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

DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT (FAMILY) FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the applicant)

Christeyns' Lactic Acid Biocidal Product Family

PT2 – PT3 – PT4

L(+) Lactic Acid as included in the Union list of approved active substances

Case Number in R4BP: BC-BR079114-31

Evaluating Competent Authority: Belgium

Date: 28 March 2022
Update: 09 January 2024

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History of modifications

Application type	refMS/ eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)
NA-APP	BE	BC-KL051103-49	28/04/2022	Initial assessment
NA-MAC	BE	BC-BR079114-31	09/01/2024	Addition of META SPC 2

1 CONCLUSION

Christeyns' Lactic Acid Biocidal Product Family is a biocidal product family of 5 meta SPCs of other liquids to be applied undiluted (meta SPC 1 and 2) and soluble concentrates (meta SPC 3, 4 and 5). All the biocidal products within this family, divided into 5 Meta SPCs, do contain L+ Lactic Acid (CAS N° 79-33-4) as active substance, used at the concentration range 6.8-80.00 % w/w. They are intended to be used indoors by non-professional, professional and/or industrial users, according to the product and the intended use.

The products are intended to be used as :

- META SPC 1 : Toilet bowl disinfectant (PT2)
- META SPC 2 : Teat disinfectant after milking (PT3)
- META SPCs 3; 4 & 5 : hard/non-porous surface disinfectant (PT2 & PT4) for institutions, industry and food industry (professional use).

Conclusion on efficacy

Taking into account the results of all the efficacy tests (Phase2/Step1 suspension tests & Phase2/Step2 surface test) provided by the Applicant in accordance with the requirements of Guidance on BPR, Volume II Efficacy – Assessment and Evaluation (Parts B+C), in the conditions of use detailed in the SPC :

Meta SPC-1 - *CHRIOX WC* (6.8% LA)		**Validated label claims**
PT2	Use #1.1 : RTU Toilet bowl disinfection Pouring (with brushing only after the required CT)	On hard/non-porous surfaces without prior cleaning Active against bacteria and yeasts With undiluted product In 15 min contact time At Room Temperature

Meta SPC-2 - MIDA AGRI 830 Post Red (8% LA)		**Validated label claims**
PT3	Use #2.1 : Teat disinfection (post-milking) Dipping	Active against bacteria and yeasts With undiluted product In 5 min contact time at +30°C

Meta SPC-3 - *Mida San 325 DA* (16% LA)		**Validated label claims**
PT2	Use #3.1 : Surface disinfection (excluding hospitals) Trigger Spraying with 20 mL/m^2	On hard/non-porous surfaces with prior cleaning Active against bacteria and yeasts Dilution : 2% In 15 min contact time At Room Temperature
	Use #3.3 : Surface disinfection Low pressure spraying / Foaming with 200 mL/m^2	
PT4	Use #3.2 : Surface disinfection Trigger Spraying with 20 mL/m^2	
	Use #3.4 : Surface disinfection Low pressure spraying / Foaming with 200 mL/m^2	
	Use #3.5 : Surface/equipment disinfection Dipping	

Meta SPC-4 - *Mida San 332 VB* (80% LA)		**Validated label claims**
PT2	Use #4.1 : Surface disinfection (excluding hospitals) Trigger Spraying with 20 mL/m^2	On hard/non-porous surfaces with prior cleaning Active against bacteria and yeasts Dilution : 10% In 15 min contact time
	Use #4.3 : Surface disinfection Low pressure spraying / Foaming with 200 mL/m^2	

	Use #4.6 : Inner surface disinfection CIP	At Room Temperature
PT4	Use #4.2 : Surface disinfection Trigger Spraying with 20 mL/m^2	
	Use #4.4 : Surface disinfection Low pressure spraying with 200 mL/m^2	
	Use #4.5 : Surface/equipment disinfection Dipping	
	Use #4.7 : Inner surface disinfection CIP	

Meta SPC-5 - *Mida San 331 LW* (24% LA)		**Validated label claims**
PT2	Use #5.1 : Surface disinfection (excluding hospitals) Trigger Spraying with 20 mL/m^2	On hard/non-porous surfaces with prior cleaning Active against bacteria and yeasts Dilution : 25% In 5 min contact time At Room Temperature
	Use #5.3 : Surface disinfection Low pressure spraying / Foaming with 200 mL/m^2	
PT4	Use #5.2 : Surface disinfection Trigger Spraying with 20 mL/m^2	
	Use #5.4 : Surface disinfection Low pressure spraying / Foaming with 200 mL/m^2	
	Use #5.5 : Surface/equipment disinfection Dipping	

It can be concluded that all products in the family are efficacious, when used in accordance with the use instructions mentioned above and proposed in the SPC.

Conclusion on the biocidal product family regarding physical, chemical and technical properties:

Products in Meta SPCs 1 and 2 are ready-to-use, and products in Meta SPCs 3-5 are concentrates. All products are aqueous liquids.

The pH of all product is acid, due to the presence of lactic acid. Their surface tensions vary between 27 and 59.8 mN/m. A high viscosity was observed for products in Meta SPC 1 and 2. This property provides for a longer adherence to surfaces which necessary for toilet bowl disinfectants (meta SPC 1) and teat dips (meta SPC 2). The dilution stability and persistent foaming were investigated for products in Meta SPCs 3-5. During the dilution stability test, the solutions are clean and without visible residues. However, the products are high foaming, and they should be used with protective gloves.

The accelerated storage and long term storage tests showed that the products in Meta SPCs 1,3,4, and 5 are stable in different HDPE packaging. Storage conditions should include restrictions for them ("Do not store at temperatures above 30°C" (Meta SPC 1 and Meta SPC 2) and "Protect from frost"). A shelf-life of 24 months is granted for all products in Meta SPCs 1,3,4, and 5. A shelf-life of 12 months is granted for the product in Meta SPC 2.

For the Meta SPC 2, the accelerated and long term storage tests were conducted with a validated analytical method and considered acceptable. A shelf-life of 1 year can be attributed to Meta SPC 2

Conclusion on the biocidal product family regarding physical hazards and respective characteristics:

Regarding the assessment of physical hazards, it could be concluded that some meta SPC have to be classified:

- Meta SPC 3 is classified as Metal Corr. 1
  Implication concerning the labelling: H290 – May be corrosive to metals

- Meta SPC 5 is classified as Flam. Liq. 3
  Implication concerning the labelling: H226 - Flammable liquid and vapour.

Conclusion on the biocidal product family regarding methods of detection and identification:

The provided HPLC-UV method is adequately validated for determination of the content of the active substance in the biocidal products in Meta SPCs 1, 2, 3, 4 and 5.
No analytical method is required for the SOCs for the products in Meta SPC 3 and 5.

For all Meta SPCs, analytical methods including those for the determination of active substance residues in food of plant origin and the environmental media as air, water and soil are referred about the CAR of lactic acid.

Conclusion on the risk for human health

MetaSPC 1 - Symbioz Gel San' Desinfectant, Chriox WC, Laco Gel WC

Meta SPC 1 is classified Skin corr 1C (H314) and Eye Dam 1 (H318).

The risk is acceptable regarding systemic and local effects, considering the adapted packaging, the viscosity of the product and if the directions for uses in the SPC are followed.

Meta SPC 2 – Mida Agri 830 post red

Meta SPC 2 is classified Eye Dam. 1 (H318).

The risk is acceptable regarding systemic and local effects, considering the wearing of protective gloves and goggles and if the directions for uses in the SPC are followed.

MetaSPC 3 – Mida San 325 DA – Quacide DA80, MetaSPC 4 – Mida San 332 VB and MetaSPC 5 – Mida San 331 LW

Meta SPC 3 and 4 are classified Skin corr 1 (H314) and Eye Dam 1 (H318).
Meta SPC 5 is classified Skin corr 1C (H314) and Eye Dam 1 (H318).

The risk is acceptable regarding systemic and local effects, considering the wearing of protective gloves, goggles and clothing and if the directions for uses in the SPC are followed.

Conclusion on the risk for consumer under indirect exposure via food

No unacceptable risk was identified for all substances.

Conclusion on endocrine disruptors

The assessment of the endocrine disrupting (ED) properties of the substances used in the biocidal product family Christeyns' Lactic Acid was performed according to the Regulation (EU) 528-2012 and Regulation (EU) 2017-2100. Based on the existing knowledge and the data provided by the applicant, there is no indication of concern for humans and for non-target organisms regarding the ED properties of the substances used in the biocidal product family Christeyns' Lactic Acid.

Conclusion on environmental risk assessment

No unacceptable risks for any of the environmental compartments are expected following the use of the products in the Christeyns Lactic Acid Biocidal Product Family. No substances of concern for the environment are present in the products.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier[1]	**Country (if relevant)**
Christeyns' Lactic Acid Biocidal Product Family	National registration with mutual recognitions in the European Union

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Christeyns N.V.
	Address	Afrikalaan 182, 9000 Gent, Belgium
Pre-submission phase started on	10/09/2018	
Pre-submission phase concluded on	25/09/2018	
Authorisation number	BE2022-0001-00-00	
Date of the authorisation	28/03/2022	
Expiry date of the authorisation	31/01/2032	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Christeyns N.V. Christeyns s.r.o. Christeyns France Food Hygiene sas Betelgeux sl Christeyns France sa Christeyns Professional Hygiene srl Christeyns UK Ltd. Christeyns Food Hygiene Ltd. Clover Chemicals Ltd.
Address of manufacturer	Christeyns N.V.: Afrikalaan 182, 9000 Gent, Belgium Christeyns s.r.o.: Vítovská 453/7, 742 35 Odry, Czech Republic Christeyns France Food Hygiene sas: ZA Les Farges, 24580 Rouffignac St. Cernin, France Betelgeux sl: Poligono Industrial Raconc, Parcelas 2 y 3,CP 46729 Ador – Valencia, Spain Christeyns France sa: 31 rue de la Maladrie, 44120 VERTOU, FRANCE Christeyns Professional Hygiene srl.: Via Aldo Moro 30, 20060 Pessano conBornago, Italy Christeyns UK Ltd.: Rutland Street, Bradford BD4 7EA, UK Christeyns Food Hygiene Ltd.: 2 Cameron Court, Winwick Quay, Warrington, WA2 8RE, UK

[1] Please fill in here the identifying product name from R4BP 3.

	Clover Chemicals Ltd. Clover House, Macclesfield Road, Whaley Bridge, High Peak. SK23 7DQ, UK
Location of manufacturing sites	Christeyns N.V.: Afrikalaan 182, 9000 Gent, Belgium Christeyns s.r.o.: Vítovská 453/7, 742 35 Odry, Czech Republic Christeyns France Food Hygiene sas: ZA Les Farges, 24580 Rouffignac St. Cernin, France Betelgeux sl: Poligono Industrial Raconc, Parcelas 2 y 3,CP 46729 Ador – Valencia, Spain Christeyns France sa: 31 rue de la Maladrie, 44120 VERTOU, FRANCE Christeyns Professional Hygiene srl.: Via Aldo Moro 30, 20060 Pessano conBornago, Italy Christeyns UK Ltd.: Rutland Street, Bradford BD4 7EA, UK Christeyns Food Hygiene Ltd.: 2 Cameron Court, Winwick Quay, Warrington, WA2 8RE, UK Clover Chemicals Ltd. Clover House, Macclesfield Road, Whaley Bridge, High Peak. SK23 7DQ, UK

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

Active substance	L(+) lactic acid
Name of manufacturer	Purac Biochem bv
Address of manufacturer	Arkelsedijk 46, 4200 AA Gorinchem, the Netherlands
Location of manufacturing sites	Arkelsedijk 46, 4200 AA Gorinchem, the Netherlands

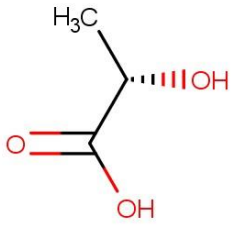
2.1.2 Product (family) composition and formulation

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	607-743-00-5
Minimum purity / content	≥95.5%
Structural formula	

2.1.2.2 Candidate(s) for substitution

Not applicable: L(+) Lactic Acid is not a candidate for substitution.

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

Not applicable (biocidal product family). See Confidential Annex for individual product compositions.

2.1.2.4 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	(S)-2-Hydroxypropanoic acid	Active substance	79-33-4	201-196-2	8.50% (PREMIX) 6.80% (TECH) 6.49% (PURE)	100% (PREMIX) 80% (TECH) 76.4% (PURE)
Isopropanol	Propan-2-ol	Solvent	67-63-0	200-661-7	0.00	10.00
Akypo LF1	Polyoxyethylene octyl ether carboxylic acid	Surfactant	53563-70-5	611-013-1	0.00	3.00
2-butoxyethanol	2-butoxy-1-ethanol	Solvent	111-76-2	203-905-0	0.00	6.00
Benzenesulfonic acid, 4-C10-13-sec-alkyl derivs	Benzenesulfonic acid, 4-C10-13-sec-alkyl derivs	Surfactant	85536-14-7	287-494-3	0.00	4.00
Alcohols, C12-14, ethoxylated, sulfates, sodium salts	Alcohols, C12-14, ethoxylated, sulfates, sodium salts	Surfactant	68891-38-3	/	0.00	12.40
1-heptanol, 2-propyl-, 7EO	1-heptanol, 2-propyl-, 7EO	Surfactant	160875-66-1	605-233-7	0.00	3.00
Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Surfactant	85586-07-8	287-809-4	0.00	3.3044 (PREMIX) 1.1565 (TECH)

More detailed information on the composition of the biocidal product family is presented in the Confidential Annex.

2.1.2.5 Information on technical equivalence

The supplier has been approved as a reference source for L(+) lactic acid.

2.1.2.6 Information on the substance(s) of concern

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, the co-formulants listed below have been identified as substance of concern:

Meta SPC	**SoCs**	**Justification**	**Hazard band**
2	Polyoxyethylene octyl ether carboxylic acid (Akypo LF1) (CAS 53563-70-5)	Classified as Eye Dam. 1 and C >3%	B
	Isopropanol (CAS 67-63-0)	Active substance not in Annex I	C
3	Dodecylbenzenesulfonic acid (Sulfosil) (CAS 85536-14-7)	Classified as Skin Corr. 1C and C >3%	B
	Laurylethoxy(3EO) sulphate, sodium salt (Texapon NSO UP) (CAS 68891-38-3)	Classified as Eye Dam. 1 and C >3%	B
	1-heptanol, 2-propyl-, 7EO (Lutensol XP99) (CAS 160875-66-1)	Classified as Eye Dam. 1 and C >3%	B
	2-butoxyethanol (CAS 111-76-02)	OEL TWA : 98 mg/m^3 - 20 ppm OEL STEL : 246 mg/m^3 - 50 ppm	C
5	Isopropanol (CAS 67-63-0)	Active substance not in Annex I	C
	Sulfuric acid (Ufarol NA30) (CAS 85586-07-8)	Classified as Eye Dam. 1 and C >3%	B

Please see the confidential annex for further details.

2.1.2.7 Type of formulation

Meta SPC 1 and 2: AL – Other liquids to be applied undiluted
Meta SPC 3, 4 and 5: SL – Soluble concentrates

2.1.3 Hazard and precautionary statements

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

Meta SPC 1

Classification	
Hazard category	Skin Corr. 1C 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 dust/fume/gas/mist/vapours/spray. P264 Wash hands thoroughly after handling. P280 - Wear protective gloves, protective clothing, protective clothing, eye protection, face protection. P301+P330+P331+P310 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor. P303+P361+P353+P310 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor. P305+P351+P338+P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. P363 Wash contaminated clothing before reuse. P405 Store locked up. P501 - Dispose of contents/container to appropriate disposal

Meta SPC 2

Classification	
Hazard category	Eye dam 1
Hazard statement	H318 – Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H318 – Causes serious eye damage
Precautionary statements	P280 - Wear eye protection and protective gloves P305+P351+P338+P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. P501 - Dispose of contents/container to appropriate disposal

Meta SPC 3

Classification	
Hazard category	Metal Corr. 1 Skin Corr. 1 Eye Dam. 1
Hazard statement	H290 – May be corrosive to metals H314 - Causes severe skin burns and eye damage H318 - Causes serious eye damage EUH071- Corrosive to the respiratory tract
Labelling	
Signal words	Danger
Hazard statements	H290 – May be corrosive to metals H314 - Causes severe skin burns and eye damage EUH071- Corrosive to the respiratory tract
Precautionary statements	P280 - Wear protective gloves, protective clothing, protective clothing, eye protection, face protection. P260:Do not breathe dust/fume/gas/mist/vapours/spray. P301+P330+P331+P310 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER. Immediately call a POISON CENTER/doctor P303+P361+P353+P310 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER/doctor. P305+P351+P338+P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor P363 Wash contaminated clothing before reuse. P390 – Absorb spillage to prevent material damage. P501 - Dispose of contents/container to appropriate disposal.

Meta SPC 4

Classification	
Hazard category	Skin Corr. 1 Eye Dam. 1
Hazard statement	H314 - Causes severe skin burns and eye damage H318 - Causes serious eye damage EUH071- Corrosive to the respiratory tract
Labelling	
Signal words	Danger
Hazard statements	H314 - Causes severe skin burns and eye damage EUH071- Corrosive to the respiratory tract
Precautionary statements	P280 - Wear protective gloves, protective clothing, protective clothing, eye protection, face protection. P260:Do not breathe dust/fume/gas/mist/vapours/spray. P301+P330+P331+P310 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER. Immediately call a POISON CENTER/doctor.P303+P361+P353 + P310 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician. P305+P351+P338 + P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. P363 Wash contaminated clothing before reuse. P501 - Dispose of contents/container to appropriate disposal.

Meta SPC 5

Classification	
Hazard category	Flam. Liq. 3 Skin Corr. 1C Eye dam. 1
Hazard statement	H226 - Flammable liquid and vapour. H314 - Causes severe skin burns and eye damage H318 - Causes serious eye damage EUH071- Corrosive to the respiratory tract
Labelling	
Signal words	Danger
Hazard statements	H226 - Flammable liquid and vapour. H314 - Causes severe skin burns and eye damage EUH071- Corrosive to the respiratory tract
Precautionary statements	P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P260:Do not breathe dust/fume/gas/mist/vapours/spray. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331+P310 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor. P303+P361+P353+P310 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor. P305+P351+P338 + P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. P363 Wash contaminated clothing before reuse. P501 - Dispose of contents/container to appropriate disposal.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Meta SPC 1 (Chriox WC - Phago'Gel San)

Table 1. Use 1.1 – Toilet disinfectant

Product Type	2
Where relevant, an e xact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In Households, industries, workplaces, … :

	Disinfection of toilet bowls by pouring without prior cleaning
Application method(s)	Pouring (with brushing only after the required CT) - with thickened product from a bottle with fixed directional nozzle. Product is applied around bowl and under the rim, left for several minutes, brushed with toilet brush and toilet is flushed.
Application rate(s) and frequency	Active against bacteria and yeasts With undiluted product In 15 min contact time At Room Temperature Application rate of 5 mL/toilet 1x/week (non-professional users) Multiple times per day (professional users)
Category(ies) of users	Professional and non-professional users
Pack sizes and packaging material	750 mL pre-filled bottles (HDPE) for non-professional and professional users 5 L refill cans (HDPE) for professional users  Child-proof closure: the closure needs to be pressed before it can be turned open  Tactile warning: a triangle on the flask  

Meta SPC 2 (Mida Agri 830 Post Red)

Table 2. Use 2.1 – Teat disinfectant

Product Type	3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoors – in dairy farms : After milking teat disinfection by dipping.
Application method(s)	Dip all teats into a dipping cup until they are fully covered. Apply the product to the whole teat and do not wipe it (3-10 ml per animal per milking event). Allow to dry. 
Application rate(s) and frequency	Application rate: 3-10 ml of product/cow/milking event Active against bacteria and yeasts With undiluted product In 5 min contact time at +30°C *If the product is stored at +4-7°C (i.e. in a fridge), the product must "return" to RT before use.*
Category(ies) of users	Professional users
Pack sizes and packaging material	10, 20, 25 L cans (HDPE) 200L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Meta SPC 3 (Mida San 325 DA)

Table 3. Use 3.1 – PT2 open surface disinfection, trigger spraying

Product Type	PT2
Where relevant, an exact description of the authorised use	Not relevant
Target organisms	Bacteria Yeasts
Field of use	Small and large areas - small surfaces Indoors – In non-medical areas, non-food industry (e.g. pharmaceuticals, cosmetics), warehouses, institutions, workplaces, buildings, … : Disinfection of hard/non-porous surfaces by trigger spraying with prior cleaning.

Application method(s)	The diluted solution is prepared manually and transferred to a hand-held trigger sprayer. After trigger spraying, the product is left to dry.
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 2% In 15 min contact time At Room Temperature Application rate: 20 ml / m^2 Frequency: Multiple times per day
Category(ies) of users	Professional
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 4. Use 3.2 – PT4 open surface disinfection, trigger spraying

Product Type	PT4
Where relevant, an exact description of the authorised use	Not relevant
Target organisms	Bacteria Yeasts
Field of use	Small and large areas - small surfaces Indoors – In Large-scale kitchens, restaurants, food & beverages industry, feed industry, meat industry, professional kitchens, … : Disinfection of hard/non-porous surfaces by trigger spraying with prior cleaning.
Application method(s)	The diluted solution is prepared manually and transferred to a hand-held trigger sprayer. After trigger spraying, the product is left to dry.
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 2% In 15 min contact time At Room Temperature Application rate: 20 ml / m^2 Frequency: Multiple times per day
Category(ies) of users	Professional
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 5. Use 3.3 – PT2 open surface disinfection, low-pressure spraying or foaming

Product Type	PT 2
Where relevant, an exact description of the authorised use	Disinfection by low pressure spraying or foaming can occur via fixed or mobile systems.

	1. Fixed system: 1a central: The product is automatically mixed with water in a chemical storage room outside of the production room. A hose with spray nozzle is connected on the other side of the wall, inside the production room, where the surfaces to disinfect are located.  1b. decentral: The containers with chemicals are located inside the production room, and dilutions are prepared automatically inside the production room by the satellite mixing systems.  2. Mobile systems: 2a system to fill with RTU solution. The spray application system is a mobile system (backpack model or system on wheels). The dilution can be prepared manually or transferred from a system that prepares the ready-to-use solution automatically.  2b system that prepares the RTU solution automatically. The spray application system is a mobile system (usually on wheels). The dilution is prepared automatically by the system. 
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In non-medical areas, non-food industry (e.g. pharmaceuticals, cosmetics), warehouses, institutions, workplaces, buildings, … : Disinfection of hard/non-porous surfaces by low pressure spraying or foaming with prior cleaning.
Application method(s)	Disinfection by low pressure spraying or foaming can occur via fixed or mobile systems. 1. Fixed system: 1a central: The product is automatically mixed with water in a chemical storage room outside of the production room. A hose with spray nozzle is connected on the other side of the wall, inside the production room, where the surfaces to disinfect are located.  1b. decentral: The containers with chemicals are located inside the production room, and dilutions are prepared automatically inside the production room by the satellite mixing systems.

	 2. Mobile systems: 2a system to fill with RTU solution. The spray application system is a mobile system (backpack model or system on wheels). The dilution can be prepared manually or transferred from a system that prepares the ready-to-use solution automatically.  2b system that prepares the RTU solution automatically. The spray application system is a mobile system (usually on wheels). The dilution is prepared automatically by the system. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 2% In 15 min contact time At Room Temperature Application rate: 200 ml / m^2 Frequency: Daily
Category(ies) of users	Industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom

Table 6. Use 3.4 – PT4 open surface disinfection, low-pressure spraying or foaming

Product Type	PT 4
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In Food/ feed industry and warehouses : Disinfection of hard/non-porous surfaces by low pressure spraying or foaming with prior cleaning.
Application method(s)	Disinfection by low pressure spraying or foaming can occur via fixed or mobile systems. 1. Fixed system: 1a central: The product is automatically mixed with water in a chemical storage room outside of the production room. A hose with spray nozzle is connected on the other side of the wall, inside the production room, where the surfaces to disinfect are located.  1b. decentral: The containers with chemicals are located inside the production room, and dilutions are prepared automatically inside the production room by the satellite mixing systems.  2. Mobile systems: 2a system to fill with RTU solution. The spray application system is a mobile system (backpack model or system on wheels). The dilution can be prepared manually or transferred from a system that prepares the ready-to-use solution automatically.  2b system that prepares the RTU solution automatically. The spray application system is a mobile system (usually on wheels). The dilution is prepared automatically by the system. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 2% In 15 min contact time At Room Temperature Application rate: 200 ml / m^2 Frequency: Daily

Category(ies) of users	Industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 7. Use 3.5 – PT4 Dipping of objects and instruments

Product Type	PT4
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In Food/ feed industry : Disinfection of hard/non-porous objects and instruments by dipping with prior cleaning.
Application method(s)	Objects and instruments are disinfected by submersion in a disinfection bath (volume 1- 20L). First the objects are cleaned to remove all visible dirt. The disinfection bath is prepared by pouring the disinfectant in a bath and filling it up with water. The objects are then brought into the bath and left there during the required contact time. Disinfection can also be performed by flooding, i.e. filling an empty bath, which already contains the objects or instruments. In both cases, instruments are completely immersed. After the required contact time, the objects are removed from the bath and left to dry. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 2% In 15 min contact time At Room Temperature Frequency: up to 5 times per day
Category(ies) of users	Professional - industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Meta SPC 4 (Mida San 332 VB)

Table 8. Use 4.1 – PT2 open surface disinfection, trigger spraying

Product Type	PT2

Where relevant, an exact description of the authorised use	Not relevant
Target organisms	Bacteria Yeasts
Field of use	Small and large areas - small surfaces Indoors – In non-medical areas, non-food industry (e.g. pharmaceuticals, cosmetics), warehouses, institutions, workplaces, buildings, … : Disinfection of hard/non-porous surfaces by trigger spraying with prior cleaning.
Application method(s)	The diluted solution is prepared manually and transferred to a hand-held trigger sprayer. After trigger spraying, the product is left to dry. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 10% In 15 min contact time At Room Temperature Application rate: 20 ml / m^2 Frequency: Multiple times per day
Category(ies) of users	Professional
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 9. Use 4.2 – PT4 open surface disinfection, trigger spraying

Product Type	PT4
Where relevant, an exact description of the authorised use	Not relevant
Target organisms	Bacteria Yeasts
Field of use	Small and large areas - small surfaces Indoors – In Large-scale kitchens, restaurants, food & beverages industry, feed industry, meat industry, professional kitchens, … : Disinfection of hard/non-porous surfaces by trigger spraying with prior cleaning.
Application method(s)	The diluted solution is prepared manually and transferred to a hand-held trigger sprayer. After trigger spraying, the product is left to dry. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 10% In 15 min contact time At Room Temperature Application rate: 20 ml / m^2 Frequency: Multiple times per day
Category(ies) of users	Professional
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 10. Use 4.3 – PT2 open surface disinfection, low-pressure spraying or foaming

Product Type	PT 2
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In non-medical areas, non-food industry (e.g. pharmaceuticals, cosmetics), warehouses, institutions, workplaces, buildings, … : Disinfection of hard/non-porous surfaces by low pressure spraying or foaming with prior cleaning.
Application method(s)	Disinfection by low pressure spraying or foaming can occur via fixed or mobile systems.  1. Fixed system: 1a central: The product is automatically mixed with water in a chemical storage room outside of the production room. A hose with spray nozzle is connected on the other side of the wall, inside the production room, where the surfaces to disinfect are located.  1b. decentral: The containers with chemicals are located inside the production room, and dilutions are prepared automatically inside the production room by the satellite mixing systems.  2. Mobile systems: 2a system to fill with RTU solution. The spray application system is a mobile system (backpack model or system on wheels). The dilution can be prepared manually or transferred from a system that prepares the ready-to-use solution automatically. 

	2b system that prepares the RTU solution automatically. The spray application system is a mobile system (usually on wheels). The dilution is prepared automatically by the system. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 10% In 15 min contact time At Room Temperature Application rate: 200 ml / m^2 Frequency: Daily
Category(ies) of users	Industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 11. Use 4.4 – PT4 open surface disinfection, low-pressure spraying

Product Type	PT 4
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In Food/ feed industry and warehouses : Disinfection of hard/non-porous surfaces by low pressure spraying or foaming <u>with</u> prior cleaning.
Application method(s)	Disinfection by low pressure spraying or foaming can occur via fixed or mobile systems.  1. Fixed system: 1a central: The product is automatically mixed with water in a chemical storage room outside of the production room. A hose with spray nozzle is connected on the other side of the wall, inside the production room, where the surfaces to disinfect are located.  1b. decentral: The containers with chemicals are located inside the production room, and dilutions are prepared automatically inside the production room by the satellite mixing systems.  2. Mobile systems: 2a system to fill with RTU solution. The spray application system is a mobile system (backpack model or system on wheels). The dilution can be prepared manually or transferred from a system that prepares the ready-to-use solution automatically. 

	2b system that prepares the RTU solution automatically. The spray application system is a mobile system (usually on wheels). The dilution is prepared automatically by the system 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 10% In 15 min contact time At Room Temperature Application rate: 200 ml / m^2 Frequency: Daily
Category(ies) of users	Industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 12. Use 4.5 – PT4 Dipping of objects and instruments

Product Type	PT4
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In Food/ feed industry : Disinfection of hard/non-porous objects and instruments by dipping with prior cleaning.
Application method(s)	Objects and instruments are disinfected by submersion in a disinfection bath (volume 1- 20L). First the objects are cleaned to remove all visible dirt. The disinfection bath is prepared by pouring the disinfectant in a bath and filling it up with water. The objects are then brought into the bath and left there during the required contact time. Disinfection can also be performed by flooding, i.e. filling an empty bath, which already contains the objects or instruments. In both cases, instruments are completely immersed. After the required contact time, the objects are removed from the bath and left to dry. 
Application rate(s) and frequency	Required amount depends on bath size (maximum 20 L) Active against bacteria and yeasts Dilution : 10% In 15 min contact time

	At Room Temperature Frequency: up to 5 times per day
Category(ies) of users	Professional - industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 13. Use 4.6 – PT2 Cleaning – In - Place

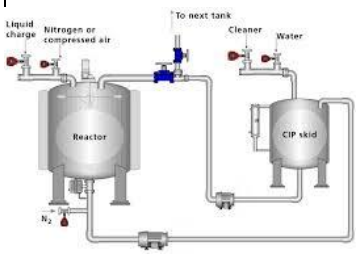
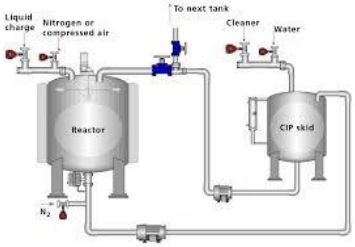
Product Type	PT2
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In non-medical areas, non-food industry (e.g. pharmaceuticals, cosmetics), warehouses, institutions, workplaces, buildings, … : Disinfection of inner hard/non-porous surfaces by CIP (with circulation) with prior cleaning.
Application method(s)	Clean-in-place (CIP) is a method of cleaning/disinfecting the interior surfaces of pipes, vessels, process equipment, filters and associated fittings, without disassembly. Most current CIP systems are fully automated with programmable logic controllers, multiple balance tanks, sensors, valves, heat exchangers, data acquisition and specially designed spray nozzle systems. The disinfectant is present in a stock tank or reservoir and dosed automatically. A typical CIP cycle could contain several steps, such as pre-rinsing, treatment with disinfectant, intermediate rinsing, treatment with acid/cleaning solution, and a final rinsing and drying step. The user is only exposed to the chemicals at the time of replacing empty containers. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 10% In 15 min contact time At Room Temperature Frequency: Daily
Category(ies) of users	Industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 14. Use 4.7 – PT4 Cleaning – In - Place

Product Type	PT4
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In Food/ feed industry : Disinfection of inner hard/non-porous surfaces by CIP (with circulation) with prior cleaning.
Application method(s)	Clean-in-place (CIP) is a method of cleaning/disinfecting the interior surfaces of pipes, vessels, process equipment, filters and associated fittings, without disassembly. Most current CIP systems are fully automated with programmable logic controllers, multiple balance tanks, sensors, valves, heat exchangers, data acquisition and specially designed spray nozzle systems. The disinfectant is present in a stock tank or reservoir and dosed automatically. A typical CIP cycle could contain several steps, such as pre-rinsing, treatment with disinfectant, intermediate rinsing, treatment with acid/cleaning solution, and a final rinsing and drying step. The user is only exposed to the chemicals at the time of replacing empty containers. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 10% In 15 min contact time At Room Temperature Frequency: Daily
Category(ies) of users	Industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Meta SPC 5 (Mida San 331 LW)

Table 15. Use 5.1 – PT2 open surface disinfection, trigger spraying

Product Type	PT2
Where relevant, an exact description of the authorised use	Not relevant
Target organisms	Bacteria Yeasts
Field of use	Small and large areas - small surfaces Indoors – In non-medical areas, non-food industry (e.g. pharmaceuticals, cosmetics), warehouses, institutions, workplaces, buildings, … : Disinfection of hard/non-porous surfaces by trigger spraying with prior cleaning.
Application method(s)	The diluted solution is prepared manually and transferred to a hand-held trigger sprayer. After trigger spraying, the product is left to dry. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 25% In 5 min contact time At Room Temperature Application rate: 20 ml / m^2 Frequency: Multiple times per day
Category(ies) of users	Professional
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 16. Use 5.2 – PT4 open surface disinfection, trigger spraying

Product Type	PT4
Where relevant, an exact description of the authorised use	Not relevant
Target organisms	Bacteria Yeasts
Field of use	Small and large areas - small surfaces Indoors – In Large-scale kitchens, restaurants, food & beverages industry, feed industry, meat industry, professional kitchens, … : Disinfection of hard/non-porous surfaces by trigger spraying with prior cleaning.
Application method(s)	The diluted solution is prepared manually and transferred to a hand-held trigger sprayer. After trigger spraying, the product is left to dry. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 25% In 5 min contact time At Room Temperature Application rate: 20 ml / m^2 Frequency: Multiple times per day
Category(ies) of users	Professional
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 17. Use 5.3 – PT2 open surface disinfection, low-pressure spraying or foaming

Product Type	PT 2
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In non-medical areas, non-food industry (e.g. pharmaceuticals, cosmetics), warehouses, institutions, workplaces, buildings, … : Disinfection of hard/non-porous surfaces by low pressure spraying or foaming with prior cleaning.
Application method(s)	Disinfection by low pressure spraying or foaming can occur via fixed or mobile systems.  1. Fixed system:  1a central: The product is automatically mixed with water in a chemical storage room outside of the production room. A hose with spray nozzle is connected on the other side of the wall, inside the production room, where the surfaces to disinfect are located. 1b. decentral: The containers with chemicals are located inside the production room, and dilutions are prepared automatically inside the production room by the satellite mixing systems.  2. Mobile systems:  2a system to fill with RTU solution. The spray application system is a mobile system (backpack model or system on wheels). The dilution can be prepared manually or transferred from a system that prepares the ready-to-use solution automatically.

	2b system that prepares the RTU solution automatically. The spray application system is a mobile system (usually on wheels). The dilution is prepared automatically by the system. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 25% In 5 min contact time At Room Temperature Application rate: 200 ml / m^2 Frequency: Daily
Category(ies) of users	Industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 18. Use 5.4 – PT4 open surface disinfection, low-pressure spraying or foaming

Product Type	PT 4
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In Food/ feed industry and warehouses : Disinfection of hard/non-porous surfaces by low pressure spraying or foaming with prior cleaning.
Application method(s)	Disinfection by low pressure spraying or foaming can occur via fixed or mobile systems.  1. Fixed system: 1a central: The product is automatically mixed with water in a chemical storage room outside of the production room. A hose with spray nozzle is connected on the other side of the wall, inside the production room, where the surfaces to disinfect are located.  1b. decentral: The containers with chemicals are located inside the production room, and dilutions are prepared

	automatically inside the production room by the satellite mixing systems.  2. Mobile systems: 2a system to fill with RTU solution. The spray application system is a mobile system (backpack model or system on wheels). The dilution can be prepared manually or transferred from a system that prepares the ready-to-use solution automatically.  2b system that prepares the RTU solution automatically. The spray application system is a mobile system (usually on wheels). The dilution is prepared automatically by the system. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 25% In 5 min contact time At Room Temperature Application rate: 200 ml / m^2 Frequency: Daily
Category(ies) of users	Industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 19. Use 5.5 – PT4 Dipping of objects and instruments

Product Type	PT4
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In Food/ feed industry : Disinfection of hard/non-porous objects and instruments by dipping with prior cleaning.
Application method(s)	Objects and instruments are disinfected by submersion in a disinfection bath (volume 1- 20L). First the objects are cleaned to remove all visible dirt. The disinfection bath is prepared by pouring the disinfectant in a bath and filling it up with water. The objects are then brought into the bath and left there during the required contact time. Disinfection can

	also be performed by flooding, i.e. filling an empty bath, which already contains the objects or instruments. In both cases, instruments are completely immersed. After the required contact time, the objects are removed from the bath and left to dry. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 25% In 5 min contact time At Room Temperature Frequency: up to 5 times per day
Category(ies) of users	Professional - industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

2.1.4.2 Use-specific instructions for use

Use 1.1 Toilet Disinfectant
Apply the product around the bowl and under the rim, leave it for 15 minutes, brush with toilet brush and flush.

Disinfection procedures **by pouring/spraying/foaming** : the surfaces to be disinfected must be wet enough in order to keep them wet during the required contact time for optimal disinfection. Then, the user should pay attention to wet surfaces completely with the disinfectant solution.

Use 2.1 Teat dipping
Ensure that teats are clean before use.
Dip all teats into a dipping cup until they are fully covered. Apply the product to the whole teat and do not wipe it (3-10 ml per animal per milking event). Allow to dry for 5 minutes.
For hygienic reasons, the wear of gloves and protective clothes is highly recommended

Use 3.1, 3.2, 4.1, 4.2, 5.1, 5.2 trigger spraying
Thoroughly pre-clean the surface. Any detergent used for cleaning should be rinsed with clean water. Dilute the product with clean water before use.
Dilution meta SPC 3 – Use 3.1/3.2: 2% against bacteria and yeasts, 15 min. contact time
Dilution meta SPC 4 – Use 4.1/4.2: 10% against bacteria and yeasts, 15 min. contact time
Dilution meta SPC 5 – Use 5.1/5.2: 25% against bacteria and yeasts, 5 min. contact time

Disinfection procedures **by pouring/spraying/foaming** : the surfaces to be disinfected must be wet enough in order to keep them wet during the required contact time for optimal disinfection. Then, the user should pay attention to wet surfaces completely with the disinfectant solution.

MAKE SURE TO WET SURFACES COMPLETELY.

Use 3.3, 3.4, 4.3, 4.4, 5.3, 5.4 Low-pressure spraying or foaming
Thoroughly pre-clean surfaces and materials. Any detergent used for cleaning should be rinsed off with clean water. Remove excess water. Apply the diluted product on the surface to be disinfected. When disinfecting, use as much liquid so that the surfaces remain wet during the required exposure time.
Apply by low-pressure spraying or foaming equipment.
Dilution meta SPC 3 – Use 3.3 & 3.4: 2% against bacteria and yeasts, 15 min. contact time
Dilution meta SPC 4 – Use 4.3 & 4.4: 10% against bacteria and yeasts, 15 min. contact time
Dilution meta SPC 5 – Use 5.3 & 5.4: 25% against bacteria and yeasts, 5 min. contact time

Disinfection procedures **by pouring/spraying/foaming** : the surfaces to be disinfected must be wet enough in order to keep them wet during the required contact time for optimal disinfection. Then, the user should pay attention to wet surfaces completely with the disinfectant solution.

Use 3.5, 4.5, 5.5, Dipping
Thoroughly pre-clean surfaces and materials. Any detergent used for cleaning should be rinsed off with clean water. Remove excess water. Dilute the product in the dipping bath. Dip the objects during the required exposure time. Remove the objects from the dipping bath and let dry.
Dilution meta SPC 3 – Use 3.5: 2% against bacteria and yeasts, 15 min. contact time
Dilution meta SPC 4 – Use 4.5: 10% against bacteria and yeasts, 15 min. contact time
Dilution meta SPC 5 – Use 5.5: 25% against bacteria and yeasts, 5 min. contact time
Disinfection procedures **by dipping** (hard/non-porous surfaces) : The bath is not intended to be re-used. Use the bath only once.

Use 4.6, 4.7 CIP
Thoroughly pre-clean the system. Any detergent used for cleaning should be rinsed with clean water. Treat piping systems and equipment by means of a circulating pump system as usual in a CIP system.
Dilution meta SPC 4 – Use 4.6 and 4.7: 10% against bacteria and yeasts, 15 min. contact time

2.1.4.3 Use-specific risk mitigation measures

Meta SPC 2
Wear protective goggles.
Avoid contact with skin and eyes
Ensure good ventilation of the work station.
Do not eat, drink or smoke when using this product.
Always wash hands after handling the product.

Use 2.1 Teat disinfection
Do not release the solution to the manure/slurry pit, only release to the sewer system.

Meta SPC 3
Avoid contact to eyes
Avoid all unnecessary exposure.
Wear chemical resistant PVC gloves (EN374 or equivalent).
Wear chemical goggles or face shield. Safety glasses with side-shields (EN 166).
Wear suitable protective clothing minimum (EN 13034) Type 6 equipment. Wear suitable protective clothing.
Provide adequate ventilation. Wear appropriate mask.
Do not eat, drink or smoke during use.

Uses 3.5, 4.5, 5.5 Dipping
No use-specific risk mitigations required for a use frequency up to 5 times per day and a dipping bath size up to 20L

Meta SPC 4
Avoid contact to eyes
Avoid all unnecessary exposure.
Wear chemical resistant PVC gloves (EN374 or equivalent).
Wear chemical goggles or face shield (EN 166).
Wear suitable protective clothing.
Provide adequate ventilation.
Do not eat, drink or smoke during use.
Keep uninvolved persons, children and pets away from treated surfaces until dried
Meta SPC 5
Avoid contact to eyes
Ensure good ventilation at the workstation.
Wear chemical resistant PVC gloves (EN374 or equivalent).
Wear chemical goggles or face shield (EN 166). Safety glasses.
Wear suitable protective clothing (EN 14605).
Provide adequate ventilation.
Keep uninvolved persons, children and pets away from treated surfaces until dried

Uses 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4 Low-pressure spraying or foaming & trigger spray:
Wear appropriate respiratory protective equipment: half/full mask FFP2 with gas filter
Bystanders are not allowed in the room during the application, except if they wear protective gloves, googles, clothing and respiratory protective equipment

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

General advice: In all cases of doubt, or when symptoms persist, seek medical attention.

Inhalation: Take victim to fresh air, in a quiet place and if necessary take medical advice.

Skin contact: Remove all contaminated clothing and footwear. Wash off with plenty of water. In case of faintness or symptoms of skin irritation appear, take medical advice.

Eye contact: Rinse immediately with plenty of water. Consult an eye specialist.

Ingestion: Rinse mouth out with water. Do NOT induce vomiting. Immediately call a POISON CENTER/doctor.

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

Dispose of in accordance with local regulations.

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

Meta SPC 1
Do not store at temperatures above 30°C
Protect from frost
Shelf-life : 2 years

Meta SPC 2
Do not store at temperatures above 30°C
Protect from frost
Shelf-life : 1 year

Meta SPC 3
Do not store at temperatures above 40°C
Protect from frost
Shelf-life : 2 years

Meta SPC 4
Do not store at temperatures above 40°C
Protect from frost
Shelf-life : 2 years

Meta SPC 5
Do not store at temperatures above 40°C
Protect from frost
Shelf-life : 2 years

2.1.5 General directions for use

2.1.5.1 Instructions for use

1) All the surfaces to be disinfected must be cleaned before the disinfection procedure (mSPC1 & mSPC2 excepted). Then, the user should thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected.

Disinfection cycle :
- If required, products must be diluted in potable water before use
- Dilution rate & contact time depends on the use considered.
  Please refer to the description of application method related to each use.
- Final rinsing (with potable water) : please refer to the description of application method related to each use.

Comply with the instructions for use.

Open containers. Small containers are transferred manually into reservoirs or dilution vessels, while large containers are pumped into reservoirs via a pump.
For all uses, no waiting period is required after application of the biocidal product or between two applications of the product, or the next access by humans or animals to the area where the biocidal product has been used.
Cleaning of equipment can be done with water.
There are no precautions to be taken to avoid the development of resistance.

2.1.5.2 Risk mitigation measures

Avoid contact with skin and eyes
Keep out of reach of children and pets

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

General advice: In all cases of doubt, or when symptoms persist, seek medical attention.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Immediately wash with plenty of water. Take off all contaminated clothing and wash it before reuse. Wash with soap and water and continue rinsing 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. Immediately call a Call 112/ambulance for medical assistance.

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.

Stop leak without risks if possible. Do not contaminate ground and surface water. Prevent entry to sewers and public waters.

<u>MetaSPC 1:</u>
If medical advice is needed, have product container or label at hand.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of in accordance with local regulations.

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

Meta SPC 1 Do not store at temperatures above 30°C Protect from frost Shelf-life : 2 years Keep out of reach of children and non-target animals/pets
Meta SPC 2 Do not store at temperatures above 30°C Protect from frost Shelf-life : 12 months
Meta SPC 3 Do not store at temperatures above 40°C Protect from frost Shelf-life : 2 years
Meta SPC 4 Do not store at temperatures above 40°C Protect from frost Shelf-life : 2 years
Meta SPC 5 Do not store at temperatures above 40°C Protect from frost Shelf-life : 2 years

2.1.6 Other information

Application codes

2.1.7 Packaging of the biocidal product

Meta SPC	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)
1	Pre-filled bottles	750 mL	HDPE	HDPE	Non-pressional/professional	Yes
1, 2 & 3-5	Cans	5 litres	HDPE	HDPE	Professional	Yes
2	Cans	10 litres	HDPE	HDPE	Professional	Yes

2-5	Cans	20 litres	HDPE	HDPE	Professional	Yes
2	Cans	25 litres	HDPE	HDPE	Professional	Yes
2	Vessels	200 litres	HDPE	HDPE	Professional	Yes
3-5	Vessels	220 litres	HDPE	HDPE	Professional	Yes
2-5	IBCs	1000 litres	HDPE	HDPE	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

New data on the products are submitted. No new data on the active substance and substances of concern contained in the products are submitted. A reference list is presented in Annex 3.

2.1.8.2 Access to documentation

The applicant has submitted a letter of access to all studies related to the approval of L(+) lactic acid as a biocidal active substance under the BPR.

2.1.8.3 Similar conditions of use

The outcome of the pre-submission phase was that this biocidal product family is eligible for Union Authorisation (Case number: BC-RC043182-54, Decision number: UPP-D-1338237-88-00/F, Asset number: EU-0019567-0000). After the pre-submission phase it was however decided not to apply for a Union Authorisation.

2.2 Assessment of the biocidal product (family)

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

2.2.1.1 Use description

Meta SPC 1 (Chriox WC - Phago'Gel San)

Table 20. Use 1.1 – Toilet disinfectant

Product Type	2
Where relevant, an e xact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In Households, industries, workplaces, … : Disinfection of toilet bowls by pouring without prior cleaning
Application method(s)	Pouring (with brushing only after the required CT) - with thickened product from a bottle with fixed directional nozzle. Product is applied around bowl and under the rim, left for several minutes, brushed with toilet brush and toilet is flushed.
Application rate(s) and frequency	Active against bacteria and yeasts With undiluted product In 15 min contact time At Room Temperature Application rate of 5 mL/toilet 1x/week (non-professional users) Multiple times per day (professional users)
Category(ies) of users	Professional and non-professional users
Pack sizes and packaging material	750 mL pre-filled bottles (HDPE) for non-professional and professional users 5 L refill cans (HDPE) for professional users  Child-proof closure: the closure needs to be pressed before it can be turned open

	 Tactile warning: a triangle on the flask  

Meta SPC 2 (Mida Agri 830 Post Red)

Table 21. Use 2.1 – Teat disinfectant

Product Type	3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoors – in dairy farms : After milking teat disinfection, by dipping.
Application method(s)	Dip all teats into a dipping cup or spray around the surface of the teats until they are fully covered. Allow to dry. 
Application rate(s) and frequency	Active against bacteria and yeasts With undiluted product In 5 min contact time *If the product is stored at +4-7°C (i.e. in a fridge), the product must "return" to RT before use.*
Category(ies) of users	Professional users

Pack sizes and packaging material	10, 20, 25 L cans (HDPE) 200L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Meta SPC 3 (Mida San 325 DA)

Table 22. Use 3.1 – PT2 open surface disinfection, trigger spraying

Product Type	PT2
Where relevant, an exact description of the authorised use	Not relevant
Target organisms	Bacteria Yeasts
Field of use	Small and large areas - small surfaces Indoors – In non-medical areas, non-food industry (e.g. pharmaceuticals, cosmetics), warehouses, institutions, workplaces, buildings, … : Disinfection of hard/non-porous surfaces by trigger spraying with prior cleaning.
Application method(s)	The diluted solution is prepared manually and transferred to a hand-held trigger sprayer. After trigger spraying, the product is left to dry.
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 2% In 15 min contact time At Room Temperature Application rate: 20 ml / m^2 Frequency: Multiple times per day
Category(ies) of users	Professional
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 23. Use 3.2 – PT4 open surface disinfection, trigger spraying

Product Type	PT4
Where relevant, an exact description of the authorised use	Not relevant
Target organisms	Bacteria Yeasts
Field of use	Small and large areas - small surfaces Indoors – In Large-scale kitchens, restaurants, food & beverages industry, feed industry, meat industry, professional kitchens, … : Disinfection of hard/non-porous surfaces by trigger spraying with prior cleaning.
Application method(s)	The diluted solution is prepared manually and transferred to a hand-held trigger sprayer. After trigger spraying, the product is left to dry.
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 2% In 15 min contact time At Room Temperature

	Application rate: 20 ml / m^2 Frequency: Multiple times per day
Category(ies) of users	Professional
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 24. Use 3.3 – PT2 open surface disinfection, low-pressure spraying or foaming

Product Type	PT 2
Where relevant, an exact description of the authorised use	Disinfection by low pressure spraying or foaming can occur via fixed or mobile systems. 1. Fixed system: 1a central: The product is automatically mixed with water in a chemical storage room outside of the production room. A hose with spray nozzle is connected on the other side of the wall, inside the production room, where the surfaces to disinfect are located. 1b. decentral: The containers with chemicals are located inside the production room, and dilutions are prepared automatically inside the production room by the satellite mixing systems. 2. Mobile systems: 2a system to fill with RTU solution. The spray application system is a mobile system (backpack model or system on wheels). The dilution can be prepared manually or transferred from a system that prepares the ready-to-use solution automatically. 2b system that prepares the RTU solution automatically. The spray application system is a mobile system (usually on wheels). The dilution is prepared automatically by the system.
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In non-medical areas, non-food industry (e.g. pharmaceuticals, cosmetics), warehouses, institutions, workplaces, buildings, … :

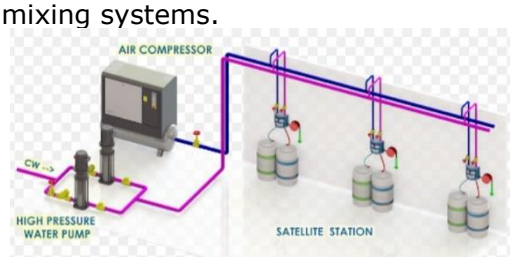
	Disinfection of hard/non-porous surfaces by low pressure spraying or foaming with prior cleaning.
Application method(s)	Disinfection by low pressure spraying or foaming can occur via fixed or mobile systems. 1. Fixed system: 1a central: The product is automatically mixed with water in a chemical storage room outside of the production room. A hose with spray nozzle is connected on the other side of the wall, inside the production room, where the surfaces to disinfect are located.  1b. decentral: The containers with chemicals are located inside the production room, and dilutions are prepared automatically inside the production room by the satellite mixing systems.  2. Mobile systems: 2a system to fill with RTU solution. The spray application system is a mobile system (backpack model or system on wheels). The dilution can be prepared manually or transferred from a system that prepares the ready-to-use solution automatically.  2b system that prepares the RTU solution automatically. The spray application system is a mobile system (usually on wheels). The dilution is prepared automatically by the system. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 2% In 15 min contact time At Room Temperature Application rate: 200 ml / m^2 Frequency: Daily
Category(ies) of users	Industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom

Table 25. Use 3.4 – PT4 open surface disinfection, low-pressure spraying or foaming

Product Type	PT 4
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In Food/ feed industry and warehouses : Disinfection of hard/non-porous surfaces by low pressure spraying or foaming with prior cleaning.
Application method(s)	Disinfection by low pressure spraying or foaming can occur via fixed or mobile systems. 1. Fixed system: 1a central: The product is automatically mixed with water in a chemical storage room outside of the production room. A hose with spray nozzle is connected on the other side of the wall, inside the production room, where the surfaces to disinfect are located.  1b. decentral: The containers with chemicals are located inside the production room, and dilutions are prepared automatically inside the production room by the satellite mixing systems.  2. Mobile systems: 2a system to fill with RTU solution. The spray application system is a mobile system (backpack model or system on wheels). The dilution can be prepared manually or transferred from a system that prepares the ready-to-use solution automatically.  2b system that prepares the RTU solution automatically. The spray application system is a mobile system (usually on wheels). The dilution is prepared automatically by the system. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 2% In 15 min contact time At Room Temperature Application rate: 200 ml / m^2 Frequency: Daily

Category(ies) of users	Industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 26. Use 3.5 – PT4 Dipping of objects and instruments

Product Type	PT4
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In Food/ feed industry : Disinfection of hard/non-porous objects and instruments by dipping with prior cleaning.
Application method(s)	Objects and instruments are disinfected by submersion in a disinfection bath (volume 1- 20L). First the objects are cleaned to remove all visible dirt. The disinfection bath is prepared by pouring the disinfectant in a bath and filling it up with water. The objects are then brought into the bath and left there during the required contact time. Disinfection can also be performed by flooding, i.e. filling an empty bath, which already contains the objects or instruments. In both cases, instruments are completely immersed. After the required contact time, the objects are removed from the bath and left to dry. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 2% In 15 min contact time At Room Temperature Frequency: up to 5 times per day
Category(ies) of users	Professional - industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Meta SPC 4 (Mida San 332 VB)

Table 27. Use 4.1 – PT2 open surface disinfection, trigger spraying

Product Type	PT2

Where relevant, an exact description of the authorised use	Not relevant
Target organisms	Bacteria Yeasts
Field of use	Small and large areas - small surfaces Indoors – In non-medical areas, non-food industry (e.g. pharmaceuticals, cosmetics), warehouses, institutions, workplaces, buildings, … : Disinfection of hard/non-porous surfaces by trigger spraying with prior cleaning.
Application method(s)	The diluted solution is prepared manually and transferred to a hand-held trigger sprayer. After trigger spraying, the product is left to dry. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 10% In 15 min contact time At Room Temperature Application rate: 20 ml / m^2 Frequency: Multiple times per day
Category(ies) of users	Professional
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 28. Use 4.2 – PT4 open surface disinfection, trigger spraying

Product Type	PT4
Where relevant, an exact description of the authorised use	Not relevant
Target organisms	Bacteria Yeasts
Field of use	Small and large areas - small surfaces Indoors – In Large-scale kitchens, restaurants, food & beverages industry, feed industry, meat industry, professional kitchens, … : Disinfection of hard/non-porous surfaces by trigger spraying with prior cleaning.
Application method(s)	The diluted solution is prepared manually and transferred to a hand-held trigger sprayer. After trigger spraying, the product is left to dry. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 10% In 15 min contact time At Room Temperature Application rate: 20 ml / m^2 Frequency: Multiple times per day
Category(ies) of users	Professional
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 29. Use 4.3 – PT2 open surface disinfection, low-pressure spraying or foaming

Product Type	PT 2
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In non-medical areas, non-food industry (e.g. pharmaceuticals, cosmetics), warehouses, institutions, workplaces, buildings, … : Disinfection of hard/non-porous surfaces by low pressure spraying or foaming with prior cleaning.
Application method(s)	Disinfection by low pressure spraying or foaming can occur via fixed or mobile systems.  1. Fixed system: 1a central: The product is automatically mixed with water in a chemical storage room outside of the production room. A hose with spray nozzle is connected on the other side of the wall, inside the production room, where the surfaces to disinfect are located.  1b. decentral: The containers with chemicals are located inside the production room, and dilutions are prepared automatically inside the production room by the satellite mixing systems.  2. Mobile systems: 2a system to fill with RTU solution. The spray application system is a mobile system (backpack model or system on wheels). The dilution can be prepared manually or transferred from a system that prepares the ready-to-use solution automatically. 

	2b system that prepares the RTU solution automatically. The spray application system is a mobile system (usually on wheels). The dilution is prepared automatically by the system. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 10% In 15 min contact time At Room Temperature Application rate: 200 ml / m^2 Frequency: Daily
Category(ies) of users	Industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 30. Use 4.4 – PT4 open surface disinfection, low-pressure spraying

Product Type	PT 4
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In Food/ feed industry and warehouses : Disinfection of hard/non-porous surfaces by low pressure spraying or foaming with prior cleaning.
Application method(s)	Disinfection by low pressure spraying or foaming can occur via fixed or mobile systems.  1. Fixed system: 1a central: The product is automatically mixed with water in a chemical storage room outside of the production room. A hose with spray nozzle is connected on the other side of the wall, inside the production room, where the surfaces to disinfect are located.  1b. decentral: The containers with chemicals are located inside the production room, and dilutions are prepared automatically inside the production room by the satellite mixing systems.  2. Mobile systems: 2a system to fill with RTU solution. The spray application system is a mobile system (backpack model or system on wheels). The dilution can be prepared manually or transferred from a system that prepares the ready-to-use solution automatically. 

	2b system that prepares the RTU solution automatically. The spray application system is a mobile system (usually on wheels). The dilution is prepared automatically by the system 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 10% In 15 min contact time At Room Temperature Application rate: 200 ml / m^2 Frequency: Daily
Category(ies) of users	Industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 31. Use 4.5 – PT4 Dipping of objects and instruments

Product Type	PT4
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In Food/ feed industry : Disinfection of hard/non-porous objects and instruments by dipping with prior cleaning.
Application method(s)	Objects and instruments are disinfected by submersion in a disinfection bath (volume 1- 20L). First the objects are cleaned to remove all visible dirt. The disinfection bath is prepared by pouring the disinfectant in a bath and filling it up with water. The objects are then brought into the bath and left there during the required contact time. Disinfection can also be performed by flooding, i.e. filling an empty bath, which already contains the objects or instruments. In both cases, instruments are completely immersed. After the required contact time, the objects are removed from the bath and left to dry. 
Application rate(s) and frequency	Required amount depends on bath size (maximum 20 L) Active against bacteria and yeasts Dilution : 10% In 15 min contact time

	At Room Temperature Frequency: up to 5 times per day
Category(ies) of users	Professional - industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 32. Use 4.6 – PT2 Cleaning – In - Place

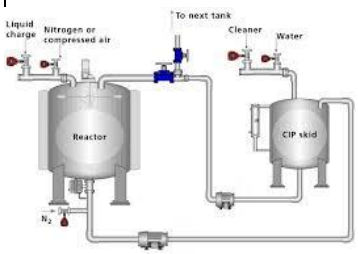
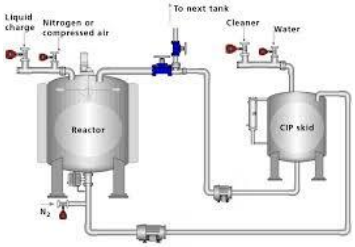
Product Type	PT2
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In non-medical areas, non-food industry (e.g. pharmaceuticals, cosmetics), warehouses, institutions, workplaces, buildings, … : Disinfection of inner hard/non-porous surfaces by CIP (with circulation) with prior cleaning.
Application method(s)	Clean-in-place (CIP) is a method of cleaning/disinfecting the interior surfaces of pipes, vessels, process equipment, filters and associated fittings, without disassembly. Most current CIP systems are fully automated with programmable logic controllers, multiple balance tanks, sensors, valves, heat exchangers, data acquisition and specially designed spray nozzle systems. The disinfectant is present in a stock tank or reservoir and dosed automatically. A typical CIP cycle could contain several steps, such as pre-rinsing, treatment with disinfectant, intermediate rinsing, treatment with acid/cleaning solution, and a final rinsing and drying step. The user is only exposed to the chemicals at the time of replacing empty containers. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 10% In 15 min contact time At Room Temperature Frequency: Daily
Category(ies) of users	Industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 33. Use 4.7 – PT4 Cleaning – In - Place

Product Type	PT4
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In Food/ feed industry : Disinfection of inner hard/non-porous surfaces by CIP (with circulation) with prior cleaning.
Application method(s)	Clean-in-place (CIP) is a method of cleaning/disinfecting the interior surfaces of pipes, vessels, process equipment, filters and associated fittings, without disassembly. Most current CIP systems are fully automated with programmable logic controllers, multiple balance tanks, sensors, valves, heat exchangers, data acquisition and specially designed spray nozzle systems. The disinfectant is present in a stock tank or reservoir and dosed automatically. A typical CIP cycle could contain several steps, such as pre-rinsing, treatment with disinfectant, intermediate rinsing, treatment with acid/cleaning solution, and a final rinsing and drying step. The user is only exposed to the chemicals at the time of replacing empty containers. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 10% In 15 min contact time At Room Temperature Frequency: Daily
Category(ies) of users	Industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Meta SPC 5 (Mida San 331 LW)

Table 34. Use 5.1 – PT2 open surface disinfection, trigger spraying

Product Type	PT2
Where relevant, an exact description of the authorised use	Not relevant
Target organisms	Bacteria Yeasts
Field of use	Small and large areas - small surfaces Indoors – In non-medical areas, non-food industry (e.g. pharmaceuticals, cosmetics), warehouses, institutions, workplaces, buildings, … : Disinfection of hard/non-porous surfaces by trigger spraying with prior cleaning.
Application method(s)	The diluted solution is prepared manually and transferred to a hand-held trigger sprayer. After trigger spraying, the product is left to dry. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 25% In 5 min contact time At Room Temperature Application rate: 20 ml / m^2 Frequency: Multiple times per day
Category(ies) of users	Professional
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 35. Use 5.2 – PT4 open surface disinfection, trigger spraying

Product Type	PT4
Where relevant, an exact description of the authorised use	Not relevant
Target organisms	Bacteria Yeasts
Field of use	Small and large areas - small surfaces Indoors – In Large-scale kitchens, restaurants, food & beverages industry, feed industry, meat industry, professional kitchens, … : Disinfection of hard/non-porous surfaces by trigger spraying with prior cleaning.
Application method(s)	The diluted solution is prepared manually and transferred to a hand-held trigger sprayer. After trigger spraying, the product is left to dry. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 25% In 5 min contact time At Room Temperature Application rate: 20 ml / m^2 Frequency: Multiple times per day
Category(ies) of users	Professional
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 36. Use 5.3 – PT2 open surface disinfection, low-pressure spraying or foaming

Product Type	PT 2
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In non-medical areas, non-food industry (e.g. pharmaceuticals, cosmetics), warehouses, institutions, workplaces, buildings, … : Disinfection of hard/non-porous surfaces by low pressure spraying or foaming with prior cleaning.
Application method(s)	Disinfection by low pressure spraying or foaming can occur via fixed or mobile systems.   1. Fixed system: 1a central: The product is automatically mixed with water in a chemical storage room outside of the production room. A hose with spray nozzle is connected on the other side of the wall, inside the production room, where the surfaces to disinfect are located. 1b. decentral: The containers with chemicals are located inside the production room, and dilutions are prepared automatically inside the production room by the satellite mixing systems.  2. Mobile systems: 2a system to fill with RTU solution. The spray application system is a mobile system (backpack model or system on wheels). The dilution can be prepared manually or transferred from a system that prepares the ready-to-use solution automatically. 

	2b system that prepares the RTU solution automatically. The spray application system is a mobile system (usually on wheels). The dilution is prepared automatically by the system. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 25% In 5 min contact time At Room Temperature Application rate: 200 ml / m^2 Frequency: Daily
Category(ies) of users	Industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 37. Use 5.4 – PT4 open surface disinfection, low-pressure spraying or foaming

Product Type	PT 4
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In Food/ feed industry and warehouses : Disinfection of hard/non-porous surfaces by low pressure spraying or foaming with prior cleaning.
Application method(s)	Disinfection by low pressure spraying or foaming can occur via fixed or mobile systems.  1. Fixed system: 1a central: The product is automatically mixed with water in a chemical storage room outside of the production room. A hose with spray nozzle is connected on the other side of the wall, inside the production room, where the surfaces to disinfect are located.  1b. decentral: The containers with chemicals are located inside the production room, and dilutions are prepared

	automatically inside the production room by the satellite mixing systems.  2. Mobile systems: 2a system to fill with RTU solution. The spray application system is a mobile system (backpack model or system on wheels). The dilution can be prepared manually or transferred from a system that prepares the ready-to-use solution automatically.  2b system that prepares the RTU solution automatically. The spray application system is a mobile system (usually on wheels). The dilution is prepared automatically by the system. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 25% In 5 min contact time At Room Temperature Application rate: 200 ml / m^2 Frequency: Daily
Category(ies) of users	Industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

Table 38. Use 5.5 – PT4 Dipping of objects and instruments

Product Type	PT4
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoors – In Food/ feed industry : Disinfection of hard/non-porous objects and instruments by dipping with prior cleaning.
Application method(s)	Objects and instruments are disinfected by submersion in a disinfection bath (volume 1- 20L). First the objects are cleaned to remove all visible dirt. The disinfection bath is prepared by pouring the disinfectant in a bath and filling it up with water. The objects are then brought into the bath and left there during the required contact time. Disinfection can

	also be performed by flooding, i.e. filling an empty bath, which already contains the objects or instruments. In both cases, instruments are completely immersed. After the required contact time, the objects are removed from the bath and left to dry. 
Application rate(s) and frequency	Active against bacteria and yeasts Dilution : 25% In 5 min contact time At Room Temperature Frequency: up to 5 times per day
Category(ies) of users	Professional - industrial
Pack sizes and packaging material	5, 20 L cans (HDPE) 220L vessels (HDPE) 1000 litre IBC with screw cap (top) and tap (bottom)

2.2.1.2 Use-specific instructions for use

Use 1.1 Toilet Disinfectant
Apply the product around the bowl and under the rim, leave it for 15 minutes, brush with toilet brush and flush.

Use 2.1 Teat disinfectant
Dip all teats into a dipping cup until they are fully covered. Allow to dry for 5 minutes.

Since the product has been tested at +30°C, if the product is stored at +4-7°C (i.e. in a fridge), a precautionary sentence should be added in the PAR/SPC/label in order to mention that the product must "return" to RT before use.

Use 3.1, 3.2, 4.1, 4.2, 5.1, 5.2 trigger spraying
All the surfaces to be disinfected must be cleaned before the disinfection procedure. Then, the user should thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected.
Dilute the product with clean water before use.
Dilution meta SPC 3 – Use 3.1/3.2: 2% against bacteria and yeasts, 15 min. contact time
Dilution meta SPC 4 – Use 4.1/4.2: 10% against bacteria and yeasts, 15 min. contact time
Dilution meta SPC 5 – Use 5.1/5.2: 25% against bacteria and yeasts, 5 min. contact time

MAKE SURE TO WET SURFACES COMPLETELY.

Use 3.3, 3.4, 4.3, 4.4, 5.3, 5.4 Low-pressure spraying or foaming

All the surfaces to be disinfected must be cleaned before the disinfection procedure. Then, the user should thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected.

Apply the diluted product on the surface to be disinfected. When disinfecting, use as much liquid so that the surfaces remain wet during the required exposure time.
Apply by low-pressure spraying or foaming equipment.
Dilution meta SPC 3 – Use 3.3 & 3.4: 2% against bacteria and yeasts, 15 min. contact time
Dilution meta SPC 4 – Use 4.3 & 4.4: 10% against bacteria and yeasts, 15 min. contact time
Dilution meta SPC 5 – Use 5.3 & 5.4: 25% against bacteria and yeasts, 5 min. contact time

Use 3.5, 4.5, 5.5, Dipping
All the surfaces to be disinfected must be cleaned before the disinfection procedure. Then, the user should thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected.

Dilute the product in the dipping bath. Dip the objects during the required exposure time. Remove the objects from the dipping bath and let dry.
Dilution meta SPC 3 – Use 3.5: 2% against bacteria and yeasts, 15 min. contact time
Dilution meta SPC 4 – Use 4.5: 10% against bacteria and yeasts, 15 min. contact time
Dilution meta SPC 5 – Use 5.5: 25% against bacteria and yeasts, 5 min. contact time

Use 4.6, 4.7 CIP
All the surfaces to be disinfected must be cleaned before the disinfection procedure. Then, the user should thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected.
Treat piping systems and equipment by means of a circulating pump system as usual in a CIP system.
Dilution meta SPC 4 – Use 4.6 and 4.7: 10% against bacteria and yeasts, 15 min. contact time

2.2.1.3 Use-specific risk mitigation measures

Meta SPC 2
Wear protective goggles.
Avoid contact with skin and eyes
Ensure good ventilation of the work station.
Do not eat, drink or smoke when using this product.
Always wash hands after handling the product.

Use 2.1 Teat disinfection
Do not release the solution to the manure/slurry pit, only release to the sewer system.

Meta SPC 3
Avoid contact to eyes
Avoid all unnecessary exposure.
Wear chemical resistant PVC gloves (EN374 or equivalent).
Wear chemical goggles or face shield. Safety glasses with side-shields (EN 166).
Wear suitable protective clothing minimum (EN 13034) Type 6 equipment. Wear suitable protective clothing.

Provide adequate ventilation. Wear appropriate mask.
Do not eat, drink or smoke during use.

Uses 3.5, 4.5, 5.5 Dipping
No use-specific risk mitigations required for a use frequency up to 5 times per day and a dipping bath size up to 20L

Meta SPC 4
Avoid contact to eyes
Avoid all unnecessary exposure.
Wear chemical resistant PVC gloves (EN374 or equivalent).
Wear chemical goggles or face shield (EN 166).
Wear suitable protective clothing.
Provide adequate ventilation.
Do not eat, drink or smoke during use.
Keep uninvolved persons, children and pets away from treated surfaces until dried
Meta SPC 5
Avoid contact to eyes
Ensure good ventilation at the workstation.
Wear chemical resistant PVC gloves (EN374 or equivalent).
Wear chemical goggles or face shield (EN 166). Safety glasses.
Wear suitable protective clothing (EN 14605).
Provide adequate ventilation.
Keep uninvolved persons, children and pets away from treated surfaces until dried

Uses 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4 Low-pressure spraying or foaming & trigger spray:
Wear appropriate respiratory protective equipment: half/full mask FFP2 with gas filter
Bystanders are not allowed in the room during the application, except if they wear protective gloves, googles, clothing and respiratory protective equipment

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

General advice: In all cases of doubt, or when symptoms persist, seek medical attention.

Inhalation: Take victim to fresh air, in a quiet place and if necessary take medical advice.

Skin contact: Remove all contaminated clothing and footwear. Wash off with plenty of water. In case of faintness or symptoms of skin irritation appear, take medical advice.

Eye contact: Rinse immediately with plenty of water. Consult an eye specialist.

Ingestion: Rinse mouth out with water. Do NOT induce vomiting. Immediately call a POISON CENTER/doctor.

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

Dispose of in accordance with local regulations.

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

Meta SPC 1 Do not store at temperatures above 30°C Protect from frost Shelf-life : 2 years Meta SPC 2 **The product is not authorized** Do not store at temperatures above 30°C Protect from frost Shelf-life : 1 year Meta SPC 3 Do not store at temperatures above 40°C Protect from frost Shelf-life : 2 years Meta SPC 4 Do not store at temperatures above 40°C Protect from frost Shelf-life : 2 years Meta SPC 5 Do not store at temperatures above 40°C Protect from frost Shelf-life : 2 years

General directions for use

1. Instructions for use

1) All the surfaces to be disinfected must be cleaned before the disinfection procedure, with some exceptions. Then, the user should thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected. 2) <u>Disinfection cycle</u> : - If required, products must be diluted in potable water before use - Dilution rate & contact time depends on the use considered. Please refer to the description of application method related to each use. - Final rinsing (with potable water) : please refer to the description of application method related to each use. <u>Disinfection procedures **by dipping** (hard/non-porous surfaces)</u> : The bath is not intended to be re-used. Use the bath only once.

Disinfection procedures **by pouring/spraying/foaming** : the surfaces to be disinfected must be wet enough in order to keep them wet during the required contact time for optimal disinfection. Then, the user should pay attention to wet surfaces completely with the disinfectant solution.

Open containers. Small containers are transferred manually into reservoirs or dilution vessels, while large containers are pumped into reservoirs via a pump.
For all uses, no waiting period is required after application of the biocidal product or between two applications of the product, or the next access by humans or animals to the area where the biocidal product has been used.
Cleaning of equipment can be done with water.
There are no precautions to be taken to avoid the development of resistance.

2. Risk mitigation measures

Avoid contact with skin and eyes
Keep out of reach of children and pets

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

General advice: In all cases of doubt, or when symptoms persist, seek medical attention.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Immediately wash with plenty of water. Take off all contaminated clothing and wash it before reuse. Wash with soap and water and continue rinsing 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. Immediately call a Call 112/ambulance for medical assistance.

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.

Stop leak without risks if possible. Do not contaminate ground and surface water. Prevent entry to sewers and public waters.

4. Instructions for safe disposal of the product and its packaging

Dispose of in accordance with local regulations.

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

Meta SPC 1 Do not store at temperatures above 30°C Protect from frost Shelf-life : 2 years Meta SPC 2 Do not store at temperatures above 30°C Protect from frost Shelf-life : 1 year (Preliminary shelf-life, test is ongoing. Finalisation: June 2023) Meta SPC 3 Do not store at temperatures above 40°C Protect from frost Shelf-life : 2 years Meta SPC 4 Do not store at temperatures above 40°C Protect from frost Shelf-life : 2 years Meta SPC 5 Do not store at temperatures above 40°C Protect from frost Shelf-life : 2 years

Other information

Application codes

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
Physical state at 20 °C and 101.3 kPa	Visual observation	Meta SPC 1 Formula 1242 (Chriox WC): 6.8% lactic acid Batch: 1014066	Opaque Liquid	Shelf-life stability study at 25ºC for 24 months on the test item "Chriox WC" Report 2018/169AM Belussi C., 2020	Acceptable
	Visual observation	Meta SPC 2 Mida Agri 830 Post Red: 8% lactic acid Batch 101221	Liquid	Shelf-life stability study at 54ºC for 14 days and at 25ºC for 24 months on the test item "Mida Agri 830 Post Red" Interim Report SS-2021-091 Frasson S., 2022	Acceptable
	Visual observation	Meta SPC 3 Mida San 325 DA: 16% lactic acid Batch: QD29	Transparent liquid	Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 325 DA" study n° 2018/238 AM Belussi C., 2021	Acceptable
	Visual observation	Meta SPC 4 Formula 735 (Mida San 332	Transparent liquid	Shelf-life Stability study at 25ºC for 24 months on the	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
		VB): 80% lactic acid Batch: AS18/034		test item " Mida San 332 VB" study n° 2018/241 AM Belussi C., 2021	
	Visual observation	Meta SPC 5 Formula 729 (Mida San 331 LW): 24% lactic acid Batch: AS18/056	Transparent liquid	Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 331 LW" study n° 2018/319 AM Belussi C., 2021	Acceptable
Colour at 20 °C and 101.3 kPa	Visual observation	Meta SPC 1 Formula 1242 (Chriox WC): 6.8% lactic acid Batch: 1014066	Light green	Shelf-life stability study at 25ºC for 24 months on the test item "Chriox WC" Report 2018/169AM Belussi C., 2020	Acceptable
	Visual observation	Meta SPC 2 Mida Agri 830 Post Red: 8% lactic acid Batch 101221	Brown	Shelf-life stability study at 54ºC for 14 days and at 25ºC for 24 months on the test item "Mida Agri 830 Post Red" Interim Report SS-2021-091	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
				Frasson S., 2022	
	Visual observation	Meta SPC 3 Mida San 325 DA: 16% lactic acid Batch: QD29	Light yellow	Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 325 DA" study n° 2018/238 AM Belussi C., 2021	Acceptable
	Visual observation	Meta SPC 4 Formula 735 (Mida San 332 VB): 80% lactic acid Batch: AS18/034	Colorless	Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 332 VB" study n° 2018/241 AM Belussi C., 2021	Acceptable
	Visual observation	Meta SPC 5 Formula 729 (Mida San 331 LW): 24% lactic acid Batch: AS18/056	Colorless	Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 331 LW" study n° 2018/319 AM Belussi C., 2021	Acceptable
Odour at 20 °C and 101.3 kPa	Sensory observation	Meta SPC 1 Formula 1242 (Chriox WC): 6.8% lactic acid	Perfumed	Physical and chemical properties report, Formula 1242 ind01	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
				Pinard O., 2020	
	Sensory observation	Meta SPC 2 Mida Agri 830 Post Red: 8% lactic acid	Slightly acid	Physical chemical properties Mida Agri 830 Post red Bono M., 2020	Acceptable
	Sensory observation	Meta SPC 3 Mida San 325 DA: 16% lactic acid	Mild acid	Physical and chemical properties report, Mida San 325 DA Lorenzo F., 2020	Acceptable
	Sensory observation	Meta SPC 4 Formula 735 (Mida San 332 VB): 80% lactic acid	Mild acid	Physical and chemical properties report, Formula 735 Neyt L., 2020	Acceptable
	Sensory observation	Meta SPC 5 Formula 729 (Mida San 331 LW): 24% lactic acid	Alcohol	Physical and chemical properties report, Formula 729 Neyt L., 2020	Acceptable
Acidity / alkalinity	CIPAC MT 191	Meta SPC 1 Formula 1242 (Chriox WC): 6.8% lactic acid Batch: 1014066	Acidity (as %w/w of H_2SO_4): 3.51% w/w	Shelf-life stability study at 25ºC for 24 months on the test item "Chriox WC" Report 2018/169AM Belussi C., 2020	Acceptable
	CIPAC MT 191	Meta SPC 2	Acidity (as H_2SO_4): 2.5g/100g	Shelf-life stability study at 54ºC for	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
		Mida Agri 830 Post Red: 8% lactic acid Batch 101221		14 days and at 25ºC for 24 months on the test item "Mida Agri 830 Post Red" Interim Report SS-2021-091 Frasson S., 2022	
	CIPAC MT 191	Meta SPC 3 Mida San 325 DA: 16% lactic acid Batch: QD29	Acidity (as %w/w of H_2SO_4): 9.32% w/w	Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 325 DA" study n° 2018/238 AM Belussi C., 2021	Acceptable
	CIPAC MT 191	Meta SPC 4 Formula 735 (Mida San 332 VB): 80% lactic acid Batch: AS18/034	Acidity (as %w/w of H_2SO_4): 38.54% w/w	Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 332 VB" study n° 2018/241 AM Belussi C., 2021	Acceptable
	CIPAC MT 191	Meta SPC 5 Formula 729 (Mida San 331 LW): 24% lactic acid	Acidity (as %w/w of H_2SO_4): 9.48% w/w	Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 331 LW"	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
		Batch: AS18/056		study n° 2018/319 AM Belussi C., 2021	
pH	CIPAC MT 75.3	Meta SPC 1 Formula 1242 (Chriox WC): 6.8% lactic acid Batch: 1014066	pH: 2.19 (100%)	Shelf-life stability study at 25ºC for 24 months on the test item "Chriox WC" Report 2018/169AM Belussi C., 2020	Acceptable
	OECD guideline 122	Meta SPC 2 Mida Agri 830 Post Red: 8% lactic acid	pH: 3.52 (100%)	Physical chemical properties Mida Agri 830 Post red Bono M., 2020	Acceptable
	CIPAC MT 75.3	Meta SPC 3 Mida San 325 DA: 16% lactic acid Batch: QD29	pH: 0.46 (100%) pH: 2.16 (1%)	Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 325 DA" study n° 2018/238 AM Belussi C., 2021	Acceptable
	CIPAC MT 75.3	Meta SPC 4 Formula 735 (Mida San 332 VB): 80% lactic acid Batch: AS18/034	pH: 0.60 (100%) pH: 2.36 (1%)	Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 332 VB" study n° 2018/241 AM	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
				Belussi C., 2021	
	CIPAC MT 75.3	Meta SPC 5 Formula 729 (Mida San 331 LW): 24% lactic acid Batch: AS18/056	pH: 3.29 (100%) pH: 3.15 (1%)	Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 331 LW" study n° 2018/319 AM Belussi C., 2021	Acceptable
Relative density / bulk density	OECD guideline 109	Meta SPC 1 Formula 1242 (Chriox WC): 6.8% lactic acid Batch: 1014066	Relative density: 1.107	Shelf-life stability study at 25ºC for 24 months on the test item "Chriox WC" Report 2018/169AM Belussi C., 2020	Acceptable
	OECD guideline 109	Meta SPC 2 Mida Agri 830 Post Red: 8% lactic acid	Density: 1014 kg/m^3	Physical chemical properties Mida Agri 830 Post red Bono M., 2020	Acceptable
	OECD guideline 109	Meta SPC 3 Mida San 325 DA: 16% lactic acid Batch: QD29	Relative density: 1.083	Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 325 DA" study n° 2018/238 AM Belussi C., 2021	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
	OECD guideline 109	Meta SPC 4 Formula 735 (Mida San 332 VB): 80% lactic acid Batch: AS18/034	Relative density: 1.188	Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 332 VB" study n° 2018/241 AM Belussi C., 2021	Acceptable
	OECD guideline 109	Meta SPC 5 Formula 729 (Mida San 331 LW): 24% lactic acid Batch: AS18/056	Relative density: 1.069	Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 331 LW" study n° 2018/319 AM Belussi C., 2021	Acceptable
Storage stability test – **accelerated storage**	/	Meta SPC 1 1242 (Chriox WC): 6.8% lactic acid	Not available. The product should be stored below 30°C.	/	Acceptable "Do not store at temperatures above 30°C" will be added to the label of Chriox WC
Storage stability test – **accelerated storage** Appearance: visual	CIPAC method MT 46.3	Mida Agri 830 Post Red: 8% lactic acid Batch 101221	54 °C / T0 / 2 weeks Appearance of the test item / Brown liquid / No change	Shelf-life stability study at 54ºC for 14 days and at 25ºC for 24 months on the test item "Mida	Acceptable The accelerated stability study demonstrates

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>BE remark</th></tr>
<tr><td></td><td>Weight loss: AP-LABCHI-0348 rev 1
Acidity: CIPAC MT191
Lactic acid content: Internal SOPa 512 REV 1
Accelerated storage: CIPAC MT 46.4</td><td></td><td>
<table>
<tr><td>Appearance of the packaging</td><td>White HDPE plastic tank (5L) close by black screw cap</td><td>No change</td></tr>
<tr><td>Weight loss</td><td>/</td><td>0.03 g/100g</td></tr>
<tr><td>Acidity (as H2SO4)</td><td>2.5 g/100g</td><td>2.2 g/100g</td></tr>
<tr><td>Lactic acid content</td><td>7.54 %w/w</td><td>6.66 %w/w (-11.7%)</td></tr>
</table>
</td><td>Agri 830 Post Red"
Interim Report SS-2021-091
Frasson S., 2022</td><td>that the active substance content in Milda Agri 830 Post Red decreased more than 10% (Not acceptable limit).

"Do not store at temperatures above 30°C" will be added to the label of Mida Agri 830 Post Red</td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>Standard: CIPAC MT 46.3

Appearance: visual
pH: CIPAC MT 75.3
Acidity: CIPAC MT 191</td><td>Meta SPC 3
Mida San 325
DA: 16% lactic acid
Batch: QD29</td><td>
<table>
<tr><td>40°C</td><td>T0</td><td>4 weeks</td><td>8 weeks</td></tr>
<tr><td>Appearance of the test item</td><td>Transparent light yellow liquid</td><td>No change</td><td>No change</td></tr>
<tr><td>Appearance of the packaging</td><td>White HDPE plastic tank (5L) close by yellow screw cap</td><td>No change</td><td>No change</td></tr>
</table>
</td><td>Control of critical parameters under stability conditions - study n° 2018/237 AM
Belussi C., 2019</td><td>Acceptable

The accelerated storage is not demonstrated at higher temperature than 40°C, the restriction measure "do not store at</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>BE remark</th></tr>
<tr><td></td><td>Relative density: OECD 109
Lactic acid content: STULV18AA2 121-1 GLP-MdP</td><td></td><td>
<table>
<tr><td>Relative density</td><td>1.084</td><td>1.085</td><td>1.087</td></tr>
<tr><td>pH (1%)</td><td>2.14</td><td>2.18</td><td>2.24</td></tr>
<tr><td>Acidity (as% w/w oh H2SO4)</td><td>8.88% w/w</td><td>9.09% w/w</td><td>9.11% w/w</td></tr>
<tr><td>Lactic Acid content</td><td>15.09% w/w</td><td>14.46% w/w (-4.2%)</td><td>14.50% w/w (-3.9%)</td></tr>
</table>

The accelerated stability study demonstrates that Milda San 325 DA is stable for 8 weeks at 40°C.</td><td></td><td>temperatures above 40°C" will be added on the label.</td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>Standard: CIPAC MT 46.3

Appearance: visual
pH: CIPAC MT 75.3
Acidity: CIPAC MT 191
Relative density: OECD 109
Lactic acid content: STULV18AA2 167-1 GLP-MdP</td><td>Meta SPC 4 Formula 735 (Mida San 332 VB): 80% lactic acid
Batch: AS18/034</td><td>
<table>
<tr><td>40°C</td><td>T0</td><td>4 weeks</td><td>8 weeks</td></tr>
<tr><td>Appearance of the test item</td><td>Transparent colorless liquid</td><td>No change</td><td>No change</td></tr>
<tr><td>Appearance of the packaging</td><td>White semistransparent HDPE plastic tank (10L) close by black screw cap</td><td>No change</td><td>No change</td></tr>
<tr><td>Relative density</td><td>1.189</td><td>1.189</td><td>1.190</td></tr>
<tr><td>pH (1%)</td><td>2.37</td><td>2.35</td><td>2.38</td></tr>
<tr><td>Acidity (as% w/w oh H2SO4)</td><td>38.59% w/w</td><td>38.57% w/w</td><td>38.49% w/w</td></tr>
</table>
</td><td>Control of critical parameters under stability conditions - study n° 2018/240 AM Belussi C., 2019</td><td>Acceptable

The accelerated storage is not demonstrated at higher temperature than 40°C, the restriction measure "do not store at temperatures above 40°C" will be added on the label.</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>BE remark</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Lactic Acid content</td><td>80.25% w/w</td><td>79.55% w/w (-0.9%)</td><td>79.94% w/w (-0.4%)</td></tr>
</table>

The accelerated stability study demonstrates that Milda San 332 VB is stable for 8 weeks at 40°C.</td><td></td><td></td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>Standard: CIPAC MT 46.3

Appearance: visual
pH: CIPAC MT 75.3
Acidity: CIPAC MT 191
Relative density: OECD 109
Lactic acid content: STULV18AA1 420-1 GLP-MdP</td><td>Meta SPC 5 Formula 729 (Mida San 331 LW): 24% lactic acid
Batch: AS18/056</td><td>
<table>
<tr><td>40°C</td><td>T0</td><td>4 weeks</td><td>8 weeks</td></tr>
<tr><td>Appearance of the test item</td><td>Transparent colorless liquid</td><td>No change</td><td>No change</td></tr>
<tr><td>Appearance of the packaging</td><td>White semistransparent HDPE plastic tank (10L) close by black screw cap</td><td>No change</td><td>No change</td></tr>
<tr><td>Relative density</td><td>1.069</td><td>1.068</td><td>1.068</td></tr>
<tr><td>pH (1%)</td><td>3.12</td><td>3.14</td><td>3.16</td></tr>
<tr><td>Acidity (as% w/w of H2SO4)</td><td>9.57% w/w</td><td>9.34% w/w</td><td>9.13% w/w</td></tr>
<tr><td>Lactic Acid content</td><td>23.30% w/w</td><td>21.48% w/w (-7.8%)</td><td>22.30% w/w (-4.3%)</td></tr>
</table>

The accelerated stability study demonstrates that Milda San 331 LW is stable for 8 weeks at 40°C.</td><td>Accelerated stability study at 40°C for 8 weeks on the test item "Mida San 331 LW" - study n° 2018/318 AM Belussi C., 2019

Amendment to Final report 2018/318 AM Belussi C., 2020</td><td>Acceptable

The accelerated storage is not demonstrated at higher temperature than 40°C, the restriction measure "do not store at temperatures above 40°C" will be added on the label.</td></tr>
<tr><td>Storage stability test – long</td><td>Storage in 750 ml HDPE</td><td>Meta SPC 1</td><td>
<table>
<tr><td></td><td>T0</td><td>6 months</td><td>12 months</td><td>24 months</td></tr>
</table></td><td>Shelf-life stability study at 25ºC for</td><td>Acceptable</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>BE remark</th></tr>
<tr><td>term storage at ambient temperature</td><td>flasks at 25°C during 24 months

Appearance: visual
Weight loss: gravitmetric
pH: CIPAC MT 75.3
Acidity: CIPAC MT 191
Viscosity: OECD 114
Lactic acid content: STULV18AA1 233-1 GLP - MdP</td><td>1242 (Chriox WC): 6.8% lactic acid
Batch: 1014066</td><td>
<table>
<tr><td>Appearance of the test item</td><td>Opaque light green liquid</td><td>No change</td><td>No change</td><td>No change</td></tr>
<tr><td>Appearance of the packaging</td><td>White plastic bottle closed by crew cap</td><td>No change</td><td>No change</td><td>No change</td></tr>
<tr><td>Weight loss</td><td>/</td><td>0.11%</td><td>0.15%</td><td>0.47%</td></tr>
<tr><td>pH (100%)</td><td>2.19</td><td>2.07</td><td>2.14</td><td>2.13</td></tr>
<tr><td>Acidity (as% w/w of H2SO4)</td><td>3.51% w/w</td><td>3.61% w/w</td><td>3.61% w/w</td><td>3.59% w/w</td></tr>
<tr><td>Viscosity (20°C)</td><td>10.3 mPa.s</td><td>10.7 mPa.s</td><td>10.8 mPa.s</td><td>9.1 mPa.s</td></tr>
<tr><td>Viscosity (40°C)</td><td>8.6 mPa.s</td><td>8.8 mPa.s</td><td>8.8 mPa.s</td><td>7.7 mPa.s</td></tr>
<tr><td>Lactic Acid content</td><td>6.43 % w/w</td><td>6.67% w/w (+3.7%)</td><td>6.68% w/w (+3.9%)</td><td>6.67 % w/w (+3.7%)</td></tr>
</table>

The study was performed for a total of 24 moth and showed no significant changes in appearance, pH, acidity, viscosity and lactic acid content.
The stability studies were conducted in the smallest size commercial containers. No incompatibilities between the products and the containers were observed. The material of larger packagings is the same as for the smallest sizes, and as the smallest size packagings have the highest packaging-to-product ratio this is considered</td><td>24 months on the test item "Chriox WC"
Report 2018/169AM
Belussi C., 2020</td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>BE remark</th></tr>
<tr><td></td><td></td><td></td><td>worst-case. Therefore, it can be concluded that the products will also be stable in larger packagings.</td><td></td><td></td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>Storage in 5 L HDPE plastic tank at 25°C during 12 months

Appearance: visual
Weight loss: AP-LABCHI-0348 rev 1
Acidity: CIPAC MT191
Viscosity: CIPAC MT192
Lactic acid content: Internal SOPa 512 REV 1</td><td>Mida Agri 830 Post Red: 8% lactic acid
Batch 101221</td><td>
<table>
<tr><td></td><td>T0</td><td>6 months</td><td>12 months</td></tr>
<tr><td>Appearance of the test item</td><td>Brown liquid</td><td>No change</td><td>No change</td></tr>
<tr><td>Appearance of the packaging</td><td>White HDPE plastic tank (5L) close by black screw cap</td><td>No change</td><td>No change</td></tr>
<tr><td>Weight loss</td><td>/</td><td>0 g/100g</td><td>0 g/100g</td></tr>
<tr><td>Acidity (as% w/w of H2SO4)</td><td>2.5 %w/w</td><td>2.1 %w/w</td><td>2.1 %w/w</td></tr>
<tr><td>Viscosity (20°C)</td><td>3400 mPa.s</td><td>3200 mPa.s</td><td>3300 mPa.s</td></tr>
<tr><td>Viscosity (40°C)</td><td>3200 mPa.s</td><td>3000 mPa.s</td><td>3000 mPa.s</td></tr>
<tr><td>Lactic Acid content</td><td>7.54 %w/w</td><td>7 %w/w (-7.2%)</td><td>7 %w/w (-7.2%)</td></tr>
</table>

The study was performed for 12 months (interim data) and showed no significant changes in appearance, acidity and viscosity.
The active substance concentration decreased to -7.2% after 6 months and remained the same after 12 months.
The stability studies were conducted in the smallest size commercial containers. No incompatibilities between the products and the containers were observed. The material of larger</td><td>Shelf-life stability study at 54ºC for 14 days and at 25ºC for 24 months on the test item "Mida Agri 830 Post Red"
Interim Report SS-2021-091
Frasson S., 2022</td><td>Acceptable</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>BE remark</th></tr>
<tr><td></td><td></td><td></td><td>packagings is the same as for the smallest sizes, and as the smallest size packagings have the highest packaging-to-product ratio this is considered worst-case. Therefore, it can be concluded that the products will also be stable in larger packagings.</td><td></td><td></td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>Storage in 5 L HDPE cans at 25°C during 24 months

Appearance: visual
pH: CIPAC MT 75.3
Acidity: CIPAC MT 191
Relative density: OECD 109
Lactic acid content: STULV18AA2 121-1 GLP - MdP</td><td>Meta SPC 3
Mida San 325
DA: 16% lactic acid
Batch: QD29</td><td>
<table>
<tr><th></th><th>T0</th><th>6 months</th><th>12 months</th><th>24 months</th></tr>
<tr><td>Appearance of the test item</td><td>Transparent light yellow liquid</td><td>No change</td><td>No change</td><td>No change</td></tr>
<tr><td>Appearance of the packaging</td><td>White plastic tank (5L) closed by crew cap</td><td>No change</td><td>No change</td><td>No change</td></tr>
<tr><td>pH (1%)</td><td>2.16</td><td>2.26</td><td>2.17</td><td>1.97</td></tr>
<tr><td>pH (100%)</td><td>0.46</td><td>0.74</td><td>1.05</td><td>0.54</td></tr>
<tr><td>Acidity (as% w/w of H2SO4)</td><td>9.32% w/w</td><td>11.68% w/w</td><td>9.42% w/w</td><td>12.45% w/w</td></tr>
<tr><td>Relative density</td><td>1.083</td><td>1.085</td><td>1.085</td><td>1.090</td></tr>
<tr><td>Lactic Acid content</td><td>15.07 % w/w</td><td>14.29% w/w (-5.2%)</td><td>14.47% w/w (-4.0%)</td><td>14.55% w/w (-3.5%)</td></tr>
</table>

The study was performed for a total of 24 months and showed no significant changes in appearance, relative density, acidity and lactic acid content.</td><td>Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 325 DA" study n° 2018/238 AM Belussi, 2021</td><td>Acceptable</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>BE remark</th></tr>
<tr><td></td><td></td><td></td><td>The pH (100%) doubled indeed after 12 months, but after 24 months it was back to a value close to the T0 value. The pH (1%) remained relatively constant during storage. There is no plausible explanation for this observation, except that it is an outlier or due to limitation of the analytical method. As the pH meter has been calibrated with buffers of pH 2, 4, 7 and 9, the measured pH (neat, diluted) of the product is out of the calibration range of the pH meter and the measured values should be taken as approximate. The stability studies were conducted in the smallest size commercial containers. No incompatibilities between the products and the containers were observed. The material of larger packagings is the same as for the smallest sizes, and as the smallest size packagings have the highest packaging-to-product ratio this is considered worst-case. Therefore, it can be concluded that the products will also be stable in larger packagings.</td><td></td><td></td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>Storage in 10 L HDPE cans at 25°C during 24 months

Appearance: visual
pH: CIPAC MT 75.3
Acidity: CIPAC MT 191
Relative density: OECD 109</td><td>Meta SPC 4 Formula 735 (Mida San 332 VB): 80% lactic acid
Batch: AS18/034</td><td>
<table>
<tr><th></th><th>T0</th><th>6 months</th><th>12 months</th><th>24 months</th></tr>
<tr><td>Appearance of the test item</td><td>Transparent colorless liquid</td><td>No change</td><td>No change</td><td>No change</td></tr>
<tr><td>Appearance of the packaging</td><td>Semitransparent HDPE plastic tank (10L)</td><td>No change</td><td>No change</td><td>No change</td></tr>
<tr><td>pH (1%)</td><td>2.36</td><td>2.39</td><td>2.16</td><td>2.13</td></tr>
<tr><td>pH (100%)</td><td>0.60</td><td>0.98</td><td>0.87</td><td>0.19*</td></tr>
<tr><td>Acidity (as% w/w of H2SO4)</td><td>38.54% w/w</td><td>29.59% w/w</td><td>28.72% w/w</td><td>28.85% w/w</td></tr>
</table>
</td><td>Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 332 VB" study n° 2018/241 AM Belussi C., 2021</td><td>Acceptable</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>BE remark</th></tr>
<tr><td></td><td>Lactic acid content: STULV18AA2167-1 GLP – MdP</td><td></td><td>
<table>
<tr><td>Relative density</td><td>1.188</td><td>1.186</td><td>1.187</td><td>1.188</td></tr>
<tr><td>Lactic Acid content</td><td>80.33 % w/w</td><td>80.19% w/w (-0.2%)</td><td>79.91% w/w (-0.5%)</td><td>80.50% w/w (+0.2%)</td></tr>
</table>
The study was performed for a total of 24 moth and showed no significant changes in appearance, relative density, acidity and lactic acid content.
The pH (100%) decreased indeed after 24 months. The pH (1%) remained relatively constant during storage. There is no plausible explanation for this observation, except that it is an outlier or due to limitation of the analytical method. As the pH meter has been calibrated with buffers of pH 2, 4, 7 and 9, the measured pH (neat, diluted) of the product is out of the calibration range of the pH meter and the measured values should be taken as approximate.
The stability studies were conducted in the smallest size commercial containers. No incompatibilities between the products and the containers were observed. The material of larger packagings is the same as for the smallest sizes, and as the smallest size packagings have the highest packaging-to-product ratio this is considered worst-case. Therefore, it can be concluded that the products will also be stable in larger packagings.</td><td></td><td></td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>Storage in 10 L HDPE cans at 25°C during 24 months</td><td>Meta SPC 5 Formula 729 (Mida San 331 LW): 24% lactic acid
Batch: AS18/056</td><td>
<table>
<tr><td></td><td>T0</td><td>6 months</td><td>12 months</td><td>24 months</td></tr>
<tr><td>Appearance of the test item</td><td>Transparent colorless liquid</td><td>No change</td><td>No change</td><td>No change</td></tr>
</table>
</td><td>Shelf-life Stability study at 25ºC for 24 months on the test item " Mida San 331 LW" study n° 2018/319 AM</td><td>Acceptable</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>BE remark</th></tr>
<tr><td></td><td>Appearance: visual
pH: CIPAC MT 75.3
Acidity: CIPAC MT 191
Relative density: OECD 109
Lactic acid content: STULV18AA1420-1 GLP – MdP</td><td></td><td>
<table>
<tr><td>Appearance of the packaging</td><td>Semitransparent HDPE plastic tank (10L) closed by screw cap</td><td>No change</td><td>No change</td><td>No change</td></tr>
<tr><td>pH (1%)</td><td>3.15</td><td>3.15</td><td>3.12</td><td>3.15</td></tr>
<tr><td>pH (100%)</td><td>3.29</td><td>3.20</td><td>3.10</td><td>3.21</td></tr>
<tr><td>Acidity (as% w/w of H2SO4)</td><td>9.48% w/w</td><td>9.44% w/w</td><td>9.10% w/w</td><td>9.09% w/w</td></tr>
<tr><td>Relative density</td><td>1.069</td><td>1.066</td><td>1.068</td><td>1.067</td></tr>
<tr><td>Lactic Acid content</td><td>22.86 % w/w</td><td>22.73% w/w (-0.6%)</td><td>23.10% w/w (+1.0%)</td><td>23.45% w/w (+2.6%)</td></tr>
</table>

The study was performed for a total of 24 moth and showed no significant changes in appearance, pH, acidity, relative density and lactic acid content.
The stability studies were conducted in the smallest size commercial containers. No incompatibilities between the products and the containers were observed. The material of larger packagings is the same as for the smallest sizes, and as the smallest size packagings have the highest packaging-to-product ratio this is considered worst-case. Therefore, it can be concluded that the products will also be stable in larger packagings.
</td><td>Belussi C., 2021</td><td></td></tr>
<tr><td>Storage stability test – low</td><td colspan="3">Not required, it is indicated on the label that the product should not be stored at temperatures < 0°C</td><td></td><td>Acceptable</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
temperature stability test for liquids					"Protect from frost" will be added to the label for all products
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Not applicable: The UV-spectrum of L(+) lactic acid shows that no absorbance in the wavelength range of 290-800 nm takes place. Therefore, L(+) lactic acid cannot undergo direct photolysis in sunlight. Furthermore, the products are packed in opaque, non-transparent HDPE containers.				Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C. Version 2.0, May 2018, Section 3.6.4.2 Point 3.4.2 Effects on content of the active substance and technical characteristics of the biocidal product, Where relevant the effects of light, temperature and humidity must be investigated as part of the storage stability studies. Effects of temperature are already addressed by performing stability studies at accelerated and ambient temperatures described above in this Table. Testing effects of humidity does not appear to be relevant for liquid products, as the products are liquids and they are stored in closed containers.				Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards**	In the above-mentioned stability reports, there were no incompatibilities observed between the products and the packaging material.				Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
container material					
Wettability	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018), Section 3.6.5.1 Point 3.5.1 Wettability, Wettability is determined to ensure the preparation is readily wetted in use. The data are required for solid preparations which are to be dispersed in water. The products in this Biocidal Product Family are not solid preparations which are to be dispersed in water and therefore this test is not required.				Not applicable
Suspensibility, spontaneity and dispersion stability	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.2 Point 3.5.2 Suspensibility, spontaneity and dispersion stability, applicability depends on the formulation type (nature) of the biocidal product. This test is required for wettable or water dispersible powders. The products in this Biocidal Product Family are not wettable or water dispersible powders and therefore this test is not required.				Not applicable
Wet sieve analysis and dry sieve test	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.3 Point 3.5.3 Wet sieve analysis and dry sieve test, applicability depends on the formulation type (nature) of the biocidal product. This test is required for wettable powders, suspension concentrates, capsule suspensions and water dispersible granules. The products in this Biocidal Product Family are not wettable powders, suspension concentrates, capsule suspensions or water dispersible granules and therefore this test is not required.				Not applicable
Emulsifiability, re-emulsifiability and emulsion stability	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.4 Point 3.5.4 Emulsifiability, re-emulsifiability and emulsion stability, applicability depends on the formulation type (nature) of the biocidal product. This test is required for emulsions and suspo-emulsions. The products in this Biocidal Product Family are not emulsions or suspo-emulsions and therefore this test is not required.				Not applicable
Disintegration time	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.5 Point 3.5.5 Disintegration time, the disintegration time is applicable to all				Not applicable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
	products that are tablets and depend on disintegration of the tablet in a solvent (water) for optimal efficacy. Applicable to ST (water soluble tablets) and WT (water dispersible tablets) formulations. The products in this Biocidal Product Family are not tablets and therefore this test is not required.				
Particle size distribution, content of dust/fines, attrition, friability	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.6 Point 3.5.6 Particle size distribution, content of dust/fines attrition, friability: Particle size The particle size distribution of powder biocidal products and granules must be addressed. The products in this Biocidal Product Family are not powders or granules and therefore this test is not required. The products in this BPF are also not presented as trigger sprayers and therefore a particle size analysis from trigger sprayers is not required. Dust The dust content of solid preparations (granules and powders) must be determined. The products in this Biocidal Product Family are not powders or granules and therefore this test is not required. Attrition, friability These data are required to determine whether a granular material is robust under normal conditions of use and transport. The products in this Biocidal Product Family are not powders or granules and therefore this test is not required.				Not applicable
Persistent foaming	/	Meta SPC 1 1242 (Chriox WC): 6.8% lactic acid	According to the ECHA Guidance on the Biocidal Products Regulation, Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C. Version 2.0 (May 2018), Section 3.6.5.7 Point 3.5.7 Persistent foaming: Applicability depends on the formulation type (nature) of the biocidal product. The data are required when the product is applied in water for use. The products in this meta SPC are ready-to-use and should not be diluted with water. The test is therefore not required.	/	Not applicable
	/	Meta SPC 2 Mida Agri 830 Post Red: 8% lactic acid	According to the ECHA Guidance on the Biocidal Products Regulation, Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C. Version	/	Not applicable

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>BE remark</th></tr>
<tr><td></td><td></td><td></td><td>2.0 (May 2018), Section 3.6.5.7 Point 3.5.7 Persistent foaming:
Applicability depends on the formulation type (nature) of the biocidal product. The data are required when the product is applied in water for use.
The products in this meta SPC are ready-to-use and should not be diluted with water. The test is therefore not required.</td><td></td><td></td></tr>
<tr><td></td><td>CIPAC MT 47.2</td><td>Meta SPC 3
Mida San 325 DA: 16% lactic acid</td><td>2% dilution: High Foaming (stable foam)

<table><tr><td>Times</td><td>Volume (mL)</td></tr><tr><td>10 seconds</td><td>>60 mL</td></tr><tr><td>1 minute</td><td>>60 mL</td></tr><tr><td>3 minutes</td><td>>60 mL</td></tr><tr><td>12 minutes</td><td>>60 mL</td></tr></table>
The main risk from foaming is a potential excessive skin exposure. The products should all be used with protective gloves which will protect the users sufficiently, and as there are only professional users, there are no safety concerns.</td><td>Persistent Foaming and Dilution Stability report Mida San 325 DA Fernando L., 2021</td><td>The level of foam generated by Mida San 325 DA exceeds 60 mL after 1 minute.

Acceptable provided that the operator wears PPE (gloves) when using the product.</td></tr>
<tr><td></td><td>CIPAC MT 47.2</td><td>Meta SPC 4
Formula 735 (Mida San 332 VB): 80% lactic acid</td><td>10% dilution : Foaming

<table><tr><td>Times</td><td>Volume (mL)</td></tr><tr><td>10 seconds</td><td>20</td></tr><tr><td>1 minute</td><td>15</td></tr><tr><td>3 minutes</td><td>10</td></tr><tr><td>12 minutes</td><td>10</td></tr></table></td><td>Persistent Foaming and Dilution Stability report Formulation 735 Neyt L., 2021</td><td>Acceptable</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>BE remark</th></tr>
<tr><td></td><td>CIPAC MT 47.2</td><td>Meta SPC 5 Formula 729 (Mida San 331 LW): 24% lactic acid</td><td>25% dilution : High foaming

<table><tr><td>Times</td><td>Volume (mL)</td></tr><tr><td>10 seconds</td><td>151.5</td></tr><tr><td>1 minute</td><td>131</td></tr><tr><td>3 minutes</td><td>454</td></tr><tr><td>12 minutes</td><td>118.5</td></tr></table>
The main risk from foaming is a potential excessive skin exposure. The products should all be used with protective gloves which will protect the users sufficiently, and as there are only professional users, there are no safety concerns.</td><td>Persistent Foaming and Dilution Stability report Formulation 729 Neyt L., 2020</td><td>The level of foam generated by Mida San 325 DA exceeds 60 mL after 1 minute.

Acceptable provided that the operator wears PPE (gloves) when using the product.</td></tr>
<tr><td>Flowability/Pourability/Dustability</td><td colspan="3">According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.8 Point 3.5.8 Flowability / Pourability / Dustability, applicability depends on the formulation type (nature) of the biocidal product.
Flowability
Data are only required for granular formulations applied through application equipment
that would subject the granules to pressure and/or heat. The products in this Biocidal Product Family are not granules and therefore this test is not required.
Pourability (rinsability)
The data are required to demonstrate that the user can make use of the maximum
amount of the preparation and that an excessive amount of the material does not remain
in the container. The method is appropriate to suspension concentrates, capsule
suspensions and suspoemulsions. The products in this Biocidal Product Family are not suspension concentrates, capsule suspensions or suspoemulsions and therefore this test is not required.
Dustability</td><td>Not applicable</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
	Data are required showing the preparation may be satisfactorily applied as a dust through the proposed application equipment and that there is no unacceptable compaction or caking following a heat test under pressure. The products in this Biocidal Product Family are not solid preparations and therefore this test is not required.				
Burning rate — smoke generators	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.9 Point 3.5.9 Burning rate - smoke generators, evidence is required that the preparation may be satisfactorily applied as a smoke and that the burning rate and burning completeness (see also sections 3.7.5.10 and 3.7.5.11 of this guidance) support the proposed use. The products in this Biocidal Product Family are not smoke generators and therefore this test is not required.				Not applicable
Burning completeness — smoke generators	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.10 Point 3.5.10 Burning completeness - smoke generators, burning completeness must be determined by weighing the preparation before and after use. The products in this Biocidal Product Family are not smoke generators and therefore this test is not required.				Not applicable
Composition of smoke — smoke generators	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.11 Point 3.5.11 Composition of smoke - smoke generators, the smoke composition must be analysed for the concentration of the active substance and decomposition products, if any, to guarantee that the produced smoke does indeed contain the active substance and no decomposition products. The products in this Biocidal Product Family are not smoke generators and therefore this test is not required.				Not applicable
Spraying pattern — aerosols	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) 3.6.5.12 Point 3.5.12 Spraying pattern - aerosols, Homogeneity must be determined according to FEA method 644 (Filled Aerosols Packs – Evaluation of Aerosol Spray Patterns). Spray diameter must be determined at 30 cm distance. The products in this Biocidal Product Family are not presented as aerosols and therefore this test is not required.				Not applicable
Physical compatibility	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C,				Not applicable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
	Version 2.0 (May 2018) Section 3.6.6 Point 3.6 Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised, data to address the physical and chemical compatibility must be provided when label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products (e.g. dyes). For the products in this Biocidal Product Family there are no label recommendations made to co-apply the biocidal products with other substances, mixtures or biocidal or non-biocidal products and therefore this test is not required.				
Chemical compatibility	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.6 Point 3.6 Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised, data to address the physical and chemical compatibility must be provided when label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products (e.g. dyes). For the products in this Biocidal Product Family there are no label recommendations made to co-apply the biocidal products with other substances, mixtures or biocidal or non-biocidal products and therefore this test is not required.				Not applicable
Degree of dissolution	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.7 Point 3.7 Degree of dissolution and dilution stability, applicability depends on the formulation type (nature) of the biocidal product. Degree of dissolution The information is required for products used in a water-soluble bag and for all tablets. The products in this Biocidal Product Family are not water-soluble bags or tablets and therefore this test is not required.				Not applicable
Dilution stability	/	Meta SPC 1 1242 (Chriox WC): 6.8% lactic acid	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.7 Point 3.7 Degree of dissolution and dilution stability, applicability depends on the formulation type (nature) of the biocidal product. Product in meta-SPC 1 is ready-to-use, thus it is not meant to be diluted with water and therefore this test is not required.	/	Not applicable

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>BE remark</th></tr>
<tr><td></td><td>/</td><td>Meta SPC 2
Mida Agri 830
Post Red: 8% lactic acid</td><td>According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.7 Point 3.7 Degree of dissolution and dilution stability, applicability depends on the formulation type (nature) of the biocidal product.
Product in meta-SPC 1 is ready-to-use, thus it is not meant to be diluted with water and therefore this test is not required.</td><td>/</td><td>Not applicable</td></tr>
<tr><td></td><td>CIPAC MT 179</td><td>Meta SPC 3
Mida San 325 DA: 16% lactic acid</td><td>2% dilution
<table><tr><td>Times</td><td>Visual aspect</td></tr><tr><td>0 minute</td><td>Clear</td></tr><tr><td>1 hour</td><td>Clear</td></tr><tr><td>8 hours</td><td>Clear</td></tr><tr><td>24 hours</td><td>Clear</td></tr></table></td><td>Persistent Foaming and Dilution Stability report Mida San 325 DA Fernando L., 2021</td><td>Acceptable</td></tr>
<tr><td></td><td>CIPAC MT 179</td><td>Meta SPC 4
Formula 735 (Mida San 332 VB): 80% lactic acid</td><td>10% dilution
<table><tr><td>Times</td><td>Visual aspect</td></tr><tr><td>0 minute</td><td>Clear – No visible residues</td></tr><tr><td>5 minutes</td><td>Clear – No visible residues</td></tr><tr><td>1 hour</td><td>Clear – No visible residues</td></tr><tr><td>8 hours</td><td>Clear – No visible residues</td></tr><tr><td>18 hours</td><td>Clear – No visible residues</td></tr><tr><td>24 hours</td><td>Clear – No visible residues</td></tr></table></td><td>Persistent Foaming and Dilution Stability report Formulation 735 Neyt L., 2021</td><td>Acceptable</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>BE remark</th></tr>
<tr><td></td><td>CIPAC MT 179</td><td>Meta SPC 5 Formula 729 (Mida San 331 LW): 24% lactic acid</td><td>25% dilution
<table><tr><td>Times</td><td>Visual aspect</td></tr><tr><td>0 minute</td><td>Clear – No visible residues</td></tr><tr><td>5 minutes</td><td>Clear – No visible residues</td></tr><tr><td>1 hour</td><td>Clear – No visible residues</td></tr><tr><td>8 hours</td><td>Clear – No visible residues</td></tr><tr><td>18 hours</td><td>Clear – No visible residues</td></tr><tr><td>24 hours</td><td>Clear – No visible residues</td></tr></table></td><td>Persistent Foaming and Dilution Stability report Formulation 729 Neyt L., 2020</td><td>Acceptable</td></tr>
<tr><td>Surface tension</td><td>EC A.5, OECD 115</td><td>Meta SPC 1 1242 (Chriox WC): 6.8% lactic acid</td><td>Neat formulation: 27 mN/m</td><td>Certificate of Analysis No. 004/18 – Laboratorio control Giorgi S., 2018</td><td>Acceptable</td></tr>
<tr><td></td><td>ASTM D1331</td><td>Meta SPC 2 Mida Agri 830 Post Red: 8% lactic acid</td><td>Neat formulation: 34.1 mN/m</td><td>Test report BEANTJ20105358 -XX882839 Kerkhofs N., 2020</td><td>Acceptable</td></tr>
<tr><td></td><td>EC A.5, OECD 115</td><td>Meta SPC 3 Mida San 325 DA: 16% lactic acid</td><td>2% Dilution: 28.9 mN/m</td><td>Certificate of Analysis No. 005/18 – Laboratorio control Giorgi S., 2018</td><td>Acceptable</td></tr>
<tr><td></td><td>EC A.5, OECD 115</td><td>Meta SPC 4 Formula 735 (Mida San 332</td><td>10% Dilution : 59.8 mN/m</td><td>Certificate of Analysis No. 001/18 –</td><td>Acceptable</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
		VB): 80% lactic acid Batch: AS21/004		Laboratorio control Giorgi S., 2018	
	EC A.5, OECD 115	Meta SPC 5 Formula 729 (Mida San 331 LW): 24% lactic acid Batch: AS21/005	25% Dilution : 33.5 mN/m	Certificate of Analysis No. 002/18 – Laboratorio control Giorgi S., 2018	Acceptable
Viscosity	EN ISO 3104	Meta SPC 1 1242 (Chriox WC): 6.8% lactic acid	20ºC: sample is in a gel-like solid state at 20°C. Kinematic viscosity can not be determined. 40ºC: 181.3 mm^2/s The product has a high viscosity.This property provides for a longer adherence to surfaces which necessary for toilet bowl disinfectants.	Test report BEANTJ20105358 -XX882835 Kerkhofs N., 2020	Acceptable
	OECD 114	Meta SPC 1 1242 (Chriox WC): 6.8% lactic acid Batch: 1806000755	20°C : pseudoplastic like fluid 10.3 mPa.s 40°C : pseudoplastic like fluid 8.6 mPa.s	Shelf-life stability study at 25ºC for 24 months on the test item "Chriox WC" Report 2018/169AM Belussi C., 2020	Acceptable
	CIPAC MT 192	Meta SPC 2 Mida Agri 830 Post Red: 8% lactic acid	20°C: 3400 mPa.s 40°C: 3200 mPa.s	Shelf-life stability study at 54ºC for 14 days and at 25ºC for 24	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE remark
		Batch 101221		months on the test item "Mida Agri 830 Post Red" Interim Report SS-2021-091 Frasson S., 2022	
	EN ISO 3104	Meta SPC 3 Mida San 325 DA: 16% lactic acid	20ºC: 1.061 mm^2/s 40ºC: 0.7069 mm^2/s	Test report BEANTJ20105358 -XX882836 Kerkhofs N., 2020	Acceptable
	EN ISO 3104	Meta SPC 4 Formula 735 (Mida San 332 VB): 80% lactic acid	20ºC: 20.18 mm^2/s 40ºC: 8.186 mm^2/s	Test report BEANTJ21100401 -XXI1030746 Kerkhofs N., 2021	Acceptable
	EN ISO 3104	Meta SPC 5 Formula 729 (Mida San 331 LW): 24% lactic acid	20ºC: 3.824 mm^2/s 40ºC: 2.048 mm^2/s	Test report BEANTJ21100401 -XXI1030747 Kerkhofs N., 2021	Acceptable

Conclusion on the physical, chemical and technical properties of the product

Meta SPC 1

Chriox WC (Meta SPC 1) is a ready-to-use product (AL). The product is a light green opaque liquid with a relative density of 1.107 and a surface tension of 27 mN/m. The pH of the pure product is 2.19. It has a kinematic viscosity of 181.3 mm^2/s (at 40°C) and a dynamic viscosity of 10.3mPa.s (at 20°C) and 8.6 mPa.s (at 40°C). This property provides for a longer adherence to surfaces which necessary for toilet bowl disinfectants.
With regard to product stability, no accelerated storage data and low temperature data are available, which is addressed by storage condition restrictions ("Do not store at temperatures above 30°C" and "Protect from frost"). Long term storage study at ambient temperature shows that Chriox WC is stable in HDPE packaging (bottle and can).
All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

Shelf-life for Chriox WC (Meta SPC 1): 24 months

Meta SPC 2

Mida Agri 830 Post Red (Meta SPC 2) is a ready-to-use product (AL). The product is a brown liquid with a density of 1014 kg/m^3 and a surface tension of 34.1 mN/m. The pH of the pure product is 3.52. It has a dynamic viscosity of 3400 mPa.s (at 20°C) and 3200 mPa.s (at 40°C).
With regard to product stability, no low temperature data is available, which is addressed by storage condition restriction ("Protect from frost"). The stability of L-(+)-Lactic acid during the accelerated storage is not demonstrated at higher temperatures, the restriction measure "do not store at temperatures above 30°C" will be added on the label. Long term storage study at ambient temperature shows that Mida Agri 830 Post Red is stable in HDPE packaging (can, vessel and IBC) for at least one year.
All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

Shelf-life for Mida Agri 830 Post Red (Meta SPC 2): 12 months

Meta SPC 3

Mida San 325 DA (Meta SPC 3) is a soluble concentrate (SL). The product is a light yellow transparent liquid with a relative density of 1.083 and a surface tension of 28.9 mN/m (2% dilution). The pH of the pure product is 0.46 and the pH of the 1% dilution is 2.16. It has a kinematic viscosity of 1.061 mm^2/s (at 20°C) and 0.7069 mm^2/s (at 40°C). The product is high foaming and it should be used with protective gloves.
With regard to product stability, no low temperature data is available, which is addressed by storage condition restriction ("Protect from frost"). The accelerated storage is not demonstrated at higher temperature than 40°C, the restriction measure "do not store at temperatures above 40°C" will be added on the label. Accelerated storage and long term storage study at ambient temperature shows that Mida San 325 DA is stable in HDPE packaging (can, vessel and IBC).
All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

Shelf-life for Mida San 325 DA (Meta SPC 3): 24 months

Meta SPC 4

Mida San 332 VB (Meta SPC 4) is a soluble concentrate (SL). The product is a colorless transparent liquid with a relative density of 1.188 and a surface tension of 59.8 mN/m (10% dilution). The pH of the pure product is 0.60 and the pH of the 1% dilution is 2.36. It has a kinematic viscosity of 20.18 mm^2/s (at 20°C) and 8.186 mm^2/s (at 40°C). The product is foaming.

With regard to product stability, no low temperature data is available, which is addressed by storage condition restriction ("Protect from frost"). The accelerated storage is not demonstrated at higher temperature than 40°C, the restriction measure "do not store at temperatures above 40°C" will be added on the label. Accelerated storage and long term storage study at ambient temperature shows that Mida San 332 VB is stable in HDPE packaging (can, vessel and IBC).
All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

Shelf-life for Mida San 332 VB (Meta SPC 4) : 24 months

Meta SPC 5

Mida San 331 LW (Meta SPC 5) is a soluble concentrate (SL). The product is a colorless transparent liquid with a relative density of 1.069 and a surface tension of 33.5 mN/m (25% dilution). The pH of the pure product is 3.29 and the pH of the 1% dilution is 3.15. It has a kinematic viscosity of 3.824 mm^2/s (at 20°C) and 2.048 mm^2/s (at 40°C). The product is high foaming and it should be used with protective gloves.
With regard to product stability, no low temperature data is available, which is addressed by storage condition restriction ("Protect from frost"). The accelerated storage is not demonstrated at higher temperature than 40°C, the restriction measure "do not store at temperatures above 40°C" will be added on the label. Accelerated storage and long term storage study at ambient temperature shows that Mida San 331 LW is stable in HDPE packaging (can, vessel and IBC).
All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

Shelf-life for Mida San 331 LW (Meta SPC 5) : 24 months

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Be remark
Explosives	/	Meta SPC 1, 3, 4 and 5	According to the ECHA guidance on the application of the CLP criteria, Section 2.1.4.2, The screening procedure may be used for new substances or mixtures which are suspected of having explosive properties. As the products in this Biocidal Product Family do not contain any new ingredients or ingredients classified as explosive (active ingredients or coformulants), and there are no chemical reactions between the products or between the products and air, there is no reason to expect that they would have any explosive properties and testing for explosive properties is not necessary. In addition, experience with manufacturing and handling of the products does not indicate any explosive properties.	/	Acceptable
	DSC MTC ST/SG/AC, 10/11/Rev.05 – Part III, Appendix 6, Section 3	Meta SPC 2 Mida Agri 830 Post Red: 8% lactic acid Batch 321922	The Mida Agri 830 Post Red presents a total mean area (j/g) of -48.40 j/g, which is less than 500j/g and therefore the test item is not a candidate for classification as a UN Class 1 explosive substance.	Determination of the explosive properties of the product MIDA AGRI 830 Report 23126-01C M. Lodi (2023)	Acceptable
Flammable gases	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.2 Point 4.2 Flammable gases Criteria for flammable gases are described in the section 2.2 of Annex I to the CLP Regulation, Test according to ISO 10156 and EN 1839. The products in this Biocidal Product Family are not gases and therefore this test is not required.				Not applicable
Flammable aerosols	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.3 Point 4.3 Flammable aerosols Criteria for flammable aerosols are described in the section 2.36 of Annex I to the CLP Regulation. Test according to 75/324/EC amended by 2008/47/EC which are harmonised with UNMTC Section 31. The products in this Biocidal Product Family are not aerosols and therefore this test is not required.				Not applicable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Be remark
Oxidising gases	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.4 Point 4.4 Oxidising gases Criteria for oxidising gases are described in the section 2.4 of Annex I to the CLP Regulation. Tests or calculation methods as described in ISO 10156 (Gases and gas mixtures. Determination of fire potential and oxidising ability for the selection of cylinder valve outlets) as amended should be performed. The products in this Biocidal Product Family are not gases and therefore this test is not required.				Not applicable
Gases under pressure	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.5 Point 4.5 Gases under pressure, Criteria for gases under pressure are described in the section 2.5 of Annex I to the CLP Regulation. The products in this Biocidal Product Family are not gases and therefore this test is not required.				Not applicable
Flammable liquids	EN ISO 2719	Meta SPC 1 1242 (Chriox WC): 6.8% lactic acid	No flashpoint detected, test discontinued at 88°C due to excessive foaming. Not flammable	Test report BEANTJ20105358-XX882835 Kerkhofs N., 2020	Acceptable
	EN ISO 2719	Meta SPC 2 Mida Agri 830 Post Red: 8% lactic acid	No flashpoint detected, test discontinued at 101°C due to boiling. Not flammable	Test report BEANTJ20105358-XX882839 Kerkhofs N., 2020	Acceptable
	EN ISO 2719	Meta SPC 3 Mida San 325 DA: 16% lactic acid	No flashpoint detected, test discontinued at 103°C due to boiling. Not flammable	Test report BEANTJ20105358-XX882836 Kerkhofs N., 2020	Acceptable
	EN ISO 2719	Meta SPC 4 Formula 735 (Mida San 332 VB): 80% lactic acid	No flashpoint detected, test discontinued at 118°C due to excessive foaming. Not flammable	Test report BEANTJ21100401-WWI1029754 Kerkhofs N., 2021	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Be remark
	EN ISO 13736	Meta SPC 5 Formula 729 (Mida San 331 LW): 24% lactic acid	33°C Flam. Liq. 3 H226: Flammable liquid and vapour	Test report BEANTJ18103902-XVIII454064 De Ridder A., 2018	Acceptable Mida San 331 LW is classified as Flam. Liq. 3 H226: Flammable liquid and vapour
Flammable solids	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.7 Point 4.7 Flammable solids, Criteria for flammable solids are described in the section 2.7 of Annex I to the CLP. Regulation. Test according to UN Test N.1 as described in Section 33.2.1 of the UN-MTC. The products in Biocidal Product Family are not solids and therefore this test is not required.				Not applicable
Self-reactive substances and mixtures	According to the ECHA Guidance on Application of the CLP criteria, Version 5.0, July 2017, Section 2.8.4.2, substances and mixtures must be considered for classification in this hazard class as a self-reactive substance or mixture unless: Annex I: 2.8.2.1. […] (a) they are explosives, according to the criteria given in 2.1; (see waiver above - explosives) (b) they are oxidising liquids or solids, according to the criteria given in 2.13 or 2.14, except that mixtures of oxidising substances, which contain 5 % or more of combustible organic substances shall be classified as self-reactive substances according to the procedure defined in 2.8.2.2; (see waiver below - oxidizing liquids) (c) they are organic peroxides, according to the criteria given in 2.15; (see waiver below - organic peroxides) (d) their heat of decomposition is less than 300 J/g; or (e) their self-accelerating decomposition temperature (SADT) is greater than 75 °C for a 50 kg package (See UN RTDG, Manual of Test and Criteria, sub-sections 28.1, 28.2, 28.3 and Table 28.3.) 2.8.2.2. Mixtures of oxidising substances, meeting the criteria for classification as oxidizing substances, which contain 5 % or more of combustible organic substances and which do not meet the criteria mentioned in (a), (c), (d) or (e) in 2.8.2.1, shall be subjected to the selfreactive substances classification procedure; Such a mixture showing the properties of a self-reactive substance type B to F (see 2.8.2.3) shall be classified as a self-reactive substance.				Acceptable

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Be remark</th></tr>
<tr><td></td><td colspan="4">The mixtures in this BPF do not contain any oxidizing or combustible organic substances.
According to the UN Manual of Tests and Criteria, 7th revised edition (2019) Appendix 6, A6.5.1 the classification procedure for self-reactive substances does not need to be applied if (a) there are no chemical groups with explosive or self-reactive properties:
<table><tr><th>Structural feature</th><th>Examples</th></tr><tr><td>Mutually reactive groups</td><td>Aminonitriles, haloanilines, organic salts of oxidizing acids</td></tr><tr><td>S=O</td><td>Sulphonyl halides, sulphonyl cyanides, sulphonyl hydrazides</td></tr><tr><td>P-O</td><td>Phosphites</td></tr><tr><td>Strained rings</td><td>Epoxides, aziridines</td></tr><tr><td>Unsaturation</td><td>Olefins, cyanates</td></tr></table>or (b) the SADT is greater than 75°C or the exothermic decomposition energy is less than 300 J/g.
There are no chemical groups in this BPF with explosive or self-reactive properties.</td><td></td></tr>
<tr><td></td><td>Heat-accumulation storage test (HAST) as described in the United Nations Manual of Tests and Criteria, seventh revised edition, test H.4.</td><td>Meta SPC 3
Mida San 325 DA: 16% lactic acid</td><td>A SADT test will be conducted on the worst-case product of the BPF. 'Meta SPC 3' was selected for testing as this formulation has the highest content of other ingredients (other than AS and water). It also has the lowest water content, i.e. it is the least diluted.
'Meta SPC 4' was left out as this is purely an aqueous dilution of lactic acid while pure lactic acid is only classified as irritating. A dilution will thus by no means have self-reactive properties.

The self-accelerating decomposition temperature (SADT) of Mida San 325 DA was determined to be higher than 75 °C. Hence, Mida San 325 DA is by definition not classified as a self-reactive substance. This conclusion can be applied to the entire range of lactic acid formulations.</td><td>Some hazard properties of a series of lactic acid formulations
TNO 2021 R10710
W.A. Mak, 2021</td><td></td></tr>
<tr><td></td><td>DSC
MTC
ST/SG/AC, 10/11/Rev.05 – Part III,</td><td>Meta SPC 2
Mida Agri 830 Post Red: 8% lactic acid
Batch 321922</td><td>The Mida Agri 830 Post Red presents a total mean area (j/g) of -48.40 j/g, which is less than 300j/g and therefore the test item is not a candidate for classification as self-reactive substances and mixtures.</td><td>Determination of the explosive properties of the product MIDA AGRI 830</td><td>Acceptable</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Be remark
	Appendix 6, Section 3			Report 23126-01C M. Lodi (2023)	
Pyrophoric liquids	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.9 Point 4.9 Pyrophoric liquids, Criteria for pyrophoric liquids are described in the section 2.9 of Annex I to the CLP Regulation, a test according to UN Test N.3 as described in Section 33.3.1.5 of the UN-MTC should be conducted. However, according to the additional classification considerations in CLP Annex I, 2.9.4, the classification procedure for pyrophoric liquids need not be applied when experience in manufacture or handling shows that the liquid does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the liquid is known to be stable at room temperature for prolonged periods of time (days)). From experience with manufacture and handling, it is known that the products in this BPF do not ignite spontaneously on coming into contact with air at normal temperatures. From the stability studies presented in this assessment report it is demonstrated that the liquids are stable at room temperature for prolonged periods of time (up to 24 months).				Acceptable
Pyrophoric solids	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.10 Point 4.10 Pyrophoric solids, Criteria for pyrophoric solids are described in the section 2.10 of Annex I to the CLP Regulation. Test according to UN Test N.2 as described in Section 33.3.1.4 of the UN-MTC. The products in this Biocidal Product Family are not solids and therefore this test is not required.				Not applicable
Self-heating substances and mixtures	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.11.4.2, In general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore liquids are not classified as self-heating. However, if liquids are adsorbed on a large surface (e.g. on powder particles), a self-heating hazard should be considered. The latter is not the case for the products in this BPF and therefore the test is not required. According to the UN Manual of Tests and Criteria, 7th revised edition (2019) Appendix 6, A6.5.3.1, the classification procedure for pyrophoric solids and liquids need not be applied when experience, in production or handling, shows that the substance does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the substance is known to be stable at room temperature for prolonged periods of time). The absence of self-heating properties of the products in this BPF is confirmed by experience in production and handling, and by stability studies.				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Be remark
Substances and mixtures which in contact with water emit flammable gases	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.12 Point 4.12 Substances and mixtures which in contact with water emit flammable gases, Criteria for substances and mixtures which in contact with water emit flammable gases are described in section 2.12 of Annex I to the CLP Regulation. Test according to UN Test N.5 as described in Section 33.4.1.4 of the UN-MTC The products in this Biocidal Product Family do not contain any substances (active substance or coformulants) which emit flammable gases in contact with water and therefore this test is not required.				Acceptable
Oxidising liquids	/	Meta SPC 1, 3, 4 and 5	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.13 Point 4.13 Oxidising liquids, Criteria for oxidising liquids are described in the section 2.13 of Annex I to the CLP Regulation. Test according to UN Test O.2 as described in Section 34.4.2 of the UN-MTC. The products in this Biocidal Product Family (active substance or coformulants) do not contain any substances which are classified as oxidising and therefore this test is not required. Furthermore, experience in the handling of these products indicates that they are not oxidizing. According to the UN Manual of Tests and Criteria, 7th revised edition (2019) Appendix 6, A6.6.1.1, for organic compounds the classification procedure need not be applied if the compound does not contain oxygen, fluorine or chlorine. The products in this BPF indeed do not contain oxygen, fluorine or chlorine and therefore the test is not required.	/	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Be remark
	34.4.2 Test O.2 for oxidizing liquids of Manual of Tests and Criteria - UN	Meta SPC 2 Mida Agri 830 Post Red: 8% lactic acid Batch 321922	The mean pressure rise time for Mida Agri 830 Post Red (1:1 mixture with cellulose) was greater than the mean pressure rise time of the reference (1:1 mixture with 65% aqueous Nitric Acid and cellulose), therefore the test item is considered as a not oxidizing substance.	Determination of the oxidizing properties of the Mida Agri 830 Pso Red Report: 23126-02C E. Morganti (2023)	Acceptable
Oxidising solids	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.14 Point 4.14 Oxidising solids, Criteria for oxidising solids are described in the section 2.14 of Annex I to the CLP Regulation. Test according to UN Test O.17 as described in Section 34.4.1 of the UN-MTC. The products in this Biocidal Product Family are not solids and therefore this test is not required.				Not applicable
Organic peroxides	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.15 Point 4.15 Organic peroxides, Criteria for organic gases are described in the section 2.15 of Annex I to the CLP Regulation. Test according to UN Test series A to H as described in Section 28 of the UN-MTC. The products in this Biocidal Product Family do not contain any substances (active substance or coformulants) which are classified as organic peroxides and therefore this test is not required.				Acceptable
Corrosive to metals	Method 37.4	Meta SPC 1 1242 (Chriox WC): 6.8% lactic acid	Aluminium: Not corrosive (the maximum weight loss after 7 days : 2.31%) Steel: Not Corrosive (the maximum weight loss after 7 days : 4.37%) A uniform very thin layer of abrasion without any evidence of pitting point was observed for each metal specimen: steel and aluminium.	Determination of the Corrosion to Metal of Chriox WC code 1242 20113-01C Gazzotti L., 2020	Acceptable
	Method 37.4	Meta SPC 2 Mida Agri 830 Post Red: 8% lactic acid	Aluminium (Type 7075-T6): Not corrosive (the maximum weight loss after 7 days : 7.295%) Steel (Type S235JR+CR): Not Corrosive (the maximum weight loss after 7 days : 2.411%)	Corrosion to Metal of Mida Agri 830 Post Red 20110-01C Gazzotti L., 2020	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Be remark
			A uniform thin layer of abrasion without any evidence of pitting point was observed for each metal specimen: steel and aluminium.		
	Method 37.4	Meta SPC 3 Mida San 325 DA: 16% lactic acid	Aluminium: Not corrosive (the maximum weight loss after 7 days : 8.74%) Steel: Corrosive (the maximum weight loss after 7 days : 53.31%) A uniform layer of corrosion without any evidence of pitting point was observed for the steel specimen. For aluminum specimen a uniform opacification of the metal surface was observed. Corrosive to metals category 1 H290: May be corrosive to metals	Determination of the Corrosion to Metal of Mida San 325 DA 20114-01C Gazzotti L., 2020	Acceptable Mida San 325 DA is classified as Metal Corr.1 H290: May be corrosive to metals
	Method 37.4	Meta SPC 4 Formula 735 (Mida San 332 VB): 80% lactic acid	Aluminium: Not corrosive (the maximum weight loss after 7 days : 0.263%) Steel: Not Corrosive (the maximum weight loss after 7 days : 2.248%) A uniform very thin layer of abrasion without any evidence of pitting point was observed for steel metal specimen. For the aluminium, only a uniform opacification of the metal surface was observed.	Determination of the Corrosion to Metal of Mida San 332 VB 20098-01C Gazzotti L., 2020	Acceptable
	Method 37.4	Meta SPC 5: Formula 729 (Mida San 331 LW): 24% lactic acid	Aluminium: Not corrosive (the maximum weight loss after 7 days : 0.555%) Steel: Not Corrosive (the maximum weight loss after 7 days : 5.949%) A uniform thin layer of abrasion without any evidence of pitting point was observed for each metal specimen: steel and aluminium.	Determination of the Corrosion to Metal of Mida San 331 LW 20097-01C Gazzotti L., 2020	Acceptable
Auto-ignition temperatures of products (liquids and gases)	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.17 Point 4.17 Additional physical indicators for hazards, 2.7.17.1 Point 4.17.1 Auto-ignition temperature (liquids and gases), The test procedure is applicable to gases, liquids and vapours which, in the presence of air, can be ignited by a hot surface.				Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Be remark
	The products in this Biocidal Product Family do not contain any pyrophoric liquids (active substance or coformulants): the auto-ignition temperature of isopropanol is ca. 399°C. Note : An auto-ignition test will be conducted on the product from meta SPC 3 (the worst case). The results of the test can be added to the PAR as post-authorization data.				
Relative self-ignition temperature for solids	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.17.2 Point 4.17.2 Relative self-ignition temperature for solids, Criteria for self-heating substances are described in Section 2.11 of Annex I to the CLP Regulation. Test according to UN Test N.4 as described in Section 33.3.1.6 of the UN-MTC. The products in this Biocidal Product Family are not solids and therefore this test is not required.				Not applicable
Dust explosion hazard	According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.17.3 Point 4.17.3 Dust explosion hazard, A dust explosion hazard is applicable to all powders and products containing, or able to produce, dust that can either ignite or explode when exposed to an ignition source when dispersed in air (relevant for particulates up to 1 mm in diameter). The products in this Biocidal Product Family are not powders or contain/produce powders and therefore this test is not required.				Not applicable

2.2.3 Physical hazards and respective characteristics

Conclusion on the physical hazards and respective characteristics of the product
Meta SPC 1, 2 and 4 Based on the evaluation of different physical hazards of Chriox WC (Meta SPC1), Mida Agri 830 Post Red (Meta SPC 2) and Mida San 332 VB (Meta SPC 4), it can be concluded that they do not have explosive and oxidising properties. The products are not flammable liquid and have no property to ignite by contact with water or air. They are considered as not corrosive to metals. **Meta SPC 3** Based on the evaluation of different physical hazards of Mida San 325 DA, it can be concluded that it does not have explosive and oxidising properties. The product is not flammable liquid. An SADT test on the worst-case formulation (Mida San 325 DA) will be conducted to confirm the absence of self-heating or self-reactive properties. It is considered to be corrosive to metals. Therefore, H290 (Metal Corr. 1) is assigned. **Meta SPC 5** Based on the evaluation of different physical hazards of Mida San 331 LW, it can be concluded that it does not have explosive and oxidising properties. It is considered as not corrosive to metals. The product is classified as Flam Liq 3 according to CLP table 2.6.1. Therefore, H226 is assigned.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues										
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Precision**	**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD			
Active substance in 1242 (Chriox WC)	HPLC-UV	3 fortifications with 2 measurements (50%, 100% and 150%)	Between 3.43% - 10.30% w/w with respect to the sample, correspondin g to 50.47% - 151.40 of the theorical value of the analyse in the sample (n=5) R= 0.9979 R^2=0.9958 Slope= 362.6911 Intercept= -9.2367	No peak of blanck or placebo interferes with that of the analyte. Any interference <3% can be neglected.	99.26 % – 99.95 %	99.66 %	0.26%	Assay = 6.65% w/w RSD = 0.31%	/	Validation of an HPLC-UV method for the identification and the quantification of the active ingredient lactic acid in the test item "Chriox WC" STUV18AA1233-1 GLP Cassese S., 2018

e-CA remark: HPLC method

Instrument	HPLC-UV

Column	Aminex HPX-87H, 300*7.8nm, BIO RAD, s/N 447821
Column temperature	50°C
Wavelenght UV	210 nm
Injection Volume	5 µL
Flow	0.6 mL/min
Stop time	20 min
Mobile phase	100% H2SO4 5mM
Autosampler temperature	10°C
Retention time	Around 12.2 min

Preparation of sample solution:

About 294mg of the test item were exactly weighed into a 10mL volumetric flask and brought to volume with the solvents mixture phosphoric acid 6.5M: water 1:5.

Preparation of placebo:

About 269mg of the placebo exactly weighed into a 10mL volumetric flask and brought to volume with the solvents mixture phosphoric acid 6.5M: water 1:5.

Mida Agri 830 Post Red (Batch: 101221)	HPLC-UV	1 fortifications with 3 measurements (100%)	Between 3.90 – 12.32 g/100g with respect to the sample, corresponding to 49% - 154 % of the theorical value of the	No interferences were observed in placebo and blank solution at retention times of the analyte	98% - 99%	99%	1	Assay = 7.54% w/w RSD = 0.85%	/	Validation of an analytical procedure for the determination of the active substance L-(+)-Lactic acid (CAS 79-33-4) in the product "Mida Agri 830 Post Red",

			analyse in the sample (n=5) R= 1 R^2=1 Slope= 1435 Intercept= 0							FR21.503921. 0002 Bazza G., 2021.

e-CA remark: HPLC method (réf: SOPa-LABCHI-512)

Column	Aminex HPX-87H, 300*7.8nm*9µm
Column temperature	25°C
Mobile phase	4mM Sulfiric acid solution
Flow	0.6 mL/min
Elution	Isocratic
Injection Volume	20 µL
Detector	214nm -/+ 4nm
Run time	20 minutes
L-(+)-Lactic acid retention time	Peak 1 at about 11 min, peak 2 at about 12 min

Preparation of the Test Solution:

About 523 mg of test item were accurately weighed into a 20 mL volumetric flask and diluted to volume with blank solution. 4mL of this solution were diluted to 20 mL with blank solution.

Preparation of the placebo:

520.3mg of placebo were accurately weighed into a 20 mL volumetric flask and diluted to volume with blank solution.										
Active substance in Mida San 325 DA	HPLC-UV	3 fortifications with 2 measurements (50%, 100% and 150%)	Between 8.0% - 24.0% w/w with respect to the sample, corresponding to 50.1% - 150.2 of the theorical value of the analyse in the sample (n=5) R= 1.0000 R^2=1.0000 Slope= 701.4510 Intercept= 11.9962	No peak of blanck or placebo interferes with that of the analyte. Any interference <3% can be neglected.	99.87 % - 100.36 %	100.14 %	0.18%	Assay = 15.00% w/w RSD= 0.29%	/	Validation of an HPLC-UV method for the identification and the quantification of the active ingredient lactic acid in the test item "Mida San 325 DA" STUV18AA2121-1 GLP Cassese S., 2018

e-CA remark: HPLC method

Instrument	HPLC-UV
Column	Restek Allure Organic Acid – 300*4.6 mn, 5µ, s/n 18020404T
Column temperature	35°C
Wavelenght UV	210 nm
Injection Volume	15 µL

<table>
<tr><td>Flow</td><td>1.0 mL/min</td></tr>
<tr><td>Stop time</td><td>30 min</td></tr>
<tr><td>Mobile phase</td><td>A%: KH2PO4 20 mM, pH=2.5
B%: CAN
<table>
<tr><td>t(min)</td><td>0</td><td>9</td><td>11</td><td>20</td><td>20.1</td><td>30</td></tr>
<tr><td>A%</td><td>100</td><td>100</td><td>40</td><td>40</td><td>100</td><td>100</td></tr>
<tr><td>B%</td><td>0</td><td>0</td><td>60</td><td>60</td><td>0</td><td>0</td></tr>
</table></td></tr>
<tr><td>Autosampler temperature</td><td>20°C</td></tr>
</table>

Preparation of sample solution:

About 125mg of the test item were exactly weighed into a 10mL volumetric flask and brought to volume with the solvents mixture (phosphoric acid 5.5M: water 1:5.)

Preparation of placebo:

About 100.1mg of the placebo exactly weighed into a 10mL volumetric flask and brought to volume with the solvents mixture (phosphoric acid 5.5M: water 1:5.)

Active substance in Formula 735 (Mida San 332 VB)	HPLC-UV	3 fortifications with 2 measurements (50%, 100% and 150%)	Between 40.14% - 120.43% w/w with respect to the sample, correspondin g to 50.18% - 150.54 of the theorical value of the	No peak of blank or placebo interferes with that of the analyte. Any interference <3% can be neglected.	99.59 % - 100.56 %	99.97 %	0.37%	Assay = 79.73% w/w RSD= 0.41%	/	Validation of an HPLC-UV method for the identification and the quantification of the active ingredient lactic acid in the test item "Mida San 332 VB" STUV18AA2167-1 GLP

			analyse in the sample (n=5) R= 1.0000 R^2=0.9999 Slope= 682.2547 Intercept= -2.9759							Cassese S., 2018

e-CA remark: HPLC method

Instrument	HPLC-UV
Column	Restek Allure Organic Acid – 300*4.6 mn, 5µ, s/n 18020404T
Column temperature	35°C
Wavelenght UV	210 nm
Injection Volume	15 µL
Flow	1.0 mL/min
Stop time	30 min
Mobile phase	A%: KH2PO4 20 mM, pH=2.5 B%: CAN
Autosampler temperature	20°C

t(min)	0	8	10	15	15.1	25
A%	100	100	50	50	100	100
B%	0	0	50	50	0	0

Preparation of sample solution: About 625mg of the test item were exactly weighed into a 50mL volumetric flask and brought to volume with the solvents mixture phosphoric acid 5.5M. An aliquot of this solution was treated according to the hydrolysis process (an aliquot of the stock solutions were transferred in 50mL glass vials were stopped. The solutions were heated to 90°C for 120min. The solutions were cooled.). Then 2.0mL of the hydrolysis solution were transferred into a 10mL volumetric flask and brought to volume with HP water. Preparation of placebo: About 80mg of the placebo exactly weighed into a 20mL volumetric flask and brought to volume with the solvents mixture phosphoric acid 5.5M (sol P). 1mL of this solution (sol P) was transferred into a 10mL volumetric flask and brought to volume with HP water.										
Active substance in Formula 729 (Mida San 331 LW)	HPLC-UV	3 fortifications with 2 measurements (50%, 100% and 150%)	Between 12.00% - 36.00% w/w with respect to the sample, corresponding to 50.0% - 150.0 of the theorical value of the analyse in the sample (n=5) R= 1.0000 R^2=1.0000 Slope= 365.8616 Intercept= -1.9408	No peak of blanck or placebo interferes with that of the analyte. Any interference <3% can be neglected.	*99.87 % - 100.87 %*	*100.39 %*	*0.34*	Assay = 21.85% w/w* RSD= 0.26%	/	Validation of an HPLC-UV method for the identification and the quantification of the active ingredient lactic acid in the test item "Mida San 331 LW" STUV18AA1420-1 GLP Cassese S., 2018
e-CA remark: HPLC method Instrument: HPLC-UV										

Column	Aminex HPX-87H, 300*7.8nm, BIO RAD, s/N 447821
Column temperature	50°C
Wavelenght UV	210 nm
Injection Volume	5 µL
Flow	0.6 mL/min
Stop time	17 min
Mobile phase	100% H2SO4 5mM
Autosampler temperature	20°C
Retention time	Around 12.3 min

Preparation of sample solution:

About 416.7mg of the test item were exactly weighed into a 10mL volumetric flask and brought to volume with the solvents mixture phosphoric acid 5.5M. Then 2.0mL of the hydrolysis solution were transferred into a 10mL volumetric flask and brought to volume with HP water.

Preparation of placebo:

About 80mg of the placebo exactly weighed into a 20mL volumetric flask and brought to volume with the solvents mixture phosphoric acid 5.5M Then, 2.0mL was transferred into a 10mL volumetric flask and brought to volume with HP water.

*The sample used for the validated method of Mida San 331 LW contained 21.85% of Lactic Acid. This concentration is out of the tolerance limits of AS content at the point of manufacture as stated in the APCP guidance. The method validation study is meant to prove that the method is specific, linear, precise and accurate in the range of applicability. The method was validated between 50% and 150% of active ingredient theoretical content, in this case the theoretical content is 24%w/w so the method was validated between 12%w/w and 36%w/w. In this range the method is able to quantify correctly the active ingredient content. If the active ingredient concentration in the sample used for validation study is different from the theoretical concentration, that is not a problem because it still falls in the applicability range. Moreover, the range of applicability is calculated on theoretical value and not on the experimental value.

Analytical methods for Substances of Concern (SoCs)

Analytical methods for Substances of Concern (SoCs) are not presented. According to the Technical Agreements for Biocides (APCP, 2.0, 2020), analytical methods are not required for SoCs that cannot be formed during storage and their concentrations remain unchanged. Between manufacture and use, there are no external sources of these SoCs which are coformulants. The products are stored in closed containers and nothing is added. The SoCs also can't be formed during storage. There are no chemical reactions in the products between the active substance and coformulants, or between coformulants so their concentration remains unchanged. Theoretically an increase of the identified SoCs is not possible. The only effects of storage on SoCs that could be expected, are 1) a decrease of the concentration of the active substance or coformulants due to degradation or evaporation (solvents), or 2) an increase of non-volatile components due to a concentration effect caused by evaporation of coformulants (solvents) with a high vapour pressure such as isopropanol and 2-butoxyethanol.
In case of 1) a decrease of coformulants like the solvents, there is no concern because the hazard profile of the products decreases. Degradation of substances in a biocidal product is only seen as a problem for the active substance because the level of efficacy can decrease.
If there is 2) an increase of SoCs, there is also no concern because the other SoCs besides solvents are only classified for local human health effects. These substances are qualitatively evaluated in the risk assessment as they are contributing to the skin corrosion and or eye damaging classification of the product. Developing an analytical method for substances which are not quantitatively assessed seems to be redundant.

Furthermore, a potential increase of these coformulants, is not going to change the classification of the products:

- [redacted]Assuming that all isopropanol evaporates, it will result in a 1% increase of the concentration of the other coformulants. This will not change the classification for eye damage.
- [redacted]. The product is already classified as Skin Corr. 1C and Eye Dam. 1, and a potential increase in SoCs with such properties is not going to change the classification.
- [redacted]This increase is also not going to change the classification of the product.

Personal protective equipment is already necessary and protecting the professional users sufficiently. As regards to potential residues in food, it should be noted that these products are only used in diluted form and the ready-to-use products are not classified as hazardous, and the hazards are only local and not systemic.
In conclusion, there is no reason to assume that there would be an increase of SoCs during storage and if there would be an increase, there is no concern about an increased hazard of the products. There is no need to analyze the concentration of SoC coformulants in these biocidal products from a hazard point of view.

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Not required, no relevant residues expected by the CA (CAR lactic acid, Germany, 2017)									

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, no relevant residues expected by the CA (CAR lactic acid, Germany, 2017)									

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, no relevant residues expected by the CA (CAR lactic acid, Germany, 2017)									

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		
Not required, no relevant residues expected by the CA (CAR lactic acid, Germany, 2017)									

Analytical methods for animal and human body fluids and tisues									
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, no relevant residues expected by the CA (CAR lactic acid, Germany, 2017)									

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, no relevant residues expected by the CA (CAR lactic acid, Germany, 2017)									

Conclusion on the methods for detection and identification of the product
Meta SPCs 1, 2, 3, 4 and 5 The provided HPLC-UV method is adequately validated for determination of the content of the active substance in the biocidal products Chriox WC (Meta SPC1), Mida Agri 830 Post Red (Meta SPC 2), Mida San 325 DA (Meta SPC 3), Mida San 332 VB (Meta SPC 4) and Mida San 331 LW (Meta SPC 5). No analytical method is required for the SOCs for Mida San 325 DA (Meta SPC 3) and Mida San 331 LW (Meta SPC 5). **All Meta SPCs** Analytical methods including those for the determination of active substance residues in food of plant origin and the environmental media as air, water and soil are referred about the CAR of the active substance.

2.2.5 Efficacy against target organisms

2.2.5.1 Function (organisms to be controlled) and field of use (products/objects to be protected) for the products of the family

Main group 01: DISINFECTANTS
Product types :

- PT2 (*Disinfectants and algaecides not intended for direct applications to humans or animals*)
- PT3 (*Veterinary Hygiene*)
- PT4 (*Food & feed Area*)

All the biocidal products within this family, divided into 5 Meta SPCs, do contain L+ Lactic Acid (CAS N° 79-33-4) as active substance, used at the concentration range 6.80 – 80.00 % w/w. They are intended to be used indoors by non-professional, professional and/or industrial users, according to the product and the intended use.

The products are intended to be used as :

- META SPC 1 : Toilet bowl disinfectant (PT2)
- META SPC 2 : Teat disinfectant after milking (PT3)
- META SPCs 3; 4 & 5 : hard/non-porous surface disinfectant (PT2 & PT4) for institutions, industry and food industry (professional use).

The organisms to be controlled are bacteria and yeasts.
The objects or organisms to be protected are hard surfaces or lactating animals.

2.2.5.2 Mode of action and effects on target organisms, including unacceptable suffering

In solution, L(+) lactic acid exists in a pH-dependent equilibrium between the undissociated and dissociated form. Only in its undissociated state, the acid is able to pass the cell membrane. At a relatively low pH, the uncharged acid enters the cell. Inside the cell, the L(+) lactic acid dissociates due to the higher pH. The molecules remain inside the cell, because the resulting ions cannot pass the membrane. The pH inside the cell is lowered and metabolic reactions are inhibited. Further effects are also reported. Decrease

of the membrane permeability for amino acids, organic acids, phosphates resulting in uncoupling of both substrate transport and oxidative phosphorylation from the electron transport system. Furthermore, an inhibition of the glycolysis by the lactate ion is observed. (Assessment Report Lactic Acid, Germany, 2015).

No resistance to lactic acid has been observed in the course of the efficacy studies. Furthermore, development of resistance is considered unlikely due to the non-specific mode of action (Doc III B5.11). (Assessment Report Lactic Acid, Germany, 2015).

Mida San 331 LW contains a small amount of isopropanol. This ingredient is used for quick drying of the product on surfaces. EN1650 test reports against *C. albicans* are available for the complete formulation and the formulation without IPA. The tests were conducted in clean conditions with 15 min. contact time at 20°C. The results of both formulations are very similar, which demonstrates that IPA does not contribute to the efficacy of the formulation. It is also noted that alcohols such as IPA are only effective against obligatory target organisms as of a concentration of 30-70% (Assessment report propan-2-ol, Germany, 2015) whereas the concentration of IPA in Mida San 331 LW is only a fraction of that (exact concentration disclosed in the Confidential Annex), and its function is only to enhance quick drying on the treated surfaces.

2.2.5.3 Efficacy data

Efficacy tests performed according to suspension and surface standards have been submitted :
Phase 2/Step 1 efficacy tests are mandatory for products intended to be used for inner surface disinfection via CIP procedures.
Phase 2/Step 1 and Step 2 efficacy tests are mandatory for products intended to be used for surface disinfection via soaking, spraying and foaming procedures.

Impact of co-formulants on the efficacy of the products :
The action of co-formulant sulfamic acid on the efficacy of the product in Meta SPC 3 has been addressed with efficacy data on the same formula without sulfamic acid (EN1650 *C. albicans*). At 2% the reduction to the standard formula was >4.41 while for the formula with sulfamic acid was >3.04 (Test reports 180061893 and 180061891).
According to the TAB for Efficacy (2018) the difference between both log reductions should be less than 1.5. The difference between the log reduction of the full formula and the formula without isopropanol is 1.37, thus it is proved that isopropanol is not a second active. The same testing was performed with the norm EN1276 for bacteria, the results for log reduction were the same between the normal formula and the formula without sulfamic acid (Test reports 180099449 and 180099450). It was therefore shown that sulfamic acid has no impact in the efficacy and so it is not a second active substance in this product.

Experimental data on the efficacy of the biocidal product against target organisms **Meta SPC-1 - CHRIOX WC *(6.8% LA)*** **PT2** - Use #1.1 : RTU Toilet bowl disinfection (pouring)				
Test product	**Function & Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference & R.I.**
Chriox WC 125% Batch N°SO16/136 (8.5% LA) CoA provided in the report	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276 (2010/2011)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 80% • I.S. : 3g/L BSA (dirty conditions)	**Bactericidal activity** at 80% in 5 min at +20°C in dirty conditions.	Doc. "Chriox WC - EN 1276 - 100% - 5 min. dirty_EN" Report N°3887-1 **R.I. 2** non-active concentration NOT tested
1242 Product Batch N°Ind01PR564F125%180814 (8.5% LA) CoA provided in the report	**Bactericidal activity** *Enterococcus hirae*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 5 - 15 min • Concentrations tested : 100% • I.S. : 3g/L BSA (dirty conditions)	**Bactericidal activity** at 100% in 5 & 15 min at +20°C on hard/non-porous surfaces wo prior cleaning.	Doc. "20181123 EN 13697 ente. hirae 5 min" & "20181123 EN 13697 ente. hirae 15 min" Reports N°RE18-612-1 & N°RE18-612-2 **R.I. 2** non-active concentration NOT tested
1242 Product Batch N°Ind01 - PR564F125%181217 (8.5% LA)	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 100%	**Bactericidal activity** at 100% in 5 min at +20°C on hard/non-porous surfaces wo prior cleaning.	Doc. "RE19-015-1_ANG_CHRISTEYNS Fran" Report N°RE19-015-1

CoA provided		• I.S. : 3g/L BSA (dirty conditions)		**R.I. 2** non-active concentration NOT tested
1242 Product Batch N°PR562F125%191014 (8.5% LA) CoA provided	**Yeasticidal activity** *Candida albicans*	**EN 1650 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 60 min • Concentrations tested : 20 – 40 - 80% • I.S. : 3g/L BSA (dirty conditions)	**Yeasticidal activity** at 100% in 15 min at +20°C on hard/non-porous surfaces without prior cleaning.	Doc. "Chriox_WC_-_EN_1650_C._albicans_-_100pct_-_60_min._EN" Report N°190095861 **R.I. 1** **Key Study**
Chriox WC 125% Batch N°1242-20200304 (8.5% LA)	**Yeasticidal activity** *Candida albicans*	**EN 1650 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 20 – 40 - 80% • I.S. : 3g/L BSA (dirty conditions)	**Yeasticidal activity** at 80% in 15 min at +20°C in dirty conditions.	Doc. "Chriox WC 125pct EN1650 yeasts 15 min. 200018957" Report N°20001895 **R.I. 1** **Key Study**
Chriox WC 125% Batch N°1242-20200304 (8.5% LA)	**Yeasticidal activity** *Candida albicans*	**EN 1650 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 30 min • Concentrations tested : 20 – 40 - 80% I.S. : 3g/L BSA (dirty conditions)	**Yeasticidal activity** at 80% in 30 min at +20°C in dirty conditions.	Doc. "Chriox WC 125pct EN1650 yeasts 30 min. 200018958" Report N°200018958 **R.I. 1** **Key Study**
1242 Product Batch N°Ind01PR564F125%180814 (8.5% LA)	**Yeasticidal activity** *Candida albicans*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 100% • I.S. : 3g/L BSA (dirty conditions)	**Yeasticidal activity** at 100% in 15 min at +20°C on hard/non-porous surfaces without prior cleaning.	Doc. "20181123 EN 13697 candi. albicans" Report N°RE18-613-1 **R.I. 2** non-active concentration NOT tested

CoA provided				
Chriox WC Batch N°1242-20200304 (6.8% LA)	**Permanence of *Chriox WC* on vertical wall surfaces**	**Determination of the flow time of *Chriox WC* on a vertical wall.** Materials and method : 2 mL of product put on the top of a tile.	After 1h the product duly remains on the wall. Since the product remains on the wall for at least 1h, a contact time of 15 min seems acceptable.	Doc. "Chriox WC 20200304 report flowing test" **R.I. 2**

Meta SPC-1 - Conclusion on the efficacy of the product *CHRIOX WC (6.8% LA)* ***Summary of the use conditions validated after evaluation of the studies***			
AS A REMINDER : *- For "surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are necessary and both tests must be taken into account and therefore the higher concentration & contact time required is the limiting one and thus be set up as the necessary concentration.* *- Please note that one single Use concentration/Contact Time will be validated for basic requirements (see Annex IV in ECHA EFF guidance from May 2016/April 2018).*			
EN 1276	80% - 5 min - +20°C - DIRTY	EN 13697 - B	100% - 5 & 15 min - +20°C - DIRTY
EN 1650 – Y	80% - 15 min - +20°C – DIRTY	EN 13697 – Y	100% - 15 min - +20°C – DIRTY

<table>
<tr><th colspan="3">Conclusion on the efficacy of the product CHRIOX WC (6.8% LA) & validated label claims</th></tr>
<tr><td colspan="3">Please note that, since required by other MSs, for surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are mandatory and must be taken into account and therefore the higher concentration required is the limiting one and thus be set up as the necessary concentration.
Please also note that one single use instructions (with Use concentration/Contact Time/T°C) will be validated for basic efficacy requirements.</td></tr>
<tr><th colspan="2">Meta SPC-1 - CHRIOX WC (8% LA)</th><th>Validated label claims</th></tr>
<tr><td>PT2</td><td>Use #1.1 : RTU Toilet bowl disinfection
Pouring (with brushing only after the required CT)</td><td>On hard/non-porous surfaces without prior cleaning
Active against bacteria and yeasts
With undiluted product
In 15 min contact time
At Room Temperature</td></tr>
</table>

Experimental data on the efficacy of the biocidal product against target organisms				
Meta SPC-2 - MIDA AGRI 830 Post Red (8% LA) **PT3 -** Use #2.1 : RTU Teat disinfection (post-milking)				
Test product	**Function & Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference & R.I.**
MIDA AGRI 830 Post Red Batch N°1036-19 (6% LA) CoA provided in the report	**Bactericidal activity** *E.coli* *Staphylococcus aureus* *Streptococcus uberis* *Pseudomonas aeruginosa*	**EN 1656 (2009/2010)** Quantitative suspension test • Temperature : +30 ± 1°C • Contact time : 5 min • Concentrations tested : 25 – 50 - 80 % • I.S. : Milk 1%	**Bactericidal activity** (for teat disinfection) at 25% in 5 min at +30°C in presence of milk	Doc. "1656 MIDA AGRI 830" Report N°AAC43841 (STULV19AA0610-1 V2) **R.I. 1** **Key Study**
MIDA AGRI 830 Post Red Batch N°1036-19 (6% LA) CoA provided in the report	**Fungicidal/Yeasticidal activity** *Candida albicans*	**EN 1657 (2016)** Quantitative suspension test • Temperature : +30 ± 1°C • Contact time : 5 min • Concentrations tested : 25 – 50 - 80 % • I.S. : Milk 1%	**Yeasticidal activity** at 25% in 5 min at +30°C in presence of milk	Doc. "1657MIDA AGRI 830" Report N°AAC43884 (STULV19AA0612-1 V2) **R.I. 1** **Key Study**
MIDA AGRI 830 Post Red Batch N°1036-19 (6% LA) CoA provided in the report	**Bactericidal activity** *E.coli* *Staphylococcus aureus* *Streptococcus uberis*	**EN 16437 (2014) modified** Bactericidal activity when applied to synthetic skin (VITRO-SKIN) • Temperature : +30 ± 1°C • Contact time : 5 min • Concentrations tested : 25 – 50 - 80 % • I.S. : Milk 1%	**Bactericidal activity** (for teat disinfection) at 100% in 5 min at +30°C on skin without prior cleaning	Doc. "16437 MIDA AGRI 830" Report N° STULV19AA0690-1) **R.I. 1** **Key Study**

Meta SPC-2 - Conclusion on the efficacy of the product MIDA AGRI 830 Post Red (8% LA) ***Summary of the use conditions validated after evaluation of the studies***			
AS A REMINDER : *- For "surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are necessary and both tests must be taken into account and therefore the higher concentration & contact time required is the limiting one and thus be set up as the necessary concentration.* *- Please note that one single Use concentration/Contact Time will be validated for basic requirements (see Annex IV in ECHA EFF guidance from May 2016/April 2018).*			
EN 1656	25% - 5 min - +30°C - MILK	EN 16437 - B	100% - 5 min - +30°C - MILK
EN 1657 – Y	25% - 5 min - +30°C - MILK		

<table>
<tr><th colspan="3">Conclusion on the efficacy of the product MIDA AGRI 830 Post Red (8% LA) & validated label claims</th></tr>
<tr><td colspan="3">Please note that, since required by other MSs, for surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are mandatory and must be taken into account and therefore the higher concentration required is the limiting one and thus be set up as the necessary concentration.
Please also note that one single use instructions (with Use concentration/Contact Time/T°C) will be validated for basic efficacy requirements.</td></tr>
<tr><th colspan="2">Meta SPC-2 - MIDA AGRI 830 Post Red (8% LA)</th><th>Validated label claims</th></tr>
<tr><td>PT3</td><td>Use #2.1 : Teat disinfection (post-milking)
Dipping</td><td>Active against bacteria and yeasts
With undiluted product
In 5 min contact time
at +30°C

Since the product has been tested at +30°C, if the product is stored at +4-7°C (i.e. in a fridge), a precautionary sentence should be added in the PAR/SPC/label in order to mention that the product must “return” to RT before use, as agreed by WG-Eff members.</td></tr>
</table>

Experimental data on the efficacy of the biocidal product against target organisms **Meta SPC-3 - *Mida San 325 DA* (16% LA)** **PT2** (excluding hospitals) **-** Use #3.1 : Surface disinfection (trigger spraying) **PT2** (excluding hospitals) **-** Use #3.3 : Surface disinfection (low-pressure spraying or foaming) **PT4** - Use #3.2 : Surface disinfection (trigger spraying) **PT4 -** Use #3.4 : Surface disinfection (low-pressure spraying or foaming) **PT4** - Use #3.5 : Surface/objects disinfection (dipping)				
Test product	**Function & Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference & R.I.**
Mida San 325 DA (16% LA)	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276 (2010/2011)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 2 – 4 - 8% • I.S. : 0.3g/L BSA (clean conditions)	**Bactericidal activity** at 4% in 5 min at +20°C in clean conditions.	Doc. "180061892 MIDA SAN 325 DA (1276 bact 5 MIN LIMPIAS) INGLES_180061892" **R.I. 1** **Key Study**
Mida San 325 DA w/wo sulfamic acid (16% LA)	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276 (2010/2011)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.2 – 0.4 – 0.8% • I.S. : 0.3g/L BSA (clean conditions)	**Bactericidal activity** **Product with sulfamic acid** at 0.4% in 5 min at +20°C in clean conditions **Product wo sulfamic acid** at 0.4% in 5 min at +20°C in clean conditions ⇨ No impact of sulfamic acid on the efficacy of the product ***Mida San 325 DA*.**	Doc. "Mida San 325 DA wo sulfamic - EN1276 BACT_EN_180099450" Doc. "Annex_2_-_Mida_San_325_DA_-_EN1276_BACT_EN_180099449" **R.I.1**

Quacide DA 80 ⇔ **Mida San 325 DA** (16% LA)	**Bactericidal activity** *Salmonella typhimurium* *Listeria monocytogenes*	**EN 1276 (1988 + A1 2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 1% • I.S. : 0.3g/L BSA (clean conditions)	**Active against *Salmonella typhimurium* & *Listeria monocytogenes*** at 1% in 5 min at +20°C in clean conditions	Doc. "Mida San 325 DA (Quacide DA 80) - EN1276 Salm&List_190003355_EN" **R.I. 2** non-active concentration NOT tested
Mida San 325 DA (16% LA)	**Yeasticidal activity** *Candida albicans*	**EN 1650 (2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 1 – 2 - 4% • I.S. : 0.3g/L BSA (clean conditions)	**Yeasticidal activity** at 2% in 15 min at +20°C in clean conditions.	Doc. "Mida San 325 DA - EN1650 yeast_EN_180061893" **R.I. 1** **Key Study**
Pinaran Foam Eco II (Mida San 325 DA) (16% LA)	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 13697 (2002/2007)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 0.5 - 1 – 2 % • I.S. : 0.3g/L BSA (clean conditions)	**Bactericidal activity** at 2% in 5 min at +20°C on hard/non-porous surfaces with prior cleaning.	Doc. "Mida San 325 DA (Pinaran Foam Eco II) - EN13697 bacteria_190003353_EN (1)" **R.I. 3** the test was conducted according to EN 13697: APRIL 2002
Mida San 325 DA Batch N° DA1108 (16% LA)	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 13697 (2002/2007)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 0.5 - 1 – 2 % • I.S. : 0.3g/L BSA (clean conditions)	**Bactericidal activity** at 1% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning.	Doc. "CHRISTEYNS 210086040 Mida San 325 DA (UNE EN 13697 2015+A1 2020 - LIMPIAS) BACT INGLES »

				CHRISTEYNS 210086040 Mida San **R.I. 1** **Key Study**
Mida San 325 DA Batch N° QD260220 (16% LA)	**Yeasticidal activity** *Candida albicans*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 1 – 2 - 4% • I.S. : 0.3g/L BSA (clean conditions)	**Yeasticidal activity** at 2% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning.	Doc. "Mida San 325 DA EN13697 yeasts 200016481" **R.I. 1** **Key Study**
Pinaran Foam Eco II (Mida San 325 DA) (16% LA)	**Fungicidal/Yeasticidal activity** *Candida albicans* *Aspergillus brasiliensis*	**EN 13697 (2002/2007)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 12.5 – 25 - 50 % • I.S. : 0.3g/L BSA (clean conditions)	**Yeasticidal activity** at 12.5% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning. **Fungicidal/Yeasticidal activity** at 50% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning.	Doc. "Mida San 325 DA (Pinaran Foam Eco II) - EN13697 yeast&fungi_190003354_EN **R.I. 1** **Key Study**

Meta SPC-3 - Conclusion on the efficacy of the product *Mida San 325 DA* (16% LA) ***Summary of the use conditions validated after evaluation of the studies***			
AS A REMINDER : *- For "surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are necessary and both tests must be taken into account and therefore the higher concentration & contact time required is the limiting one and thus be set up as the necessary concentration.* *- Please note that one single Use concentration/Contact Time will be validated for basic requirements (see Annex IV in ECHA EFF guidance from May 2016/April 2018).*			
EN 1276	0.4% - 5 min - +20°C - CLEAN	EN 13697 - B	2% - 5 min - +20°C – CLEAN

			Read-across from Meta SPC4 with the product Mida San 332 VB which contains 80% LA and water as solvent. According to all the tests submitted, this product is bactericidal/yeasticidal at 10% (> 8% LA) on surfaces in 15 min. Since the product Mida San 325 DA (16% LA) is bactericidal at 2% => 8% LA final, I think that the efficacy as validated is sufficiently demonstrated.
		EN 13697 - B	1% - 15 min - +20°C - CLEAN
EN 1650 – Y	2% - 15 min - +20°C - CLEAN	EN 13697 - Y	2% - 15 min - +20°C - CLEAN

<table>
<tr><th colspan="3">Conclusion on the efficacy of the product Mida San 325 DA (16% LA) & validated label claims</th></tr>
<tr><td colspan="3">Please note that, since required by other MSs, for surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are mandatory and must be taken into account and therefore the higher concentration required is the limiting one and thus be set up as the necessary concentration.
Please also note that one single use instructions (with Use concentration/Contact Time/T°C) will be validated for basic efficacy requirements.</td></tr>
<tr><th colspan="2">Meta SPC-3 - Mida San 325 DA (16% LA)</th><th>Validated label claims</th></tr>
<tr><td rowspan="2">PT2</td><td>Use #3.1 : Surface disinfection (excluding hospitals)
Trigger Spraying with 20 mL/m^2</td><td rowspan="5">On hard/non-porous surfaces with prior cleaning
Active against bacteria and yeasts
Dilution : 2%
In 15 min contact time
At Room Temperature</td></tr>
<tr><td>Use #3.3 : Surface disinfection
Low pressure spraying / Foaming with 200 mL/m^2</td></tr>
<tr><td rowspan="3">PT4</td><td>Use #3.2 : Surface disinfection
Trigger Spraying with 20 mL/m^2</td></tr>
<tr><td>Use #3.4 : Surface disinfection
Low pressure spraying / Foaming with 200 mL/m^2</td></tr>
<tr><td>Use #3.5 : Surface/object disinfection
Dipping</td></tr>
</table>

Experimental data on the efficacy of the biocidal product against target organisms **Meta SPC-4 - *Mida San 332 VB* (80% LA)** **PT2** (excluding hospitals) **-** Use #4.1 : Surface disinfection (trigger spraying) **PT2** (excluding hospitals) **-** Use #4.3 : Surface disinfection (low-pressure spraying or foaming) **PT4** - Use #4.6 : CIP with circulation **PT4** - Use #4.2 : Surface disinfection (trigger spraying) **PT4 -** Use #4.4 : Surface disinfection (low-pressure spraying) **PT4** - Use #4.5 : Surface/objects disinfection (dipping) **PT4** - Use #4.7 : CIP with circulation				
Test product	**Function & Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference & R.I.**
Mida San 332 VB Batch N° AS18/022 (80% LA)	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276 (2010/2011)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 2.5 – 5 - 10% • I.S. : 0.3g/L BSA (clean conditions)	**Bactericidal activity** at 5% in 5 min at +20°C in clean conditions.	Doc. "Mida San 332 VB - EN1276 - 5% - 5 min. 180044195" **R.I. 1** **Key Study**
Mida San 332 VB Batch N° AS18/022 (80% LA)	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 2 – 5 - 10% • I.S. : 0.3g/L BSA (clean conditions)	**Bactericidal activity** at 5% in 5 min at +20°C on hard/non-porous surfaces with prior cleaning.	Doc. "Mida San 332 VB - EN13697 bacteria - 5% - 5 min. 180044198"
Mida San 332 VB Batch N° AS18/022	**Fungicidal/ Yeasticidal activity** *Candida albicans* *Aspergillus brasiliensis*	**EN 1650 (2008+A1:2013)** Quantitative suspension test • Temperature : +20 ± 1°C	**Yeasticidal activity** at 10% in 15 min at +20°C in clean conditions.	Doc. "Mida San 332 VB EN1650 LEV 180044197"

(80% LA)		• Contact time : 15 min • Concentrations tested : 2 – 5 – 10 - 20 – 40 - 80% • I.S. : 0.3g/L BSA (clean conditions)	**Yeasticidal activity** at 20% in 15 min at +20°C in clean conditions. **+ Fungicidal/Yeasticidal activity** at 40% in 15 min at +20°C in clean conditions.	Doc. "Mida San 332 VB EN1650 FUNG 180044196" **R.I. 1**
Mida San 332 VB Batch N° AS20/001 (80% LA)	**Yeasticidal activity** *Candida albicans*	**EN 1650 (2008+A1:2013)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 10 - 20 – 40 % • I.S. : 0.3g/L BSA (clean conditions)	**Yeasticidal activity** at 40% in 5 min at +20°C in clean conditions. *Please note that there is no yeasticidal activity at 20% in 5 min.*	Doc. "Mida San 332 VB EN1650 5 min. clean 40pct 200017892" **R.I. 1**
Mida San 332 VB Batch N° AS18/022 (80% LA)	**Fungicidal/ Yeasticidal activity** *Candida albicans* *Aspergillus brasiliensis*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 10 – 25 - 50% • I.S. : 0.3g/L BSA (clean conditions)	**Yeasticidal activity** at 10% in 15 min at +20°C in clean conditions. **Fungicidal/Yeasticidal activity** at 50% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning.	Doc. "Mida San 332 VB - EN13697 10% yeasts, 50% fungi - 15 min. 180044199" **R.I. 1** **Key Study**
Mida San 332 VB Batch N° AS20/001 (80% LA)	**Yeasticidal activity** *Candida albicans*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 5 - 10 – 20% • I.S. : 0.3g/L BSA (clean conditions)	**Yeasticidal activity** at 20% in 5 min at +20°C in clean conditions.	Doc. "Mida San 332 VB EN13697 yeasts 200017891" **R.I. 1** **Key Study**

Meta SPC-4 - Conclusion on the efficacy of the product *Mida San 332 VB* (80% LA)
Summary of the use conditions validated after evaluation of the studies

AS A REMINDER : *- For "surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are necessary and both tests must be taken into account and therefore the higher concentration & contact time required is the limiting one and thus be set up as the necessary concentration.* *- Please note that one single Use concentration/Contact Time will be validated for basic requirements (see Annex IV in ECHA EFF guidance from May 2016/April 2018).*			
EN 1276	5% - 5 min - +20°C - CLEAN	EN 13697 - B	5% - 5 min - +20°C - CLEAN
EN 1650 – Y only	40% - 5 min - +20°C – CLEAN 10% - 15 min - +20°C - CLEAN	EN 13697 - Y	20% - 5 min - +20°C – CLEAN 10% - 15 min - +20°C - CLEAN
EN 1650 – F/Y	40% - 15 min - +20°C - CLEAN	EN 13697 - F/Y	50% - 15 min - +20°C - CLEAN

<table>
<tr><th colspan="3">Conclusion on the efficacy of the product Mida San 332 VB (80% LA) & validated label claims</th></tr>
<tr><td colspan="3">Please note that, since required by other MSs, for surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are mandatory and must be taken into account and therefore the higher concentration required is the limiting one and thus be set up as the necessary concentration.
Please also note that one single use instructions (with Use concentration/Contact Time/T°C) will be validated for basic efficacy requirements.</td></tr>
<tr><th colspan="2">Meta SPC-4 - Mida San 332 VB (80% LA)</th><th>Validated label claims</th></tr>
<tr><td rowspan="3">PT2</td><td>Use #4.1 : Surface disinfection (excluding hospitals)
Trigger Spraying with 20 mL/m^2</td><td rowspan="7">On hard/non-porous surfaces with prior cleaning
Active against bacteria and yeasts
Dilution : 10%
In 15 min contact time
At Room Temperature</td></tr>
<tr><td>Use #4.3 : Surface disinfection
Low pressure spraying / Foaming with 200 mL/m^2</td></tr>
<tr><td>Use #4.6 : Inner surface disinfection
CIP</td></tr>
<tr><td rowspan="4">PT4</td><td>Use #4.2 : Surface disinfection
Trigger Spraying with 20 mL/m^2</td></tr>
<tr><td>Use #4.4 : Surface disinfection
Low pressure spraying with 200 mL/m^2</td></tr>
<tr><td>Use #4.5 : Surface/equipment disinfection
Dipping</td></tr>
<tr><td>Use #4.7 : Inner surface disinfection
CIP</td></tr>
</table>

Experimental data on the efficacy of the biocidal product against target organisms **Meta SPC-5 - *Mida San 331 LW* (24% LA)** **PT2** (excluding hospitals) **-** Use #5.1 : Surface disinfection (trigger spraying) **PT2** (excluding hospitals) **-** Use #5.3 : Surface disinfection (low-pressure spraying or foaming) **PT4** - Use #5.2 : Surface disinfection (trigger spraying) **PT4 -** Use #5.4 : Surface disinfection (low-pressure spraying or foaming) **PT4** - Use #3.5 : Surface/objects disinfection (dipping)				
Test product	**Function & Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference & R.I.**
Mida San 331 LW Batch N°AS18/021 (24% LA)	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276 (2010/2011)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 2 - 5 min • Concentrations tested : 2 - 2.5 – 5 - 10% • I.S. : 0.3g/L BSA (clean conditions)	**Bactericidal activity** at 5% in 2 min at +20°C in clean conditions. at 5% in 5 min at +20°C in clean conditions.	Doc. "Mida San 331 LW - EN1276 - 5% - 2 min. 180044201" Doc. "Mida San 331 LW - EN1276 - 5% - 5 min. 180044200" **R.I. 1** **Key Study**
Mida San 331 LW Batch N°AS18/021 (24% LA)	**Bactericidal activity** *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 2 - 5 min • Concentrations tested : 10 – 25 - 50% • I.S. : 0.3g/L BSA (clean conditions)	**Bactericidal activity** at 50% in 2 min at +20°C on hard/non-porous surfaces with prior cleaning. at 25% in 5 min at +20°C on hard/non-porous surfaces with prior cleaning.	Doc. "Mida San 331 LW - EN13697 bacteria - 50% - 2 min. 180044206" Doc. "Mida San 331 LW - EN13697 bacteria - 25% - 5 min. 180044205" **R.I. 1** **Key Study**
Mida San 331 LW Batch N°AS18/021	**Yeasticidal activity** *Candida albicans*	**EN 1650 (2008)** Quantitative suspension test	**Yeasticidal activity** at 20% in 15 min at +20°C in dirty conditions.	Doc. "Mida San 331 LW - EN1650 20% yeasts 15 min. - 180079437"

(24% LA)		• Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 10 – 20 – 40 % • I.S. : 0.3g/L BSA (clean conditions)		**R.I. 1** **Key Study**
Mida San 331 LW Wo IPA Batch N°AS18/043 (24% LA)	**Yeasticidal activity** *Candida albicans*	**EN 1650 (2008)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 10 – 40 – 50 % • I.S. : 3g/L BSA (dirty conditions)	**Yeasticidal activity** at 40% in 15 min at +20°C in dirty conditions.	Doc. "Mida San 331 LW without IPA - EN1650 yeasts - 40pct - 15 min. - 180084360" **R.I. 2**
Mida San 331 LW Batch N°AS18/021 (24% LA)	**Fungicidal/Yeasticidal activity** *Candida albicans* *Aspergillus brasiliensis*	**EN 1650 (2008)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 20 – 40 - 80% • I.S. : 0.3g/L BSA (clean conditions)	**Fungicidal/Yeasticidal activity** at 80% in 15 min at +20°C in clean conditions	Doc. "Mida San 331 LW - EN1650 20% yeasts, 80% fungi - 15 min. 180044202" **R.I. 1** **Key Study**
Mida San 331 LW Batch N°AS18/021 (24% LA)	**Yeasticidal activity** *Candida albicans*	**EN 1650 (2008)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 2 – 5 - 10% • I.S. : 0.3g/L BSA (clean conditions)	**Yeasticidal activity** at 5% in 15 min at +20°C in clean conditions	Doc. "Mida San 331 LW - EN1650 yeasts - 5% - 15 min. 180044203" **R.I. 1** **Key Study**
Mida San 331 LW Batch N°AS18/021 (24% LA)	**Yeasticidal activity** *Candida albicans*	**EN 1650 (2008)** Quantitative suspension test • Temperature : +20 ± 1°C • Contact time : 2 min • Concentrations tested : 2 – 5 - 10% • I.S. : 0.3g/L BSA (clean conditions)	**Yeasticidal activity** at 10% in 2 min at +20°C in clean conditions	Doc. "Mida San 331 LW - EN1650 yeasts - 10% - 2 min. 180044301" **R.I. 1** **Key Study**
Mida San 331 LW Batch N°AS18/021	**Fungicidal/Yeasticidal activity** *Candida albicans*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces	**Yeasticidal activity**	Doc. "Mida San 331 LW - EN13697 50% yeasts, fungi NOK - 15 min. 180044207"

(24% LA)	*Aspergillus brasiliensis*	• Temperature : +20 ± 1°C • Contact time : 15 min • Concentrations tested : 25 – 50 - 100% • I.S. : 0.3g/L BSA (clean conditions)	at 25% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning. **NO Fungicidal/Yeasticidal activity** at 100% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning.	**R.I. 1** **Key Study**
Mida San 331 LW Batch N°AS20/002 (24% LA)	**Fungicidal/Yeasticidal activity** *Candida albicans* *Aspergillus brasiliensis*	**EN 13697 (2015)** Quantitative carrier test – hard & non-porous surfaces • Temperature : +20 ± 1°C • Contact time : 5 min • Concentrations tested : 10 - 25 – 50 % • I.S. : 0.3g/L BSA (clean conditions)	**Yeasticidal activity** at 25% in 5 min at +20°C on hard/non-porous surfaces with prior cleaning.	Doc. "Mida San 331 LW 13697 yeasts 200017893" **R.I. 1** **Key Study**

Meta SPC-5 - Conclusion on the efficacy of the product *Mida San 331 LW* (24% LA) ***Summary of the use conditions validated after evaluation of the studies***			
AS A REMINDER : *- For "surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are necessary and both tests must be taken into account and therefore the higher concentration & contact time required is the limiting one and thus be set up as the necessary concentration.* *- Please note that one single Use concentration/Contact Time will be validated for basic requirements (see Annex IV in ECHA EFF guidance from May 2016/April 2018).*			
EN 1276	5% - 2 & 5 min - +20°C - CLEAN	EN 13697 - B	50% - 2 min - +20°C – CLEAN 25% - 5 min - +20°C - CLEAN
EN 1650 – Y	10% - 2 min - +20°C - CLEAN	EN 13697 - Y	25% - 5 min - +20°C - CLEAN

<table>
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<tr><td colspan="3">Please note that, since required by other MSs, for surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are mandatory and must be taken into account and therefore the higher concentration required is the limiting one and thus be set up as the necessary concentration.
Please also note that one single use instructions (with Use concentration/Contact Time/T°C) will be validated for basic efficacy requirements.</td></tr>
<tr><th colspan="2">Meta SPC-5 - Mida San 331 LW (24% LA)</th><th>Validated label claims</th></tr>
<tr><td rowspan="2">PT2</td><td>Use #5.1 : Surface disinfection (excluding hospitals)
Trigger Spraying with 20 mL/m^2</td><td rowspan="5">On hard/non-porous surfaces with prior cleaning
Active against bacteria and yeasts
Dilution : 25%
In 5 min contact time
At Room Temperature</td></tr>
<tr><td>Use #5.3 : Surface disinfection
Low pressure spraying / Foaming with 200 mL/m^2</td></tr>
<tr><td rowspan="3">PT4</td><td>Use #5.2 : Surface disinfection
Trigger Spraying with 20 mL/m^2</td></tr>
<tr><td>Use #5.4 : Surface disinfection
Low pressure spraying / Foaming with 200 mL/m^2</td></tr>
<tr><td>Use #5.5 : Surface/equipment disinfection
Dipping</td></tr>
</table>

2.2.5.4 Occurrence of resistance and resistance management

Development of resistance is considered unlikely due to the non-specific mode of action. (Assessment Report L(+)Lactic Acid, Germany, 2015).

2.2.5.5 Known limitations

Limitations on efficacy, including observations on undesirable or unintended side effects are not described for L(+)Lactic acid. (Assessment Report L(+)Lactic Acid, Germany, 2015).

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

Not applicable: the products are not intended to be authorised for use in combination with other biocidal products.

2.2.6 Risk assessment for human health

New data/information on human health and exposure is generated for the products due to differences in product composition and/or intended use compared to representative product(s) for the active substance(s) listed in the Union list of approved active substances under Regulation No. 528/2012.

2.2.6.1 Assessment of effects on Human Health

For the classification of the products, CLP mixture rules were used. For L(+) lactic acid, the classification described in the Assessment Report (Germany, 2015) was used: Eye Dam. 1; H318, Skin Irrit. 2; H315. This was later revised (RAC opinion corrigendum December 2019) to Skin Corr. 1C with a GCL of 5%.

Skin corrosion and irritation

Summary table of human data on skin corrosion irritation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
Key study, OECD guideline 439 (In Vitro Skin Irritation: Reconstructed Human Epidermis (RHE) Test) GLP: Y Reliability: 1 (reliable without restriction)	Mida Agri 830 Post Red Lot 131620 (colourless product) – metaSPC 2 – 6% lactic acid (RTU)	Test Reconstructed Human Epidermis (RHE) – EpiDerm® model Exposure duration: 60 min Replicates:3	The mean viability of the test item's three replicates was 97.1% of the mean value of the negative control. Mean viability of the negative control: 100% Mean viability of the positive control: 2.3% Conclusion: the test item is 'Non-irritant (No category)'.	Noè, F. (2020) (CH-0755/2020)
Key study, OECD guideline 431 (In Vitro Skin Corrosion: Reconstructed Human Epidermis (RHE) Test) GLP: N Reliability: 2 (reliable with restrictions)	Mida Agri 830 Post Red Lot 107120 – metaSPC 2 – 6% lactic acid (RTU)	Test Reconstructed Human Epidermis (RHE) – EpiDerm® model Exposure duration: 3 and 60 min Replicates:2	The mean viability of the test item's two replicates was 83.1% of the mean value of the negative control after 3 minutes and 22.5 % of the mean value of the negative control after 60 minutes Mean viability of the negative control: 100% after 3 and 60 min Mean viability of the positive control: 8% after 3 min and 3.5% after 60 min Conclusion: the test item is 'Not corrosive'.	Bocchiettto, E. (2020)

For the other products, no new data is provided. The classification of the products is based on CLP mixture rules. The reference IUCLID datapoint is in Section 8.1.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Meta SPC 1: Skin Corr. 1C Meta SPC 2: / Meta SPC 3: Skin Corr. 1 Meta SPC 4: Skin Corr. 1 Meta SPC 5: Skin Corr. 1C
Justification for the value/conclusion	For metaSPC 3 and metaSPC 4: pH<2 => therefore both metaSPC are classified as Skin corr 1. For metaSPC 1 and metaSPC5: According the RAC opinion (corrigendum December 2019), lactic acid is classified as skin Corr 1C with a GLC of 5%. Since acid concentration is >5%, they are classified Skin Corr 1C. For meta SPC 2: A skin irritation test (OECD 439) and a skin corrosion test (OECD 431) was conducted on the product Mida Agri 830 Post Red, because this product is intended for direct application on cows' teat skin.
Classification of the product according to CLP	Meta SPC 1: Skin Corr. 1C Meta SPC 2: / Meta SPC 3: Skin Corr. 1 Meta SPC 4: Skin Corr. 1 Meta SPC 5: Skin Corr. 1C

Data waiving	
Information requirement	Skin corrosion and irritation
Justification	CLP mixture rules are used to define the classification of the products. The classification of the product in meta SPC 2 was revised, based on the result of an OECD 439 test.

Eye irritation

No new data is provided. The classification of the products is based on CLP mixture rules. The reference IUCLID datapoint is in Section 8.2.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Meta SPC 1: Eye Dam. 1 Meta SPC 2: Eye Dam. 1 Meta SPC 3: Eye Dam. 1 Meta SPC 4: Eye Dam. 1 Meta SPC 5: Eye Dam. 1
Justification for the value/conclusion	All products are classified for Eye Dam. 1 because they all contain more than 3% L(+) lactic acid. (CLP Table 3.3.3)
Classification of the product according to CLP and DSD	Meta SPC 1: Eye Dam. 1 Meta SPC 2: Eye Dam. 1 Meta SPC 3: Eye Dam. 1

	Meta SPC 4: Eye Dam. 1 Meta SPC 5: Eye Dam. 1

Data waiving	
Information requirement	Eye irritation
Justification	CLP mixture rules are used to define the classification of the products.

Respiratory tract irritation

No new data is provided. The classification of the products is based on CLP mixture rules. The reference IUCLID datapoint is in Section 8.2.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	The products are not classified.
Justification for the conclusion	L(+) lactic acid is not classified for respiratory tract irritation. The products also do not contain any coformulants that contribute to the classification for respiratory tract irritation.
Classification of the product according to CLP	The products are not classified.

Data waiving	
Information requirement	Respiratory tract irritation
Justification	CLP mixture rules are used to define the classification of the products.

Skin sensitization

No new data is provided. The classification of the products is based on CLP mixture rules. The reference IUCLID datapoint is in Section 8.3.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	The products are not classified.
Justification for the value/conclusion	L(+) lactic acid is not classified for skin sensitization. MetaSPC 5 contains a coformulant which is not sensitising, but which contains a sensitising substance. This substance is however present at concentrations <0,1% in the final product and thus the EUH208 statement is not required. The other products do not contain any co-formulants that contribute to the classification for skin sensitization.
Classification of the product according to CLP and DSD	The products are not classified.

Data waiving	
Information requirement	Skin sensitization.

Justification	CLP mixture rules are used to define the classification of the products.

Respiratory sensitization (ADS)

No new data is provided. The classification of the products is based on CLP mixture rules. The reference IUCLID datapoint is in Section 8.4.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	The products are not classified.
Justification for the value/conclusion	L(+) lactic acid is not classified for respiratory sensitization. The products also do not contain any coformulants that contribute to the classification for respiratory sensitization.
Classification of the product according to CLP and DSD	The products are not classified.

Data waiving	
Information requirement	Respiratory sensitization.
Justification	CLP mixture rules are used to define the classification of the products.

Acute toxicity

Acute toxicity by oral route

No new data is provided. The classification of the products is based on CLP mixture rules. The reference IUCLID datapoint is in Section 8.5.1.

Value used in the Risk Assessment – Acute oral toxicity	
Value	Meta SPC 1: ATEmix = 50270 mg/kg Meta SPC 2: ATEmix = 30000 mg/kg Meta SPC 3: ATEmix = 4826 mg/kg Meta SPC 4: ATEmix = 4429 mg/kg Meta SPC 5: ATEmix = 181818 mg/kg
Justification for the selected value	All ATEmix values are above the limit for classification for acute oral toxicity of 2000 mg/kg (CLP Table 3.1.1)
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Acute oral toxicity
Justification	The classification is based on CLP mixture rules.

Acute toxicity by inhalation

No new data is provided. The classification of the products is based on CLP mixture rules. The reference IUCLID datapoint is in Section 8.5.2.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Meta SPC 1: ATEmix = not toxic via inhalation (no raw materials classified for acute toxicity via inhalation) Meta SPC 2: ATEmix = not toxic via inhalation (no raw materials classified for acute toxicity via inhalation) Meta SPC 3: ATEmix = 25 mg/l Meta SPC 4: ATEmix = not toxic via inhalation (no raw materials classified for acute toxicity via inhalation) Meta SPC 5: ATEmix = not toxic via inhalation (no raw materials classified for acute toxicity via inhalation)
Justification for the selected value	All ATEmix values are above the limit for classification for acute inhalation toxicity of 5 mg/kg for dusts and mists (CLP Table 3.1.1)
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Acute inhalation toxicity
Justification	The classification is based on CLP mixture rules.

Acute toxicity by dermal route

No new data is provided. The classification of the products is based on CLP mixture rules. The reference IUCLID datapoint is in Section 8.5.2.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Meta SPC 1: ATEmix = not toxic via dermal exposure (no raw materials classified for acute dermal toxicity) Meta SPC 2: ATEmix = (no raw materials classified for acute dermal toxicity) Meta SPC 3: ATEmix = 18333 mg/kg Meta SPC 4: ATEmix = (no raw materials classified for acute dermal toxicity) Meta SPC 5: ATEmix = (no raw materials classified for acute dermal toxicity)
Justification for the selected value	All ATEmix values are above the limit for classification for acute dermal toxicity of 2000 mg/kg (CLP Table 3.1.1)
Classification of the product according	Not classified

Data waiving	
Information requirement	Acute dermal toxicity
Justification	The classification is based on CLP mixture rules.

Information on dermal absorption

No new data is provided. The classification of the products is based on CLP mixture rules. The reference IUCLID datapoint is in Section 8.6.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	L(+) Lactic acid
Value(s)*	75%
Justification for the selected value(s)	Assessment report L(+) Lactic acid (Germany, 2015): worst-case default value is 75% dermal absorption (no information available about dermal absorption of L(+) lactic acid from the products).

Data waiving	
Information requirement	Dermal absorption
Justification	The worst-case default value from the active substance Assessment Report (Germany, 2015) is used.

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

According to the BPR guidance (Volume III Human Health – Assessment & Evaluation (Parts B+C), version 4.0 December 2017) co-formulants are checked for each identification criteria mentioned in the annex A.

1) Co-formulants contributing to the classification

Meta SPC	**SoCs**	**Justification**	**Hazard band**
2	Polyoxyethylene octyl ether carboxylic acid (Akypo LF1) (CAS 53563-70-5)	Classified as Eye Dam. 1 and C >3%	B
3	Dodecylbenzenesulfonic acid (Sulfosil) (CAS 85536-14-7)	Classified as Skin Corr. 1C and C >3%	B
	Laurylethoxy(3EO) sulphate, sodium salt (Texapon NSO UP) (CAS 68891-38-3)	Classified as Eye Dam. 1 and C >3%	B
	1-heptanol, 2-propyl-, 7EO (Lutensol XP99) (CAS 160875-66-1)	Classified as Eye Dam. 1 and C >3%	B
5	Sulfuric acid (Ufarol NA30) (CAS 85586-07-8)	Classified as Eye Dam. 1 and C >1%	B

2) Active substances, other than those included in Annex I of the BPR, for which a draft final Competent Authority Report -CAR (with agreed reference values) is available (including draft final CARs for Product Types other than the one of the actual biocidal product under evaluation).

Isopropanol (CAS 67-63-0)

For isopropanol information is available in the PT2 AS assessment report (13 January 2015). The threshold limits and other values for human health risk assessment are presented below.

For professional workers	Value
$AEC_{acute/medium/long-term}$	52.6 ppm
$AEL_{acute/medium/long-term}$	17.9 mg/kg bw/day
ADI	2.4 mg/kg/d
Dermal flux	0.85 $mg/cm^2/h$
Inhalative absorption	100%

3) Substances for which there are Community workplace exposure limits.

2-butoxyethanol (CAS 111-76-2)

For 2-butoxyethanol information is available in Directive 2000/39/EC – Indicative occupational exposure limits. This information is summarised in the table below.

For professional workers	Value
OEL TWA	98 mg/m^3
	20 ppm
OEL STEL	246 mg/m^3
	50 ppm

Based on the Guidance on BPR: Volume III Parts B+C (2017), p. 424, it is indicated that if the IOELV is driven by systemic effects, then route to route extrapolation should be performed to derive a systemic IOELV. Based on the REACH dossier, 2-butoxyethanol can be considered to be systemic. Therefore, it is proposed to use the DNELs established in the REACH dossier:

For professional workers	Value
Systemic	
EU-OEL long term, inhalation	98 mg/m^3
EU-OEL acute, inhalation	1091 mg/m^3
EU-OEL long term, dermal	125 mg/kg bw/day
EU-OEL acute, dermal	89 mg/kg bw/day
Local	
EU-OEL - inhalation	246 mg/m^3
Inhalative absorption	100% (default)

Available toxicological data relating to a mixture

Toxicological test data on the mixtures are only available on Mida Agri 830 Post Red. The classification of the other products is based on CLP mixture rules.

2.2.6.2 Exposure assessment

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

Please note that following the WG discussions, only local risk assessment is considered relevant for this active substance. Therefore, only **local dermal risk assessment** will be performed for the active substance (qualitative for metaSPC 1, 3, 4 and 5 and semi-quantitative for metaSPC 2) and **no systemic assessment** would be performed.

There are some co-formulants of toxicological concern in this BPF family. Two co-formulants are assigned to **band C** according annex A BPR guidance (Volume III Human Health – Assessment & Evaluation (Parts B+C), version 4.0 December 2017). Therefore, for theses co-formulants, a complete risk assessment has to be performed. These co-formulants are :

- 2-butoxyethanol (111-76-02) because it has an EU OEL (MetaSPC 3)
- Isopropanol (67-63-0) because it is an approved biocidal AS (MetaSPC 2 & 5)

For SoC Isopropanol, since the AEL systemic is derived from the AEC (according to the assessment report, p 25), the quantitative local risk assessment is already covered by the systemic risk assessment and thus will not be performed.

In addition, some others co-formulants are assigned to band B or A. In accordance with the guidance, a qualitative risk assessment is performed.

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	yes	yes	yes	yes	yes	no	n.a.
Dermal	yes	yes	yes	yes	yes	no	n.a.
Oral	no	no	no	no	no	no	yes

Inhalation exposure covers exposure to vapour and aerosols in the air, but as lactic acid is not volatile, vapour exposure is not considered to be relevant. The SoC, isopropanol and 2-butoxyethanol are volatile and thus exposure to vapour and aerosols will be considered.

List of scenarios

Summary table: scenarios			
Scenario n°	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
Meta SPC 1: Toilet bowl disinfectants, use 1.1			
1.1	Pouring	The product is poured into the toilet bowl.	Professional Consumer
1.2	Brushing	The toilet is brushed.	Professional Consumer
1.3	Flushing	The toilet is flushed.	Professional Consumer
Meta SPC 2: Teat dip, use 2.1			
2.1	Loading	The product is loaded into dip cups	Professional
2.2	Application	The product is applied on teats by dipping.	Professional
2.3	Post-application	The product is left to dry on teats.	Professional
2.4	Cleaning	The dip cups are cleaned.	Professional
Meta SPC 4: CIP uses 4.6,4.7			
3.1	Mixing/loading	The concentrate is diluted automatically by the CIP system.	Professional Industrial
3.2	Application	The diluted product is circulated in the installation by the CIP system.	Professional Industrial
3.3	Post-application	The product is left to dry on surfaces.	Professional Industrial
Meta SPC 3,4,5: Trigger spraying, uses 3.1,3.2,4.1,4.2,5.1, 5.2			
4.1	Mixing/loading	The concentrate is diluted in a bucket and transferred to a trigger sprayer flask.	Professional
4.2	Application	The surface is sprayed on surfaces manually using the trigger sprayer.	Professional
4.3	Post-application	The surface is left to dry.	Professional
Meta SPC 3,4,5: Dipping, uses 3.5,4.5,5.5			
5.1	Mixing/loading	The concentrate is diluted in the dipping bath, manually or automatically.	Professional
5.2	Application	The objects are dipped into the dipping bath.	Professional
5.3	Post-application	The objects are removed from the dipping bath and left to dry.	Professional
Meta SPC 3,4,5: Low-pressure spraying, uses 3.3,3.4,4.3,4.4,5.3,5.4			
6.1	Mixing/loading	The concentrate is diluted manually or automatically in the low-pressure spraying system.	Professional Industrial
6.2	Application	The product is sprayed on the surface.	Professional Industrial
6.3	Post-application	The surface is left to dry.	Professional Industrial

Industrial exposure

Industrial scenarios: CIP and low-pressure spraying are evaluated together with the professional scenarios.

Professional exposure

Scenario [1.1-1.2-1.3]

Description of Scenarios [1.1-1.2-1.3]
Disinfection of toilet bowls and drains is done by pouring of thickened product from a bottle with fixed directional nozzle. The product is applied around the bowl and under the rim, left for several minutes, brushed with toilet brush and the toilet is flushed. The products are only used indoors. The product is classified as Skin Corr. 1C and Eye Dam. 1 and the only substance contributing to the classification is L(+) lactic acid. There are no substances of concern. A qualitative local risk assessment has to be performed.

Scenario [2.1-2.2-2.3-2.4-2.5]
For lactic acid, only semi-quantitative local risk assessment would be performed.
The following systemic assessment is performed for SoC propan-2-ol.

Description of Scenarios [2.1-2.2-2.3-2.4-2.5]
Teat disinfectants are applied on teats by dipping after milking. The product is transferred manually from the refill container into a dip cup. As lactating animals are usually milked three times per day, teat dipping also occurs three times per day. The volume of bottles used for cows is about 300 ml. A gentle squeeze of the bottle dispenses about 30 ml into the cup. Teat insertion displaces the dip and covers the entire teat. The dip volume needed per cow varies between 3 mL and 10 ml.
Details of Scenario 2.1 – Loading RTU solution
During the loading phase, professional users are in contact with the product, which is classified as H318. For details, see the local risk assessment in section 2.2.6.3. For hygienic reasons users are expected to wear gloves during teat dipping, therefore dermal exposure is expected to be negligible, nonetheless dermal exposure to isopropanol is considered. Dermal exposure to the SoC isopropanol, during the loading phase is calculated using the mixing and loading model 4 (according to HEAdhoc recommendation 13). For the dermal exposure, the total amount of the required solution that is needed per day is of importance. The amount of solution needed for one day is 3 x 10 ml/cow x 82 cows/day = 2460 ml/day. The indicative value of 0.2 ml (applicable to pouring from a 5 L container) from Mixing and loading model 4 is considered the most appropriate. One bottle contains 300ml, so in total 9 (8,2) loadings are required. Exposure to vapour occurs during the loading phase and is calculated using the consumer exposure model ConsExpo web model "Exposure to vapour: evaporation – constant release" for the substance of concern isopropanol (based on HEAdhoc Recommendation 13 – nr. 1).
Details of Scenario 2.1 – Loading RTU solution – inhalation exposure (vapour)

Parameters	**Value**
Exposure duration	0.75 minutes (Cleaning Products Fact Sheet, 2018)
concentration	[redacted]
Vapour pressure	5780 Pa
Product amount[1]	12675 g (25L can – density: 1,014g/l))
Emission duration	0.25 minutes (Cleaning Products Fact Sheet, 2018)
Molecular weight	60.1 g/mol
Molecular weight matrix[2]	22.18 g/mol
Release area	20 cm^2 (HEAdhoc Recommendation No. 13, nr. 1)
Mass transfer coefficient	28900 m/hr (HEAdhoc Recommendation No. 13, nr. 1 - Langmuir)
Room volume	168 m^3 (HEAdhoc Recommendation No. 13)
Inhalation rate	1.25 m^3/h (HEAdhoc recommendation 14)

Ventilation rate	4/hour (HEAdhoc Recommendation No. 13, nr. 1)
Inhalation penetration	100% (default)

[1]According to the ConsExpo Cleaning Products Fact Sheet, the product amount is half the amount of the bottle content.
[2]Calculated as the average molecular weight of the rest of the total product (the product minus isopropanol)(RIVM report 2016-0171 p. 31)

For complete calculation of this scenario, please refer to annex 3.2.

Details of Scenario 2.1 – Loading RTU solution – dermal exposure		
Tier 1	Isopropanol concentration	[redacted]
	Density	1.014 g/ml
	Dermal penetration	50% (default value for water-based dilution product)
	Body weight	60 kg (HEAdhoc Recommendation No. 14)
	Indicative potential hand exposure value for pouring from a 5 L container (75th percentile)	0.2 mL
	Total amount / day	1.8 mL (0,2*9 loadings) = 1825 mg

Systemic exposure: (1825 *[redacted]*50%) / 60 =0.15 mg/kg bw/d

Details of Scenario 2.2 – Application by dipping

According to HEAdhoc Recommendation 13, during the application by dipping, the dermal exposure is already covered by the mixing and loading step and the inhalation exposure by the cleaning phase.

Details of Scenario 2.3 –Post-application

Concerning exposure to vapours, the application phase and the post-application are simultaneous if we consider all treated cows together. The exposure is calculated using the consumer exposure model ConsExpo web model "Exposure to vapour: evaporation – constant release" for the substance of concern **isopropanol** (based on HEAdhoc Recommendation 13 – nr. 4,8).

Details of Scenario 2.3 – Post-application – Vapour	
Parameters	Value
Exposure/emission duration	180 minutes (HEAdhoc Recommendation No. 13, nr. 8 – 2 times milking)
Amount product applied per cow	10 ml (product specific information)
Density	1.014 g/ml

Product amount[1]	3326 g
Emission duration	0.25 minutes (Cleaning Products Fact Sheet, 2006)
concentration	[redacted]
Vapour pressure	5780 Pa
Emission duration	180 minutes (HEAdhoc Recommendation No. 13, nr. 8)
Molecular weight	60.1 g/mol
Molecular weight matrix	22.18 g/mol
Kow	0.05 (CAR Isopropanol)
Release area	14432 cm^2 (HEAdhoc Recommendation No. 13, nr. 8)
Mass transfer coefficient (Thibodeaux)	20.1 m/hr (HEAdhoc Recommendation No. 13)
Room size	168 m^3 (HEAdhoc Recommendation No. 13, nr. 8)
Inhalation rate	1.25 m^3/h (HEAdhoc recommendation 14)
Ventilation rate	4/hour (HEAdhoc Recommendation No. 13, nr. 1)
Inhalation penetration	100% (default)
[1]Product amount: 10 ml/cow * 3 times/day * 82 cows * 1.014 g/l [2]Calculated as the average molecular weight of the rest of the total product (the product minus isopropanol) (RIVM report 2016-0171 p. 31)	
Details of Scenario 2.4 – Cleaning of the equipment	
Exposure to vapours which occurs during the cleaning phase is lower in comparison with exposure during the mixing and loading and application operations and is thus not calculated. In line with HEAdhoc recommendation no. 13, for cleaning of equipment, RISKOFDERM 'Loading liquid, automated or semi-automated' for the cleaning phase of different equipment (dipping cup, spraying nozzle etc.) is used. The indicative value is 0.92 mg/min and a duration of 5 minutes is considered.	
concentration	[redacted]
Dermal penetration	50% (default value for water-based dilution product)
Body weight	60 kg (HEAdhoc Recommendation No. 14)
Indicative value	0.92 mg/min (HEAdhoc Recommendation No. 13, nr. 11)
Exposure duration	5 min/day (HEAdhoc Recommendation No. 13, nr. 11)

Estimated dermal uptake= (0.92*5*[redacted]*50%)/60

Calculations for scenario [2.1-2.3-2.4]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake Mg/kg bw/d**	**Estimated dermal uptake Mg/kg bw/d**	**Estimated oral uptake Mg/kg bw/d**	**Estimated total uptake Mg/kg bw/d**
Scenario [2.1] - vapour	1	0.014	0.15	/	0.164
Scenario [2.3] vapour	1	0.72	/	/	0.72
Scenario [2.4]	1	/	$3.8x10^{-4}$	/	$3.8x10^{-4}$

The calculation sheets and output tables are presented in Annex 3.2.

Further information and considerations on scenario [2.1-2.2-2.3-2.4]

Local exposure concentration of isopropanol in air.

Combined scenarios – Use 2 – Teat disinfection (PT3)

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
metaSPC 2 - isopropanol				
Scenarios [1,3,4] Tier 1	0.73	0.15	-	0.88

Scenario [3.1,3.2,3.3]

Description of Scenario [3.1,3.2,3.3] – CIP disinfection
The product is classified as Skin Corr. 1 and Eye Dam. 1 and the only substance contributing to the classification is L(+) lactic acid. There are no substances of concern. A qualitative local risk assessment has to be performed.

Scenario [4.1,4.2,4.3]

Description of Scenario [4.1,4.2,4.3] – Surface disinfection using a trigger spray	
Details of Scenario 4.1 – Mixing and loading	
Primary exposure (dermal + inhalation). Dilution step is done by pouring the concentrate into a bucket filled with water, in order to obtain the required dilution and then transferred to a trigger spray flask. This task is done manually (3 times daily). This exposure is done on pure product. As metaSPC 3 and metaSPC 5 contain substances of concern, the exposure to 6% 2-butoxyethanol and to 10% isopropanol is also considered for metaSPC 3 and metaSPC 5 respectively. The products in metaSPC 3 and 5 are classified as H314 and H318. As included in the TAB (version November 2018, TOX19, p.10), for oral or dermal exposure no systemic risk assessment needs to be performed, based on the following argumentation: *The use of appropriate personal protective equipment and risk mitigation measures will always be required for corrosive substances. Exposure to corrosive concentrations would thus be negligible. Therefore, exposure to corrosive concentrations can be excluded and systemic risk assessment would not be necessary for such concentrations*. Therefore, a qualitative local risk assessment is performed (see section 2.2.6.3). Inhalation exposure to vapour is considered for the substances of concern. For a worst-case assessment, the product is manually poured from a 25L container into the bucket. The air concentration of 2-butoxyethanol and isopropanol during mixing and loading has been calculated using Consexpo (evaporation from a constant surface) and the default parameters in the Consexpo Cleaning Products Fact Sheet for mixing and loading of a liquid cleaner.	
Details of Scenario 4.1 – Mixing and loading – inhalation exposure (vapour)	
Parameters	**Value**
Exposure duration	0.75 minutes (Consexpo Cleaning Products Fact Sheet)
Concentration 2-butoxyethanol	[redacted]
Concentration isopropanol	10%
Vapour pressure 2-butoxyethanol	117 Pa
Vapour pressure isopropanol	5780 Pa
Emission duration	0.3 minutes (Consexpo Cleaning Products Fact Sheet)
Product amount[1] – metaSPC 3	10830 g (20L can – density: 1,083g/l)
Product amount[1] – metaSPC 5	10690 g (20L can – density: 1,069g/l)
Molecular weight 2-butoxyethanol	118.17 g/mol
Molecular weight isopropanol	60.1 g/mol
Molecular weight matrix[2] – metaSPC 3	32.94 g/mol
Molecular weight matrix[2] – metaSPC 5	22.66 g/mol
Room volume	1 m^3 (Consexpo Cleaning Products Fact Sheet)
Ventilation rate	0.6 /h (Consexpo Cleaning Products Fact Sheet – unspecified room)

Inhalation rate	1.25 m^3/h (HEAdhoc recommendation 14)
Release area	20 cm^2 (Consexpo Cleaning Products Fact Sheet)
Mass transfer coefficient	10 m/hr (Consexpo Cleaning Products Fact Sheet)
Inhalation penetration	100% (default)
[1]According to ConsExpo Cleaning Products Factsheet, the product amount is half of the amount of the bottle content. [2]Calculated as the average molecular weight of the rest of the total product (the product minus isopropanol) (RIVM report 2016-0171 p. 31)	
Details of Scenario 4.2 – Spraying	
Primary exposure dermal and inhalation. The working solution is sprayed on surfaces with a trigger sprayer. After the contact time, the product is left to dry. The disinfection can be done up to 150 times per day (p.35 Biocides_Human Health Exposure methodology). Spraying is done with diluted product. The product in metaSPC 5 is classified as skin corrosive after dilution. As included in the TAB (version November 2018, TOX19, p.10), for oral or dermal exposure no systemic risk assessment needs to be performed, based on the following argumentation: *The use of appropriate personal protective equipment and risk mitigation measures will always be required for corrosive substances. Exposure to corrosive concentrations would thus be negligible. Therefore, exposure to corrosive concentrations can be excluded and systemic risk assessment would not be necessary for such concentrations*. Therefore, a qualitative local risk assessment is performed (see section 2.2.6.3). The product in metaSPC 3 is not classified as corrosive after dilution, therefore, a quantitative dermal exposure is performed for the substance of concern 2-butoxyethanol using the Trigger spray consumer spraying and dusting model 2. Inhalation exposure to vapour and aerosols are considered for the substances of concern, butoxyethanol and isopropanol. To assess the exposure during the spray application with a trigger sprayer, the Consumer Spraying and Dusting model 2 from the TnSG (2008) is used and the exposure to vapour is calculated using the "Exposure to vapour: evaporation – constant release" in Consexpo. The concentration 2- butoxyethanol and isopropanol in the dilutions is respectively, 0.12% and 2.5%.	
Skin classification dilution metaSPC 3: /	
Skin classification dilution metaSPC 5: Skin Corr. 1	
Details of Scenario 4.2 – Spraying - vapour	
Exposure duration	3.2 min (8 hours (working day) – 150 applicants/day)
Concentration 2-butoxyethanol (diluted)	[redacted]
Concentration isopropanol (diluted)	[redacted]
Vapour pressure 2-butoxyethanol	117 Pa
Vapour pressure isopropanol	5780 Pa
Emission duration	1 min/0.5m^2 (HEAdhoc Recommendation No. 15)

Product amount – metaSPC 3	10.83 g/application (density: 1,083g/l)
Product amount – metaSPC 5	10.59 g/application (density: 1,059g/l)
Application rate	20 ml/m^2
Molecular weight 2-butoxyethanol	118.17 g/mol
Molecular weight isopropanol	60.1 g/mol
Molecular weight matrix[2] – metaSPC 3	32.94 g/mol
Molecular weight matrix[2] – metaSPC 5	22.66 g/mol
Room volume	20m^3 (Default Consexpo)
Ventilation rate	0.6 /h (Consexpo Cleaning Products Fact Sheet – unspecified room)
Inhalation rate	1.25 m^3/h (HEAdhoc recommendation 14)
Release area	0.5 m^2 (HEAdhoc Recommendation No. 15)
Mass transfer coefficient	10 m/hr (Consexpo Cleaning Products Fact Sheet)
Inhalation penetration	100%
Body weight	60 kg (HEAdhoc recommendation 14)
[2]Calculated as the average molecular weight of the rest of the total product (the product minus isopropanol) (RIVM report 2016-0171 p. 31)	
Details of Scenario 4.2 – Spraying - aerosol	
Indicative exposure value	10.5 mg/m^3 (Consumer Spraying and Dusting model 2
Concentration 2-butoxyethanol (diluted)	[redacted]
Concentration isopropanol (diluted)	[redacted]
Inhalation rate	1.25 m^3/h (HEAdhoc recommendation 14)
Body weight	60 kg (HEAdhoc recommendation 14)
Inhalation penetration	100% (default)
Spray duration	2.5 hours (HEAdhoc Recommendation No. 15, 150 applications – 1min/0.5 m^2)
Estimated inhal uptake 2-butoxyethanol = (1.25 * 2.5 * 10.5 * 0.12% * 100%) /60 Estimated inhal uptake isopropanol = (1.25 * 2.5 * 10.5 * 2.5% * 100%) /60	
Details of Scenario 4.2 – Spraying – dermal exposure – metaSPC 3 – butoxyethanol	
Indicative exposure value	45.8 mg/min (Trigger spray consumer spraying and dusting model 2 for hands, forearms, legs, feet and face)
Concentration 2-butoxyethanol (diluted)	[redacted]
Dermal penetration	50% (default value for water-based dilution product)

Body weight	60 kg (HEAdhoc recommendation 14)
Spray duration	2.5 hours (HEAdhoc Recommendation No. 15, 150 applications – 1min/0.5 m^2) =150 min
Estimated dermal uptake= (45.8*150*[redacted] 50%)/60 =0.069 mg/kg	
Details of Scenario 4.3 – Post-application	
Secondary exposure to vapours which occurs during the drying phase is lower in comparison with exposure during the mixing and loading and application operations and is thus covered by these scenarios. Secondary dermal exposure by touching treated surfaces is assessed using HEEG opinion 7.	
Details of Scenario 4.3 – Post-application – dermal exposure	
Concentration 2-butoxyethanol (diluted)	[redacted]
Concentration isopropanol (diluted)	[redacted]
Application rate	20 ml/m^2 (product specific data) =2.2 mg/cm² (for metaSPC 3, density=1.083) =2.1 mg/cm²((for metaSPC 5, density = 1.069)
Dermal penetration	50% (default value for water-based dilution product)
Transfer coefficient (surface area treated with product that is in contact with the skin per unit of time)	6000 cm^2/h (HEEG opinion 7)
Dislodgeable fraction	30% (HEEG opinion 7)
Contact time	1 h
Body weight	60 kg (HEAdhoc recommendation 14)
Estimated dermal uptake 2-butoxyethanol = (2.2*6000*1*30%*[redacted] 50%)/60 =0.04 mg/kg Estimated dermal uptake isopropanol =(2.1*6000*1*30%*[redacted] 50%)/60 =0.79 mg/kg	

Calculations for scenario [4.1,4.2,4.3]

Summary table: estimated exposure from professional uses – 2-butoxyethanol – MetaSPC 3					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake** mg/kg bw/day	**Estimated dermal uptake** mg/kg bw/day	**Estimated oral uptake**	**Estimated total uptake** mg/kg bw/day
Scenario [4.1] - vapour	1	6.1×10^{-6}			6.1×10^{-6}
Scenario [4.2] - aerosol	1	6.6×10^{-4}	6.9×10^{-2}	/	7.1×10^{-2}
Scenario [4.2] - vapour	1	1.1×10^{-3}		/	
Scenario [4.3]	1	/	4×10^{-2}	/	4×10^{-2}

Summary table: estimated exposure from professional uses – isopropanol – MetaSPC 5					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake** mg/kg bw/day	**Estimated dermal uptake** mg/kg bw/day	**Estimated oral uptake**	**Estimated total uptake** mg/kg bw/day
Scenario [4.1] - vapour	1	3.6×10^{-4}			3.6×10^{-4}
Scenario [4.2] - aerosol	1	0.014	/	/	0.66
Scenario [4.2] - vapour	1	0.65			
Scenario [4.3]	1	/	0.79	/	0.79

The output tables are presented in Annex 3.2.

Further information and considerations on scenario [4.1,4.2,4.3]
Local exposure concentration of 2-butoxyethanol in air.

Summary table: estimated exposure from professional uses to the SoC 2-butoxyethanol		
Substance	**Scenario**	**Local exposure**
2-butoxyethanol	4.1	0.0079 mg/m^3
	4.2	0.0065 mg/m^3
	4.3	Not applicable

Combined scenarios – Use 4 - Trigger spraying (PT2/PT4)

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
metaSPC 3 - butoxyethanol				
Scenarios [4.1,4.2,4.3] Tier 1	1.97 x 10^{-3}	10.9 x 10^{-2}	-	11.1 x 10^{-2}
metaSPC 5 - isopropanol				
Scenarios [4.1,4.2,4.3] Tier 1	0.66	0.79	-	1.45

Scenario [5.1,5.2,5.3]

Description of Scenario [5.1,5.2,5.3] – Disinfection by dipping
Objects and instruments are disinfected by submersion into a disinfection bath (volume 1-20L). The disinfection bath is prepared by pouring the disinfectant in a bath and filling it up with water. The products are then brought into the bath and left there during 15 min for metaSPC 3 and 4 and 5 min for metaSPC 5.
Details of Scenario 5.1 – Mixing and loading - manual
Primary exposure (dermal + inhalation). Dilution step is done by pouring the concentrate into a bath, in order to obtain the required dilution. This task is done manually (five times daily). This exposure is done on pure product. As metaSPC 3 and metaSPC 5 contain substances of concern, the exposure to 6% 2-butoxyethanol and to 10% isopropanol is also considered for metaSPC 3 and metaSPC 5 respectively. The products in metaSPC 3, 4 and 5 are classified as H314 and H318. As included in the TAB (version November 2018, TOX19, p.10), for oral or dermal exposure no systemic risk assessment needs to be performed, based on the following argumentation: *The use of appropriate personal protective equipment and risk mitigation measures will always be required for corrosive substances. Exposure to corrosive concentrations would thus be negligible. Therefore, exposure to corrosive concentrations can be excluded and systemic risk assessment would not be necessary for such concentrations*. Therefore, a qualitative local risk assessment is performed (see section 2.2.6.3). Inhalation exposure to vapour is considered for the substances of concern. For a worst-case assessment, the product is manually poured from a 25L container into the bucket. The air concentration of 2-butoxyethanol and isopropanol during mixing and loading has been calculated using Consexpo (evaporation from a constant surface) and the default parameters in the Consexpo Cleaning Products Fact Sheet for mixing and loading of a liquid cleaner.
Details of Scenario 5.1 – Mixing and loading – Inhalation exposure to vapour – manual loading

Parameters	**Value**
Exposure duration	0.75 minutes (Consexpo Cleaning Products Fact Sheet)
Concentration 2-butoxyethanol	[redacted]
Concentration isopropanol	[redacted]
Vapour pressure 2-butoxyethanol	117 Pa
Vapour pressure isopropanol	5780 Pa
Emission duration	0.3 minutes (Consexpo Cleaning Products Fact Sheet)
Product amount[1] – metaSPC 3	10830 g (20L can – density: 1,083g/l)
Product amount[1] – metaSPC 5	10690 g (20L can – density: 1,069g/l)
Molecular weight 2-butoxyethanol	118.17 g/mol
Molecular weight isopropanol	60.1 g/mol
Molecular weight matrix[2] – metaSPC 3	32.94 g/mol
Molecular weight matrix[2] – metaSPC 5	28.66 g/mol

Room volume	1 m^3 (Consexpo Cleaning Products Fact Sheet)
Ventilation rate	0.6 /h (Consexpo Cleaning Products Fact Sheet – unspecified room)
Inhalation rate	1.25 m^3/h (HEAdhoc recommendation 14)
Release area	20 cm^2 (Consexpo Cleaning Products Fact Sheet)
Mass transfer coefficient	10 m/hr (Consexpo Cleaning Products Fact Sheet)
Inhalation penetration	100% (default)
[1]According to ConsExpo Cleaning Products Factsheet, the product amount is half of the amount of the bottle content. [2]Calculated as the average molecular weight of the rest of the total product (the product minus isopropanol) (RIVM report 2016-0171 p. 31)	
Details of Scenario 5.2 – Dipping	
Primary exposure dermal and inhalation. The objects are brought into the disinfection bath or bucket. After the required contact time, the objects are removed from the disinfection bath. The contact time for products in metaSPC 3 and 4 is 15 min and in metaSPC5 is 5 min (5 times daily). The products in metaSPC 4 and 5 are classified as skin corrosive after dilution. As included in the TAB (version November 2018, TOX19, p.10), for oral or dermal exposure no systemic risk assessment needs to be performed, based on the following argumentation: *The use of appropriate personal protective equipment and risk mitigation measures will always be required for corrosive substances. Exposure to corrosive concentrations would thus be negligible. Therefore, exposure to corrosive concentrations can be excluded and systemic risk assessment would not be necessary for such concentrations*. Therefore, a qualitative local risk assessment is performed (see section 2.2.6.3). The product in metaSPC 3 is not classified as corrosive after dilution, therefore, a quantitative dermal exposure is performed for the substance of concern 2-butoxyethanol using HEEG Opinion 16 (exposure of both hands and forearms) and the dermal exposure calculation presented in HEAdhoc recommendation 6, nr. 1. Inhalation exposure to vapour is considered for the substances of concern, 2-butoxyethanol and isopropanol. To assess the exposure during dipping Dipping Model 1 (HEAdhoc Recommendation 6, nr. 8) is used and the exposure to vapour is calculated using the "Exposure to vapour: evaporation – constant release" in Consexpo. The concentration 2- butoxyethanol and isopropanol in the dilutions is respectively, 0.12% and 2.5%.	
Skin classification dilution metaSPC 3: /	
Skin classification dilution metaSPC 4: Skin Corr. 1	
Skin classification dilution metaSPC 5: Skin Corr. 1	
Details of Scenario 5.2 – Dipping – inhalation exposure to vapour	
Exposure duration – metaSPC 3	15 min
Exposure duration – metaSPC 5	5 min
Concentration 2-butoxyethanol (diluted)	[redacted]

Concentration isopropanol (diluted)	[redacted]
Vapour pressure 2-butoxyethanol	117 Pa
Vapour pressure isopropanol	5780 Pa
Emission duration	See exposure duration
Product amount[1] – metaSPC 3	0.43 g (2% of 20L (density: 1,083g/l))
Product amount[1] – metaSPC 5	5.30 g (25% of 20L (density: 1,059g/l))
Molecular weight 2-butoxyethanol	118.17 g/mol
Molecular weight isopropanol	60.1 g/mol
Molecular weight matrix[2] – metaSPC 3	32.94 g/mol
Molecular weight matrix[2] – metaSPC 5	28.66 g/mol
Room volume	20m^3 (Cleaning Consexpo Cleaning Products Fact Sheet – unspecified room)
Ventilation rate	0.6 /h (Consexpo Cleaning Products Fact Sheet – unspecified room)
Inhalation rate	1.25 m^3/h (HEAdhoc recommendation 14)
Release area: 20L, bath height: 10cm	2000 cm^2
Mass transfer coefficient	10 m/hr (Consexpo Cleaning Products Fact Sheet)
Inhalation penetration	100%
[1]According to ConsExpo Cleaning Products Factsheet, the product amount is half of the amount of the bottle content. [2]Calculated as the average molecular weight of the rest of the total product (the product minus isopropanol) (RIVM report 2016-0171 p. 31)	
Details of Scenario 5.2 – Dipping – dermal exposure – metaSPC 3 – 2-butoxyethanol	
Indicative value hands	25.7 mg/min
Indicative value body	178 mg/min
Dermal absorption	50% (default value for water-based dilution product)
Body weight	60 kg (HEAdhoc recommendation 14)
Concentration 2-butoxyethanol (diluted)	0.12%
Duration / day	15*5 =75 min
Estimated dermal uptake: ((25.7 + 178)*75*[redacted] * 50%)/60	
Details of Scenario 5.3 – Post-application	

In the post-application phase, the objects are removed from the bath or bucket and the dipping bath or bucket is cleaned with water. Dermal exposure when taking out the objects is covered by the dermal exposure assessed in scenario 5.2 – dermal exposure. Exposure during the emptying of the bath or bucket to the diluted solution is negligible compared to exposure during mixing and loading in which the pure product is handled.

Calculations for scenario [5.1,5.2,5.3]

Summary table: estimated exposure from professional uses – 2-butoxyethanol – MetaSPC 3					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** mg/kg bw/day	**Estimated dermal uptake** mg/kg bw/day	**Estimated oral uptake**	**Estimated total uptake** mg/kg bw/day
Scenario [5.1] - vapour	1	1.0×10^{-5}	/	/	1.0×10^{-5}
Scenario [5.2]	1	3.4×10^{-4}	0.15	/	0.15
Scenario [5.3]	1	/	0.15	/	0.15

Summary table: estimated exposure from professional uses – isopropanol – MetaSPC 5					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** mg/kg bw/day	**Estimated dermal uptake** mg/kg bw/day	**Estimated oral uptake**	**Estimated total uptake** mg/kg bw/day
Scenario [5.1] - vapour	1	7.40×10^{-4}	/	/	7.40×10^{-4}
Scenario [5.2] - vapour	1	3.3×10^{-2}	/	/	3.3×10^{-2}
Scenario [5.3]	1	/	/	/	/

The calculation sheets and output tables are presented in Annex 3.2.

Further information and considerations on scenario [5.1,5.2,5.3]

Local exposure concentration of 2-butoxyethanol in air.

Summary table: estimated exposure from professional uses to the SoC 2-butoxyethanol		
Substance	**Scenario**	**Local exposure**
2-butoxyethanol	5.1	0.0079 mg/m^3
	5.2	0.013 mg/m^3
	5.3	Not applicable

Combined scenarios – Use 5 - Dipping (PT4)

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
metaSPC 3 - butoxyethanol				
Scenarios [5.1,5.2,5.3] Tier 1	1 x 10^{-5}	0.30	/	0.30
metaSPC 5 - isopropanol				
Scenarios [5.1,5.2,5.3] Tier 1	3.4 x 10^{-2}	/	/	3.4 x 10^{-2}

Scenario [6.1,6.2,6.3]

Description of Scenario [6.1,6.2,6.3] – Surface disinfection using low-pressure spraying	
Details of Scenario 6.1 – Mixing and loading	
Primary exposure (dermal + inhalation). Dilution can be prepared manually or automatically (3 times daily), and exposure is done on pure product. As metaSPC 3 and metaSPC 5 contain substances of concern, the exposure to 6% 2-butoxyethanol and to 10% isopropanol is also considered for metaSPC 3 and metaSPC 5 respectively. The products in metaSPC 3, 4 and 5 are classified as H314 and H318. As included in the TAB (version November 2018, TOX19, p.10), for oral or dermal exposure no systemic risk assessment needs to be performed, based on the following argumentation: *The use of appropriate personal protective equipment and risk mitigation measures will always be required for corrosive substances. Exposure to corrosive concentrations would thus be negligible. Therefore, exposure to corrosive concentrations can be excluded and systemic risk assessment would not be necessary for such concentrations*. Therefore, a qualitative local risk assessment is performed (see section 2.2.6.3). Inhalation exposure to vapour is considered for the substances of concern. For a worst-case assessment, the product is manually poured from a 25L container into the bucket. The air concentration of 2-butoxyethanol and isopropanol during mixing and loading has been calculated using Consexpo (evaporation from a constant surface) and the default parameters in the Consexpo Cleaning Products Fact Sheet for mixing and loading of a liquid cleaner. Automatic dilution is covered by the manual dilution step.	
Details of Scenario 6.1 – Mixing and loading – inhalation exposure (vapour)	
Parameters	**Value**
Exposure duration	0.75 minutes (Consexpo Cleaning Products Fact Sheet)
Concentration 2-butoxyethanol	[redacted]
Concentration isopropanol	[redacted]
Vapour pressure 2-butoxyethanol	117 Pa
Vapour pressure isopropanol	5780 Pa
Emission duration	0.3 minutes (Consexpo Cleaning Products Fact Sheet)
Product amount[1] – metaSPC 3	10830 g (20L can – density: 1,083g/l)
Product amount[1] – metaSPC 5	10690 g (20L can – density: 1,069g/l)
Molecular weight 2-butoxyethanol	118.17 g/mol
Molecular weight isopropanol	60.1 g/mol
Molecular weight matrix[2] – metaSPC 3	32.94 g/mol
Molecular weight matrix[2] – metaSPC 5	22.66 g/mol
Room volume	1m^3 (Consexpo Cleaning Products Fact Sheet)
Ventilation rate	0.6/h (Consexpo Cleaning Products Fact Sheet – unspecified room)

Inhalation rate	1.25 m^3/h (HEAdhoc recommendation 14)
Release area	20 cm^2 (Consexpo Cleaning Products Fact Sheet)
Mass transfer coefficient	10 m/hr (Consexpo Cleaning Products Fact Sheet)
Inhalation penetration	100% (default)
[1]According to ConsExpo Cleaning Products Factsheet, the product amount is half of the amount of the bottle content. [2]Calculated as the average molecular weight of the rest of the total product (the product minus isopropanol) (RIVM report 2016-0171 p. 31)	
Details of Scenario 6.2 – Spraying	
Primary exposure dermal and inhalation. The working solution is sprayed on surfaces with a trigger sprayer. This step takes 30 min depending on the surface to be disinfected. After the contact time, the product is left to dry. The disinfection can be done one time per day. Spraying is done with diluted product. The products in metaSPC 4 and 5 are classified as skin corrosive after dilution. As included in the TAB (version November 2018, TOX19, p.10), for oral or dermal exposure no systemic risk assessment needs to be performed, based on the following argumentation: *The use of appropriate personal protective equipment and risk mitigation measures will always be required for corrosive substances. Exposure to corrosive concentrations would thus be negligible. Therefore, exposure to corrosive concentrations can be excluded and systemic risk assessment would not be necessary for such concentrations*. Therefore, a qualitative local risk assessment is performed. The product in metaSPC 3 is not classified as corrosive after dilution, therefore, a quantitative dermal exposure is performed for the substance of concern 2-butoxyethanol using Spraying model 1. Inhalation exposure to vapour and aerosols are considered for the substances of concern, butoxyethanol and isopropanol. To assess the exposure during the spray application with a low-pressure sprayer, Spraying model 1 is used and the exposure to vapour is calculated using the "Exposure to vapour: evaporation – constant release" in Consexpo. The concentration 2-butoxyethanol and isopropanol in the dilutions is respectively, 0.12% and 2.5%.	
Skin classification dilution metaSPC 3: /	
Skin classification dilution metaSPC 4: Skin Corr. 1	
Skin classification dilution metaSPC 5: Skin Corr. 1	
Details of Scenario 6.2 – Spraying - vapour	
Exposure duration	30 minutes (based on experience)
Concentration 2-butoxyethanol (diluted)	[redacted]
Concentration isopropanol (diluted)	[redacted]
Vapour pressure 2-butoxyethanol	117 Pa
Vapour pressure isopropanol	5780 Pa
Emission duration	30 minutes (based on experience)
Product amount[1] – metaSPC 3	5415 g (density: 1,083g/l)
Product amount[1] – metaSPC 5	5345 g (density: 1,059g/l)

Application rate	200 ml/m^2
Molecular weight 2-butoxyethanol	118.17 g/mol
Molecular weight isopropanol	60.1 g/mol
Molecular weight matrix[2] – metaSPC 3	32.94 g/mol
Molecular weight matrix[2] – metaSPC 5	22.66 g/mol
Room volume	80m^3 (HEAdhoc recommendation 6, Nr. 5)
Ventilation rate	0.6 /h (Consexpo Cleaning Products Fact Sheet – unspecified room)
Inhalation rate	1.25 m^3/h (HEAdhoc recommendation 14)
Release area	25 m^2 (Based on ESD – PT2, small scale applications: 25m^2)
Mass transfer coefficient	10 m/hr (Consexpo Cleaning Products Fact Sheet)
Inhalation penetration	100%
[1]According to ConsExpo Cleaning Products Factsheet, the product amount is half of the amount of the bottle content. [2]Calculated as the average molecular weight of the rest of the total product (the product minus isopropanol) (RIVM report 2016-0171 p. 31)	
Details of Scenario 6.2 – Spraying - aerosol	
Indicative exposure value	104 mg/m^3 (Spraying Model 1)
Concentration 2-butoxyethanol (diluted)	[redacted]
Concentration isopropanol (diluted)	[redacted]
Inhalation rate	1.25 m^3/h (HEAdhoc recommendation 14)
Body weight	60 kg (HEAdhoc recommendation 14)
Inhalation penetration	100% (default)
Spray duration	0.5 hour
Estimated inhalation exposure 2-butoxyethanol = (104*1.25*0.5*[redacted] 100%)/60 Estimated inhalation exposure Isopropanol = (104*1.25*0.5*[redacted] 100%)/60	
Details of Scenario 6.2 – Spraying – dermal exposure – metaSPC 3 – butoxyethanol	
Indicative exposure value	181 mg/min (Spraying Model 1)
Concentration 2-butoxyethanol (diluted)	0.12%
Dermal penetration	50% (default value for water-based dilution product)
Body weight	60 kg (HEAdhoc recommendation 14)
Spray duration	30 min
Estimated dermal exposure= (181*30*50%*0.12%)/60	

Details of Scenario 6.3 – Post-application	
Secondary exposure to vapours which occurs during the drying phase is lower in comparison with exposure during the mixing and loading and application operations and is thus covered by these scenarios. Secondary dermal exposure by touching treated surfaces is assessed using HEEG opinion 7.	
Details of Scenario 6.3 – Post-application – dermal exposure	
Concentration 2-butoxyethanol (diluted)	0.12%
Concentration isopropanol (diluted)	[redacted]
Application rate	200 ml/m^2 (product specific data) =22 mg/cm² (for metaSPC 3, density=1.083) =21 mg/cm²((for metaSPC 5, density = 1.069)
Transfer coefficient (surface area treated with product that is in contact with the skin per unit of time)	6000 cm^2/h (HEEG opinion 7)
Dermal penetration	50% (default value for water-based dilution product)
Dislodgeable fraction	30% (HEEG opinion 7)
Contact time	1 h
Body weight	60 kg (HEAdhoc recommendation 14)
Estimated dermal uptake 2-butoxyethanol = (22*6000*1*30%*[redacted] 50%)/60 = 0.4 mg/kg Estimated dermal uptake isopropanol =(21*6000*1*30%*[redacted] 50%)/60 =7.9 mg/kg	

Calculations for scenario [6.1,6.2,6.3]

Summary table: estimated exposure from professional uses – 2-butoxyethanol – MetaSPC 3					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** mg/kg bw/day	**Estimated dermal uptake** mg/kg bw/day	**Estimated oral uptake**	**Estimated total uptake** mg/kg bw/day
Scenario [6.1] - vapour	1	6.1×10^{-6}			6.1×10^{-6}
Scenario [6.2] - aerosol	1	1.30×10^{-3}	5.4×10^{-2}	/	6.5×10^{-2}
Scenario [6.2] - vapour	1	9.00×10^{-3}		/	
Scenario [6.3]	1	/	0.4	/	0.4

Summary table: estimated exposure from professional uses – isopropanol – MetaSPC 5					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** mg/kg bw/day	**Estimated dermal uptake** mg/kg bw/day	**Estimated oral uptake**	**Estimated total uptake** mg/kg bw/day
Scenario [6.1] - vapour	1	3.6×10^{-4}			3.6×10^{-4}
Scenario [6.2] - aerosol	1	2.7×10^{-2}	/	/	4.83
Scenario [6.2] - vapour	1	4.8			
Scenario [6.3]	1	/	7.9	/	7.9

The calculation sheets and output tables are presented in Annex 3.2.

Further information and considerations on scenario [6.1,6.2,6.3]

Local exposure concentration of 2-butoxyethanol in air.

Summary table: estimated exposure from professional uses to the SoC 2-butoxyethanol		
Substance	**Scenario**	**Local exposure**
2-butoxyethanol	6.1	0.0079 mg/m^3
	6.2	1.2 mg/m^3
	6.3	Not applicable

Combined scenarios – Use 6 – Low pressure spraying (PT2/PT4)

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
metaSPC 3 - butoxyethanol				
Scenarios [6.1,6.2,6.3] Tier 1	1 x 10^{-2}	0.45	-	0.46
metaSPC 5 - isopropanol				
Scenarios [6.1,6.2,6.3] Tier 1	4.83	7.9	-	12.73

Non-professional exposure

Please refer to the qualitative risk assessment below. Calculations were not performed, as L(+) lactic acid is not hazardous, and no reference values (AEL, NOAEL or DNEL) have been established.

Exposure of the general public

Exposure of the general public can only occur via dietary exposure which is discussed below.

Monitoring data

Monitoring data are not available and are also not considered to be necessary.

Dietary exposure

L(+) lactic acid is a naturally produced by plants, animals, and humans. The major sources of L(+) lactic acid in the human organism are endogenous production (e. g. via anaerobic catabolism of glycogen and glucose) production by gastrointestinal 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 (DocIII6.2.01-CAR).

The L(+) lactic acid has only local effects toxicity, it's considered to be a skin irritant (skin irrit.2) and severe eye irritant (see CAR of active substance). But if you refer to the RAC opinion (corrigendum version published on 03/12/2019), this substance should be classified as corrosive for skin and eyes.

Therefore, neither an ADI nor an ARfD have been set. Likewise, 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).

We can postulate that the residues in food from the intended use (PT4 and PT3) are expected to be low compared to naturally occurring levels in food (i.e. diary product,..). Therefore, no dietary risk assessment of lactic acid is required.

Regarding the dietary exposure of propan-2-ol (SOC band C, meta SPC 2), due to its high vapor pressure (5780 Pa at 25°C), this substance evaporates completely within the time of application (5 min) of the biocidal products PT4 and PT3. In the case of the residue transfer does occur, the propan-2-ol will evaporate from the food before it is eaten.

In addition, the isopropanol (IPA) is also used as a solvents with outlets in cosmetics and personal care products, de-icers, paints, resins, pharmaceuticals, food, inks and adhesives. A pharmaceutical grade of IPA allows its use in the preparation of a number of pharmaceutical products such as medicinal tablets as well as disinfectants, sterilisers and skin creams. Little or no growth is expected in solvent applications due to stricter regulations on volatile organic compounds (VOCs).

IPA is used in the extraction and purification of natural products such as vegetable and animal oil and fats. Other applications include its use as a cleaning and drying agent in the manufacture of electronic parts and metals, and as an aerosol solvent in medical and veterinary products. It can also be used as a coolant in beer manufacture, a coupling agent, a polymerisation modifier, a de-icing agent and a preservative.[2]

The isopropanol is also listed in Commission Implementing Regulation (EU) No 872/2012[3] as flavouring substances intended to be used in or on foodstuffs.

2-butoxyethanol is also listed as SOC band C, this substance has a high vapour pressure (117 Pa at 25°C) so that we can also expected that it evaporates completely within the time of application of the biocidal products PT4. In the case of the residue transfer does occur, the 2-butoxyethanol will evaporate from the food before it is eaten.

Concerning the SOCs band B (alcohols, C13-15-branched and linear, ethoxylated, glycolic acid ethoxylate octyl ether, cocamidopropyl betaine , sodium hydroxide, lauryl ether sulfate, PEG-10 propylheptyl ether, amines, C12-14-alkyldimethyl, n-oxides, sulfuric acid, mono-C12-14-alkyl esters, sodium salts), only a qualitative risk assessment needs to be performed according to the ECHA guidance on risk assessment on human health.

[2] https://www.icis.com/explore/resources/news/2007/11/05/9076020/isopropanol-ipa-uses-and-market-data/

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0872&from=EN

Regarding meta SPC 3 after dilution, the product (PT4) doesn't induce a local toxicological effect.

Regarding meta SPC 5 after dilution, the product (PT4) could induce a local toxicological effect (irritating or even corrosive effect) on the gastrointestinal tract, it depends on the fraction of product ingested (depend to the physicochemical properties: solubility, log Pow, volatility, biodegradability, light sensibility, pH, pKa). The irritating/corrosive effects are not induced by the SOC (sulfuric acid, mono-C12-14-alkyl esters, sodium salts) but by the active substance.

Conclusion:

Exposure to residues of L-lactic acid on treated surfaces is still possible. However it's relevant to consider that the residues in food from the intended use (PT4..) are expected to be low compared to naturally occurring levels in food (i.e. diary product,..). Therefore the intended use does not significantly contribute to consumer exposure to L(+) lactic acid, no dietary risk assessment is required.

Neither an ADI nor an ARfD have been set. Likewise, 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).

The isopropanol and the 2-butoxyethanol (SOC band C) are highly volatile substances so that no residue is expected after evaporation.

Finally regarding the SOCs band B, these substances are present in insufficient concentrations after dilution to induce local toxicological effects. Therefore no unacceptable risk is expected for consumers.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Food industry	Food additive	EFSA Journal 2020;18(3):6032

Information of non-biocidal use of the substance of concern (isopropanol)

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s)**
1.	Veterinary use	All food producing species: used as bactericide and antiseptic	Based on regulation (EU) No. 37/2010**Erreur ! Signet non défini.** no MRL is required
2.	Feed additive	Carrier solvent for flavourings	Based on regulation (EU) No.2017/55 max. 25 mg/kg of complete feeding stuff with a moisture content of 12%.
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)

Information of non-biocidal use of the substance of concern (2-butoxyethnol)

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s)**
1.	Cosmetics	To dissolve other substances and to decrease the viscosity of hair dyes and colors	No MRL available
2.	Paints	Solvent	No MRL available

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Only in the case of teat dip solutions (meta SPC2), there is livestock exposure. As lactic acid is a food ingredient, and there is normally only contact with the teat dip or spray solutions via the skin (teat dipping or spraying) it is not considered necessary to calculate exposure of livestock. The products are not classified as hazardous for the skin, so there is no concern about using them for the purpose or teat dipping. The co-formulants show only local toxicological effects, so no dietary risk is expected via consumption of animal products.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

As the active substance is a food ingredient and there is no concern about residues, there is no need to estimate the transfer into foods as a result of professional and/or industrial applications.
What concerns the substances of concern, isopropanol and 2-butoxyethanol, no transfer into food is expected due to the high volatility of these substances.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

The only non-professional use is as a toilet disinfectant, and from this use there is no transfer into foods possible.

Exposure associated with production, formulation and disposal of the biocidal product

Exposure associated with production and formulation is subject to EU and national worker protection legislation, such as the EU Chemical Agents Directive, (Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work) and has residual risk controlled through control measures and the use of Personal Protective Equipment (PPE). It is therefore outside the scope of a biocidal product authorisation dossier to evaluate exposure during production and formulation as this is already covered by other legislation.

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation – Lactic acid

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
Systemic					
AELshort-term	No values have been established for L(+) lactic acid, due to the low hazard. (Assessment Report L(+) lactic acid, Germany, 2015				
AELmedium-term					
AELlong-term					
ARfD					
ADI					
Local					
NOAEC	Dermal NOAEC of 10%				

Reference values to be used in Risk Characterisation – Isopropanol

For professional workers	Value
$AEC_{acute/medium/long-term}$	52.6 ppm (129 mg/m^3)
$AEL_{acute/medium/long-term}$	17.9 mg/kg bw/day
ADI	2.4 mg/kg/d

Reference values to be used in Risk Characterisation –2-butoxyethanol

For professional workers	Value
Systemic	
EU-OEL long term, inhalation	98 mg/m^3*
EU-OEL acute, inhalation	1091 mg/m^3
EU-OEL long term, dermal	125 mg/kg bw/day
EU-OEL acute, dermal	89 mg/kg bw/day
Local	
EU-OEL - inhalation	246 mg/m^3

*Assuming a human inhalation volume of 10 m³ / 8h (1 working day) (according to recommendation 14, 1,25 m³/h) and an absorption in the respiratory tract of 100%, the daily limit is (10 * 98)/60 = 16.3 mg/kg/day.
This value will be used in the table below.

Maximum residue limits or equivalent

Not applicable: MRLs have not been established for L(+) lactic acid, isopropanol and 2-butoxyethanol. Regarding isopropanol the default value correspond to 0.01 mg/kg according to Art 18(1)(b) Reg. 396/2005.

Specific reference value for groundwater

Not applicable.

Risk for industrial users

See professional users

Risk for professional users

Systemic effects

As no reference exposure values are available for the active substance, exposure was not calculated. The active substance is not hazardous, so it is concluded that there is no systemic risk for professional users from using lactic acid biocidal products.

A systemic risk assessment is however performed for the substances of concern, isopropanol and 2-butoxyethanol.

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d		AEL or EU-OEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)		Acceptable (yes/no)
Scenario 2 – isopropanol – metaSPC 2 (inhalation/dermal)	1 – no PPE	200 (ppm)		17,9	0.88	4.9		yes
Scenario 4 – isopropanol – metaSPC 5 (inhalation/dermal)	1 – no PPE	200 (ppm)		17,9	1.45	8.1		yes
Scenario 5 – isopropanol – metaSPC 5 (inhalation/dermal)	1 – no PPE	200 (ppm)		17,9	3.4×10^{-2}	0.2		yes
Scenario 6 – isopropanol – metaSPC 5 (inhalation/dermal)	1 – no PPE	200 (ppm)		17,9	12.73	71.1		yes
Scenario 4 - butoxyethanol - metaSPC 3 - inhalation/dermal	1 – no PPE	Inhal	152	16.3	1.97×10^{-2}	0.12	0.21	yes
		Dermal	150	125	11.1×10^{-2}	0.09		
Scenario 5 - butoxyethanol - metaSPC 3 - inhalation/dermal	1 – no PPE	Inhal	152	16.3	1×10^{-5}	0.00006	0.24	yes
		Dermal	150	125	0.3	0.24		

Scenario 6-butoxyethanol - metaSPC 3 - dermal	1 – no PPE	Inhal	152	16.3	1×10^{-2}	0.06	0.42	yes
		Dermal	150	125	0.45	0.36		

Local effects – inhalation

Substance	Tier	Exposure limit value (mg/m^3)	Estimated inhalation exposure (mg/m^3)	Estimated exposure/ limit value (%)	Acceptable (yes/no)
2-butoxyethanol - scenario 4 - metaSPC 3	5 – no PPE	246	0.0079	0.003	Yes
2-butoxyethanol - scenario 5 - metaSPC 3	6 – no PPE	246	0,013	0.005	Yes
2-butoxyethanol - scenario 6 - metaSPC 3	7 – no PPE	246	1.2	0.5	Yes

Local effects – dermal

To assess the dermal local effects for ERO-MP a qualitative risk assessment according to the Guidance document Volume III Part B section 4.3.2 is performed.

MetaSPC 1 - Symbioz Gel San' Desinfectant, Chriox WC, Laco Gel WC

Hazard category	Effects in terms of C&L	Frequency and duration of potential exposure	Degree of potential exposure under best practice conditions	Relevant RMM & PPE	Support for acceptable risk
High	Skin Corr 1C (H314) – Eye Dam Cat 1 (H318)	Once per week, few minutes	Low	- Packaging design eliminating exposure - Labelling - Instructions for use - High viscosity of product (aerosol formation and potential for splashes reduced) - Avoid contact with skin and eyes - Keep out of reach of children and pets	Acceptable: + Practically no exposure + Short duration + No aerosol formation

The precautionary statements P304 + P340 (IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing) are optional and taking is not relevant for the specific use of metaSPC1.
The precautionary statement P321 (specific treatment) is only recommended in exceptional cases where specific treatment is known and required. This is not the case for this product.

MetaSPC 2 – Mida Agri 830 Post Red

The product in metaSPC 2 is not classified for skin corrosivity/irritation, therefore a semi-quantitative local risk assessment using the dermal NOAEC of 10% is required. The 10% lactic acid tested was dissolved in water. The product Mida Agri 830 Post Red is also aqueous based ([redacted] water). In addition to water, the product contains only alkyl ether carboxylic acid which is classified as Skin Irrit. 2 at a concentration of [redacted] insufficient to trigger skin irritation.
The product is a ready to use solution containing 8% lactic acid and thus below the NOAEC of 10% during all stages of the teat disinfection. Thus, it can be concluded that there are no risks associated with the use of the product.

However, it's classified as eye damage 1 (H318), therefore, a local risk assessment is performed:

Hazard category	Effects in terms of C&L	Frequency and duration of potential exposure	Degree of potential exposure under best practice conditions	Relevant RMM & PPE	Support for acceptable risk
High	Eye Dam Cat 1 (H318)	3 times daily 10 sec / cow => 41 min/day	Low	- Wearing of goggles and protective gloves* - Labelling - Instructions for use - Washing hands/face/eyes after accidental exposure	Acceptable: + Only accidental exposure + Professionals using PPE + Professionals following instructions for use

*Even if the product is not classified for the skin, it's assumed that wearing gloves will reduce the risk of accidental contact between product on hands and eyes (especially after the milking).

MetaSPC 3 – Mida San 325 DA – Quacide DA80

The product in metaSPC 3 is classified as Skin Corr. 1 and Eye Dam. 1, therefore, a local risk assessment is performed for the mixing and loading step. The in-use dilution is however not classified anymore and thus no local risk assessment is required.

Hazard category	Effects in terms of C&L	Frequency and duration of potential exposure	Degree of potential exposure under best practice conditions	Relevant RMM & PPE	Support for acceptable risk
High	Undiluted product (pH =0.46): Skin Corr 1(H314) – Eye Dam Cat 1 (H318) EUH071	Few minutes per day or less (exposure to concentrated products occurs only in the mixing/loading phase)	Low, splashes, hand to eye transfer	- Wearing of protective gloves, goggles and clothing - Labelling - Instructions for use - Rinsing recommended after use - Washing hands/face/eyes after accidental exposure	Acceptable: + Only accidental exposure + Professionals using PPE + Professionals following instructions for use + Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed;

					- Training for staff on good practice. - Good standard of personal hygiene.

MetaSPC 4 – Mida San 332 VB and MetaSPC 5 – Mida San 331 LW

The products in metaSPC 4 and 5 are classified as Skin Corr. 1 and Eye Dam. 1, therefore, a local risk assessment is performed for the mixing and loading step. The diluted solution is also classified thus a local risk assessment is required for the different types of application (trigger spraying, dipping, low pressure spraying).
Regarding CIP use, the user is only exposed to the chemicals at the time of replacing empty containers.
Since a typical CIP cycle contain a final rinsing and a drying step, the exposure to the product for cleaning/maintenance of pumps is negligible.

Hazard category	Effects in terms of C&L	Frequency and duration of potential exposure	Degree of potential exposure under best practice conditions	Relevant RMM & PPE	Support for acceptable risk
High	Mixing and loading. Undiluted product: Skin Corr. 1 (H314) – Eye Dam Cat 1 (H318) EUH071	Few minutes per day	Low, splashes, hand to eye transfer	- Wearing of protective gloves, goggles and clothing - Labelling - Instructions for use - Washing hands/face/eyes after accidental exposure	Acceptable: + Only accidental exposure + Professionals using PPE + Professionals following instructions for use + Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice. - Good standard of personal hygiene.
	Trigger sprayer. Diluted: Skin Corr. 1C (H314) – Eye Dam Cat 1 (H318) EUH071	Few minutes per day	Low, splashes, hand to eye transfer	- Wearing of protective gloves, goggles, clothing, and respiratory protective equipment - Labelling - Instructions for use - Spraying away from user - Washing hands/face/eyes after accidental exposure	Acceptable: + Only accidental exposure + Professionals using PPE + Professionals following instructions for use + Good standard of personal hygiene. + Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice. - Good standard of personal hygiene.
	Low pressure spraying. Diluted: Skin Corr 1C (H314) – Eye Dam Cat 1 (H318) EUH071	Few minutes per day	Medium, splashes, hand to eye transfer	- Wearing of protective gloves, goggles, clothing and respiratory protective equipment (half/full mask FFP2 with gas filter) - Labelling - Instructions for use - Spraying away from user	Acceptable: + Professionals using PPE + Professionals following instructions for use + Good standard of personal hygiene. + Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice. - Good standard of personal hygiene.

				- Washing hands/face/eyes after accidental exposure	
	Dipping. Diluted: Skin Corr 1C (H314) – Eye Dam Cat 1 (H318) EUH071	Few minutes per day	High potential for dermal contact, low for eyes	- Wearing of protective gloves, googles and clothing. - Labelling - Instructions for use - Washing hands after use	Acceptable: + Only accidental exposure + Professionals using PPE + Professionals following instructions for use + Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice. - Good standard of personal hygiene.

Conclusion

The products are used by professionals wearing appropriate personal protective equipment. The professional users can be expected to follow the instructions of use. All scenarios are acceptable and do no not pose a risk to professional users.

Risk for non-professional users

The only non-professional use is for the toilet disinfectants. Exposure is avoided by using a special designed application part in the packaging. It is therefore not considered necessary to calculate exposure in this scenario as there is normally no actual exposure to the product.

Local effects

MetaSPC 1 - Symbioz Gel San' Desinfectant, Chriox WC, Laco Gel WC

Hazard category	Effects in terms of C&L	Frequency and duration of potential exposure	Degree of potential exposure under best practice conditions	Relevant RMM & PPE	Support for acceptable risk
High	Skin Corr 1C (H314) – Eye Dam Cat 1 (H318)	Once per week, few minutes	Low	- Packaging design eliminating exposure - Labelling - Instructions for use - High viscosity of product (aerosol formation and potential for splashes reduced) - Child proof closure - Avoid contact with skin and eyes - Keep out of reach of children and pets	Acceptable: + Practically no exposure + Short duration + No aerosol formation

MetaSPC 4 & 5

Hazard category	Effects in terms of C&L	Frequency and duration of potential exposure	Degree of potential exposure under best practice conditions	Relevant RMM & PPE	Support for acceptable risk
High	Diluted product Skin Corr 1C (H314) –	Once per week, few minutes	Secondary exposure via dermal & oral route for Children & pets with wet	RMM: Keep out of reach of pets and children until dry surfaces	Acceptable

	Eye Dam Cat 1 (H318) EUH071		treated surfaces		

Conclusion

Exposure of non-professional users to the toilet disinfectants is sufficiently prevented by using child proof closures and packaging eliminating exposure.

Risk for the general public

The only potential exposure of the general public to the products is via residues in food which is discussed below.

Risk for consumers via residues in food

There is no risk for consumers via residues in food, as lactic acid is actually an approved food ingredient. Please refer to the sections above (Estimating Livestock Exposure to Active Substances used in Biocidal Products).

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

The combined exposure towards the substances of concern was addressed in the sections above. Adding up the risk characterisation ratios of the substances of concerns and all scenario resulted in safe use.

2.2.7 Risk assessment for animal health

According to the CAR of the active substance, lactic acid is classified for skin irritation and eye damage. The teat dip formulations (metaSPC 3) are not classified for skin irritation or corrosion based on OECD 404 test and the lactic acid concentration is lower than the dermal NOAEC of 10%, so they are not hazardous for animals.

However the exposure of animals to isopropanol is possible, this approach is assessed as follows:

Description of Scenario 7

The product is used for teat disinfection. The worst case in-use concentration is 1% isopropanol (Meta SPC2). The product is applied by spraying.

The exposure to livestock by dermal route is estimated considering the evaporation time according to the HEAdhoc Recommendation 6, Nr. 1.

For inhalation route, exposure to vapour: Since the cow stays in the milking parlour only during her milking, the risk is already covered by the risk assessment for human.

According to the ESD for PT3, the default value for a dairy cow herd size is 100 animals. Dairy cows are regularly milked twice (see 3 times) per day. The lactation period for dairy cows is normally 270 to 300 days, as two months before calving, dairy cows do not produce milk. Considering a lactating period of 300 days, 82 milk producing cows are milked per day, from a herd of 100 dairy cows.

	Parameters	**Value**
Tier 1	Surface exposed (4 teats)	176 cm^2 (Headhoc recommendation 13)
	Dermal flux rate (in aqueous solution)	0.85 mg/cm^2/h (Boatman et al. 1998)[4]
	Dermal absorption	100% (default)
	Body weight of cow	650 kg (default)
	Weight fraction isopropanol (diluted)	0.01
	Amount of liquid on 4 teats	10 ml/cow (10.14 g, density: 1.014)
	Number of applications	3
	For dermal exposure, the evaporation time is calculated according to the following equation: t = m x R x T / (M x β x p x A) x K = 17.3 s (0.0048 hour) t: time [s] m: mass of isopropanol on surface: 0.1014 g R: gas constant: 8.314 J/K/mol T: skin/surface temperature: 303.15 K M: molar mass: 60.1 g/mol β: mass transfer coefficient, for calculation see TGD: 8.7 m/h p: vapour pressure of the pure substance: 5780 Pa (25 °C) A: surface area (4 teats): 176 cm^2 = 0,0176 m^2 K: conversion factor: 3600 0.85 mg/cm^2/hour x 0.0048 hour x 3 applications x 176 cm^2/650 kg = 0.0033 mg/kg bw/d	

4 Boatman et al. (1998). Dermal absorption and pharmacokinetics in the male and female F-344 rat.

Calculations for Scenario [7]

According to the CAR of AS (PT4), the NOAEL for acute systemic effects in rats (hypoactivity) after inhalation of propan-2-ol was 286 mg/kg bw/d (NOAEC: 500 ppm). In rats and mice, the NOAELs for acute narcotic effects in chronic toxicity studies were 300 and 506 mg/kg bw/d, respectively. AF of 10 for interspecies variability (expert judgment).

Summary table: systemic exposure from dairy cattle							
Exposure scenario	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**	**NOAEL (mg/kg bw/d)**	**AEL (AF 10, mg/kg bw/d)**	**Ratio (%)**	**Acceptable**
Scenario [7] Propan-2-ol- Tier 1	/	0.0033	0.0033	286 (acute)	28.6	0.012	Yes
				300 (chronic)	30	0.011	Yes

Based risk assessment we can expected the exposure levels to be lower than the toxicological reference values (NOAEL..) so that the risk can be considered acceptable.

2.2.8 Risk assessment for the environment

New calculations were performed for the products of the BPF is required due to differences in product composition and/or intended use compared to the representative product(s) for the active substance approval.

The environmental risk assessment needs to be performed for lactic acid as active substance and for isopropanol as potential substance of concern (see 2.1.2.6).

Due to the relatively high vapour pressure, isopropanol evaporates completely within a short time. This means that almost all available isopropanol will have evaporated before it is further emitted to other environmental compartments. Therefore, the main emission pathway of isopropanol will be via the air.
Criteria for the examination of environmental risks to air are not specified in the form of a numerical standard. The assessment of potential impacts on air quality is aimed to minimize the risk for stratospheric ozone depletion. There are no indications that isopropanol contributes to depletion of the ozone layer as the compounds are not listed as 'controlled substances' listed in Annex I of Regulation (EC) No 1005/2009 of the European Parliament.
Although the half-life in air for isopropanol is above the 2-day trigger value to identify chemicals that could be of potential concern for long range transport through the atmosphere (isopropanol: 3.1 days), the active substance is known to be readily biodegradable once deposited and unacceptable risks to terrestrial and aquatic environments are therefore not expected. Consequently, the environmental risk to air is considered acceptable.
Based on the above, isopropanol will not be further assessed.

An overview of all the uses and scenarios is presented in Section 2.2.8.2.

2.2.8.1 Effects assessment on the environment

Information on the ecotoxicity of L(+) lactic acid is presented in the Table below.

Parameter	Value (1)	Unit
	L(+) lactic acid	
$PNEC_{water}$	3.9	mg/l
$PNEC_{sed}$	4.8 22.2	mg/kg ww mg/kg dw
$PNEC_{STP}$	10	mg/l
$PNEC_{soil}$	1.9 2.15	mg/kg ww mg/kg dw

(1) Assessment Report L(+) lactic acid, Germany, 2015

As indicated by the BCF_{fish} (0.048 L/kg) and the $BCF_{earthworm}$ (6.78 L/kg) as well as by the surface tension (70.7 mN/m), the bioaccumulation potential of L(+) lactic acid and thus the risk of secondary poisoning is considered to be low.[5]

L(+) lactic acid is considered to be neither persistent (readily biodegradable but failing the 10-days window criterion) nor bioaccumulative, nor does L(+) lactic acid fulfil the toxicity criterion ($NOEC_{algae}$ = 1.1 g a.s./L). Hence, the P, vP as well as the B, vB and the T criterions are not fulfilled.[6]

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 on products of the BPF. All data are therefore derived from the L(+)-lactic acid CAR.

The classification of the biocidal products is calculated using CLP mixture rules. Test data on the products are not available. None of the products is classified as hazardous for the environment. Details of these calculations can be found in the confidential annex.

Further Ecotoxicological studies

No new environmental studies have been carried out on products of the BPF. All data are therefore derived from the L(+)-lactic acid CAR.

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

No data is available.

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

No data is available.

5 Assessment Report L(+) lactic acid, Germany, 2015
6 Assessment Report L(+) lactic acid, Germany, 2015

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

No data is available.

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

No data is available.

Foreseeable routes of entry into the environment on the basis of the use envisaged

Please refer to section Fate and distribution in exposed environmental compartments.

Further studies on fate and behaviour in the environment (ADS)

No data is available.

Leaching behaviour (ADS)

No data is available.

Testing for distribution and dissipation in soil (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 and no further calculations are needed.

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

No data is available.

Testing for distribution and dissipation in air (ADS)

No 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 applicable.

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 applicable.

2.2.8.2 Exposure assessment

General information

An overview of all the uses and scenarios is presented in the Table below.

OVERVIEW OF USES

Uses PTs	Users	Use Areas	Meta SPC				
			1 Chriox WC	2 Mida Agri 830 Post Red	3 Mida San 325 DA	4 Mida San 332 VB	5 Mida San 331 LW
Toilet bowl disinfection PT2	Consumer Professional	Households Institutions Buildings Workplaces	use 1.1(1)	-	-	-	-
Teat dipping PT3	Professional	Dairy farms	-	use 2.1(2)	-	-	-
CIP PT2	Industrial	Pharmaceutical industry Cosmetic industry	-	-		use 4.6(3)	
CIP PT4	Industrial	Large-scale kitchens Food industry	-	-		use 4.7(3)	
Trigger spraying PT2	Professional	Institutions Buildings Workplaces	-	-	Use 3.1(4)	Use 4.1(4)	Use 5.1(4)
Trigger spraying PT4	Professional	Restaurants Large-scale kitchens Food industry	-	-	Use 3.2(6)	Use 4.2(6)	Use 5.2(6)
Dipping of instruments PT4	Professional	Restaurants Large-scale kitchens Food industry	-	-	Use 3.5(5)	Use 4.5(5)	Use 5.5(5)
Low-pressure spraying / foaming PT2	Industrial	Pharmaceutical industry Cosmetic industry	-	-	Use 3.3(4)	Use 4.3(4)	Use 5.3(4)
Low-pressure spraying / foaming PT4	Industrial	Large-scale kitchens Food industry	-	-	Use 3.4 (6)	Use 4.4(6)	Use 5.4(6)

(1) Scenario 1; (2) Scenario 2; (3) Scenario 3; (4) Scenario 4; (5) Scenario 5; (6) Scenario 6;

Justification of selected scenarios and worst-case products for each scenario

For meta SPC 1, there is only 1 product and 1 use. The scenario covers exactly the use of this one product.

For meta SPC 2, there is also only 1 product and 1 use. The scenario also covers exactly the use of this product.

Products in meta SPC 3, 4 and 5 are all concentrates to be diluted in water. For the CIP use, meta SPC 4 was selected because it is the only product used for CIP disinfection. For trigger spraying, low-pressure spraying and foaming and dipping, the product in meta SPC 4 was selected as worst-case product because it has the highest in-use concentration of lactic acid.

Assessed PT	**PT 2**
Assessed scenarios	Scenario 1: Disinfection of toilets
ESD(s) used	Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), March 2001 Justification: This scenario exactly covers the described use.
Justification of selected ESD(s)	This scenario exactly covers the described use.
Justification of selected worst-case product	Chriox WC was selected for the calculations. There is only one product for this use and scenario in meta SPC 1.
Approach	Average consumption
Distribution in the environment	Calculated based on BPR Vol IV Part B+C (2017)
Groundwater simulation	Not applicable.
Confidential Annexes	NO
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: No
Assessed PT	**PT 3**
Assessed scenarios	Scenario 2: Disinfection of teats
ESD(s) used	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, May 2011 Justification: This scenario exactly covers the described use.
Justification of selected ESD(s)	This scenario exactly covers the described use.
Justification of selected worst-case product	Mida Agri 830 Post Red was selected for the calculations. There is only one product for this use and scenario in meta SPC 2.
Approach	Average consumption
Distribution in the environment	Calculated based on BPR Vol IV Part B+C (2017)
Groundwater simulation	Not applicable.
Confidential Annexes	NO
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: No
Assessed PT	**PT 2/PT4**
Assessed scenarios	Scenario 3: Disinfection by Cleaning-In-Place (CIP) in PT2/PT4
ESD(s) used	Assessment of entire plants (e.g. breweries, dairies, beverage processing plants) (IHO 2006) (ESD Table 5, p.14-15)
Justification of selected ESD(s)	This scenario covers Cleaning-In-Place (CIP) applications. It is expected that PT2 use is also covered by the PT4 scenario.
Justification of selected worst-case product	The selected product is the only product used for CIP disinfection: - **Meta SPC 4: 10% dosage, 80% LA => 8% LA**
Approach	Average consumption
Distribution in the environment	Calculated based on BPR Vol IV Part B+C (2017)
Groundwater simulation	Not applicable.
Confidential Annexes	NO
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: No

Assessed PT	**PT 2**
Assessed scenarios	Scenario 4: Disinfection of hard surfaces in institutions, buildings, workplaces by trigger spraying and low-pressure spraying/foaming.
ESD(s) used	Emission scenario for calculating the release of disinfectants used for sanitary purposes in hospitals based on the amount of solution of disinfectant used on a day (ESD RIVM 2001, Table 3.6, p.20)
Justification of selected ESD(s)	This scenario was selected as a worst-case scenario to cover the use in institutions, buildings and workplaces.
Justification of selected worst-case product	The selected worst-case product is the one with the highest in-use lactic acid concentration: - Meta SPC 3: 2% dosage, 16% LA => 0.32% LA - **Meta SPC 4: 10% dosage, 80% LA => 8% LA** - Meta SPC 5: 25% dosage, 24% LA => 6% LA The worst-case product is the product in meta SPC 4.
Approach	Average consumption
Distribution in the environment	Calculated based on BPR Vol IV Part B+C (2017)
Groundwater simulation	Not applicable.
Confidential Annexes	NO
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: No
Assessed PT	**PT4**
Assessed scenarios	Scenario 5: Disinfection of instruments by dipping in PT4
ESD(s) used	Emission scenario for disinfection of medical equipment was used (PT2) (TAB ENV 45).
Justification of selected ESD(s)	This scenario covers the dipping uses in PT4. Uses outside of hospitals, e.g. food industry, pharmaceutical industry, are covered by this scenario. The use is limited to 5 times per day.
Justification of selected worst-case product	The selected worst-case product is the one with the highest in-use lactic acid concentration: - Meta SPC 3: 2% dosage, 16% LA => 0.64% LA - **Meta SPC 4: 10% dosage, 80% LA => 8% LA** - Meta SPC 5: 25% dosage, 24% LA => 6% LA The worst-case product is the product in meta SPC 4.
Approach	Average consumption
Distribution in the environment	Calculated based on BPR Vol IV Part B+C (2017)
Groundwater simulation	Not applicable.
Confidential Annexes	NO
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: No
Assessed PT	**PT4**
Assessed scenarios	Scenario 6: Disinfection by trigger spraying and low-pressure spraying or foaming of hard surfaces in in the food industry (e.g. slaughterhouses and large-scale kitchens and canteens).
ESD(s) used	Emission scenario on the disinfection in large scale catering kitchens, canteens, slaughterhouse and butcheries was used from the Emission scenario document for PT4 (JRC, 2011), § 2.2, p.17
Justification of selected ESD(s)	This scenario covers disinfection of hard surfaces in PT4.

Justification of selected worst-case product	The selected worst-case product is the one with the highest in-use lactic acid concentration: - Meta SPC 3: 2% dosage, 16% LA => 0.32% LA - **Meta SPC 4: 10% dosage, 80% LA => 8% LA** - Meta SPC 5: 25% dosage, 24% LA => 6% LA The worst-case product is the product in meta SPC 4.
Approach	Average consumption
Distribution in the environment	Calculated based on BPR Vol IV Part B+C (2017)
Groundwater simulation	Not applicable.
Confidential Annexes	NO
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: No

Emission estimation

Scenario [1] Disinfection of toilets[7]

For the toilet disinfection use, the Emission Scenario Document for calculating the release of disinfectants used for sanitary purposes based on an average consumption was used. The calculated break-even tonnage for this scenario was 126 tonnes/year. The tonnage used for this scenario was lower (see confidential annex), which means that the average consumption approach is preferred.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: **Disinfection of toilets**			
Application rate of biocidal product	0.002	l/cap/d	Pick list: ESD Table 2.2
Concentration of active substance in the product	6.8 0.0692	% w/w kg/l (1)	-
Number of inhabitants feeding one STP	10,000	-	D
Fraction released to wastewater	1	-	D
Fraction of substance disintegrated during or after application (before release to the sewage system)	0	-	D
Penetration factor of disinfectant	0.5	-	D

(1) Relative density of product in meta SPC 1: 1.017

Calculations for Scenario 1

$Elocal_{water} = NIocal * Q_{product} * C_{product} * F_{penetr} * F_{water}$

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission ($Elocal_{compartment}$) [kg/d^{-1}]**	**Remarks**
L(+) Lactic acid	STP	0.692	

Scenario [2: Teat dipping][8]

Teat disinfection is performed to disinfect the dairy cow's teats. The application can be done during the grazing season and also out of the grazing season.

Following the application, the product will be either emitted to the sewage treatment plant (STP) or to the manure storage system.

7 Emission scenario for calculating the release of disinfectants used for sanitary purposes based on an average consumption (ESD RIVM 2001, Table 2.2, p.10)

8 Emission scenario document for Product Type 3 (JRC, 2011)

According to TAB ENV 249,

"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).
For all these reasons, it can be stated that lactic acid does not cause unacceptable risk for soil, groundwater and also the indirect release to surface water (via STP and via manure).
Thus, no further quantitative assessment for soil, groundwater the indirect release to surface water (via STP and via manure) are needed.

For direct release to surface water a quantitative assessment is however still needed. As in the case for other natural occurring substances, a comparison of the PEC with the natural background concentration instead of the PNEC is acceptable. "

Since for meta SPC 2 of the BPF, no direct release to surface water is expected, and all emissions will be directed to either STP or manure storage, a further quantitative assessment is not deemed necessary. It can be assumed that the use of the product does not cause unacceptable risks for any of the environmental compartments.

Scenario [3: Cleaning-In-Place in PT2/PT4]

The scenario Assessment of entire plants (e.g. breweries, dairies, beverage processing plants) (IHO 2006) (ESD Table 5, p.14-15) was used. Since no default amount for L(+)-lactic acid was available in the ESD, tonnage data from the applicant were used. The results of the calculation are detailed in the confidential annex.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 3: **Cleaning-In-Place in PT2/PT4**			
Amount of biocidal active substance used per year in the local plant	*	kg/year	S
Number of emission days per year	231	d/year	-
Fraction released to wastewater	1	-	D
Fraction of the product eliminated due to on-site pre-treatment of wastewater	0	-	D

Fraction of substance disintegrated during or after application (before release to the sewer system)	0	-	D
Capacity of the STP off site	2000	m3/d	D

* See confidential annex

Calculations for Scenario 3

$Elocal_{water} = (Qai/T_{emission}) * 1000 * F_{water} * (1-F_{elim}) * (1-F_{dis})$

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission ($Elocal_{compartment}$) [kg/d^{-1}]**	**Remarks**
L(+) Lactic acid	STP	See confidential annex	

Scenario [4: Disinfection of hard surfaces in institutions, buildings, workplaces by trigger spraying][9]

For the trigger spraying use in PT2, the emission scenario for calculating the release of disinfectants used for sanitary purposes based on an average consumption was used (ESD RIVM 2001, Table 2.2, p.10) was used. The calculated break-even tonnage for this scenario was 433 tonnes/year. The tonnage used for this scenario was lower (see confidential annex), which means that the average consumption approach is preferred.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 4: Hard surface disinfection by trigger spraying in PT2			
Number of inhabitants feeding one STP	10,000	cap	D
Consumption per capita	0.005	L/cap/d	Average consumption for general purpose according to ESD PT02 (2011)
Concentration of active substance in the product (undiluted product) In-use concentration of active substance after 10% dilution	80 0.95[1] 8 0.095[1]	% w/w kg/l % w/w kg/l	S
Penetration factor of disinfectant	0.5	-	D

9 Emission scenario for calculating the release of disinfectants used for sanitary purposes (ESD RIVM 2001, Table 2.2, p.10)

Fraction of the product released to waste-water	1	-	D
Fraction of substance disintegrated during or after application (before release to the sewer system)	0	-	D

(1) Relative density of product in meta SPC 4: 1.188

Calculations for Scenario 4

$Elocal_{water} = NIocal * Q_{product} * C_{product} * F_{penetr} * F_{water}$

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission ($Elocal_{compartment}$) [kg/d^{-1}]**	**Remarks**
L(+) Lactic acid	STP	2.38	

Scenario [5: Dipping of instruments in PT4][10]

For the scenario of dipping of instruments in PT4, the Emission scenario for disinfection of medical equipment was used (TAB ENV 45). This scenario covers the dipping uses in PT4. Uses outside of hospitals, e.g. food industry, are covered by this scenario, because use in hospitals can be regarded as a worst-case approach. Meta SPC 4 represents the worst case for the dipping scenario, with an in-use concentration of 8% (w/w).

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 6: **Dipping of instruments in PT2**			
Number of baths per day	5	d^{-1}	D
Volume of solution in dipping bath	0.02	m^3	
Concentration of active substance in the product (undiluted form) In-use concentration of active substance in the product (dilution at 10%)	80 0.950 8 0.095	% w/w kg/l (1) % w/w kg/l	-
Fraction released to wastewater	1	-	D

(1) Relative density of product in meta SPC 4: 1.188

Calculations for Scenario 5

10 Emission scenario for calculating the releases of disinfectants used in hospitals for disinfection of other contaminated instruments (ESD RIVM 2001, Table 3.8, p.26)

$Elocal_{water}$ = Nbaths * $Q_{product}$ * $C_{product}$

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission ($Elocal_{compartment}$) [kg/d^{-1}]**	**Remarks**
L(+) Lactic acid	STP	9.5	

Scenario [6: Disinfection by trigger spraying and low-pressure spraying or foaming of hard surfaces in in the food industry (e.g. slaughterhouses and large-scale kitchens and canteens)]

For the disinfection of hard surfaces in PT4, the scenario on the disinfection in large scale catering kitchens, canteens, slaughterhouse and butcheries was used from the Emission scenario document for PT4 (JRC, 2011), § 2.2, p.17 was used. For the calculations, the worst-case product of meta SPC 3, 4 and 5 was selected: meta SPC 4 with the highest in-use concentration of lactic acid (8%). Disinfection of slaughterhouses can be considered a worst-case situation.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 6: **Disinfection by low-pressure spraying or foaming of hard surfaces in PT2/PT4 in industrial areas and in the food industry (e.g. slaughterhouses and large-scale kitchens and canteens) and by trigger spraying in PT4 applications**			
Application rate of biocidal product Application rate of the active substance	0.2 18.96	l/m^2 g/m^2	S
Concentration of active substance in the product (concentrated form) Concentration of active substance in the product (RTU solution at 10%)	80 0.95 8 0.095	% w/w kg/l (1) % w/w kg/l	-
Surface area to be disinfected Slaughterhouses Kitchens and canteens	 10,000 2,000	 m^2 m^2	D
Number of applications per day	1	/d	D
Fraction released to wastewater	1	-	D
Fraction of substance disintegrated during or after application (before release to the sewage system)	0	-	D
Fraction eliminated due to on-site pre-treatment	0	-	D

Calculations for Scenario 6

$Elocal_{water}$ = Qai_{appl} * $AREA_{surface}$ * N_{appl} * (1-F_{dis}) * (1-F_{elim}) * F_{water} /1000

Resulting local emission to relevant environmental compartments			
Substance	**Compartment**	**Local emission ($Elocal_{compartment}$) [kg/d^{-1}]**	**Remarks**
L(+) Lactic acid	STP	38	Kitchens and canteens
L(+) Lactic acid	STP	190	Slaughterhouses

A summary of the results is presented in the Table below.

Overview emissions		
Scenario	**Value**	**Unit**
1	0.692	kg/d
2 –release via STP/manure	0.100	kg/d
3	*	kg/d
4	2.38	kg/d
5	9.5	kg/d
6 - large scale kitchens	38	kg/d
6 –large scale slaughterhouses	190	kg/d

* See confidential annex

For all scenarios except scenario 2, the emission is directed completely to the STP. For scenario 2, emission to both STP and slurry/manure is calculated.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	Yes	Yes	No	No	Yes	No	Yes	Q	No
Scenario 2	Yes	Yes	No	No	Yes	No	Yes	Q	No
Scenario 3	Yes	Yes	No	No	Yes	No	Yes	Q	No
Scenario 4	Yes	Yes	No	No	Yes	No	Yes	Q	No
Scenario 5	Yes	Yes	No	No	Yes	No	Yes	Q	No
Scenario 6	Yes	Yes	No	No	Yes	No	Yes	Q	No

Tier 1
Calculations are based on the data as presented in the AR.

Tier 2

For the scenario with the highest emissions (Scenario 6 – slaughterhouses), an additional Tier 2 calculation was performed.

In the CAR, the level of degradation within the 10-day window could not be assessed in the ready biodegradation test, which was performed, and thus lactic acid was considered to be readily biodegradable failing the 10-day window criterion.
However, lactic acid is predicted to be readily biodegradable by the validated QSAR model BIOWIN v4.10. Additionally, as product from the lactic acid fermentation, it naturally occurs as well in animal cells as in bacteria, which also provide enzymes metabolizing both enantiomers. Overall, the degradation rate constant of 0.3/h can be considered as too conservative.
Therefore, in this Tier 2 calculation, the degradation rate constant in the STP was considered to be 1/h, corresponding with a readily biodegradable active substance, passing the 10d window.

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	Ref. (1)
Melting point	53 (solid) -80 (93% solution)	°C	Ref. (1)
Boiling point	204.2 (100%) Not determinable (93%)	°C	Ref. (1)
Vapour pressure (at X°C)	0.4 at 20°C	Pa	Ref. (1)
Water solubility (at X°C)	Miscible	mg/l	Ref. (1)
Log Octanol/water partition coefficient	-0.74 (T = 20 °C, 100 % L-(+)-Lactic acid)	Log 10	Ref. (1)
Organic carbon/water partition coefficient (Koc)	20.9 L/kg	l/kg	Ref. (1)
Henry's Law Constant (at X C)[if measured data available]	3.6×10^{-5} at 20°C	$Pa/m^3/mol$	Ref. (1)
Biodegradability	Ready biodegradable (but failing the 10 day window)	-	Ref. (1)
Rate constant for STP (Tier 1)	$K_{STP} = 0.3$	h^{-1}	Ref. (1)
Rate constant for STP (Tier 2)	$K_{STP} = 1$	h^{-1}	Tier 2 argumentation above
DT_{50} for biodegradation in surface water	No information available	d or hr (12ºC)	Ref. (1)
DT_{50} for hydrolysis in surface water	No hydrolysis	d or hr (at 12ºC /pH)	Ref. (1)
DT_{50} for photolysis in surface water	The UV-spectrum of L(+) lactic acid shows that no absorbance in the wavelength range of 290-800 nm takes place. Therefore, L(+) lactic acid cannot undergo direct photolysis in sunlight.	d or hr	Ref. (1)
DT_{50} for degradation in soil	90	d or hr (at 12ºC)	Ref. (1)
DT_{50} for degradation in air	tropospherical half-life of Lactic acid: 2.71	d	Ref. (1)

(1) Assessment Report L(+) lactic acid (Germany, 2015)

Calculated fate and distribution in the STP (Simple Treat 4.0)		
	Tier 1	**Tier 2**
Compartment	Percentage [%]	
	All scenarios	
Air	2.53E-05	1.35E-05
Water	22.5	8.007
Sludge	0.207	0.195
Degraded in STP	77.3	91.8

For the input and output values of SimpleTreat 4.0, see section 3.2 in the confidential Annex.

Calculated PEC values lactic acid

Summary table on calculated PEC values						
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/l]	[mg/l]	[mg/kg_{dwt}]	[mg/kg_{dwt}]	[mg/l]	[mg/m^3]
Scenario 1	7.78E-02	7.78E-03	4.43E-02	2.64E-03	n.a.	n.a.
Scenario 3	See confidential annex				n.a.	n.a.
Scenario 4	2.68E-01	2.68E-02	1.52E-01	9.09E-03	n.a.	n.a.
Scenario 5	1.07E+00	1.07E-01	6.08E-01	3.63E-02	n.a.	n.a.
Scenario 6 - kitchens	4.27E+00	4.27E-01	2.43E-00	1.45E-01	n.a.	n.a.
Scenario 6 – slaughterhouses Tier 1	2.14E+01	2.14E+00	1.22E+01	7.26E-01	n.a.	n.a.
Scenario 6 – slaughterhouses Tier 2	7.61	0.761	4.33	0.684	n.a.	n.a.

* *For scenario 2, DE CA commented that PECsoil values were not consistent with their calculations. Since Meta SPC 2 will not be authorised, the calculated values were not revised.*

Calculated PEC values substances of concern

There are no substances of concern for the environment.

Primary and secondary poisoning

Primary poisoning

Not relevant.

Secondary poisoning

There is no potential for bioaccumulation and consequently no concern for secondary Poisoning (Assessment Report L(+) lactic acid, Germany, 2015).

2.2.8.3 Risk characterisation

Atmosphere

According to the assessment report of L(+) lactic acid, there is no significant release of this substance to air. Therefore, environmental exposure to the air compartment was not assessed for the biocidal products.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
Scenario	**PEC/PNEC$_{STP}$**
Scenario 1	7.78E-03
Scenario 3	See confidential annex
Scenario 4	2.68E-02
Scenario 5	1.07E-01
Scenario 6 - kitchens	4,27E-01
Scenario 6 – slaughterhouses – Tier 1	**2.14**
Scenario 6 – slaughterhouses – Tier 2	0.761

Conclusion: For all scenarios, except scenario 6 – slaughterhouses, there is no risk for the organisms in the STP in Tier 1. In a Tier 2 calculation, taking account of a more realistic degradation rate in the STP, no risks are present for Scenario 6..

Aquatic compartment

Summary table on calculated PEC/PNEC values (1)				
Scenario	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
Scenario 1	1.99E-03	1.99E-03	-	-
Scenario 3	See confidential annex	See confidential annex	-	-
Scenario 4	6.86E-03	6.86E-03	-	-
Scenario 5	2.74E-02	2.74E-02	-	-
Scenario 6 - kitchens	1.10E-01	1.10E-01	-	-
Scenario 6 – slaughterhouses Tier 1	5.47E-01	5.47E-01	-	-
Scenario 6 – slaughterhouses Tier 1	1.95E-01	1.95E-01		

Conclusion: For all scenarios there is no risk for the aquatic compartment.

Terrestrial compartment

Calculated PEC/PNEC values	
Scenario	**PEC/PNEC$_{soil}$**
Scenario 1	1.23E-03
Scenario 3	See confidential annex
Scenario 4	4.23E-03
Scenario 5	1.69E-02
Scenario 6 - kitchens	6.75E-02
Scenario 6 –slaughterhouses – Tier 1	3.38E-01
Scenario 6 –slaughterhouses – Tier 2	3.18E-01

Conclusion: There is no risk for the terrestrial compartment from any of the emission scenarios.

Groundwater

At WG II-2020, it was stated that:

A quantitative assessment of lactic acid in groundwater is however not not necessary. 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.

Primary and secondary poisoning

Primary poisoning

Primary poisoning is not expected as there is normally no oral exposure.

Secondary poisoning

Lactic acid has no potential for bioaccumulation and therefore there is no concern for secondary poisoning.

Conclusion: Primary poisoning is not expected as there is normally no oral exposure of non-target organisms and there is no concern for secondary poisoning.

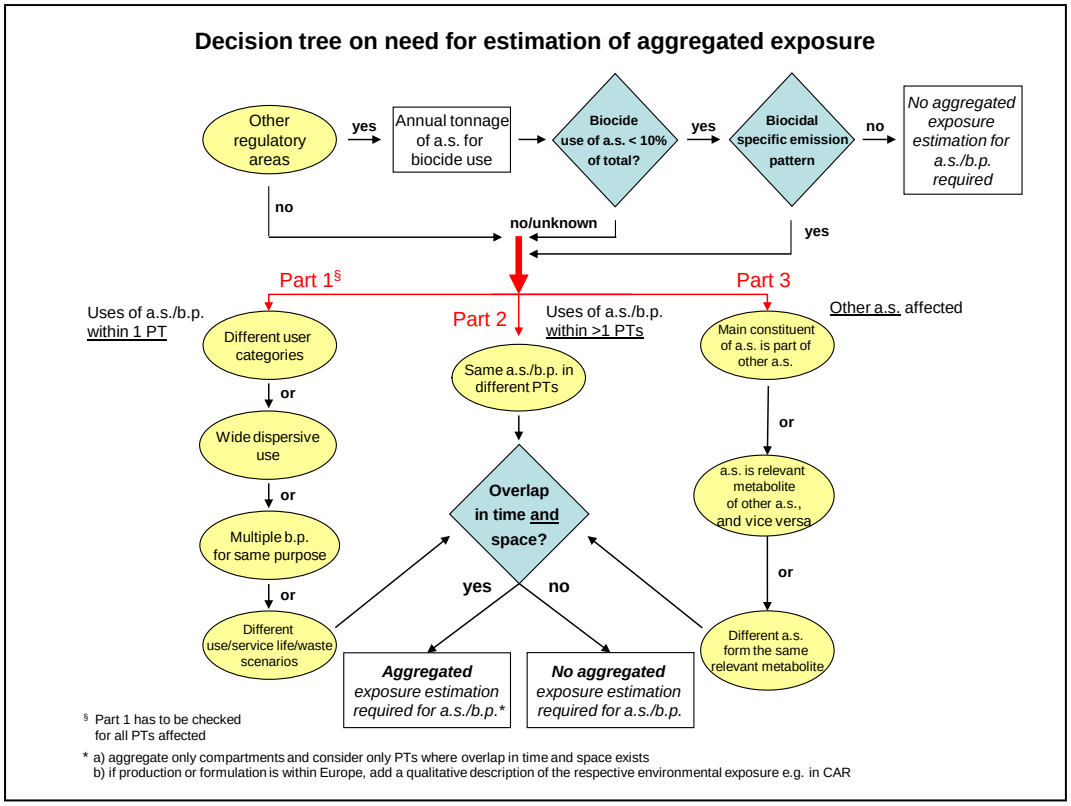
Mixture toxicity

Evaluation of mixture toxicity is not applicable, as there are no SoCs for the environment.

Aggregated exposure (combined for relevant emission sources)

L(+) lactic acid is widely used in the food, pharmaceutical and cosmetical industry, with a total yearly use of more than 1 million tonnes. Biocidal use will account for less than 10% of the total use.

Therefore, it is not considered necessary to conduct an aggregated risk assessment.



Overall conclusion on the risk assessment for the environment of the products
No unacceptable risks for any of the environmental compartments are expected following the use of the products in the Christeyns Lactic Acid Biocidal Product Family. No substances of concern for the environment are present in the products.

2.2.9 Assessment of ED properties

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in Christeyns' Lactic Acid BPF:

1. Assessment of the ED properties of the active substances in Christeyns' Lactic Acid BPF:
   - According to section 2.1.1 of the final CA document, the assessment of ED properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the rMS should not evaluate the ED properties of these substances nor request additional data on the ED properties in the context of product authorisation procedures. As L(+) lactic acid is not part of the list[11] of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.
   - Therefore, BE eCA considers that there are no concerns regarding ED properties of L(+) lactic acid.

2. Assessment of the ED properties of non-active substances (co-formulants) in Christeyns' Lactic Acid BPF:
   - After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex - ED assessment), none of the co-formulants has been identified as having ED properties or are subject to an on-going

[11] Please refer to CA-September18.Doc.7.5.a-final .

evaluation or a decision regarding their ED properties. Based on the available information, BE eCA considers that there is no concern regarding the ED properties of these co-formulants.

Overall conclusion on the biocidal product/family regarding ED properties:
Based on the existing knowledge and the data provided by the applicant, there is no indication of concern for humans and for non-target organisms regarding the ED properties of the substances used in the biocidal product family Christeyns' Lactic Acid.
If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product/family authorisation will be revised according to CA-March18.Doc.7.b-final, section 2.3 (47).

2.2.10 Measures to protect man, animals and the environment

Please refer to summary of the product assessment and to the relevant sections of the assessment report.

2.2.11 Assessment of a combination of biocidal products

Not relevant.

2.2.12 Comparative assessment

Not relevant.

3 Annexes

3.1 List of studies for the biocidal product (family)

The list of studies is presented as a separate document (export file from IUCLID).

3.2 Output tables from exposure assessment tools

HUMAN HEALTH RISK ASSESSMENT

Consexpo reports

ConsExpo Isopropanol 160821.c2

ConsExpo butoxyethanol 1608

ENVIRONMENTAL RISK ASSESSMENT

SimpleTreat 4.0 Export file			
Calculation mode:	SimpleTreat 4.0		
Version:	4.0.9		
Date:	Sunday, 14 March 2021		
Input			
Substance	**User value**	Default value	Unit
Chemical class	**Acid**		-
Molecular weight	**90,08**		g/mole
Octanol-water particion coefficient (Kow)			-
Aparent Kow at actual pH (Dow)			-
Vapour pressure	**0,4**		Pa
Vapour pressure used (temp. corrected)	**2,802013E-01**		Pa
Temperature for determining vapour pressure	**293,15**	293,15	Kelvin
Solubility (S)	**100000**		mg/l
Solubility used (temp. corrected)	**9,312837E+04**		mg/l
Temperature for determining solubility	**293,15**	293,15	Kelvin
pKa	**3,86**		-
Henry coefficient (H)	**3,6E-05**	1,962013E-07	Pam3/mole
Henry coefficient used (temp. corrected - only for user value)	**3,35262145798651E-05**		Pam3/mole
Temperature for determining Henry coefficient (only for user value)	**293,15**	2,931500E+02	Kelvin
Organic carbon partition coefficient (Koc)	**20,9**		l/kg
Partition coefficient in raw sewage (Kps)		6,270000E+00	l/kg
Partition coefficient in activated sludge (Kpas)		7,733000E+00	l/kg
Mode of operation			
Facility type	**Municipal**	Municipal	-
Operation mode	**Primary solids removal**	Primary solids removal	-
Sewage flow (Q)	**0,2**	0,2	m3/d PE
Mass of sewage solids (SO)	**0,09**	0,09	kg/d PE
Mass of O2 binding material in sewage (BOD)	**60**	60	g O2/d PE
Fraction of BOD in sewage solids (FB)	**0,5417**	0,5417	-
Fraction of sewage solids removed by primary sedimentation (FS)	**0,67**	0,67	-
Sludge loading rate (kslr)	**0,1**	0,1	-
pH	**7**	7	-
Surface or bubble aeration	**surface**	surface	-
Biodegradation			
Biodegradation method selected	**OECD 301 series, 310, 302 series**		-
Biodegradation constant	**0,3**		hr-1
Biodegradation constant used (temp. corrected)			hr-1
Temperature for determining biodegradation constant			Kelvin
Biodegradation applies to	**Aqueous phase**		-
Emission scenario			
Temperature environment	**288,15**	288,15	Kelvin
Wind speed	**3**	3	m/s
Number of inhabitants	**10000**	10000	Person
Emission rate chemical	**1**	1	kg/d
Output			
Elimination percentages		**Value**	**Unit**
Elimination in the primary settler			
Volatilization		0,00	%
Via primary sludge		0,19	%
Total		0,00	%
Elimination in the aerator			
Stripping		0,00	%
Biodegradation		77,31	%
Total		0,00	%
Elimination in the solids liquid separator			
Volatilization		0,00	%
Via surplus sludge		0,02	%
Total		0,00	%
Total elimination from waste water		**77,52**	%
Total emission via effluent		**22,48**	%
Balance		**0,00**	%
Concentrations			
Air		4,24E-12	g/m3
Combined sludge		2,54E+00	mg/kg
Primary sludge		3,13E+00	mg/kg
Surplus sludge		8,70E-01	mg/kg
Raw sewage		5,00E-01	mg/l
Dissolved		4,99E-01	mg/l
Associated		1,41E-03	mg/l
Settled sewage		4,99E-01	mg/l
Dissolved		4,99E-01	mg/l
Associated		4,64E-04	mg/l
Mixed liquor		1,16E-01	mg/l
Dissolved		1,12E-01	mg/l
Associated		3,48E-03	mg/l
Effluent		1,12E-01	mg/l
Dissolved		1,12E-01	mg/l
Associated		2,61E-05	mg/l
In solids effluent		8,70E-01	mg/kg

SimpleTreat 4.0 - SimpleTreat Lactic Acid

File Edit Calculation mode Export Help

Substance | Mode of operation | Biodegradation | Emission scenario | Distribution | Elimination and emission | Concentrations

Distribution

Show results as ○ Graph ◉ Table

Air	2,525E-05	%
Water	22,48	%
Primary settler	0,1885	%
Surplus sludge	0,01842	%
Biodegradation	77,31	%

3.3 New information on the active substance

There is no new information on the active substance presented in the current dossier.

3.4 Residue behaviour

There is no concern about residues.

3.5 Summaries of the efficacy studies

Please refer to the IUCLID file.

3.6 Confidential Annex

The confidential annex is presented as a separate document.

3.7 Other