering the qualitative local risk assessment.

Use 26: Disinfection of sanitary installations (toilet bowls, drains, sinks, etc.) – PT 2 (Meta-SPC 7, 8, 9)**Primary exposure**

As products from meta-SPC 7, 8 and 9 are RTU products they are intended to be directly poured into sanitary installations for disinfection.

Only dermal exposure is expected during the different tasks.

A qualitative local risk assessment is performed for dermal exposure as the RTU products are classified for human health.

Scenario 12: Disinfection of sanitary installations by direct spreadingTask [12.1] – Application by pouring**Description of Task [12.1] – Application by pouring**

The products are ready-to-use products and are therefore directly available for application by spreading. In case of toilet bowl application, the product is directly applied/poured by squeezing the bottle under the rim of the toilet bowl. The neck of the container is angled so that the hand is not directly underneath the aperture when squeezing. Because of the packaging design, the risk of direct dermal contact to the product during application is considered to be limited.

As RTU products from the meta-SPC 7, 8 and 9 are classified, a qualitative risk assessment is performed.

Task [12.2] – Post-application by brushing**Description of Task [12.2]: Post-application by brushing**

According to the applicant, after the pouring, the product is left to soak for several minutes (leave-on/contact time). Once the required contact time is reached, the toilet bowl is brushed and during this brushing step, dermal contact with the product may occur.

Based on the classification of the RTU products, a qualitative risk assessment is performed.

Task [12.3]: Post-application rinsing of the toilet bowl

Description of Scenario [12.3] Post-application rinsing of the toilet bowl

The rinsing step is performed by flushing the toilet. Therefore, there is no contact between the non-professional user and the solution contained inside the toilet bowl. As exposure is considered negligible, no qualitative risk assessment is undertaken.

Combined exposure

Not relevant.

Risk characterisation for primary exposure for Use 26 (Toilet bowl disinfection by direct flooding) – Non Professionals

The products of meta-SPC **8** are classified Skin corrosive category 1 (H314) and Severe eye damage (H318). The products of meta-SPC **7** & **9** are classified Skin irritant (H315) and Severe eye damage (H318).

All the products are intended to be applied by non professionals. Considering that, a qualitative risk assessment is performed. Please refer to tables below.

The non-professional will be exposed few minutes during the pouring in sanitary installations. Considering this and additional RMM, the risk is deemed acceptable for non-professionals users.

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Outcome of qualitative local risk assessment for Toilet bowl disinfection by non professional users –

| Hazard | | Exposure information | | | | | Risk | | |
|-----------------|-------------------------|----------------------|--|--------------------------|---|---|---|--------------------|--|
| Hazard category | Effects in terms of C&L | PT | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant RMM | Conclusion on risk | Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓) |
| HIGH | Skin Corr. Cat 1 (H314) | 2 | Toilet disinfection (application/brushing) | Skin | Frequency: daily Duration: few minutes per day | Dermal contact | No PPE, <u>Labelling:</u> <ul style="list-style-type: none"> • According to CLP • Instructions for use and Storage • P sentence on the label • “Wash hand after use” “Avoid any contact with the eyes and with the skin” “Minimisation of splashes” <u>Packaging:</u> <ul style="list-style-type: none"> • Child-proof closure (Cap is having temper proof lock; applicant’s data) • With fixed directional nozzle (angled neck) | Acceptable | (↓) Instruction of use and RMM on the label (↓) Low exposure duration (few minutes per day) (↑) Potentially high frequency (↓) Packaging with fixed directional nozzle (↓) child-proof closure |
| | Eye Dam. Cat 1 (H318) | | | Eye | | Eye exposure through potential splashes or hand to eye transfer | | | |

| | | | | | | | | | |
|------|--------------------------|--|--|------|--|---|--|--|--|
| LOW | Skin Irrit. Cat 2 (H315) | | | Skin | | Dermal contact | No PPE, <u>Labelling:</u> <ul style="list-style-type: none">• According to CLP• Instructions for use and Storage• P sentence on the label• "Wash hand after use" "Avoid any contact with the eyes and with the skin" | | |
| HIGH | Eye Dam. Cat 1 (H318) | | | Eye | | Eye exposure through potential splashes or hand to eye transfer | "Minimisation of splashes" "the packaging must be adapted with a child proof closure" | | |

Conclusion for Use #26: Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding - PT2 (Meta-SPC 7, 8 and 9)

For products pertaining to **Meta SPC 8**, risk is acceptable **for application by pouring followed by brushing** considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM):

- Wash hands after use
- Avoid any contact with the eyes and with the skin
- Avoid splashes and spills

For products pertaining to **Meta SPC 7 & 9**, the risk is acceptable **for application by pouring followed by brushing** considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM):

- Wash hands after use
- Avoid any contact with the eyes and with the skin
- Avoid splashes and spills
- The packaging must be adapted with a child proof closure

General Public - Secondary exposure**Scenario [13]: Exposure of a bystander****Description of Scenario 13**

General public present during the application by spraying can be exposed by inhalation and dermally to aerosols generated by the spray equipment.

General public will not be exposed greater than the user performing the task (see primary exposure).

Scenario [14]: Dermal exposure of the public to the wet product and oral exposure due to hand-to-mouth transfer**Description of Scenario 14**

General public can touch the wet surface during the contact time of the diluted/RTU products.

Infant after touching the wet surface can be exposed orally to products after hand to mouth transfer.

As the in-use dilution/RTU of the meta-SPC 1, 4, 5, 7, 8 and 9 are classified for human health, a qualitative risk assessment has to be performed.

Risk characterisation for general public (PT 2, 4)

Outcome of qualitative local risk assessment (dermal /inhalation)

According to the qualitative risk assessment, dermal exposure to aerosols generated by the spray equipment is also possible for the general public if present. The following risk mitigation measure is therefore required for general public:

- Do not be present in the treatment area during disinfection process by trigger spray

Diluted products of meta-SPC 7 and 9 (Uses 25, 28, 30, 32) are classified skin irritant (H315) and serious eye damage (H318), therefore the following risk mitigation measures are required:

- Do not touch the surface until it is rinsed and completely dried;
- Children should not be present during disinfection and until the surface is rinsed and dried

Overall conclusion on the risk assessment for human health from local exposure

Professional user

| Overall conclusion on the risk assessment for human health from local exposure | | | |
|--|--|---|--|
| Use number ¹ | Use description ² | Conclusion ³ | Set of RMMs ³ |
| 1, 2, 9, 10, 17, 21 | Disinfection of hard surfaces and equipment by manual spraying- PT 2 & 4 Meta-SPC 1, 2, 3, 4, 5 Meta-SPC 6 and 7 | Acceptable with the following risk mitigation measure | <u>Professional user:</u> During mixing and loading: gloves, protective coverall and chemical goggles_ <u>For application and rinsing with a compression sprayer:</u> gloves, protective coverall and chemical goggles <u>Professional bystander:</u> "Do not be present in the treatment area during disinfection process by compression sprayer. If it is necessary to be present, wear same PPE as the professional user." <u>General public:</u> "Do not be present in the treatment area during disinfection process by compression sprayer." "Do not touch the surface until it is rinsed and completely dried" "Children should not be present during disinfection and until the surface is rinsed and dried" |

| | | | |
|---------------|---|---|--|
| 3, 11 | Disinfection of equipment by manual dipping/soaking- PT2/4 Meta-SPC 1, 2, 3, 4, 5, 10 | Acceptable with the following risk mitigation measure | <p><u>Professional user:</u></p> <p>For mixing and loading task: wear gloves, protective coverall and chemical goggles</p> <p>For application task and rinsing : wear gloves, protective coverall and chemical goggles "Do not immerse hands in the bath" " Let the equipment soak for the necessary time in the bath of cleaning/disinfectant solution, then empty the bath, and finish by rinsing without touching the equipment that has remained in the tank"</p> |
| | Disinfection of equipment by manual dipping/soaking- PT2/4 Meta-SPC 6 | Acceptable with the following risk mitigation measure | <p><u>Professional user:</u></p> <p>For mixing and loading task, wear gloves, protective coverall and chemical goggles</p> <p>For application task and rinsing of equipment wear gloves, protective coverall and chemical goggles</p> |
| 4, 12, 19, 23 | Disinfection of hard surfaces by wiping / scrubbing- PT2/4 Meta-SPC 1, 2, 3, 4, 5, 8 | Acceptable with the following risk mitigation measure | <p><u>Professional user:</u></p> <p>During mixing and loading: gloves, protective coverall and chemical goggles</p> <p>For application by wiping / scrubbing and rinsing: gloves, protective coverall, chemical goggles. "Pour the solution direct on the surface and wipe with a cloth / brush"</p> <p><u>Professional bystander:</u></p> <p>"Do not touch the surface until it is completely dried"</p> <p><u>General public:</u></p> <p>"Do not touch the surface until it is rinsed and completely dried"</p> <p>"Children should not be present during disinfection and until the surface is rinsed and dried"</p> |
| | Disinfection of hard surfaces by mopping /brushing scrubbing- PT2/4 Meta-SPC 1, 2, 3, 4, 5, 8 | Acceptable with the following risk mitigation measure | <p><u>Professional user:</u></p> <p>During mixing and loading: gloves, protective coverall and chemical goggles</p> <p>For application by mopping / scrubbing/brushing and rinsing: gloves, protective coverall, chemical goggles. "A mop/brush with a handle has to be used to apply the diluted solution" "Do not immerse hands in the diluted solution"</p> <p><u>Professional bystander:</u></p> |

| | | | |
|--------------------------|---|--|---|
| | | | <p>“Do not touch the surface until it is completely dried”</p> <p><u>General public:</u></p> <p>“Do not touch the surface until it is rinsed and completely dried”</p> <p>“Children should not be present during disinfection and until the surface is rinsed and dried”</p> |
| | <p>Disinfection of hard surfaces by wiping / scrubbing- PT2/4 Meta-SPC 6, 7, 9</p> | | <p><u>Professional user:</u></p> <p>During mixing and loading: gloves, protective coverall and chemical goggles</p> <p>For application by wiping / scrubbing and rinsing: gloves, protective coverall, chemical goggles.</p> <p><u>Professional bystander:</u></p> <p>“Do not touch the surface until it is completely dried”</p> <p><u>General public:</u></p> <p>“Do not touch the surface until it is rinsed and completely dried”</p> <p>“Children should not be present during disinfection and until the surface is rinsed and dried”</p> |
| | <p>Disinfection of hard surfaces by mopping /brushing scrubbing- PT2/4 Meta-SPC 6, 7, 9</p> | <p>Acceptable with the following risk mitigation measure</p> | <p><u>Professional user:</u></p> <p>During mixing and loading: gloves, protective coverall and chemical goggles</p> <p>For application by mopping / scrubbing/brushing and rinsing: gloves, protective coverall, chemical goggles.</p> <p><u>Professional bystander:</u></p> <p>“Do not touch the surface until it is completely dried”</p> <p><u>General public:</u></p> <p>“Do not touch the surface until it is rinsed and completely dried”</p> <p>“Children should not be present during disinfection and until the surface is rinsed and dried”</p> |
| <p>Uses 5, 6, 13, 14</p> | <p>Disinfection of equipment by dish</p> | <p>Acceptable with the following</p> | <p><u>Professional user:</u></p> |

| | | | |
|---------------------|---|---|---|
| | washing/cleaning washer- PT2/4 Meta-SPC 6 | risk mitigation measure | During mixing and loading: gloves, protective coverall and chemical goggles |
| Uses 18, 22, 33, 34 | Disinfection of hard surfaces by trigger spray- PT2/4 Meta-SPC 1, 4, 5 | Acceptable with the following risk mitigation measure | <p><u>Professional user:</u></p> <p>During mixing and loading and rinsing: gloves, protective coverall and chemical goggles</p> <p>For application with a trigger spray: gloves, protective coverall, chemical goggles, respiratory protective equipment against aerosol</p> <p><u>Professional bystander:</u></p> <p>“Do not be present in the treatment area during disinfection process by trigger. If it is necessary to be present, wear same RPE and PPE as the professional user.”</p> <p>“Do not touch the surface until it is completely dried”</p> <p><u>General public:</u></p> <p>“Do not be present in the treatment area during disinfection process by trigger.”</p> <p>“Do not touch the surface until it is rinsed and completely dried”</p> <p>“Children should not be present during disinfection and until the surface is rinsed and dried”</p> |
| | Disinfection of hard surfaces by trigger spray- PT2/4 Meta-SPC 7 | Acceptable with the following risk mitigation measure | <p><u>Professional user:</u></p> <p>For application with a trigger spray and rinsing : gloves, protective coverall, chemical goggles</p> <p><u>Professional bystander:</u></p> <p>“Do not be present in the treatment area during disinfection process by trigger. If it is necessary to be present, wear same PPE as the professional user.”</p> <p>“Do not touch the surface until it is completely dried”</p> <p><u>General public:</u></p> <p>“Do not be present in the treatment area during disinfection process by trigger.”</p> <p>“Do not touch the surface until it is rinsed and completely dried”</p> |

| | | | |
|---------------------------|---|--|--|
| | | | <p>“Children should not be present during disinfection and until the surface is rinsed and dried”</p> |
| | <p>Disinfection of hard surfaces by trigger spray- PT2/4 Meta-SPC 8</p> | <p>Acceptable with the following risk mitigation measure</p> | <p><u>Professional user:</u></p> <p>For application with a trigger spray and rinsing: gloves, protective coverall, chemical goggles, respiratory protective equipment against aerosol</p> <p><u>Professional bystander:</u></p> <p>“Do not be present in the treatment area during disinfection process by trigger. If it is necessary to be present, wear same RPE and PPE as the professional user.”</p> <p>“Do not touch the surface until it is completely dried”</p> <p><u>General public:</u></p> <p>“Do not be present in the treatment area during disinfection process by trigger.”</p> <p>“Do not touch the surface until it is rinsed and completely dried”</p> <p>“Children should not be present during disinfection and until the surface is rinsed and dried”</p> |
| <p>Uses 7, 15, 35, 36</p> | <p>Disinfection of inner surfaces by CIP and without circulation - PT2/4 Meta-SPC 6</p> | <p>Acceptable with the following risk mitigation measure</p> | <p><u>Professional user:</u></p> <p>For mixing and loading and maintenance of circuit system, wear gloves, protective coverall and chemical goggles</p> <p>For maintenance of dosing pumps, wear gloves, protective coverall, chemical goggles and respiratory protective equipment against aerosols</p> |
| <p>Use 20</p> | <p>Cleaning and disinfection of surfaces in sanitary areas, toilet bowls and drains by spreading/flooding – PT 2 Meta-SPC 7, 8, 9</p> | <p>Acceptable with the following risk mitigation measure</p> | <p><u>Professional user:</u></p> <p>For pouring and brushing after application : wear gloves, protective coverall and chemical goggles</p> |

Non-professional user

Overall conclusion on the risk assessment for human health from local exposure

| Use number | Use description | Conclusion | Set of RMMs |
|---------------------------|--|--|--|
| Uses 25, 28, 30, 32 | Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing- PT 2 Application by mopping/ wiping/ scrubbing/ pouring Meta-SPC 7 and 9 | Acceptable, with application of RMM | <u>Non professional user during application and rinsing:</u> "Wash hands after use" "Avoid contact with eyes and skin " "The packaging must be adapted with a child proof closure" <u>General public:</u> "Do not touch the surface until it is rinsed and totally dried" "Children should not be present during disinfection and until the surface is rinsed and dry" |
| | Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing- PT 2 Meta-SPC 1, 4, 5, 8 | Not acceptable | |
| | Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer- PT 2 Meta-SPC 1, 4, 5 & 7 | Not acceptable | |
| Use 26 | Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding- PT2 Meta-SPC 8 | Acceptable, with application of RMM | <u>Non professional user during the pouring and brushing:</u> "Wash hands after use" "Avoid any contact with the eyes and the skin" "Avoid splashes and spills" |
| | Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding- PT2 Meta-SPC 7 and 9 | Acceptable, with application of RMM | <u>Non professional user during the pouring and brushing:</u> "Wash hands after use" "Avoid any contact with the eyes and the skin" "Avoid splashes and spills" "The packaging must be adapted with a child proof closure" |

Monitoring data

Not submitted.

Dietary exposure

By definition PT 2 is for application on surfaces that are not used for direct contact with food or feedingstuffs. Therefore, residue in food or feed are not expected for SOPRODIS.

Regarding the uses of PT 4, residues in food or feed might be expected.

For L(+) lactic acid, the following evaluation was provided in the Assessment Report, 2007:

“L(+) lactic acid is a naturally occurring alpha-hydroxy acid found in plants, animals and humans. Major sources of L(+) lactic acid in the human organism are endogenous production (e.g. via anaerobic catabolism of glycogen and glucose) production by gastro intestinal microorganisms and uptake via food. The production of L(+) lactic acid as an intermediary metabolite in a 70 kg resting man is estimated to be in the range of 117-230 g/d but can be much higher during exercise. The mean daily per capita intake of L(+) lactic acid and D(-) lactic acid from milk and milk products has been estimated to be approximately 1 g in Switzerland (Walther, 2006). The estimated overall intake via food in the EU and the USA is estimated to be 1.65-2.76 g/person/day.

L(+) lactic acid has been approved in the EU as a food additive without an ADI or upper limit (quantum satis; Dir. 95/2/EC), as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMEA 2008).”

Moreover, “Because of the very low systemic toxicity of L(+) lactic acid, derivation of any systemic toxicological reference dose was regarded unnecessary. Considering the intended uses, exposure is estimated to be clearly below endogenous production (>100 g/person/day) and dietary exposure (>1 g/person/day). Therefore, neither an ADI nor an ARfD have been set”.

Information of non-biocidal use of the active substance

| Summary table of other (non-biocidal) uses | | | |
|---|----------------------------------|--|--|
| | Sector of use¹ | Intended use | Reference value(s)² |
| 1. | Food | Lactic Acid (E 270) – Food additive | Quantum satis (Regulation (EU) 1129/2011) |
| 2. | Veterinary | Lactic Acid – All food producing species | No MRL required (Regulation (EC) No 37/2010) |
| 3. | Cosmetic | Lactic Acid – Used as buffering humectant or skin conditioning | Up to a maximum level of 2.5% and a pH ≥ 5 (SCCBFP, 2000) |
| 4. | Feed additives | Feed additive for ruminants and pigs | 50 000 mg lactic acid/kg complete feed for functional ruminants and pigs (EFSA Journal 2015;13(12):4198) |

¹ e.g. plant protection products, veterinary use, food or feed additives

² e.g. MRLs. Use footnotes for references.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not relevant.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Not relevant.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not relevant.

Risk for consumers via residues in food

By definition, PT 2 biocidal product is not intended for direct application to humans or animals and is not used for direct contact with food or feedingstuffs.

Regarding PT 4 uses, considering properties of L(+) lactic acid, no significant exposure via food is expected. Based on the low concentration of L(+) lactic acid, the endogenous production and the authorized use of this active substance as food additive (E 270), significant indirect exposure in food is not expected.

2.2.7 Risk assessment for animal health

The risk for animal health is considered covered by human health assessment.

2.2.8 Risk assessment for the environment

The biocidal products family "Famille de produits Acide Lactique TP2-4 SOPRODIS" are surface disinfectants containing L(+) Lactic acid and whose uses belong to the product-types 2 and 4. They are intended to be used in industrial, professional and non-professional areas. The biocidal product family (BPF) contains several biocidal products (BP) grouped into ten sub-groups (Meta-SPC).

The family groups together ready-to-use and concentrated products. All product uses take place inside, leading to the exposure of the STP as a primary receiving environmental compartment.

Substances of Concern and Metabolites:

No metabolites are formed and no substance of concern is identified.

The following risk assessment is therefore carried out for the active substance only.

2.2.8.1 Effects assessment on the environment

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

No new environmental studies have been carried out with the BPF. The classification of the different meta-SPC, summarized in the table below, has been calculated from classifications of the active substance and co-formulants (see the detailed calculation based on the composition in the confidential annex).

| | Meta-SPC 1 | Meta-SPC 2 | Meta-SPC 3 | Meta-SPC 4 | Meta-SPC 5 | Meta-SPC 6 | Meta-SPC 7 | Meta-SPC 8 | Meta-SPC 9 | Meta-SPC 10 |
|----------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|-------------|
| Classification | n.c. | n.c. | n.c. | n.c. | n.c. | n.c. | n.c. | n.c. | n.c. | n.c. |

n.c.: Not classified

Further Ecotoxicological studies

No new data is available.

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

No new data is available.

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

Not relevant.

| | |
|-------------------------|---|
| Data waiving | |
| Information requirement | Not relevant |
| Justification | The products are not in the form of bait or granules. |

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

Not relevant.

| | |
|-------------------------|---|
| Data waiving | |
| Information requirement | Not relevant |
| Justification | The products are not in the form of bait or granules. |

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

Not relevant.

Foreseeable routes of entry into the environment on the basis of the use envisaged

The family groups together ready-to-use and concentrated products. All products uses take place inside, leading to the exposure of the STP as a primary receiving environmental compartment.

Further studies on fate and behaviour in the environment (ADS)

At WGII2020, it was stated that Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food constituent and also a growth regulator intended to increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L(+) Lactic acid naturally occurs as a fermentation by-product of anaerobic degradation of organic matter. This substance may covalent bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD+ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not be taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations (Tier 1). Modelling of groundwater exposure in case of Lactic acid largely overestimates concentrations and is considered unrealistic.

For all these reasons, it can be stated that Lactic acid does not cause unacceptable risk for groundwater, without need for further calculations.

A new experimental study is available for L(+) Lactic acid biodegradability at the product authorisation stage and shows that the substance is readily biodegradable fulfilling the 10 days window. In the exposure assessment, it allows to refine the DT50 in soil to 30 days and the Fwater calculated with Simple Treat 4.0.

As:

- In the AR (2017), DT50_{soil} has already been reduced to 30 days with expert judgement,
- The modification of the Fwater has no impact on the conclusions of this dossier,

The study is not proposed to be discussed at European level for this particular case. However, it has been assessed by the eCA and add support to the final conclusion of the dossier (see overall conclusion).

The results are presented in the following table:

| | | | Inoculum | | Degradation | Ref. |
|--|--|--|----------|--|-------------|------|
|--|--|--|----------|--|-------------|------|

| Guide line / Test Method | Test type | Test parameter | Type | Conc. | Adaptation. | Additional substrate | TS conc. | Incubation period | Degree [%] | |
|--------------------------|-----------|----------------|--|---|-------------|----------------------|-----------|-------------------|---|--|
| OECD 301D | ThOD | Oxygen demand | Activated sludge (microorganisms from a domestic waste water treatment plant) was supplied by sewage plant Rossdorf, Germany | 2.5 mL of the filtered inoculum were added to 5L of aqueous test medium | No | No | 5.06 mg/L | 28 days | 7 days: 61% 12 days: 72% 28 days: 79% | Ready Biodegradability of Lactic acid 80% food grade in a Closed Bottle Test Dr. Ute Hammesfahr (2018-Project 80031161). IUCLID available section 13 |

Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment

| | |
|--|--|
| Value/conclusion | L-(+) lactic acid is readily biodegradable, fulfilling the 10-days window. Considering this and its $K_{p_{soil}}$ value (0.4L/kg), $DT_{50_{soil}}$ is 30 days (Vol IV Part B+C, 2017). |
| Justification for the value/conclusion | Under the OECD 301D test conditions the percentage biodegradation of L(+) Lactic acid 80% food grade reached in the mean 51% after 3 days of incubation and continuously increased to 61% at 7d, 71% after 14 days and 79% after 28 days. The percentage biodegradation did exceed 60% within the 10-day window. All the validity criteria are fulfilled and no deviations from the OCDE guidance is observed. |

Leaching behaviour (ADS)

No new data is available.

Testing for distribution and dissipation in soil (ADS)

No new data is available.

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

No new data is available.

Testing for distribution and dissipation in air (ADS)

No new data is available.

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)

Not relevant.

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)

Not relevant.

PNEC values summary table

L(+) lactic acid

Based on the L(+) lactic acid assessment report (2017), the relevant PNECs for the environmental risk characterisation are reported below.

| PNEC | | Justification |
|------------------------------|---------------|--|
| PNEC _{STP} | 10 mg/L | An NOEC of 100 mg/L from an activated sludge respiration test no inhibitory effect is reported in the AR (2017). An assessment factor (AF) of 10 was applied to the NOEC to derive the PNEC. |
| PNEC _{water} | 3.9 mg/L | The PNEC _{water} presented in the AR (2017) was derived from the EC ₅₀ of 3900 mg/L for fish and an AF of 1000. |
| PNEC _{sediment,EPM} | 4.8 mg/kg wwt | Equilibrium partitioning method. |
| PNEC _{soil,EPM} | 1.9 mg/kg wwt | Equilibrium partitioning method. |

2.2.8.2 Exposure assessment

The biocidal products family "Famille de produits Acide Lactique TP2-4" contains surface disinfectants whose uses belong to the product-types 2 and 4. They are intended to be used in industrial, professional, and non-professional areas.

The family groups together ready-to-use and concentrated products. All products uses take place inside, leading to the exposure of the STP as a primary receiving environmental compartment.

A total of 5 emissions scenarios were assessed in order to cover all the products uses. The following exposure assessment is carried out for the active substance L(+) Latic.

General information

| | |
|---------------------------------|--|
| Assessed PT | PT 2 |
| Assessed scenarios | <p>PT2 - Scenario 1: Industrial area – Large and small scale applications</p> <p>PT2 - Scenario 2: Disinfectants used in the sanitary sector (general surfaces + lavatories).</p> |
| ESD(s) used | <ul style="list-style-type: none"> Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), March 2001. Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products, 2011. |
| Approach | <p>PT2 - Scenario 1: Average consumption</p> <p>PT2 - Scenario 2: Average consumption + tonnage</p> |
| Distribution in the environment | <p>Estimated according to:</p> <ul style="list-style-type: none"> Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C) Assessment report: L(+) lactic acid - Product-types 02, 03 and 04, June 2017. Technical Agreements for Biocides Environment, Version DB, 09 November 2021. |
| Groundwater simulation | No |
| Confidential Annexes | Yes |
| Life cycle steps assessed | <p>All scenarios:</p> <p>Production: No</p> <p>Formulation: No</p> |

| | |
|---------------------------------|--|
| | Use: Yes Service life: No |
| Remarks | To cover all claimed doses, the concentration of lactic acid in Meta SPC 10 was used as the worst case for the environmental risk assessment, as it is the highest one (i.e. 68.82 g/L). |
| Assessed PT | PT4 |
| Assessed scenarios | PT4 - Scenario 3: Disinfectants used in entire plants PT4 - Scenario 4: Disinfection of large scale kitchens/canteens and slaughterhouses PT4 - Scenario 5: Disinfection dipping scenario for medium to small-scale applications |
| ESD(s) used | <ul style="list-style-type: none"> Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas, 2011. |
| Approach | PT4 - Scenario 3: Average consumption PT4 - Scenario 4: Average consumption PT4 - Scenario 5: Average consumption |
| Distribution in the environment | Estimated according to: <ul style="list-style-type: none"> Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C) Assessment report: L(+) lactic acid - Product-types 02, 03 and 04, June 2017. Technical Agreements for Biocides Environment, Version DB, 02 February 2021. |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | All scenarios: Production: No Formulation: No Use: Yes Service life: No |
| Remarks | To cover all claimed doses, the concentration of lactic acid in Meta SPC 10 was used as the worst case for the environmental risk assessment, as it is the highest one (i.e. 68.82 g/L). |

Emission estimation**PT2 scenarios****2.2.8.2.1 PT2 - Scenario 1: Industrial area – Large and small scale applications**

The scenario for the surface disinfection in industrial areas covers the following uses (intended for META-SPC 1, 2, 3, 4, 5, 6, 7, 8 and 9) in the fields of industries (including cosmetic and pharmaceutical industries), health care facilities (excluding the hospitals) and veterinary health care (please note that the use numbers are those into brackets in the section 'authorised uses' of each META-SPC):

- Disinfection of hard surfaces and equipment by manual liquid spraying (use #1, #17)
- Disinfection of hard surfaces and equipment by manual liquid spraying using mural cleaning station (liquid/foam spraying) (use #2)
- Disinfection of equipment by manual dipping/soaking (use #3)
- Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing by professionals (use #4, #19)
- Disinfection of equipment by automatic application in cleaning washer (use #5)
- Disinfection of cleaning washer by automatic application (use #6)
- Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer by professionals (use #18, #33)

Local emission due to disinfection of industrial areas were calculated using ESD for PT2 Disinfection in industrial premises (RIVM, 2011). This scenario applies to disinfection of a wide range of surfaces: small surfaces such as furniture and bigger surfaces such as rooms, walls or floors. Industrial premises are considered as local emission sources which release their wastewater to a local STP.

The scenario is based on the concentration of the active substance and the volume applied on a surface: an application rate 0.1 L/m² was used as default value and worst-case. Surface areas of 1000 m² and 25 m² was assessed for large and small scale applications respectively.

| Input parameters for calculating the local emission | | | | |
|--|--------------|------------------|----------------|---|
| Input | Value | Unit | S/D/O/P | Remarks |
| PT2 - Scenario 1: Industrial area – Large and small scale applications | | | | |
| Application rate of biocidal product (Vform) | 0.1 | l/m ² | D | Default value TAB ENV 26 |
| Concentration of substance in the product (Cform) | 68.82 | g/l | S | Lactic acid (absolute worst case META SPC 10) |
| Surface area to be disinfected (AREA _{surface}) | 1000 25 | m ² | D | Large scale Small scale |
| Number of applications per day (Nappl) | 1 | 1/d | D | |

| | | | | |
|--|---|---|---|--|
| Fraction of substance disintegrated during or after application (before release to the sewer system) (F_{dis}) | 0 | - | D | |
| Fraction released to wastewater (F_{water}) | 1 | - | D | |

Calculations for Scenario 1

$$E_{localwater} = V_{form} * C_{form} * AREA_{surface} * Nappl * (1 - F_{dis}) * F_{water} / 100$$

| Resulting local emission to relevant environmental compartments | | |
|---|--------------------------------|---------|
| Compartment | Local emission (Elocal) [kg/d] | Remarks |
| Emission rate to wastewater (standard STP) for industrial applications (large scale) (Elocalwater) | 6.88E+00 | - |
| Emission rate to wastewater (standard STP) for industrial applications (small scale) (Elocalwater) | 1.72E-01 | - |

2.2.8.2.2 PT2 - Scenario 2: Disinfectants used in the sanitary sector (general surfaces + lavatories).

For the evaluation of this scenario, two approaches exist: the average consumption and the tonnage based approaches. The tonnage based approach is described in the confidential PAR and the average consumption below. After a comparison with the tonnage approach, the consumption based scenario is considered as the worst-case approach.

The scenario for the disinfection for sanitary purpose covers the following uses (intended for META-SPC 1, 2, 3, 4, 5, 6, 7, 8 and 9) in the fields of households and institutions (please note that the use numbers are those into brackets in the section 'authorised uses' of each META-SPC):

- Disinfection of hard surfaces and equipment by manual liquid spraying (use #1, #17)
- Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) (use #2)
- Disinfection of equipment by manual dipping/soaking (use #3)
- Disinfection of cleaning washer by automatic application (use #6)

- Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (use #19, #25, #30)
- Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (use #18, #24)
- Disinfection of toilet bowls and sanitary facilities by direct spreading/flooding (use #20, #26, #29, #33)

| Input parameters for calculating the local emission | | | | |
|--|---------|---------|---------|---------|
| Input | Value | Unit | S/D/O/P | Remarks |
| PT2 - Scenario 2: Disinfectants used in the sanitary sector (general surfaces+lavatories) (average consumption). | | | | |
| Number of inhabitants feeding one STP (Nlocal) | 10000 | cap | D | |
| Fraction released to wastewater (F _{water}) | 1 | - | D | |
| Concentration of active substance in the product (C _{form}) | 0.06882 | kg/l | S | |
| Consumption per capita (general surfaces) (V _{form}) | 0.007 | l/cap/d | D | |
| Fraction of substance disintegrated during or after application (before release to the sewer system) (F _{dis}) | 0 | - | D | |
| Penetration factor of disinfectant (F _{penetr}) | 0.5 | - | D | |

Calculations for Scenario 2

$$E_{localwater} = N_{local} * V_{form} * C_{form} * F_{penetr} * (1 - F_{dis}) * F_{water}$$

| Resulting local emission to relevant environmental compartments | | |
|--|---|---------|
| Compartment | Local emission (E _{local}) [kg/d] | Remarks |
| Emission rate to wastewater (standard STP) for general purposes and lavatory | 2.41E+00 | - |

PT4 scenarios

2.2.8.2.3 PT4 - Scenario 3: Disinfectants used in entire plants

The scenario for the disinfection in entire plants covers the following uses (intended for META-SPC 6) in the fields of agri-food industries (including meat industries, food and feed industries, non-alcoholic beverages and alcoholic beverages industries, drinking water, excluding milk industries), collective central kitchens, food and feed areas, food shops and restaurants (please note that the use numbers are those into brackets in the section 'authorised uses' of each META-SPC):

- Disinfection of inner surfaces by CIP (use #15)
- Disinfection of the inner surfaces of small kitchen appliances by CIP (use #36)

Please note this scenario can also cover the PT 02 use #7 Disinfection of inner surfaces by CIP.

In food, drink and milk industries (FDM), multiple disinfection processes may take place at the same time in several different units (e.g. CIP, disinfection of storage tanks, disinfection of surface, disinfection of process lines...) using the same disinfectant.

FDM are considered as a local point source of emission. This ESD is providing a method to assess the emission from the entire plant.

The emission estimation is based on the consumption of disinfectants by a model plant. As no annual tonnage for a local plant was known for the products assessed, the amount of biocidal active substance used per year in the local plant is derived from the Competent Authority Report of Lactic acid (CAR doc IIB8.3 confidential).

As this scenario is based on confidential data, it is presented in the confidential annex.

2.2.8.2.4 PT4 - Scenario 4: Disinfection of large and small scale kitchens/canteens and slaughterhouses

The scenario for the disinfection of large scale kitchens/canteens and slaughterhouses covers the following uses (intended for META-SPC 1, 2, 3, 4, 5, 6, 7, 8 and 9) in the fields of agri-food industries (including meat industries, food and feed industries, non-alcoholic beverages and alcoholic beverages industries, drinking water, excluding milk industries), collective central kitchens, food and feed areas, food shops, restaurants and domestic kitchens (please note that the use numbers are those into brackets in the section 'authorised uses' of each META-SPC):

- Disinfection of dish washing machine and crate washer (use #14)
- Disinfection of equipment by dish washing machine and crate washer (use #13)
- Disinfection of hard surfaces (small surfaces) and equipment by manual spraying using a trigger sprayer (use #22, #27, #31, #34)
- Disinfection of hard surfaces and equipment by manual liquid spraying (use #9, #21)
- Disinfection of hard surfaces by manual spraying using mural cleaning station (liquid/foam spraying) (use #10)
- Disinfection of hard surfaces by wiping / mopping / brushing / scrubbing (use #12, #23, #28, #32)
- Disinfection of the inner surfaces of small kitchen appliances without circulation (use #35)

An application rate of 0.1 L.m² was used as default value and worst-case. Therefore, the application rate of Lactic acid is 6.57 g/m², considering the absolute worst-case in-use concentration of 65.72 g/L (META SPC 10).

The small scale applications are only relevant for RTU products (META SPC 7, 8 and 9).

| Input parameters for calculating the local emission | | | | |
|--|---------------|------------------|----------------|--|
| Input | Value | Unit | S/D/O/P | Remarks |
| PT4 - Scenario 4: Disinfection of large scale kitchens/canteens and slaughterhouses | | | | |
| Application rate of the substance (Qa.i.appl) | 6.882 | g/m ² | S | |
| Surface area to be disinfected - Large scale (AREA _{surface}) | 10000 2000 | m ² | D | Slaughterhouses Kitchens and canteens |
| Surface area to be disinfected - Small scale (AREA _{surface}) - Only relevant for RTU | 10 50 | m ² | D | Slaughterhouses Kitchens and canteens |
| Number of applications per day (Nappl) | 1 | 1/d | D | |
| Fraction of substance disintegrated during or after application (before release to the sewer system) (F _{dis}) | 0 | - | D | |
| Fraction of substance eliminated due to onsite pre-treatment of waste water (F _{elim}) | 0 | - | D | |
| Fraction released to wastewater (F _{water}) | 1 | - | D | |

Calculations for Scenario 4

$$E_{\text{localwater}} = Q_{a.i.appl} * AREA_{\text{surface}} * N_{\text{appl}} * (1-F_{\text{dis}}) * (1-F_{\text{elim}}) * F_{\text{water}}/1000$$

| Resulting local emission to relevant environmental compartments | | |
|--|--|----------------|
| Compartment | Local emission (E_{local}) [kg/d] | Remarks |
| Large scale | | |
| Catering kitchens | | |

| Resulting local emission to relevant environmental compartments | | |
|--|---|----------------|
| Compartment | Local emission (Elocal) [kg/d] | Remarks |
| Emission rate to wastewater | 1.38E+01 | - |
| Slaughterhouses | | |
| Emission rate to wastewater | 6.88E+01 | - |
| Small scale | | |
| Catering kitchens | | |
| Emission rate to wastewater | 3.44E-01 | - |
| Slaughterhouses | | |
| Emission rate to wastewater | 6.88E-02 | - |

2.2.8.2.5 PT4 - Scenario 5: Disinfection by dipping for medium to small-scale applications

The scenario for the disinfection by dipping for medium to small-scale applications covers the following use (intended for META-SPC 1, 2, 3, 4, 5, 6 and 10) in the fields of agri-food industries (including meat industries, food and feed industries, non-alcoholic beverages and alcoholic beverages industries, drinking water, excluding milk industries), collective central kitchens, food and feed areas, food shops and restaurants (please note that the use numbers are those into brackets in the section 'authorised uses' of each META-SPC):

- Disinfection of equipment by manual dipping/soaking (use #11)

Local emission due to disinfectants used in food and feed areas for the use in baths were calculated using the scenario of the Technical Agreements for Biocides (TAB) – 02 February 2021 - ENV 271 PT4.

| Input parameters for calculating the local emission | | | | |
|--|--------------|-------------|----------------|----------------|
| Input | Value | Unit | S/D/O/P | Remarks |
| PT4 - Scenario 5: Disinfection dipping scenario for medium to small-scale applications | | | | |
| Concentration of substance in the dipping bath (Cform) | 68.82 | g/L | S | |
| Volume of solution in a dipping bath (Vbath) | 100 | L | D | |

| | | | | |
|---|---|---|---|--|
| Number of sites using the disinfection solution connected to the same STP (N_{appl}) | 5 | - | D | |
| Fraction of substance disintegrated during or after application (before release to the sewage system) (F_{dis}) | 0 | - | D | |
| Fraction of substance eliminated due to onsite pre-treatment of wastewater (F_{elim}) | 0 | - | D | |
| Fraction released to wastewater (F_{water}) | 1 | - | D | |

Calculations for Scenario 5

$$E_{localwater} = C_{form} * V_{bath} * N_{appl} * (1 - F_{dis}) * (1 - F_{elim}) * F_{water}$$

| Resulting local emission to relevant environmental compartments | | |
|---|---------------------------------------|---------|
| Compartment | Local emission (E_{local}) [kg/d] | Remarks |
| Emission rate to wastewater | 3.44E+01 | - |

2.2.8.2.6 Summary of local emission to relevant environmental compartments

| Summary of local emission to relevant environmental compartments | |
|--|---|
| Scenarios | $E_{localwater}$ [kg/d] for Lactic acid |
| PT2 - Scenario 1: Industrial area – Large scale applications | 6.88E+00 |
| PT2 - Scenario 1: Industrial area – Small scale applications | 1.72E-01 |
| PT2 - Scenario 2: Disinfectants used in the sanitary sector (general surfaces + lavatories) | 2.41E+00 |
| PT4 - Scenario 3: Disinfectants used in entire plants | see confidential PAR |
| PT4 - Scenario 4: Disinfection of large scale kitchens and canteens (large scale) | 1.38E+01 |

| | |
|---|----------|
| PT4 - Scenario 4: Disinfection of slaughterhouses (large scale) | 6.88E+01 |
| PT4 - Scenario 4: Disinfection of kitchens and canteens (small scale) | 3.44E-01 |
| PT4 - Scenario 4: Disinfection of slaughterhouses (small scale) | 6.88E-02 |
| PT4 - Scenario 5: Disinfection dipping scenario for medium to small-scale applications | 3.44E-01 |

Fate and distribution in exposed environmental compartments

Lactic acid

| Identification of relevant receiving compartments based on the exposure pathway – Lactic acid | | | | | | | | | |
|--|-------------|---------------------|-----------|-------------------|-----|-----|------|--------------|-------|
| | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| Scenario 1 | Yes | Yes | No | No | Yes | No | Yes | n.r. | No |
| Scenario 2 | Yes | Yes | No | No | Yes | No | Yes | n.r. | No |
| Scenario 3 | Yes | Yes | No | No | Yes | No | Yes | n.r. | No |
| Scenario 4 | Yes | Yes | No | No | Yes | No | Yes | n.r. | No |
| Scenario 5 | Yes | Yes | No | No | Yes | No | Yes | n.r. | No |

n.r.: not relevant

| Input parameters (only set values) for calculating the fate and distribution in the environment – Lactic acid | | | |
|--|--|------------------------|--|
| Input | Value | Unit | Remarks |
| Molecular weight | 90.08 | g/mol | AR 2017 |
| Vapour pressure (at 20°C) | 0.4 | Pa | AR 2017 |
| Water solubility (at 12°C) | 1E+06 | mg/l | AR 2017 |
| Log Octanol/water partition coefficient | -0.74 | Log 10 | AR 2017 |
| Organic carbon/water partition coefficient (Koc) | 20 | l/kg | AR 2017 |
| Henry's Law Constant (at 20°C) | 3.60E-05 | Pa/m ³ /mol | Calculated |
| Biodegradability | Readily biodegradable failing the 10 days window | - | AR 2017 |
| DT ₅₀ for degradation in soil | 30 | d (at 12°C) | 30d as refinement for 90d value in AR (WGII2020) |

| | | | |
|---------------------------------|----------|-----------------|--|
| | | | |
| ktotal (0.2 m relevant for STP) | 2.61E-02 | d ⁻¹ | Calculated (k _{bio} + k _{volat} + k _{leach}) |
| BCF fish | 4.80E-02 | L/kg | AR 2017 – Not relevant for a risk assessment |
| BCF earthworms | 6.78E+00 | L/kg | AR 2017 – Not relevant for a risk assessment |

Calculated PEC values

| Summary table on calculated PEC values for Lactic acid | | | | | |
|--|----------------------|----------------------|-------------------------|---------------------------------------|-------------------|
| | PEC _{STP} | PEC _{water} | PEC _{sed} | PEC _{soil} (<i>twa</i>) | PEC _{GW} |
| | [mg/l] | [mg/l] | [mg/kg _{wwt}] | [mg/kg _{wwt}] | [µg/l] |
| PT2 - Scenario 1: Industrial area – Large scale applications | 7.74E-01 | 7.73E-02 | 9.42E-02 | 1.76E-02 | 1.14E+01 |
| PT2 - Scenario 1: Industrial area – Small scale applications | 1.93E-02 | 1.93E-03 | 2.35E-03 | 4.40E-04 | 2.84E-01 |
| PT2 - Scenario 2: Disinfectants used in the sanitary sector (general surfaces+lavatories). | 1.85E-01 | 1.85E-02 | 2.25E-02 | 4.20E-03 | 2.71E+00 |
| PT4 - Scenario 3: Disinfectants used in entire plants | see confidential PAR | | | | |
| PT4 - Scenario 4: Disinfection of large scale kitchens and canteens (large scale) | 2.71E-01 | 2.71E-02 | 3.30E-02 | 6.16E-03 | 3.98E+00 |
| PT4 - Scenario 4: Disinfection of slaughterhouses (large scale) | 1.31E-01 | 1.31E-02 | 1.60E-02 | 2.99E-03 | 1.93E+00 |
| PT4 - Scenario 4: Disinfection of | 1.55E+00 | 1.55E-01 | 1.88E-01 | 3.52E-02 | 2.27E+01 |

| | | | | | |
|--|----------|----------|----------|----------|-----------------|
| kitchens and canteens (small scale) | | | | | |
| PT4 - Scenario 4: Disinfection of slaughterhouses (small scale) | 7.74E+00 | 7.73E-01 | 9.42E-01 | 1.76E-01 | 1.14E+02 |
| PT4 - Scenario 5: Disinfection dipping scenario for medium to small-scale applications | 3.87E-02 | 3.87E-03 | 4.71E-03 | 8.79E-04 | 5.68E-01 |

The concentration of the active substance L(+) Lactic acid in groundwater exceeds the quality standard for pesticides and biocidal products according to Directive 2006/118/EC for drinking water (0.1 µg/L). A qualitative argumentation for non-performing Focus Pearl refinement is developed in the following section "Risk characterization".

Primary and secondary poisoning

Primary poisoning

As the proposed uses of BPs will not result in direct exposures to birds and mammals, the risk for the primary poisoning is considered acceptable for L(+) Lactic acid.

Secondary poisoning

As detailed in the exposure assessment section above, active substance L(+) Lactic Acid has a log Kow <3 and BCF < 100. Thus, these values indicate a negligible potential risk for bioconcentration in biota and no accumulation of substances in the food chain is expected. The secondary poisoning assessment is not relevant for this substance.

2.2.8.3 Risk characterisation

2.2.8.3.1 Atmosphere

Conclusion: As stated in the L(+) lactic acid assessment report, L(+) lactic acid is not considered to be used as fumigant. The vapour pressure of L(+) lactic acid is 0.4 Pa at 20°C and the Henry constant is 3.6×10^{-5} indicating that direct evaporation and volatility from water are expected to be insignificant. In general, emissions of L(+) lactic acid to the atmosphere are unlikely to occur. Due to an estimated half-life in the atmosphere of 2.71 d corresponding to 3.91 d for the chemical lifetime the potential for long-range transport of L(+) lactic acid in air is indicated (ref. to Annex D of the Stockholm Convention on Persistent Organic Pollutants (17th May 2004): "... a chemical that migrates significantly through the air, its half-life in air should be greater than two days ..."). However, according to the Vol IV Part B+C (2017) effects on stratospheric ozone and acidification are not

expected because L(+) lactic acid does not contain halogens, nitrogen or sulphur substituents. L(+) lactic acid shows no absorption bands in the so-called atmospheric window (range from 800 to 1200 nm). Therefore, L(+) lactic acid has no global-warming potential.

2.2.8.3.2 Sewage treatment plant (STP)

| Summary table on calculated PEC/PNEC values | |
|---|-----------------------------|
| | PEC/PNEC _{STP} |
| PT2 - Scenario 1: Industrial area – Large scale applications | 7.74E-02 |
| PT2 - Scenario 1: Industrial area – Small scale applications | 1.93E-03 |
| PT2 - Scenario 2: Disinfectants used in the sanitary sector (general surfaces+lavatories). | 2.71E-02 |
| PT4 - Scenario 3: Disinfectants used in entire plants | < 1 see confidential PAR |
| PT4 - Scenario 4: Disinfection of large scale kitchens and canteens (large scale) | 1.31E-02 |
| PT4 - Scenario 4: Disinfection of slaughterhouses (large scale) | 1.55E-01 |
| PT4 - Scenario 4: Disinfection of kitchens and canteens (small scale) | 7.74E-01 |
| PT4 - Scenario 4: Disinfection of slaughterhouses (small scale) | 3.87E-03 |
| PT4 - Scenario 5: Disinfection dipping scenario for medium to small-scale applications | 7.74E-04 |

n.r.: not relevant

Conclusion: All the calculated risk characterisation ratios are below the trigger value of 1. Therefore, risks for the STP compartment are acceptable.

2.2.8.3.3 Aquatic compartment

| Summary table on calculated PEC/PNEC values | |
|---|---------------------------|
| | PEC/PNEC _{water} |

| | |
|---|-----------------------------|
| PT2 - Scenario 1: Industrial area – Large scale applications | 1.89E-02 |
| PT2 - Scenario 1: Industrial area – Small scale applications | 4.74E-04 |
| PT2 - Scenario 2: Disinfectants used in the sanitary sector (general surfaces+lavatories). | 6.63E-03 |
| PT4 - Scenario 3: Disinfectants used in entire plants | < 1 see confidential PAR |
| PT4 - Scenario 4: Disinfection of large scale kitchens and canteens (large scale) | 3.79E-02 |
| PT4 - Scenario 4: Disinfection of slaughterhouses (large scale) | 1.89E-01 |
| PT4 - Scenario 4: Disinfection of kitchens and canteens (small scale) | 9.47E-04 |
| PT4 - Scenario 4: Disinfection of slaughterhouses (small scale) | 1.89E-04 |
| PT4 - Scenario 5: Disinfection dipping scenario for medium to small-scale applications | 9.47E-02 |

Conclusion: All the calculated risk characterisation ratios are below the trigger value of 1. Therefore, risks for the water compartment (sediment compartment covered by surface water - EPM) are acceptable.

2.2.8.3.4 Terrestrial compartment

| Calculated PEC/PNEC values | |
|---|-----------------------------|
| | PEC/PNEC _{soil} |
| PT2 - Scenario 1: Industrial area – Large scale applications | 9.26E-03 |
| PT2 - Scenario 1: Industrial area – Small scale applications | 2.31E-04 |
| PT2 - Scenario 2: Disinfectants used in the sanitary sector (general surfaces+lavatories). | 3.24E-03 |
| PT4 - Scenario 3: Disinfectants used in entire plants | < 1 see confidential PAR |

| | |
|---|----------|
| PT4 - Scenario 4: Disinfection of large scale kitchens and canteens (large scale) | 1.85E-02 |
| PT4 - Scenario 4: Disinfection of slaughterhouses (large scale) | 9.26E-02 |
| PT4 - Scenario 4: Disinfection of kitchens and canteens (small scale) | 4.63E-04 |
| PT4 - Scenario 4: Disinfection of slaughterhouses (small scale) | 9.26E-05 |
| PT4 - Scenario 5: Disinfection dipping scenario for medium to small-scale applications | 4.63E-02 |

Conclusion: All the calculated risk characterisation ratios are below the trigger value of 1. Therefore, risks for the soil compartment are acceptable.

2.2.8.3.5 Groundwater

| | PEC_{localgroundwater} (µg/l) |
|---|--|
| PT2 - Scenario 1: Industrial area – Large scale applications | 1.14E+01 |
| PT2 - Scenario 1: Industrial area – Small scale applications | 2.84E-01 |
| PT2 - Scenario 2: Disinfectants used in the sanitary sector (general surfaces+lavatories). | 2.71E+00 |
| PT4 - Scenario 3: Disinfectants used in entire plants | > 0.1 see confidential PAR |
| PT4 - Scenario 4: Disinfection of large scale kitchens and canteens (large scale) | 3.98E+00 |
| PT4 - Scenario 4: Disinfection of slaughterhouses (large scale) | 1.93E+00 |
| PT4 - Scenario 4: Disinfection of kitchens and canteens (small scale) | 2.27E+01 |
| PT4 - Scenario 4: Disinfection of slaughterhouses (small scale) | 1.14E+02 |
| PT4 - Scenario 5: Disinfection dipping scenario for medium to small-scale applications | 5.68E-01 |

Conclusion: The calculated value for PEC_{local} groundwater for Lactic acid exceeds the limit value in groundwater of 0.1 µg.L⁻¹ for biocides (Directives 2006/118/EC and 98/83/EC).

Nevertheless, for L(+) Lactic acid, it was decided during the WG-II-2020 that only arguments to support a qualitative assessment without further calculations should be provided. The harmonized justification is presented below:

"Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food constituent and also a growth regulator intended to increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L(+) lactic acid naturally occurs as a fermentation by-product of anaerobic degradation of organic matter. This substance may covalent bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD⁺ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations (tier 1). Modelling of groundwater exposure in case of lactic acid largely overestimates concentrations and is considered unrealistic.

For all these reasons, it can be stated that Lactic acid does not cause unacceptable risk for groundwater and no further calculations are needed."

2.2.8.3.6 Primary and secondary poisoning

Primary poisoning

As the proposed uses of BPs will not result in direct exposures to birds and mammals, the risk for the primary poisoning is considered acceptable.

Secondary poisoning

As detailed in the exposure assessment section above, active substance L(+) Lactic Acid has a log K_{ow} <3 and BCF < 100. Thus, these values indicate a negligible potential risk for bioconcentration in biota and no accumulation of substances in the food chain is expected. The secondary poisoning assessment is not relevant for this substance.

2.2.8.3.7 Mixture toxicity

The product only contains one active substance and no environmentally relevant substances of concern. Therefore, a mixture assessment is not necessary.

2.2.8.3.8 Aggregated exposure (combined for relevant emission sources)

As stated in the L(+) lactic acid assessment report, According to the " Decision tree on the need for estimation of aggregated exposure" (BIP6 . 7 Decision Tree Agg Expo) the requirement for aggregated exposure estimations was checked for L(+) lactic acid. L(+) lactic acid is also regulated in other regulatory areas (e.g. cosmetics regulation, food legislation). The amount of L(+) lactic acid that is used annually for biocidal purposes amounts to 5% of the total production and import volume of L(+) lactic acid in the EU in 2012. Thus, the biocidal use of L(+) lactic acid accounts for less than 10% of the total production and import volume in the EU."

The intended uses of the BPF products are widely dispersive and do not represent a specific emission pattern. Consequently, it has been concluded that no aggregated exposure assessment for a.s. L(+) lactic acid has to be performed.

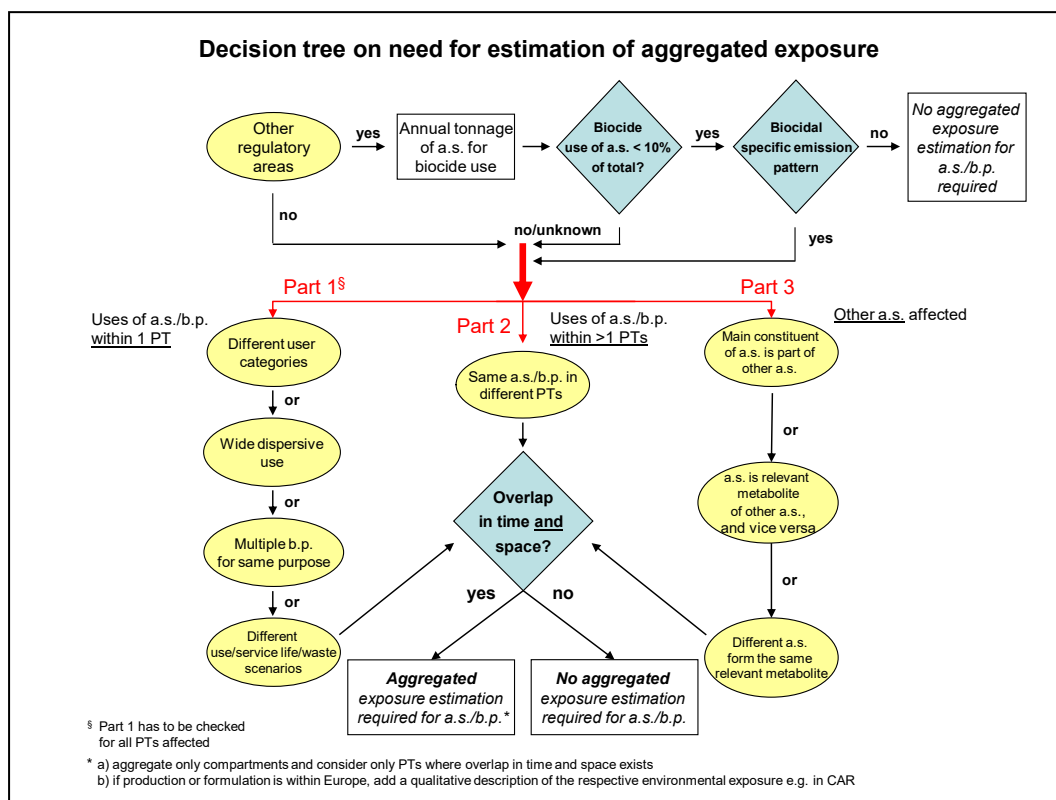


Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product

The environmental risk assessment has been conducted for the active substance L(+) Lactic acid only.

It has been demonstrated that uses of the BPF does not pose a risk to the environmental compartments. No specific risk mitigation measure is required.

3 ANNEXES

3.1 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) |
|------------|------|---|---|---|
| [REDACTED] | 2020 | COM23/METASPC1-X – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000159213 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | COM23/METASPC1-X – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447272 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | COM23/METASPC1-X – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447272 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | COM23/METASPC1-X – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000159213 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | COM23/METASPC1-X – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447272 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | COM23/METASPC1/PRODUCT1-X – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000159213 | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |








| | | | | |
|--|------|--|-----|---|
| | | Not GLP; Unpublished | | |
| | 2020 | COM23/METASPC1-X – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447272 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | COM23/METASPC1/PRODUCT1-X – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 20°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000159213 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | COM23/METASPC1/PRODUCT1-X – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 40°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000159213 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | Yeasticidal activity of product Com 23 – Product 1-X in accordance with the European standard EN 13697 (July 2019) Dirty conditions – 20°C HYDRACHIM Laboratoire <i>R20201022-EN13697 20°C 15min Product 1-X</i> Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | Yeasticidal activity of product Com 23 – Product 1-X in accordance with the European standard EN 13697 (July 2019) Dirty conditions – 40°C HYDRACHIM Laboratoire <i>R20201022-EN13697 40°C 15min Product 1-X</i> Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | COM23/METASPC2-X – Evaluation of bactericidal activity according to BS EN 1276:201– 20°C Mérieux NutriSciences Chelab s.r.l | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |








| | | | | |
|------------|------|--|-----|---|
| | | Test Report 20/000159247 Not GLP; Unpublished | | |
| ██████████ | 2020 | COM23/METASPC2-X – Evaluation of bactericidal activity according to BS EN 1276:201– 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447261 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| ██████████ | 2020 | COM23/METASPC2/PRODUCT2-X – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000159247 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| ██████████ | 2020 | COM23/METASPC2-X – Evaluation of bactericidal activity according to BS EN 1276:201– 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447261 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| ██████████ | 2020 | COM23/METASPC2-X – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000159247 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| ██████████ | 2020 | COM23/METASPC2-X – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447261 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| ██████████ | 2020 | COM23/METASPC2-X – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447261 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| ██████████ | 2020 | COM23/METASPC2/PRODUCT2-X – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447261 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |

| | | | | |
|--|------|--|-----|--|
| | | Mérieux NutriSciences Chelab s.r.l. Test Report 20/000159247 Not GLP; Unpublished | | |
| | 2020 | COM23/METASPC2/PRODUCT2-X – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 20°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000159247 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | COM23/METASPC2/PRODUCT2-X – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 40°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000159247 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | COM23/METASPC2-X – Evaluation of yeasticidal activity according to BS EN 13697:2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000159247 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | COM23/METASPC2/PRODUCT2-X – Evaluation of yeasticidal activity according to BS EN 13697:2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000447261 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2019 | COM23/METASPC3-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000022074 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | COM23/METASPC3-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Mérieux NutriSciences Chelab s.r.l. | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |






| | | | | |
|--|------|--|-----|---|
| | | Test Report 20/000447225 Not GLP; Unpublished | | |
| | 2019 | COM23/METASPC3-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000022074 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | COM23/METASPC3-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000447225 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | COM23/META SPC 3-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000159182 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2019 | COM23/METASPC3-1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000022074 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | COM23/METASPC3-1 – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000447225 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2019 | COM23/METASPC3-1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000022074 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |






| | | | | |
|---|------|--|-----|---|
|  | 2020 | COM23/METASPC3-1 – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000447225 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/META SPC 3-1 – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000159182 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/META SPC 3-1 – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 20°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000159182 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/META SPC 3-1 – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 40°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000159182 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/META SPC 3-1 Evaluation of yeasticidal activity according to BS EN 13697:2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000386217 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/META SPC 3-1 Evaluation of yeasticidal activity according to BS EN 13697:2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000447225 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/META SPC 3-1 – Evaluation of yeasticidal activity according to BS EN 13697:2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000159182 | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |







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| | | Not GLP; Unpublished | | |
|  | 2019 | COM23/METASPC4 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000214030 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/METASPC4-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447157 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | COM23/METASPC4 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000214030 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/METASPC4-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000159100 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/METASPC4-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447157 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | COM23/METASPC4 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000214030 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/METASPC4-1 – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447157 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |






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|  | 2019 | COM23/METASPC4 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000214030 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | COM23/METASPC4-1 – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000159100 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/METASPC4-1 – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447157 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | COM23/METASPC4 – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000214030 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/METASPC4-1 – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000159100 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/METASPC4-1 – Evaluation of yeasticidal activity according to BS EN 13697:2015 + A1:2019 – 20°C, 15 min Mérieux NutriSciences Chelab s.r.l Test Report 20/000159100 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/METASPC4-1 – Evaluation of yeasticidal activity according to BS EN 13697:2015 + A1:2019 – 20°C, 30 min Mérieux NutriSciences Chelab s.r.l Test Report 20/000159100 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |






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| [REDACTED] | 2020 | COM23/METASPC4-1 – Evaluation of yeasticidal activity according to BS EN 13697:2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000159100 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | Evaluation of the bactericidal activity according to the NF EN 1276 : 2019 standard Product : Com23/Méta SPC 4-1/2020-07-09 Batch : Com23/Méta SPC 4-1/2020-07-09 Laboratoire MIDAC Test Report RE20-1401-1 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | Evaluation of the bactericidal activity according to the NF EN 1276 : 2019 standard Product : COM23/MétaSPC 4-TAB3/2020-07-09 Batch : COM23/MétaSPC 4-TAB3/2020-07-09 Laboratoire MIDAC Test Report RE20-1403-1 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | Test of virucidal activity of the product COM23/MÉTASPC 4-1/2020-07-09 against adenovirus type 5, murine norovirus, poliovirus type 1 with 60 minutes of contact time in dirty conditions (3g/L of BSA) according to NF EN 14476 + A2 (2019) standard S.A.S VIRHEALTH Test Report R2012LVGFB001 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | Test of virucidal activity of the product COM23/MÉTASPC 4-1/2020-07-09 against adenovirus type 5, murine norovirus, poliovirus type 1 with 30 minutes of contact time in dirty conditions (3g/L of BSA) according to NF EN 14476 + A2 (2019) standard S.A.S VIRHEALTH Test Report R2012LVGFB007 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |

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|  | 2020 | <p>Test of virucidal activity of the product COM23/MÉTASPC 4-1/2020-07-09 against bovine coronavirus with 5 minutes of contact time in dirty conditions (3g/L of BSA) according to NF EN 14476 + A2 (2019) (additional conditions) S.A.S VIRHEALTH Test Report R2012LVGFB002 Not GLP; Unpublished</p> | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | <p>Test of virucidal activity of the product COM23/MÉTASPC 4-1/2020-07-09 against murine parvovirus with 30 minutes of contact time in dirty conditions (3g/L of BSA) according to NF EN 14476 + A2 (2019) S.A.S VIRHEALTH Test Report R2012LVGFB010 Not GLP; Unpublished</p> | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | <p>Test of virucidal activity of the product COM23/METASPC5-1 against poliovirus type 1 with 60 minutes of contact time in dirty conditions (3g/L of BSA) according to NF EN 14476 + A2 (2019) S.A.S VIRHEALTH Test Report R2012LVGFB008 Not GLP; Unpublished</p> | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | <p>Preliminary test of virucidal activity of product COM23/MetaSPC5-1 against poliovirus type 1 with 60 minutes of contact time in dirty conditions (3g/L of BSA) according to NF EN 14476+A2 standard S.A.S VIRHEALTH Test Report PR2010LVGFB001-3 Not GLP; Unpublished</p> | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | <p>COM23/METASPC5-1 – PRODUCT 5-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000025008 Not GLP; Unpublished</p> | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |








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|  | 2020 | Evaluation of the bactericidal activity according to the NF EN 1276 : 2019 standard – Product : COM23/MetaSPC5-1 Batch : COM23/METASPC5-1/2020-07-21-1 – 20°C Laboratoire MIDAC Test Report n°RE20-1010-2 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | Evaluation of the bactericidal activity according to the NF EN 1276 : 2019 standard – Product : COM23/MetaSPC5-1 Batch : COM23/METASPC5-1/2020-07-21-1 Partial test against the strains Campylobacter jejuni and Lactobacillus brevis – 20°C Laboratoire MIDAC Test Report n° RE20-1010-3 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | COM23/METASPC5-1 – PRODUCT 5-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000025008 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/METASPC5-1 – PRODUCT 5-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000461956 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | Evaluation of the bactericidal activity according to the NF EN 1276 : 2019 standard – Product : COM23/MetaSPC5-1 Batch : COM23/METASPC5-1/2020-07-21-1 – 40°C Laboratoire MIDAC Test Report n°RE20-1025-2 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |








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|  | 2020 | Evaluation of the bactericidal activity according to the NF EN 1276 : 2019 standard – Product : COM23/MetaSPC5-1 Batch : COM23/METASPC5-1/2020-07-21-1 – 40°C Laboratoire MIDAC Test Report n°RE20-1025-3 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/METASPC5-1 - PRODUCT 5-1 – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000025008 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | Evaluation of the bactericidal activity according to the NF EN 13697 +A1 : 2019 standard – Product : COM23/MetaSPC5-1 Batch : COM23/METASPC5-1/2020-07-21-1 – 20°C Laboratoire MIDAC Test Report n°RE20-1011-1 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | Evaluation of the bactericidal activity according to the NF EN 13697 +A1 : 2019 standard – Product : COM23/MetaSPC5-1 Batch : COM23/METASPC5-1/2020-07-21-1 – 20°C Laboratoire MIDAC Test Report n°RE20-1012-1 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | COM23/METASPC5-1 – PRODUCT 5-1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000025008 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | Evaluation of the bactericidal activity according to the NF EN 13697 +A1 : 2019 standard – Product : COM23/MetaSPC5-1 Batch : COM23/METASPC5-1/2020-07-21-1 – 40°C Laboratoire MIDAC | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |

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| | | Test Report n°RE20-1014-1 Not GLP; Unpublished | | |
|  | 2020 | Evaluation of the bactericidal activity according to the NF EN 13697 +A1 : 2019 standard – Product : COM23/MetaSPC5-1 Batch : COM23/METASPC5-1/2020-07-21-1 – Additional test against the strain Enterococcus faecium – 40°C Laboratoire MIDAC Test Report n°RE20-1013-1 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | Evaluation of the bactericidal activity according to the NF EN 13697 +A1 : 2019 standard – Product : COM23/MetaSPC5-1 Batch : COM23/METASPC5-1/2020-07-21-1 – 40°C Laboratoire MIDAC Test Report n°RE20-1015-1 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | COM23/METASPC5-1 - PRODUCT 5-1 Evaluation of yeasticidal activity according to BS EN 1650:2019 – 40°C; 15 min Mérieux NutriSciences Chelab s.r.l Test Report 20/000025008 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | COM23/METASPC5-1 - PRODUCT 5-1 – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 20°C; 30 min Mérieux NutriSciences Chelab s.r.l Test Report 20/000025008 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | Evaluation of the yeasticidal activity according to the NF EN 13697 +A1 : 2019 standard – Product : COM23/MetaSPC5-1 – Batch : COM23/METASPC5-1/2020-07-21-1 – 40°C; 15 min Laboratoire MIDAC Test report n° RE20-1018-2 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |

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|  | 2020 | <p>Evaluation of the yeasticidal activity according to the NF EN 13697 +A1 : 2019 standard – Product : COM23/MetaSPC5-1 – Batch : COM23/METASPC5-1/2020-07-21-1 – 40°C; 30 min Laboratoire MIDAC Test report n° RE20-1019-2 Not GLP; Unpublished</p> | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | <p>Evaluation of the yeasticidal activity according to the NF EN 13697 +A1 : 2019 standard – Product : COM23/MetaSPC5-1 – Batch : COM23/METASPC5-1/2020-07-21-1 – 20°C; 15 min Laboratoire MIDAC Test report n° RE20-1016-2 Not GLP; Unpublished</p> | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | <p>Evaluation of the yeasticidal activity according to the NF EN 13697 +A1 : 2019 standard – Product : COM23/MetaSPC5-1 – Batch : COM23/METASPC5-1/2020-07-21-1 – 20°C; 30 min Laboratoire MIDAC Test report n° RE20-1017-2 Not GLP; Unpublished</p> | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | <p>Evaluation of the effectiveness of LSN 5-1 – Test virus: human rotavirus strain Wa – Method: EN 14476:2013+A1:2015 (dirty conditions), quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in human medicine – 20°C DR. BRILL + DR. STEINMANN : INSTITUTE FOR HYGIENE AND MICROBIOLOGY Test report L19/0627R.2 Not GLP; Unpublished</p> | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | <p>Evaluation of the effectiveness of LSN 5-1 – Test virus: bovine coronavirus (BCoV) (surrogate of human coronaviruses) – Method: based on EN 14476:2013+A2:2019 (3.0 g/l BSA), quantitative suspension test for the evaluation of virucidal activity of chemical</p> | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |

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| | | <p>disinfectants and antiseptics used in human medicine (phase 2/ step 1) – 20°C DR. BRILL + DR. STEINMANN : INSTITUTE FOR HYGIENE AND MICROBIOLOGY Test report L20/0262BC.1 Not GLP; Unpublished</p> | | |
| | 2020 | <p>Evaluation of the effectiveness of LSN 5-1 – Test virus: murine norovirus (as surrogate of human norovirus) – Method: based on EN 14476:2013+A2:2019 (3.0 g/l BSA), quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in human medicine (phase 2/ step 1) – 20°C DR. BRILL + DR. STEINMANN : INSTITUTE FOR HYGIENE AND MICROBIOLOGY Test report L19/0627M.2 Not GLP; Unpublished</p> | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | <p>Test of virucidal activity of the product COM23/METASPC5-1 against adenovirus type 5 with 15 minutes of contact time in dirty conditions (3g/L of BSA) according to NF EN 14476 + A2 (2019) S.A.S. VIRHEALTH Test report R2012LVGFB006 Not GLP; Unpublished</p> | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | <p>COM23/META SPC 6-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C; 15 min Mérieux NutriSciences Chelab s.r.l Test Report 20/000212177 Not GLP; Unpublished</p> | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | <p>COM23/METASPC6-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447288 Not GLP; Unpublished</p> | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |








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|  | 2020 | COM23/META SPC 6-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000212177 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/METASPC6-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447288 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/META SPC 6-1 – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 20°C; 15 min Mérieux NutriSciences Chelab s.r.l Test Report 20/000212177 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/META SPC 6-1 – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447288 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | COM23/METASPC6-1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000022154 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/METASPC6-1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000212177 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/METASPC6-1 – Evaluation of bactericidal activity according to BS EN 13697: 2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000447288 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |

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|  | 2019 | COM23/METASPC6-1 – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 20°C; 30 min Mérieux NutriSciences Chelab s.r.l Test Report 20/000022154 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | COM 23 - FORMULE 2-2 BIS – Evaluation of yeasticidal activity according to UNI EN 1650:2013 – 40°C; 15 min Mérieux NutriSciences Chelab s.r.l Test Report 20/000022154 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | COM23/METASPC6-1 – Evaluation of yeasticidal activity according to BS EN 13697:2015 + A1:2019 – 20°C; 30 min Mérieux NutriSciences Chelab s.r.l Test Report 20/000022154 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | COM23/METASPC6-1 – Evaluation of yeasticidal activity according to BS EN 13697:2015 + A1:2019 – 40°C; 15 min Mérieux NutriSciences Chelab s.r.l Test Report 20/000022154 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2018 | FORMULE 3-7 - Evaluation of bactericidal activity according to UNI EN 1276:2009 / EC1:2011 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report N. 18/000530536 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | COM23/METASPC7-1 – Evaluation of bactericidal activity against E. coli K12 according to BS EN 1276:2019 – 20°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000025084 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | COM23/META SPC 7-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000367130 | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |

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| | | Not GLP; Unpublished | | |
| | 2019 | COM23/METASPC7-1 – Evaluation of bactericidal activity against E. coli K12 according to BS EN 1276:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000025084 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2018 | FORMULE 3-7 - Evaluation of bactericidal activity according to UNI EN 13697: 2015 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report N. 18/000530536 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2019 | COM23/METASPC7-1 – Evaluation of bactericidal activity according to UNI EN 13697:2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000025084 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | COM23/META SPC 7-1 – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000367130 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2018 | FORMULE 3-7 – Evaluation of yeasticidal activity according to UNI EN 1650:2013 – 20°C Mérieux NutriSciences Chelab s.r.l. Test Report 18/000530536 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2018 | FORMULE 3-7 – Evaluation of yeasticidal activity according to UNI EN 13697:2015 – 20°C Mérieux NutriSciences Chelab s.r.l. Test Report 18/000530536 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |

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| [REDACTED] | 2020 | UNI EN 14476+A2:2019 – Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area (phase 2, step 1) – 20°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000367130 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | Test of virucidal activity of the product COM23/METASPC7-1 against poliovirus type 1 with 60 minutes of contact time in dirty conditions (3g/L of BSA) according to NF EN 14476 + A2 (2019) standard – 20°C S.A.S. VIRHEALTH Test Report R2010LVGFB002-3 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | Test of virucidal activity of the product COM23/METASPC7-1 against influenza virus H1N1 with 5 minutes of contact time in dirty conditions (3g/L of BSA) according to NF EN 14476 + A2 (2019) S.A.S. VIRHEALTH Test Report R2012LVGFB004 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | Test of virucidal activity of the product COM23/METASPC7-1 against modified vaccinia virus with 5 minutes of contact time in dirty conditions (3g/L of BSA) according to NF EN 14476 + A2 (2019) (additional conditions). S.A.S. VIRHEALTH Test Report R2012LVGFB005-1 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | Test of virucidal activity of the product COM23/METASPC7-1 against bovine coronavirus with 5 minutes of contact time in dirty conditions (3g/L of BSA) according to NF EN 14476 + A2 (2019) S.A.S. VIRHEALTH Test Report R2012LVGFB003 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |

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| [REDACTED] | 2020 | Evaluation of the effectiveness of LSN 7-1 – Test virus: human rotavirus strain Wa – Method: EN 14476:2013+A1:2015 (dirty conditions), quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in human medicine – 20°C DR. BRILL + DR. STEINMANN: INSTITUTE FOR HYGIENE AND MICROBIOLOGY Test Report L19/0626R.2 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | COM23/METASPC8-2 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000175182 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | Bactericidal activity of product Com 23 – Product 8-2 in accordance with the European standard EN 1276 (August 2019) Dirty conditions – 20°C HYDRACHIM Laboratoire R20201023-EN1276 20°C 60 min Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2019 | COM23/METASPC8-2 – Evaluation of bactericidal activity according to UNI EN 13697: 2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000025068 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | Bactericidal activity of product Com 23 – Product 8-2 in accordance with the European standard EN 13697 (July 2019) Dirty conditions – 20°C HYDRACHIM Laboratoire R20201023-EN13697 20°C 30 min Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| [REDACTED] | 2020 | COM23/METASPC8-2 – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000175182 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |

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|  | 2020 | COM23/METASPC8-2 – Evaluation of yeasticidal activity according to BS EN 13697:2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000175182 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | PAE GEL PRO/GP SURFACES – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000033180 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | Bactericidal activity of product Com 23 – Product 9-2 in accordance with the European standard EN 1276 (August 2019) Dirty conditions – 20°C HYDRACHIM Laboratoire <i>R20201027-EN1276 20°C 60 min</i> Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2020 | Bactericidal activity of product Com 23 – Product 9-2 in accordance with the European standard EN 13697 (July 2019) Dirty conditions – 20°C HYDRACHIM Laboratoire <i>R20201027-EN13697 20°C 60 min</i> Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | PAE GEL PRO/GP SURFACES – Evaluation of bactericidal activity according to UNI EN 13697: 2015 + A1:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000033180 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | PAE GEL PRO/GP SURFACES – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 20°C Mérieux NutriSciences Chelab s.r.l Test Report 20/000033180 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
|  | 2019 | PAE GEL PRO/GP SURFACES – Evaluation of yeasticidal activity according to BS EN 13697: 2015 + A1:2019 – 20°C | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |

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| | | Mérieux NutriSciences Chelab s.r.l Test Report 20/000033180 Not GLP; Unpublished | | |
| | 2020 | COM23/METASPC10-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000159147 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | COM23/METASPC10-1 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000398595 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | COM23/METASPC10-1 – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000159147 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | COM23/METASPC10-1 – Evaluation of bactericidal activity according to BS EN 13697:2015 + A1:2019 – 40°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000398595 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2019 | COM23/METASPC10-1 - PRODUCT 10-1 – Evaluation of yeasticidal activity according to BS EN 1650:2019 – 40°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000024947 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | COM23/METASPC10-1 – Evaluation of yeasticidal activity according to BS EN 13697:2015 + A1:2019 – 40°C | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |

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| | | Mérieux NutriSciences Chelab s.r.l. Test Report 20/000159147 Not GLP; Unpublished | | |
| | 2020 | COM23/CITRIC ACID6 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 40°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000381276 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2020 | COM23/CITRIC ACID6 – Evaluation of bactericidal activity according to BS EN 1276:2019 – 20°C Mérieux NutriSciences Chelab s.r.l. Test Report 20/000381276 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2019 | COM 23 - FORMULE SOLUTION ACQUEUSE ACIDE CITRIQUE 5% M/M Evaluation of bactericidal activity according to UNI EN 1276:2009 / EC1:2011 Mérieux NutriSciences Chelab s.r.l. Test Report 19/000046004 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |
| | 2019 | COM 23 - FORMULE SOLUTION ACQUEUSE ACIDE CITRIQUE 5% M/M Evaluation of yeasticidal activity according to UNI EN 1650:2013 Mérieux NutriSciences Chelab s.r.l. Test Report 19/000046004 Not GLP; Unpublished | YES | GFB (GROUPEMENT DES FORMULATEURS DE BIOCIDES) |

3.2 Confidential annex

See the separate confidential annex.