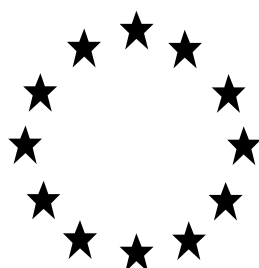


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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



Lactic acid based products – CID LINES NV

Product types PT1 – PT2 – PT3 – PT4

L-(+)-lactic acid

Case Number in R4BP: BC-RC051007-54

Evaluating Competent Authority: Belgium

Date: March 2021

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# 1 CONCLUSION

## INTRODUCTION TO THE FAMILY

The Biocidal Product Family "Lactic acid based products – CID LINES NV" contains disinfectant products with L-(+)-lactic acid as active substance that belong to PT1, PT2, PT3 and PT4 (Main Group 01).

Initially, the family applied for authorization consists out of 15 metaSPCs:

MetaSPC 1 <sup>1</sup>	Hygienic handwash (PT1)
MetaSPC 2	Ready to use algacide (PT2)
MetaSPC 3	Concentrated algacide (PT2) hard surface disinfection in food and feed industry (PT4)
MetaSPC 4 <sup>2</sup>	Hard surface disinfection for sanitary hygiene, hygiene in kitchens and disinfection of toilet bowls (PT2 and PT4)
MetaSPC 5	Pre-dip, skin wash and skin disinfection (PT3)
MetaSPC 6	Pre-dip (PT3)
MetaSPC 7	Hard surface disinfection (PT2 and PT4)
MetaSPC 8	Post-dip (PT3)
MetaSPC 9	Post-dip (PT3)
MetaSPC 10	Post-dip (PT3)
MetaSPC 11	Hard surface and equipment disinfection in Food and Feed area (PT4) and for veterinary hygiene (PT3)
MetaSPC 12	Inner surface disinfection by CIP and Crate wash (PT4)
MetaSPC 13	Hard surface disinfection in Food and feed industry (PT4)
MetaSPC 14 <sup>3</sup>	Coronary band disinfection (PT3)
MetaSPC 15 <sup>4</sup>	Hygienic handrub (PT1)

<sup>1</sup> or <sup>4</sup> For non professional use #2, according to the qualitative risk assessment (see human health risk assessment), the risk is unacceptable because local exposure (eyes contact by splash or children who rub their eyes during the hand-washing process) to the corrosive product cannot be avoided.

<sup>2</sup> Taking into account that the biocidal product is intended to be used by non professional by spraying application and the biocidal product present in Meta SPC 4 are classified as eye dam.1 after discussion during the WGIII2021 it has been decided no risk mitigation measures to prevent all risks of ocular exposure could ensure a sufficient level of safety for this class of users, therefore uses requiring spray application cannot be allowed for non-professionals.

<sup>3</sup>For the products applied for as products of metaSPC 14 intended to be used for coronary band disinfection, unacceptable risks for animal health were identified. Therefore, this metaSPC cannot be authorized.

## PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES

The BPF is composed by 15 meta-SPCs, with all products ready-to-use or concentrate-to-dilute liquids, except the meta-SPC 7, containing impregnated wipes.

Meta SPCs 1 and 8 are viscous liquids, the rest of meta-SPCs contains colourless to coloured clear liquids. The pH of the products of the BPF is in the range -0.14 to 4.45. The relative density of the products is in the range 1.0044 to 1.1772.

2 years of shelf life could be granted, pending a submission of long term storage results as soon as available. This proposal is supported based on the accelerated storage tests and in accordance with the Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology: "Accelerated storage data generated can be used to give an indication that the biocidal product will be stable for two years at ambient temperature. These data can be used to demonstrate that the product

is likely to be stable for two years at ambient storage to support an authorisation. Yet, this does not negate the need to generate ambient storage data, which must be generated to confirm the ambient storage of the biocidal product.”.

Persistent foaming tests on products to be used diluted (meta-SPC 3, 4, 5, 11, 13 and 14) show a volume exceeding 60 ml. However, for the use of the products, PPE are needed and they cover the risk brought by the excessive foaming. The dilution stability of the products to be diluted is shown to be acceptable. The surface tension is between 20.96 mN/m and 34.27 mN/m for the highest in use concentrations of products. The viscosity is in the range < 10 cP and 1033 cP at 20 °C and very similar at 40 °C.

## **PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS**

The products from the meta-SPCs 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 14, 15 do not present any physical hazards.

The products from the following meta-SPCs should be classified for the corresponding physical hazard::

- Meta SPC 10: Flam. Liq. 3,
- Meta SPC 12: Corr. to metals 1
- Meta SPC 13: Corr. to metals 1

## **METHODS FOR DETECTION AND IDENTIFICATION**

The applicant has provided validated methods (HPLC-ULV) for the active substance, and for the SoCs butyldiglycol and isopropanol.

## **EFFICACY**

Meta SPC 1: hygienic handwash allows the reduction of “transient bacteria flora” on hands when used undiluted with 10 mL & water at RT in 1 min.

Meta SPC 2: ready-to-use algaecide is active against unicellular green algae and blue-green algae (cyanobacteria) at 100% at +20-25°C in 3h contact time, on hard/non-porous surfaces without prior cleaning.

Meta SPC 3: concentrated algaecide is active against unicellular green algae and blue-green algae (cyanobacteria) at 0.5% at +20°C in 3h contact time on hard/non-porous surfaces without prior cleaning. The products are also effective against bacteria and yeasts at 4% at +40°C in 5 sec. contact time on hard/non-porous surfaces without prior cleaning, in food and feed industry.

Meta SPC 4: Activity against bacteria and yeasts at 20% at +20°C in 15 min contact time on hard/non-porous surfaces without prior cleaning, for healthcare and non-healthcare areas. The products are also effective for toilet bowl disinfection (bacteria and yeast) at 100% at +20°C in 5 min contact time.

Meta SPC 5: effective against bacteria and yeast for teat disinfection (pre-milking without prior cleaning) and intact skin wash/disinfection (of the udder of dairy and beef cattle before calving and of the udder of sows before farrowing) at 40% at +30°C in 1 min contact time.

Meta SPC 6: effective for teat disinfection (pre-milking with wipes without prior cleaning) against bacteria and yeast at 100% at +30°C in 1 min contact time.

Meta SPC 7: pre-impregnated wipes active against bacteria, yeasts and viruses at +20°C in 2 min contact time on hard/non-porous surfaces with prior cleaning, in healthcare and non-healthcare areas.

Meta SPC 8, 9 and 10: effective for teat disinfection (post-milking) against bacteria and yeast at 100% at +30°C in 5 min contact time.

Meta SPC 11:

- PT3 hard surface disinfection on hard/non-porous surfaces with prior cleaning: active against bacteria and yeasts at 4% at +10°C in 30 min contact time;
- PT4 hard/non-porous surface disinfection with prior cleaning by spraying/immersion : Active against bacteria and yeasts at 3% at +20°C in 2 min contact time / 1% at +20°C in 15 min contact time
- PT4 hard/non-porous surfaces without prior cleaning: Active against bacteria and yeasts : at +7°C - 15% in 30 sec. contact time by DIPPING and at +7°C - 8% in 2 min contact time by SPRAYING

Meta SPC 12: Active against bacteria and yeasts at +50°C on hard/non-porous surfaces

- inner surface disinfection – CIP with circulation:
  - with prior cleaning: 2% in 2 min contact time / 1% in 30 min contact time
  - without prior cleaning: 4% in 2 min contact time / 1% in 30 min contact time
  - In Dairy industry: 2% in 15 min contact time
- inner surface disinfection – without circulation:
  - with prior cleaning: 2% in 2 min contact time
  - without prior cleaning : 4% in 2 min contact time / 2% in 30 min contact time
- crate wash: Without prior cleaning : 4% in 2 min contact time

Meta SPC 13: Hard/non-porous surface disinfection (bacteria and yeast) by foaming in food and feed industry with prior cleaning at 1% and without prior cleaning at 5% in 30 min (at +20°C).

Meta SPC 14: Coronary band & interdigital skin of hooves disinfection without prior cleaning (bacteria and yeast) at 6% - +30°C and 5 min contact time.

Meta SPC 15: Ready to use handrub effective at 6ml to against bacteria and yeast in 1 minute, on clean hands.

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.

## **RISK ASSESSMENT FOR HUMAN HEALTH**

Classification:

- Skin corrosion/irritation: MetaSPCs 3, 12, 13 and 14 are classified as H314. MetaSPCs 4 and 11 are classified as H315.
- Eye irritation: MetaSPCs 2 and 7 of the family are classified as H319. All other metaSPCs (1, 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14 and 15) of the family are classified as H318.
- Skin sensitization: For meta SPC 4 and 10 the classification EUH208 is required, due to the presence of co-formulants.

The family contains substances of concern as co-formulant: sodium lauryl sulphate, sodium lauryl ether sulfate, sulfonic acids, C14-17-sec-alkane, sodium salts, C6 alkyl glucoside, methane sulfonic acid, sulphuric acid, isopropanol and butyldiglycol. A quantitative risk assessment was performed for isopropanol and Butyldiglycol.

Acceptable risks are foreseen for

- professional using products of MetaSPC 1 and MetaSPC 15 for hand disinfection without PPE.
- professional using products of MetaSPC 2 and 7 for general surface disinfection including surface in contact with food, toilet disinfection and algaecidewithout PPE

- professional using products of metaSPC 5, 6, 8, 9 for teats disinfection. However, as metaSPC 5, 6, 8, 9 and 10 are classified H318, eye damage 1, chemical goggles need to be worn.
- professional using products of MetaSPC 4 and 11 for general surface disinfection including surface in contact with food, toilet disinfection and algaecide. However, as the products of metaSPC 4 and 11 are irritant for skin/eye gloves and goggles are needed.
- professional using products of MetaSPC 3. As the products of metaSPC 3 are corrosive for skin/eye gloves, goggles and protective coverall are needed. These PPE also cover the exposure to foam.
- professional using products of MetaSPC 12 for CIP. However, as the products of metaSPC 12 are corrosive for skin/eye gloves, goggles and protective coverall are needed.
- professional using products of MetaSPC 13,. As the products of metaSPC 13 are corrosive for skin/eye gloves, goggles and protective coverall are needed. These PPE also cover the exposure to foam.
- professional using products of MetaSPC 14 as animal skin disinfectant when PPE are worn. However, due to the animal health assessment, this use should not be authorised.
- non-professional using products of MetaSPC 2 and 7 for general surface disinfection including surface in contact with food, toilet disinfection and algaecide without PPE (due to the reversible effect).
- non-professional using products of MetaSPC4 for PT2 surface disinfection by applying risk mitigation measures.

Unacceptable risks were identified for the following uses, and lead to the non-authorization of the uses:

- non-professional using products of MetaSPC 1 and MetaSPC 15 for hand disinfection. Therefore this use #2 will not be allowed for non-professional use as the risk of exposure (eyes contact) to the corrosive product cannot be excluded.
- non professional spraying application in Meta SPC 4 classified as eye dam.1. No risk mitigation measures to prevent all risks of ocular exposure could ensure a sufficient level of safety for this class of users.
- Meta SPC 14 is classified as skin corr.1B, taking into account that the biocidal product is intended to be apply on animal skin (PT3) the risk in not acceptable . Therefore this meta SPC is not authorised.

## **RISK ASSESSMENT FOR ENVIRONMENT**

L-lactic acid is a naturally occurring substance found in plants and animals and is found to be readily biodegradable. No unacceptable risks are identified for the products of the biocidal product family.

## **ASSESSMENT FOR ENDOCRINE DISRUPTING PROPERTIES**

Currently neither the active substance, nor the co-formulants of the BPs have been identified as endocrine disruptors in line with document CA-March18-Doc.7.3.b-final. Therefore, it could be concluded that the BPF and its products are also not to be considered as having ED properties.

*Reference will be made to the BPC opinion*

## 2 ASSESSMENT REPORT

### 2.1 Summary of the product assessment

#### Part I. - First information level

##### 2.1.1 Administrative information

###### 2.1.1.1 Identifier of the product / product family

<b>Identifier</b>	Lactic acid based products - CID LINES NV
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###### 2.1.1.2 Authorisation holder

<b>Name and address of the authorisation holder</b>	<b>Name</b>	CID LINES NV
	<b>Address</b>	Waterpoortstraat 2, 8900 Ieper, Belgium
<b>Pre-submission phase started on</b>	22/11/2018	
<b>Pre-submission phase concluded on</b>	10/01/2019	
<b>Authorisation number</b>		
<b>Date of the authorisation</b>		
<b>Expiry date of the authorisation</b>		

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

<b>Name of manufacturer</b>	CID LINES NV
<b>Address of manufacturer</b>	Waterpoortstraat 2 8900 Ieper Belgium
<b>Location of manufacturing sites</b>	Waterpoortstraat 2 8900 Ieper Belgium

## 2.1.1.4 Manufacturers of the active substance

<b>Active substance</b>	L-(+)-Lactic acid
<b>Name of manufacturer</b>	Purac Biochem bv
<b>Address of manufacturer</b>	Arkelsedijk 46 4206 Gorinchem The Netherlands
<b>Location of manufacturing sites</b>	Arkelsedijk 46 4206 Gorinchem The Netherlands

<b>Active substance</b>	L-(+)-Lactic acid
<b>Name of manufacturer</b>	Jungbunzlauer S.A.
<b>Address of manufacturer</b>	Z.I. et Portuaire B.P. 32 FR-67390 Marckolsheim France
<b>Location of manufacturing sites</b>	Z.I. et Portuaire B.P. 32 FR-67390 Marckolsheim France

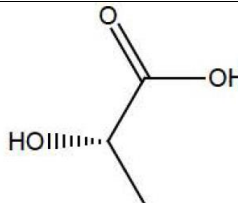
## 2.1.2 Product (family) composition and formulation

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

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

Yes   
No

### 2.1.2.1 Identity of the active substance

Main constituent(s)	
<b>ISO name</b>	L-(+)-Lactic acid
<b>IUPAC or EC name</b>	L-(+)-Lactic acid
<b>EC number</b>	201-196-2
<b>CAS number</b>	79-33-4
<b>Index number in Annex VI of CLP</b>	/
<b>Minimum purity / content</b>	>= 95.5% w/w Existence of an equilibrium system of L-(+)-Lactic acid with several oligomers
<b>Structural formula</b>	 (S)-2-hydroxypropanoic acid

### 2.1.2.2 Candidates for substitution

The active substance is not considered to be candidate for substitution, in accordance with Article 10 of BPR–Regulation 528/2012.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	2.0	70.0
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-	Anionic surfactant	85586-07-8	287-809-4	0.0	12.0

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
	alkyl esters, sodium salts					
Sodium lauryl ether sulfate	Alcohols, C12-14, ethoxylated, sulfates, sodium salts	Anionic surfactant	68891-38-3	500-234-8	0.0	8.4
Sulfonic acids, C14-17-sec-alkane, sodium salts	Sulfonic acids, C14-17-sec-alkane, sodium	Anionic surfactant	97489-15-1	307-055-2	0.0	2.25
C6 alkyl glucoside	Hexyl D-Glucoside	Nonionic surfactant	54549-24-5	259-217-6	0.0	2.4
Isopropanol	Propan-2-ol	Solvent / Processing aid	67-63-0	200-661-7	0.0	5.0
Methanesulfonic acid	Methanesulphonic acid	Acidifier	75-75-2	200-898-6	0.0	19.5
Sulphuric acid	Sulphuric acid	Acidifier	7664-93-9	231-639-5	0.0	10.5
Butyldiglycol	2-(2-butoxyethoxy)ethanol	Solvent	112-34-5	203-961-6	0.0	10.0

#### 2.1.2.4 Information on technical equivalence

The source Jungbunzlauer S.A. is technically equivalent (decision number AP-D-1403137-31-00/F) to the reference source of L-(+)-Lactic acid.

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

Please refer to section 2.1.2.3 for information on the active substance content and the content of substances of concern:

- Sodium Lauryl Sulphate
- Sodium Lauryl Ether Sulfate
- Sulfonic acids, C14-17-sec-alkane, sodium salts
- C6 alkyl glucoside
- Isopropanol
- Methanesulfonic acid
- Sulphuric acid
- Butyldiglycol



Please see the confidential annex for further details regarding SoCs and the risk assessment and the full composition of the family and its formulations.

#### 2.1.2.6 Type of formulation

AL: Other liquids to be applied undiluted (metaSPCs 1, 2, 6, 8, 9, 10 and 15) SL: Soluble liquid (metaSPCs 3, 4, 5, 11, 12, 13 and 14) WI: Wipes (metaSPC 7)
--

## Part II. - Second information level

### 2.1.3 Meta SPC 1

#### 2.1.3.1 Meta SPC administrative information

##### 2.1.3.1.1 Meta SPC identifier

<b>Identifier</b>	Meta SPC 1
-------------------	------------

##### 2.1.3.1.2 Suffix to the authorisation number

<b>Number</b>	
---------------	--

##### 2.1.3.1.3 Product type

<b>Product type</b>	PT 1 – Human Hygiene (Disinfectants)
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#### 2.1.3.2 Meta SPC composition

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	3.6	3.6
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	5.0	5.0
Isopropanol	Propan-2-ol	Solvent / Processing aid	67-63-0	200-661-7	4.0	4.0

Please see the confidential annex for further details on composition of products in MetaSPC 1.

Type(s) of formulation of the meta SPC

AL – any other liquid
-----------------------

### 2.1.3.3 Hazard and precautionary statements

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

<b>Classification:</b>	
Hazard category	Eye Dam. 1
Hazard statement	H318
<b>Labelling</b>	
Signal words	Danger
Hazard statements	H318 – Causes serious eye damage
Precautionary statements	P280 - Wear Eyes/Face protection. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER or doctor.
Note	

### 2.1.3.4 Authorised uses

#### 2.1.3.4.1 Use 1 – Hygienic handwash for professional use (PT1)

<b>Product Type</b>	PT1 - Human Hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	Indoor - Food and feed industry, Public field and Kitchens: Hygienic handwash
<b>Application method</b>	-
<b>Application rates and frequency</b>	Apply 10 mL of undiluted product (i.e. 4 pushes for both hands together) and wash your hands for at least 1 min according to the recommended hand washing procedure, before rinse and dry.
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	50 mL, 75 mL, 100 mL, 150 mL, 500 mL, 1L, 5L, 10L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000L, 1100 L HDPE (High Density Polyethylene)

#### 2.1.3.4.2 Use-specific instructions for use

See general directions for use for Meta SPC 1

#### 2.1.3.4.3 Use-specific risk mitigation measures

/

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

See general directions for Meta SPC 1

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

See general directions for Meta SPC 1

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

See general directions for Meta SPC 1

#### 2.1.3.4.7 Use 2 – Hygienic handwash for non-professional use (PT1)

**Authorization not granted.**

### 2.1.3.5 General directions for use for Meta SPC 1

#### 2.1.3.5.1 Instructions for use

Wet your hands with clean, running water at room temperature  
Turn off the tap  
Apply 10 mL of undiluted product and rub your hands for at least 1 min according to the recommended hand washing procedure, before rinse and dry.  
For professional use only

#### 2.1.3.5.2 Risk mitigation measures

/

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

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.  
IF INHALED: If symptoms occur 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.

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

The packing and content must be eliminated as dangerous waste product under the whole responsibility of the possessor of this waste product. Do not throw wastes into sewers and watercourses. Dispose in a safe manner in accordance with local/national regulations.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.

The shelf-life of the products is 2 years.

#### 2.1.3.5.6 Other information

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### 2.1.3.6 Third information level: individual products in the meta SPC

Trade name(s)	Kenosan hand scrub				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	3.6
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	5.0
Isopropanol	Propan-2-ol	Solvent / Processing aid	67-63-0	200-661-7	4.0

*Please see the confidential annex for further details on composition*

## 2.1.4 Meta SPC 2

### 2.1.4.1 Meta SPC administrative information

#### 2.1.4.1.1 Meta SPC identifier

Identifier	Meta SPC 2
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**2.1.4.1.2 Suffix to the authorisation number**

<b>Number</b>	
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**2.1.4.1.3 Product type**

<b>Product type</b>	PT 2 – Disinfectants and algacides not intended for direct application to humans or animals
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**2.1.4.2 Meta SPC composition**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	2.0	2.0

Please see the confidential annex for further details on composition of products in MetaSPC 2.

Type(s) of formulation of the meta SPC

AL – any other liquid
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**2.1.4.3 Hazard and precautionary statements**

<b>Classification: metaSPC 2</b>	
Hazard category	Eye Irr. 2
Hazard statement	H319
<b>Labelling</b>	
Signal words	Warning
Hazard statements	H319 – Causes serious eye irritation.
Precautionary statements	P101 - If medical advice is needed, have product container or label at hand. P102 - Keep out of reach of children. P103 - Read carefully and follow all instructions P264 - Wash hands thoroughly after handling. P280 - Wear eyes/face protection P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332 + P313: If skin irritation occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention. P362+P364 Take off contaminated clothing and wash it before reuse.
Note	The P phrases 101, 102 and 103 are recommended for the biocidal product intended to be used by non-professional users.

#### 2.1.4.4 Authorised use(s) 2.1.4.4.1 Use 1 – Ready to use algicide for professional use

<b>Product Type</b>	PT2 – Disinfectants and algicides not intended for direct application to humans or animals
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts unicellular green algae and blue-green algae (cyanobacteria)
<b>Field of use</b>	Outdoor & Indoor - Public field : Ready-to-use algicide, on hard/non-porous surfaces without prior cleaning.
<b>Application method(s)</b>	By brushing, by spraying (low pressure) or pouring
<b>Application rate(s) and frequency</b>	Active against bacteria, yeasts and unicellular green algae and blue-green algae (cyanobacteria): With undiluted product at 20 – 25°C In 3h contact time 100ml/m <sup>2</sup> The biocidal product is not intended to be used on surfaces come into contact with food and feed.
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

#### 2.1.4.4.2 Use-specific instructions for use

See general directions for use for Meta SPC 2

#### 2.1.4.4.3 Use-specific risk mitigation measures

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

see general directions for use for Meta SPC 2

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

see general directions for use for Meta SPC 2

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

see general directions for use for Meta SPC 2

2.1.4.4.7 Use 2 – Ready to use algicide for non-professional use

<b>Product Type</b>	PT2– Disinfectants and algicides not intended for direct application to humans or animals
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts unicellular green algae and blue-green algae (cyanobacteria)
<b>Field of use</b>	Outdoor & Indoor - Public field : Ready-to-use algicide, on hard/non-porous surfaces without prior cleaning.
<b>Application method(s)</b>	By brushing, by spraying (low pressure) or pouring
<b>Application rate(s) and frequency</b>	Active against bacteria, yeasts and unicellular green algae and blue-green algae (cyanobacteria): With undiluted product at 20 – 25°C In 3h contact time 100ml/m <sup>2</sup> The biocidal product is not intended to be used on surfaces come into contact with food and feed.
<b>Category of users</b>	non-professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L 1 kg, 5 kg, 10 kg HDPE (High Density Polyethylene)

2.1.4.4.8 Use-specific instructions for use

Comply with the instructions for use (see general directions for use).

2.1.4.4.9 Use-specific risk mitigation measures

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

If medical advice is needed, have product container or label at hand.

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

see general directions for use for Meta SPC 2

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

see general directions for use for Meta SPC 2

### 2.1.4.5 General directions for use for Meta SPC 2

2.1.4.5.1 Instructions for use

Comply with the instructions for use

The to be disinfected surfaces must be wet enough in order to keep them wet during the approved contact time for optimal disinfection. The following precautionary sentence will be added on the product label : "Make sure to wet surfaces completely". The required contact time has to be respected until further treatments (e.g. brushing the surfaces).

Use 100 ml solution /m<sup>2</sup>

2.1.4.5.2 Risk mitigation measures

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

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. If symptoms occur 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.

If medical advice is needed, have product container or label at hand

2.1.4.5.4 Instructions for safe disposal of the product and its packaging

The packing and content must be eliminated as dangerous waste product under the whole responsibility of the possessor of this waste product. Do not throw wastes into sewers and watercourses. Dispose in a safe manner in accordance with local/national regulations.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.



The shelf-life of the products is 2 years.  
Keep out of reach of children and non-target animals/pets.

#### 2.1.4.5.6 Other information

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#### 2.1.4.6 Third information level: individual products in the meta SPC

Trade name(s)	RTU Algaecide				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	2

Please see the confidential annex for further details on composition.

### 2.1.5 Meta SPC 3

#### 2.1.5.1 Meta SPC administrative information

##### 2.1.5.1.1 Meta SPC identifier

Identifier	Meta SPC 3
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##### 2.1.5.1.2 Suffix to the authorisation number

Number	
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##### 2.1.5.1.3 Product type

Product type	PT2– Disinfectants and algaecides not intended for direct application to humans or animals PT4 – Food and Feed area
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Type(s) of formulation of the meta SPC

SL – Soluble concentrate

#### 2.1.5.2 Meta SPC composition

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	70.0	70.0

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	6.0	6.0

Please see the confidential annex for further details on composition of products in MetaSPC 3.

### 2.1.5.3 Hazard and precautionary statements

<b>Classification: metaSPC 3</b>	
Hazard category	Skin Corr. 1C Eye Dam. 1
Hazard statement	H314 H318
<b>Labelling</b>	
Signal words	Danger
Hazard statements	H314 - Causes severe skin burns and eye damage
Precautionary statements	P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves, protective clothing, Eyes/Face protection. P301+P330+P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER/doctor P363 - Wash contaminated clothing before reuse. P405 - Store locked up P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation
Note	The P321 is recommended only in exceptional cases where specific treatment is known and required. This is not the case for the product, which does not require any special measures in addition to the application.

## 2.1.5.4 Authorised use(s)

### 2.1.5.4.1 Use 1 - Concentrated algaecide

<b>Product Type</b>	PT2- Disinfectants and algaecides not intended for direct application to humans or animals
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	unicellular green algae and blue-green algae (cyanobacteria)
<b>Field of use</b>	Outdoor & Indoor - Food and feed industry; Public field : concentrated algicide, on hard/non-porous surfaces without prior cleaning.
<b>Application method(s)</b>	By spraying (low pressure) or pouring
<b>Application rate(s) and frequency</b>	Active against unicellular green algae and blue-green algae (cyanobacteria) : 100 mL/m <sup>2</sup> Dilute the product to 0.5% in water, to reach an in use concentration of 0.35% Lactic acid. at 20-25°C In 3h contact time
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

### 2.1.5.4.2 Use-specific instructions for use

See general directions for use for Meta SPC 3

### 2.1.5.4.3 Use-specific risk mitigation measures

see general directions for use for Meta SPC 3

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

see general directions for use for Meta SPC 3

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

see general directions for use for Meta SPC 3

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

see general directions for use for Meta SPC 3

2.1.5.4.7 Use 2 - Disinfection of hard/non-porous surfaces in the food industry (e.g. processing machines)

<b>Product Type</b>	PT4 – Food and Feed area
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	in Food/feed industry : Disinfection of hard/non-porous surfaces (e.g. processing machines) without prior cleaning
<b>Application method(s)</b>	Spraying Soaking (the bath is intended to be used only once)
<b>Application rate(s) and frequency</b>	Active against bacteria and yeasts at +40°C: Dilute the product to 4% in water, to reach an in use concentration of 2.8% Lactic acid. In 5 sec. contact time 100 mL/m <sup>2</sup>
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

2.1.5.4.8 Use-specific instructions for use

see general directions for use for Meta SPC 3

2.1.5.4.9 Use-specific risk mitigation measures

see general directions for use for Meta SPC 3

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

see general directions for use for Meta SPC 3

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

see general directions for use for Meta SPC 3

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

see general directions for use for Meta SPC 3

### 2.1.5.5 General directions for use for Meta SPC 3

#### 2.1.5.5.1 Instructions for use

Disinfection cycle :

- Products must be diluted in potable water before use.
- Final rinsing (with potable water) : if required.

The to be disinfected surfaces must be wet enough in order to keep them wet during the approved contact time for optimal disinfection. The following precautionary sentence will be added on the product label : "Make sure to wet surfaces completely".

#### 2.1.5.5.2 Risk mitigation measures

Gloves and goggles are needed during mixing and loading of the concentrated products.

Wear protective coverall (to be specified by the authorisation holder within the product information).

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

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. 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.

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

The packing and content must be eliminated as dangerous waste product under the whole responsibility of the possessor of this waste product. Do not throw wastes into

sewers and watercourses. Dispose in a safe manner in accordance with local/national regulations.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.  
The shelf-life of the products is 2 years.

#### 2.1.5.5.6 Other information

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### 2.1.5.6 Third information level: individual products in the meta SPC

Trade name(s)	Concentrated Algaecide Kenosan Lactic CONC				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	70.0
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	6.0

*Please see the confidential annex for further details on composition*

## 2.1.6 Meta SPC 4

### 2.1.6.1 Meta SPC administrative information

#### 2.1.6.1.1 Meta SPC identifier

<b>Identifier</b>	Meta SPC 4
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#### 2.1.6.1.2 Suffix to the authorisation number

<b>Number</b>	
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#### 2.1.6.1.3 Product type

<b>Product type</b>	PT2– Disinfectants and algaecides not intended for direct application to humans or animals PT4 – Food and Feed area
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### 2.1.6.2 Meta SPC composition

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	16.0	16.0
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	5.0	5.0

Please see the confidential annex for further details on composition of products in MetaSPC 4.

Type(s) of formulation of the meta SPC

SL – Soluble concentrate

### 2.1.6.3 Hazard and precautionary statements

<b>Classification: metaSPC 4</b>	
Hazard category	Skin Irr. 2 Eye Dam. 1
Hazard statement	H315 H318 EUH208
<b>Labelling</b>	
Signal words	Danger
Hazard statements	H315 - Causes skin irritation. H318 - Causes serious eye damage. EUH208 - Contains eucalyptus globulus oil (CAS-No. 8000-48-4). May produce an allergic reaction
Precautionary statements	P101 - If medical advice is needed, have product container or label at hand. P102 - Keep out of reach of children. P103 - Read carefully and follow all instructions P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves, Eye/Face protection. P302+P352 - IF ON SKIN: Wash with plenty of water/.... P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER/doctor. P332 + P313 - If skin irritation occurs: Get medical advice/attention.

	P362 + 364 - Take off contaminated clothing and wash it before reuse
Note	<p>- The P phrases 101, 102 and 103 are recommended for the biocidal product intended to be used by non-professional users.</p> <p>- The P321 is recommended only in exceptional cases where specific treatment is known and required. This is not the case for the product, which does not require any special measures in addition to the application</p>

### 2.1.6.4 Authorized use(s)

2.1.6.4.1 Use 1– Hard surface disinfection for sanitary hygiene, other than in healthcare, for professional use (PT2)

<b>Product Type</b>	PT2 - Disinfectants and algaecides not intended for direct application to humans or animals
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	Indoor - Public field ( <b>NOT in HEALTHCARE</b> ) Disinfection of hard/non-porous surfaces (for sanitary hygiene) by spraying without prior cleaning
<b>Application method(s)</b>	By spraying (with wiping if needed, only after the end of the preconised contact time)
<b>Application rate(s) and frequency</b>	Active against bacteria and yeasts at room temperature Dilute the product 20% in water, to reach an in use concentration of 3.2% Lactic acid. In 15 min contact time 250ml/m <sup>2</sup> diluted product
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

2.1.6.4.2 Use-specific instructions for use

Comply with the instructions for use
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## 2.1.6.4.3 Use-specific risk mitigation measures

Gloves and goggles are needed during handling of the products
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## 2.1.6.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

see general directions for use for Meta SPC 4
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## 2.1.6.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

see general directions for use for Meta SPC 4
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## 2.1.6.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Keep out of reach of children and non-target animals/pets.
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## 2.1.6.4.7 Use 2 - Hard surface disinfection for sanitary hygiene, other than in healthcare, for non-professional use (PT2)

**Not granted for non-professional user (spraying application)**

## 2.1.6.4.8 Use 3 - Hard surface disinfection for hygiene in kitchens, for professional use (PT4)

<b>Product Type</b>	PT4 – Food and Feed area
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	Indoor – in food/feed areas : Disinfection of hard/non-porous surfaces (for general hygiene) by spraying without prior cleaning
<b>Application method(s)</b>	By spraying (with wiping if needed, only after the end of the preconised contact time)
<b>Application rate(s) and frequency</b>	Active against bacteria and yeasts at room temperature Dilute the product 20% in water, to reach an in use concentration of 3.2% Lactic acid. In 15 min contact time 100ml/m <sup>2</sup>

<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

#### 2.1.6.4.9 Use-specific instructions for use

Comply with the instructions for use

#### 2.1.6.4.10 Use-specific risk mitigation measures

Gloves and goggles are needed during handling of the products

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

see general directions for use for Meta SPC 4

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

see general directions for use for Meta SPC 4

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

see general directions for use for Meta SPC 4

#### 2.1.6.4.14 Use 4 – Hard surface disinfection for hygiene in kitchens, for non-professional use (PT4)

#### **Not granted for non-professional user (spraying application)**

#### 2.1.6.4.15 Use 5 – Disinfection of toilet bowls, for professional use (PT2)

<b>Product Type</b>	PT2 - Disinfectants and algaecides not intended for direct application to humans or animals
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	Indoor - Public field

	Disinfection of hard/non-porous inside surfaces of toilets, without prior cleaning
<b>Application method(s)</b>	By pouring (with brushing - only after the end of the preconised contact time)
<b>Application rate(s) and frequency</b>	Active against bacteria and yeasts at room temperature : With the undiluted product (with 16% lactic acid) In 5 min contact time 250ml/m <sup>2</sup>
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	500 mL, 700 mL, 750 mL, 1L, 1.5 L, 2 L HDPE (High Density Polyethylene) Toilet Duck

#### 2.1.6.4.16 Use-specific instructions for use

Comply with the instructions for use

#### 2.1.6.4.17 Use-specific risk mitigation measures

Gloves and goggles are needed during handling of the products

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

see general directions for use for Meta SPC 4

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

see general directions for use for Meta SPC 4

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

see general directions for use for Meta SPC 4

#### 2.1.6.4.21 Use 6 – Disinfection of toilet bowls, for non-professional use (PT2)

<b>Product Type</b>	PT2 - Disinfectants and algaecides not intended for direct application to humans or animals
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts

<b>Field of use</b>	Indoor - Public field Disinfection of hard/non-porous inside surfaces of toilets, without prior cleaning
<b>Application method(s)</b>	By pouring (with brushing - only after the end of the preconised contact time)
<b>Application rate(s) and frequency</b>	Active against bacteria and yeasts at room temperature : With the undiluted product (with 16% Lactic acid) In 5 min contact time 250ml/m <sup>2</sup>
<b>Category of users</b>	Non-professional use
<b>Pack sizes and packaging material</b>	500 mL, 700 mL, 750 mL, 1L, 1.5 L, 2 L HDPE (High Density Polyethylene) Toilet Duck

#### 2.1.6.4.22 Use-specific instructions for use

Comply with the instructions for use

#### 2.1.6.4.23 Use-specific risk mitigation measures

Avoid contact with eyes

A child proof closure is required

The product must be fitted with a pouring spout, the product must be poured gently on the wall of the toilet bowl to avoid the formation of splashes.

Wash hands after application

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

If medical advice is needed, have product container or label at hand

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

see general directions for use for Meta SPC 4

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

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

## 2.1.6.5 General directions for use for Meta SPC 4

### 2.1.6.5.1 Instructions for use

The surfaces to be disinfection must be wet enough in order to keep them wet during the preconised contact time for optimal disinfection. The following precautionary sentence will be added on the product label : "Make sure to wet surfaces completely".

### 2.1.6.5.2 Risk mitigation measures

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

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor. If skin irritation occurs: Get medical advice.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. 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

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

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

The packing and content must be eliminated as dangerous waste product under the whole responsibility of the possessor of this waste product. Do not throw wastes into sewers and watercourses. Dispose in a safe manner in accordance with local/national regulations.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.

The shelf-life of the products is 2 years.

### 2.1.6.5.6 Other information

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### 2.1.6.6 Third information level: individual products in the meta SPC

<b>Trade name(s)</b>	<b>Sanifresh</b> <b>Milcho Des</b> <b>Kenolens</b> <b>Kenolux S100</b> <b>SANI-CAL</b> <b>Sani Super</b> <b>Scrub</b> <b>MiQro Sani Des</b>				
<b>Common name</b>	<b>IUPAC name</b>	<b>Function</b>	<b>CAS number</b>	<b>EC number</b>	<b>Content (%)</b>
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	16.0
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	5.0

Please see the confidential annex for further details on composition

## 2.1.7 Meta SPC 5

### 2.1.7.1 Meta SPC administrative information

#### 2.1.7.1.1 Meta SPC identifier

<b>Identifier</b>	Meta SPC 5
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#### 2.1.7.1.2 Suffix to the authorisation number

<b>Number</b>	
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#### 2.1.7.1.3 Product type

<b>Product type</b>	PT3 – Veterinary hygiene
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### 2.1.7.2 Meta SPC composition

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	8.0	8.0
Sodium lauryl ether sulfate	Alcohols, C12-14, ethoxylated, sulfates, sodium salts	Anionic surfactant	68891-38-3	500-234-8	8.4	8.4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Sulfonic acids, C14-17-sec-alkane, sodium salts	Sulfonic acids, C14-17-sec-alkane, sodium	Anionic surfactant	97489-15-1	307-055-2	2.25	2.25

Please see the confidential annex for further details on composition of products in MetaSPC 5.

Type(s) of formulation of the meta SPC

SL – Soluble concentrate

### 2.1.7.3 Hazard and precautionary statements

Classification: metaSPC 5	
Hazard category	Eye Dam. 1
Hazard statement	H318
Labelling	
Signal words	Danger
Hazard statements	H318 - Causes serious eye damage
Precautionary statements	P280 - Wear Eyes/Face protection. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER or doctor.
Note	

### 2.1.7.4 Authorized use(s)

2.1.7.4.1 Use 1 – Teat disinfection, before milking

Product Type	PT3 - Veterinary hygiene
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor - Veterinary field Teat disinfection before milking with concentrated product (to be diluted before disinfection procedure), without prior cleaning

<b>Application method(s)</b>	By dipping By spraying with spray flacon or spray installation By wiping with a towel soaking with the diluted product
<b>Application rate(s) and frequency</b>	Active against bacteria and yeasts : Dilution : 40% <i>The product must be diluted with Room Temperature potable water.</i> In 1 min contact time
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

#### 2.1.7.4.2 Use-specific instructions for use

##### **Application rates :**

Dilution : 40% ( $\Leftrightarrow$  3.2 % LA) - *The product must be diluted with RT potable water.*

- 5 mL per cow per application for use by dipping
- 7.5 mL per cow per application for use by spray flacon
- 15 mL per cow per application for use by spray installation
- For use by wiping with a towel: prepare 10 L working solution for 25 towels.

Use one towel per cow.

#### 2.1.7.4.3 Use-specific risk mitigation measures

see general directions for use for Meta SPC 5

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

see general directions for use for Meta SPC 5

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

see general directions for use for Meta SPC 5

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

see general directions for use for Meta SPC 5



2.1.7.4.7 Use 2 – Intact skin wash/disinfection (of the udder of dairy and beef cattle before calving and of the udder of sows before farrowing)

<b>Product Type</b>	PT3 - Veterinary hygiene
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	Indoor - Veterinary field Intact skin disinfection (of the udder of dairy and beef cattle before calving and of the udder of sows before farrowing) <u>without</u> prior cleaning
<b>Application method(s)</b>	By spraying
<b>Application rate(s) and frequency</b>	Active against bacteria and yeasts : Dilution : 40% <i>The product must be diluted with Room Temperature potable water.</i> In 1 min contact time  1) dairy and beef cattle on the udder before calving: 5 mL (1 spray) on each teat 2) sows on the udder before farrowing: 20 mL  The animals should be kept standing on a clean floor for at least 5 minutes.
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

2.1.7.4.8 Use-specific instructions for use

see general directions for use for Meta SPC 5

2.1.7.4.9 Use-specific risk mitigation measures

see general directions for use for Meta SPC 5

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

see general directions for use for Meta SPC 5

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

see general directions for use for Meta SPC 5

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

see general directions for use for Meta SPC 5

### 2.1.7.5 General directions for use for Meta SPC 5

2.1.7.5.1 Instructions for use

See use specific instructions for use

2.1.7.5.2 Risk mitigation measures

Chemical goggles need to be worn.

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

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.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

2.1.7.5.4 Instructions for safe disposal of the product and its packaging

The packing and content must be eliminated as dangerous waste product under the whole responsibility of the possessor of this waste product. Do not throw wastes into sewers and watercourses. Dispose in a safe manner in accordance with local/national regulations.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.

The shelf-life of the products is 2 years.

## 2.1.7.5.6 Other information

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## 2.1.7.6 Third information level: individual products in the meta SPC

<b>Trade name(s)</b>	<b>Kenopure</b> <b>HCP Foam Concentrate</b> <b>Kenopro Lactic</b> <b>Reconet+</b> <b>MIROX Pre Lac</b> <b>Milchsäure Pre</b> <b>Milchsäure Pref</b> <b>Lactocid Pre</b> <b>Milcho Pre</b> <b>Preactive</b> <b>Precoop</b> <b>Lactipré</b> <b>Prelacti</b> <b>Prelak</b> <b>Power Prep</b> <b>Multicleaner</b> <b>Kenopure Strong</b> <b>Semex Pre</b> <b>MEPA Pure</b> <b>MEPA Foam</b> <b>Eco Lac Foam</b>				
<b>Common name</b>	<b>IUPAC name</b>	<b>Function</b>	<b>CAS number</b>	<b>EC number</b>	<b>Content (%)</b>
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	8.0
Sodium lauryl ether sulfate	Alcohols, C12-14, ethoxylated, sulfates, sodium salts	Anionic surfactant	68891-38-3	500-234-8	8.4
Sulfonic acids, C14-17-sec-alkane, sodium salts	Sulfonic acids, C14-17-sec-alkane, sodium	Anionic surfactant	97489-15-1	307-055-2	2.25

Please see the confidential annex for further details on composition

## 2.1.8 Meta SPC 6

### 2.1.8.1 Meta SPC administrative information

#### 2.1.8.1.1 Meta SPC identifier

<b>Identifier</b>	Meta SPC 6
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#### 2.1.8.1.2 Suffix to the authorisation number

<b>Number</b>	
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#### 2.1.8.1.3 Product type

<b>Product type</b>	PT3 – Veterinary hygiene
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### 2.1.8.2 Meta SPC composition

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	3.6	3.6
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	5.25	5.25

Please see the confidential annex for further details on composition of products in MetaSPC 6.

Type(s) of formulation of the meta SPC

AL – Any other liquid
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### 2.1.8.3 Hazard and precautionary statements

<b>Classification: metaSPC 6</b>	
Hazard category	Eye Dam. 1
Hazard statement	H318
<b>Labelling</b>	
Signal words	Danger
Hazard statements	H318 - Causes serious eye damage
Precautionary statements	P280 - Wear Eyes/Face protection. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER or doctor.
Note	

## 2.1.8.4 Authorized use(s)

### 2.1.8.4.1 Use 1 – Teat disinfection, before milking

<b>Product Type</b>	PT3 – Veterinary hygiene
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	Indoor - Veterinary field : Teat disinfection before milking with RTU product, without prior cleaning
<b>Application method(s)</b>	By dipping By spraying with spray flacon or spray installation By wiping with a towel soaking with the diluted product
<b>Application rate(s) and frequency</b>	Active against bacteria and yeasts : RTU (with 3.6% Lactic acid) In 1 min contact time  <i>The product must "return" to RT before use</i>
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

### 2.1.8.4.2 Use-specific instructions for use

<p><b>Application rates :</b></p> <ul style="list-style-type: none"> <li>- 5 mL per cow per application for use by dipping</li> <li>- 7.5 mL per cow per application for use by spray flacon</li> <li>- 15 mL per cow per application for use by spray installation</li> <li>- One towel per cow for use by wiping</li> </ul>
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### 2.1.8.4.3 Use-specific risk mitigation measures

see general directions for use for Meta SPC 6
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- 2.1.8.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

see general directions for use for Meta SPC 6

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

see general directions for use for Meta SPC 6

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

see general directions for use for Meta SPC 6

### **2.1.8.5 General directions for use for Meta SPC 6**

- 2.1.8.5.1 Instructions for use

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- 2.1.8.5.2 Risk mitigation measures

Chemical goggles need to be worn.

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

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.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

- 2.1.8.5.4 Instructions for safe disposal of the product and its packaging

The packing and content must be eliminated as dangerous waste product under the whole responsibility of the possessor of this waste product. Do not throw wastes into sewers and watercourses. Dispose in a safe manner in accordance with local/national regulations.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.  
The shelf-life of the products is 2 years.

### 2.1.8.5.6 Other information

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### 2.1.8.6 Third information level: individual products in the meta SPC

<b>Trade name(s)</b>	<b>Kenopure R</b> <b>Kenopure RTU</b> <b>HCP Foam RTU</b> <b>Kenoxypure RTU</b> <b>Kenopurox RTU</b> <b>Kenopure Ox RTU</b> <b>Kenopure Plus RTU</b> <b>Kenopure Extra RTU</b> <b>Kenopure oxylac RTU</b> <b>Kenoxylac predip RTU</b> <b>Kenoxilac predip RTU</b> <b>Kenopure H2O2 RTU</b> <b>Oxy Kenopure RTU</b> <b>Preactive RTU</b> <b>Precoop RTU</b> <b>Lactipré RTU</b> <b>Prelacti RTU</b> <b>Prelak RTU</b> <b>Power Prep RTU</b> <b>Prelacta Foam</b>				
<b>Common name</b>	<b>IUPAC name</b>	<b>Function</b>	<b>CAS number</b>	<b>EC number</b>	<b>Content (%)</b>
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	3.6
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	5.25

*Please see the confidential annex for further details on composition*

## 2.1.9 Meta SPC 7

### 2.1.9.1 Meta SPC administrative information

#### 2.1.9.1.1 Meta SPC identifier

<b>Identifier</b>	Meta SPC 7
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**2.1.9.1.2 Suffix to the authorisation number**

<b>Number</b>	
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**2.1.9.1.3 Product type**

<b>Product type</b>	PT2– Disinfectants and algacides not intended for direct application to humans or animals PT4 – Food and Feed area
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**2.1.9.2 Meta SPC composition**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	2.0	2.0

Please see the confidential annex for further details on composition of products in MetaSPC 7.

Type(s) of formulation of the meta SPC

WI – Wipes
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**2.1.9.3 Hazard and precautionary statements**

<b>Classification: metaSPC 7 (incl. Kenopure Wipes)</b>	
Hazard category	Eye Irr. 2
Hazard statement	H319
<b>Labelling</b>	
Signal words	Warning
Hazard statements	H319 – Causes serious eye irritation.
Precautionary statements	P101 - If medical advice is needed, have product container or label at hand. P102 - Keep out of reach of children. P103 - Read carefully and follow all instructions P264 - Wash hands thoroughly after handling. P280 - Wear eye protection/face protection. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332 + P313: If skin irritation occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention. P362+P364 Take off contaminated clothing and wash it before reuse.
Note	The P phrases 101, 102 and 103 are recommended for the biocidal product intended to be used by non-professional users.



### 2.1.9.4 Authorised use(s)

2.1.9.4.1 Use 1 – Hard surface disinfection in Food and Feed industry, for professional use (PT4)

<b>Product Type</b>	PT4 - Food and Feed area
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts Viruses
<b>Field of use</b>	Indoor – Food/feed areas Disinfection of hard/non-porous surfaces and objects, with prior cleaning
<b>Application method(s)</b>	With pre-impregnated wipes
<b>Application rate(s) and frequency</b>	Active against bacteria, yeasts and viruses : With pre-impregnated wipes at room temperature in 2 min contact time
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	Box in HDPE with lid in HDPE with 105 wipes, 200 wipes, 280 wipes, 500 wipes

2.1.9.4.2 Use-specific instructions for use

see general directions for use for Meta SPC 7

2.1.9.4.3 Use-specific risk mitigation measures

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

see general directions for use for Meta SPC 7

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

see general directions for use for Meta SPC 7

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

see general directions for use for Meta SPC 7

2.1.9.4.7 Use 2 – Hard surface disinfection in food and feed area, for non-professional use (PT4)

<b>Product Type</b>	PT4- Food and Feed area
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts Viruses
<b>Field of use</b>	Indoor – Food/feed areas Disinfection of hard/non-porous surfaces and objects, with prior cleaning
<b>Application method(s)</b>	With pre-impregnated wipes
<b>Application rate(s) and frequency</b>	Active against bacteria, yeasts and viruses : With pre-impregnated wipes at room temperature in 2 min contact time 1wipe/m <sup>2</sup>
<b>Category of users</b>	Non-professional use
<b>Pack sizes and packaging material</b>	Box in HDPE with lid in HDPE with 105 wipes, 200 wipes, 280 wipes, 500 wipes

2.1.9.4.8 Use-specific instructions for use

Comply with the instructions for use

2.1.9.4.9 Use-specific risk mitigation measures

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

If medical advice is needed, have product container or label at hand

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

see general directions for use for Meta SPC 7

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

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

2.1.9.4.13 Use 3 – Hard surface disinfection, use in healthcare, for professional use (PT2)

<b>Product Type</b>	PT2 - Disinfectants and algacides not intended for direct application to humans or animals
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts Viruses
<b>Field of use</b>	Indoor - Public field : Disinfection of hard/non-porous surfaces (walls, floors and other surfaces in indoor spaces, including bathrooms and toilets) with prior cleaning
<b>Application method(s)</b>	With pre-impregnated wipes
<b>Application rate(s) and frequency</b>	Active against bacteria, yeasts and viruses : With pre-impregnated wipes at room temperature in 2 min contact time
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	Box in HDPE with lid in HDPE with 105 wipes, 200 wipes, 280 wipes, 500 wipes

2.1.9.4.14 Use-specific instructions for use

see general directions for use for Meta SPC 7

2.1.9.4.15 Use-specific risk mitigation measures

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

see general directions for use for Meta SPC 7

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

see general directions for use for Meta SPC 7

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

see general directions for use for Meta SPC 7

2.1.9.4.19 Use 4 – Hard surface disinfection, use in healthcare, for non-professional use (PT2)

<b>Product Type</b>	PT2 - Disinfectants and algacides not intended for direct application to humans or animals
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts Viruses
<b>Field of use</b>	Indoor - Public field : Disinfection of hard/non-porous surfaces (walls, floors and other surfaces in indoor spaces, including bathrooms and toilets) in healthcare area with prior cleaning
<b>Application method(s)</b>	With pre-impregnated wipes
<b>Application rate(s) and frequency</b>	Active against bacteria, yeasts and viruses : With pre-impregnated wipes at room temperature in 2 min contact time
<b>Category of users</b>	Non-professional use
<b>Pack sizes and packaging material</b>	Box in HDPE with lid in HDPE with 105 wipes, 200 wipes, 280 wipes, 500 wipes

2.1.9.4.20 Use-specific instructions for use

Comply with the instructions for use

2.1.9.4.21 Use-specific risk mitigation measures

/

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

If medical advice is needed, have product container or label at hand

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

see general directions for use for Meta SPC 7

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

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

2.1.9.4.25 Use 5 – Hard surface disinfection, use other than in healthcare, for professional use (PT2)

<b>Product Type</b>	PT2 - Disinfectants and algaecides not intended for direct application to humans or animals
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts Viruses
<b>Field of use</b>	Indoor - Public field : Disinfection of hard/non-porous surfaces (walls, floors and other surfaces in indoor spaces, including bathrooms and toilets) with prior cleaning
<b>Application method(s)</b>	With pre-impregnated wipes
<b>Application rate(s) and frequency</b>	Active against bacteria, yeasts and viruses : With pre-impregnated wipes at room temperature in 2 min contact time
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	Box in HDPE with lid in HDPE with 105 wipes, 200 wipes, 280 wipes, 500 wipes

2.1.9.4.26 Use-specific instructions for use

see general directions for use for Meta SPC 7

2.1.9.4.27 Use-specific risk mitigation measures

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

see general directions for use for Meta SPC 7

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

see general directions for use for Meta SPC 7

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

see general directions for use for Meta SPC 7

2.1.9.4.31 Use 6 – Hard surface disinfection, use other than in healthcare, for non-professional use (PT2)

<b>Product Type</b>	PT2 - Disinfectants and algacides not intended for direct application to humans or animals
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts Viruses
<b>Field of use</b>	Indoor - Public field : Disinfection of hard/non-porous surfaces (walls, floors and other surfaces in indoor spaces, including bathrooms and toilets) with prior cleaning
<b>Application method(s)</b>	With pre-impregnated wipes
<b>Application rate(s) and frequency</b>	Active against bacteria, yeasts and viruses : With pre-impregnated wipes at room temperature in 2 min contact time
<b>Category of users</b>	Non-professional use
<b>Pack sizes and packaging material</b>	Box in HDPE with lid in HDPE with 105 wipes, 200 wipes, 280 wipes, 500 wipes

2.1.9.4.32 Use-specific instructions for use

Comply with the instructions for use

2.1.9.4.33 Use-specific risk mitigation measures

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

If medical advice is needed, have product container or label at hand.

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

see general directions for use for Meta SPC 7

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

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

## 2.1.9.5 General directions for use for Meta SPC 7

### 2.1.9.5.1 Instructions for use

Comply with the instructions for use

First clean thoroughly the surfaces and materials to be disinfected and dry the surface or materials.

Disinfect the dry surface with a wipe. Make sure the surface remains completely wetted during the required contact time.

### 2.1.9.5.2 Risk mitigation measures

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

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do.

Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

If medical advice is needed, have product container or label at hand

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

The packing and content must be eliminated as dangerous waste product under the whole responsibility of the possessor of this waste product. Do not throw wastes into sewers and watercourses. Dispose in a safe manner in accordance with local/national regulations.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use. Store at ambient temperature. Do not store below 0°C and above 40°C.

The shelf-life of the products is 2 years.

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

### 2.1.9.5.6 Other information

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### 2.1.9.6 Third information level: individual products in the meta SPC

<b>Trade name(s)</b>	<b>Kenopure Wipes</b> <b>EP-460 Wipes</b> <b>Sani Wipes</b> <b>Lactides Wipes</b> <b>Keno Lac Wipes</b> <b>KL Wipes</b> <b>Kenolux Wipes</b> <b>Power Des Wipes</b> <b>Keno L Wipes</b> <b>Keno Des Wipes</b> <b>RĘCZNIKI PAPIEROWE MYJĄCO-DEZYNFEKUJĄCE FARMA</b> <b>RĘCZNIKI PAPIEROWE MYJĄCO-DEZYNFEKUJĄCE VITTRA</b> <b>Ręczniki myjąco-dezynfekujące AGROD</b>				
<b>Common name</b>	<b>IUPAC name</b>	<b>Function</b>	<b>CAS number</b>	<b>EC number</b>	<b>Content (%)</b>
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	2

Please see the confidential annex for further details on composition

### 2.1.10 Meta SPC 8

#### 2.1.10.1 Meta SPC administrative information

##### 2.1.10.1.1 Meta SPC identifier

<b>Identifier</b>	Meta SPC 8
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##### 2.1.10.1.2 Suffix to the authorisation number

<b>Number</b>	
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##### 2.1.10.1.3 Product type

<b>Product type</b>	PT3 – Veterinary hygiene
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#### 2.1.10.2 Meta SPC composition

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	3.6	7.5
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	1.3	1.3



Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Isopropanol	Propan-2-ol	Solvent / Processing aid	67-63-0	200-661-7	1.0	3.0

Please see the confidential annex for further details on composition of products in MetaSPC 8.

Type(s) of formulation of the meta SPC

AL – Any other liquid
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### 2.1.10.3 Hazard and precautionary statements

Classification: metaSPC 8	
Hazard category	Eye Dam. 1
Hazard statement	H318
Labelling	
Signal words	Danger
Hazard statements	H318 - Causes serious eye damage
Precautionary statements	P280 - Wear Eyes/face protection. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER or doctor.
Note	

### 2.1.10.4 Authorised use(s)

2.1.10.4.1 Use 1 – Teat disinfection after milking by dipping

<b>Product Type</b>	PT3 - Veterinary hygiene
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	Indoor - Veterinary field : RTU post-dip for teat disinfection, after milking, without prior cleaning
<b>Application method(s)</b>	By dipping
<b>Application rate(s) and frequency</b>	Active against bacteria and yeasts : RTU (with 3.6 – 7.5% Lactic acid depending of the product considered)

	In 5 min contact time <i>The product must "return" to RT before use</i>
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

#### 2.1.10.4.2 Use-specific instructions for use

see general directions for use for Meta SPC 8

#### 2.1.10.4.3 Use-specific risk mitigation measures

see general directions for use for Meta SPC 8

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

see general directions for use for Meta SPC 8

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

see general directions for use for Meta SPC 8

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

see general directions for use for Meta SPC 8

### 2.1.10.5 General directions for use for Meta SPC 8

#### 2.1.10.5.1 Instructions for use

Apply the product immediately after each milking, two or three times per day. Ensure that the teat is completely covered to three quarter of its length. Fill the dipping cup with the desired amount of product, but do not use more fluid that necessary. Assume 5 mL per cow per treatment. Respect a contact time of 5 minutes. The product must be brought to a temperature above 20°C before use. In order to ensure optimal teat disinfection, the animals should be kept standing for at least 5 min.

#### 2.1.10.5.2 Risk mitigation measures

Chemical goggles need to be worn.

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

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

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

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

The packing and content must be eliminated as dangerous waste product under the whole responsibility of the possessor of this waste product. Do not throw wastes into sewers and watercourses. Dispose in a safe manner in accordance with local/national regulations.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.

The shelf-life of the products is 2 years.

### 2.1.10.5.6 Other information

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## 2.1.10.6 Third information level: individual products in the meta SPC

<b>Trade name(s)</b>	<b>Kenolac</b> <b>Kenolac Red</b> <b>Kenodip 200</b> <b>Stalosan Lac Dip</b> <b>HCP Dip</b> <b>PEZERK LV PLUS</b> <b>MIROX Dip Lac</b> <b>Milchsäure Dip</b> <b>Milchsäure Tauche</b> <b>Lactocid Dip</b> <b>GAHERLAC</b> <b>Lactidip</b> <b>Lacticoop</b> <b>Lactactiv</b> <b>Laktotop</b> <b>Superlac</b>
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	<b>MilchsäureFilmdip Super</b> <b>MEPA Lac</b> <b>Eco Lac</b> <b>BluGard Dip</b> <b>Blu-Gard Dip</b>				
<b>Common name</b>	<b>IUPAC name</b>	<b>Function</b>	<b>CAS number</b>	<b>EC number</b>	<b>Content (%)</b>
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	3.6
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	1.3
Isopropanol	Propan-2-ol	Solvent / Processing aid	67-63-0	200-661-7	1.0

<b>Trade name(s)</b>	<b>Kenolac Forte W</b>				
<b>Common name</b>	<b>IUPAC name</b>	<b>Function</b>	<b>CAS number</b>	<b>EC number</b>	<b>Content (%)</b>
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	7.5
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	1.3
Isopropanol	Propan-2-ol	Solvent / Processing aid	67-63-0	200-661-7	3.0

Please see the confidential annex for further details on composition.

## 2.1.11 Meta SPC 9

### 2.1.11.1 Meta SPC administrative information

#### 2.1.11.1.1 Meta SPC identifier

<b>Identifier</b>	Meta SPC 9
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#### 2.1.11.1.2 Suffix to the authorisation number

<b>Number</b>	
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#### 2.1.11.1.3 Product type

<b>Product type</b>	PT3 – Veterinary hygiene
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### 2.1.11.2 Meta SPC composition

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	3.6	7.5
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	0.5	1.3
Isopropanol	Propan-2-ol	Solvent / Processing aid	67-63-0	200-661-7	3.0	3.0

Please see the confidential annex for further details on composition of products in MetaSPC 9.

Type(s) of formulation of the meta SPC

AL – any other liquid
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### 2.1.11.3 Hazard and precautionary statements

<b>Classification: metaSPC 9</b>	
Hazard category	Eye Dam. 1
Hazard statement	H318
<b>Labelling</b>	
Signal words	Danger
Hazard statements	H318 - Causes serious eye damage
Precautionary statements	P280 - Wear Eyes/Face protection. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER or doctor.
Note	

### 2.1.11.4 Authorised use(s)

2.1.11.4.1 Use 1 – Teat disinfection after milking by spraying or dipping

<b>Product Type</b>	PT3 – Veterinary hygiene
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts

<b>Field of use</b>	Indoor - Veterinary field : RTU spray or dip for teat disinfection, after milking, without prior cleaning
<b>Application method(s)</b>	By spraying or dipping
<b>Application rate(s) and frequency</b>	Active against bacteria and yeasts : RTU (with 3.6% Lactic acid) In 5 min contact time  <i>The product must return to RT before use</i>
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

#### 2.1.11.4.2 Use-specific instructions for use

See general directions for use for Meta SPC 9

#### 2.1.11.4.3 Use-specific risk mitigation measures

See general directions for use for Meta SPC 9

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

See general directions for use for Meta SPC 9

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

See general directions for use for Meta SPC 9

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

See general directions for use for Meta SPC 9

### 2.1.11.5 General directions for use for Meta SPC 9

#### 2.1.11.5.1 Instructions for use

Apply the product immediately after each milking, two or three times per day. Ensure that the teat is completely covered to three quarter of its length. Fill the dipping cup or spraying flacon with the desired amount of product, but do not use more fluid that

necessary. Assume 5 mL per cow per treatment. Respect a contact time of 5 minutes. The product must be brought to a temperature above 20°C before use. In order to ensure optimal teat disinfection, the animals should be kept standing for at least 5 min.

#### 2.1.11.5.2 Risk mitigation measures

Chemical goggles need to be worn.

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

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

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

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

The packing and content must be eliminated as dangerous waste product under the whole responsibility of the possessor of this waste product. Do not throw wastes into sewers and watercourses. Dispose in a safe manner in accordance with local/national regulations.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.

The shelf-life of the products is 2 years.

#### 2.1.11.5.6 Other information

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### 2.1.11.6 Third information level: individual products in the meta SPC

<b>Trade name(s)</b>	<b>Kenolac SD</b> <b>HCP Spray</b> <b>Lactospray</b> <b>Zitzentop</b> <b>Lactosilk</b> <b>Milchsäure Spray Bühning</b> <b>Lacto SP</b> <b>Stalosan Lac Spray</b> <b>MIROX Spray Lac</b>
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	<b>Milchsäure Sprühe</b> <b>Lactocid Spray</b> <b>Milcho Spray</b> <b>GAHERLAC SPRAY</b> <b>Lactispray</b> <b>Lacticoop Spray</b> <b>Lactactiv Spray</b> <b>Laktotop Spray</b> <b>Superlac Spray</b> <b>Robolac</b> <b>MEPA Lac SD</b> <b>Eco Lac SD</b> <b>Lely Quaress Circum</b> <b>BluGard Spray</b> <b>Blu-Gard Spray</b>				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	3.6
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	1.3
Isopropanol	Propan-2-ol	Solvent / Processing aid	67-63-0	200-661-7	3.0

Trade name(s)	<b>Kenolac Forte SD</b>				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	7.5
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	1.3
Isopropanol	Propan-2-ol	Solvent / Processing aid	67-63-0	200-661-7	3.0

Please see the confidential annex for further details on composition.

## 2.1.12 Meta SPC 10

### 2.1.12.1 Meta SPC administrative information

#### 2.1.12.1.1 Meta SPC identifier

<b>Identifier</b>	Meta SPC 10
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#### 2.1.12.1.2 Suffix to the authorisation number

<b>Number</b>	
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**2.1.12.1.3 Product type**

<b>Product type</b>	PT3 – Veterinary hygiene
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**2.1.12.2 Meta SPC composition**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	3.6	3.6

Please see the confidential annex for further details on composition of products in MetaSPC 10.

Type(s) of formulation of the meta SPC

AL-Any other liquid
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**2.1.12.3 Hazard and precautionary statements**

<b>Classification: metaSPC 10</b>	
Hazard category	Flam. Liq. 3 Eye Dam. 1
Hazard statement	H226 H318 EUH208
<b>Labelling</b>	
Signal words	Danger
Hazard statements	H226 - Flammable liquid and vapour H318 - Causes serious eye damage EUH208 - Contains menthan-3-one (CAS-No. 14073-97-3) . May produce an allergic reaction
Precautionary statements	P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P280 - Wear Eyes/Face protection. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER/doctor. P370 + P378: In case of fire: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide to extinguish. P403 + P235: Store in a well ventilated place. Keep cool. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Note	

## 2.1.12.4 Authorised use(s)

### 2.1.12.4.1 Use 1 – Teat disinfection after milking by spraying or dipping

<b>Product Type</b>	PT3 – Veterinary hygiene
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	Indoor - Veterinary field : RTU spray/dip for teat disinfection, after milking, without prior cleaning
<b>Application method(s)</b>	By spraying or dipping
<b>Application rate(s) and frequency</b>	Active against bacteria and yeasts : RTU (with 3.6% Lactic acid) In 5 min contact time  <i>The product must "return" to RT before use.</i>
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

### 2.1.12.4.2 Use-specific instructions for use

Application rates:

- 7.5 mL per cow working solution for use by spraying with flacon
- 15 mL per cow working solution for use by spraying in installation
- 15 mL per cow by for use by spraying with robot
- 2.5-5 mL per cow for use by dipping/foaming

### 2.1.12.4.3 Use-specific risk mitigation measures

See general directions for use for Meta SPC 10

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

See general directions for use for Meta SPC 10

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

See general directions for use for Meta SPC 10

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

See general directions for use for Meta SPC 10

### 2.1.12.5 General directions for use for Meta SPC 10

#### 2.1.12.5.1 Instructions for use

Apply the product immediately after each milking, two or three times per day. Ensure that the teat is completely covered to three quarter of its length. Fill the dipping cup or spraying flacon with the desired amount of product, but do not use more fluid than necessary. The product must be brought to a temperature above 20°C before use. In order to ensure optimal teat disinfection, the animals should be kept standing for at least 5 min.

#### 2.1.12.5.2 Risk mitigation measures

Chemical goggles need to be worn.

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

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  
IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor. If skin irritation occurs: Get medical advice.  
IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. 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

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

The packing and content must be eliminated as dangerous waste product under the whole responsibility of the possessor of this waste product. Do not throw wastes into sewers and watercourses. Dispose in a safe manner in accordance with local/national regulations.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.

The shelf-life of the products is 2 years.

#### 2.1.12.5.6 Other information

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### 2.1.12.6 Third information level: individual products in the meta SPC

<b>Trade name(s)</b>	<b>Kenocool PEZERK LI PLUS Milcho Dip</b>				
<b>Common name</b>	<b>IUPAC name</b>	<b>Function</b>	<b>CAS number</b>	<b>EC number</b>	<b>Content (%)</b>
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	3.6

Please see the confidential annex for further details on composition.

### 2.1.13 Meta SPC 11

#### 2.1.13.1 Meta SPC administrative information

##### 2.1.13.1.1 Meta SPC identifier

<b>Identifier</b>	Meta SPC 11
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##### 2.1.13.1.2 Suffix to the authorisation number

<b>Number</b>	
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##### 2.1.13.1.3 Product type

<b>Product type</b>	PT3 – Veterinary hygiene PT4 – Food and Feed area
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#### 2.1.13.2 Meta SPC composition

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	24.0	24.0
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	12.0	12.0
Isopropanol	Propan-2-ol	Solvent / Processing aid	67-63-0	200-661-7	5.0	5.0

Please see the confidential annex for further details on composition of products in MetaSPC 11.

Type(s) of formulation of the meta SPC

SL – Soluble concentrate
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### 2.1.13.3 Hazard and precautionary statements

<b>Classification: metaSPC 11</b>	
Hazard category	Skin Irr. 2 Eye Dam. 1
Hazard statement	H315 H318
<b>Labelling</b>	
Signal words	Danger
Hazard statements	H315 - Causes skin irritation. H318 - Causes serious eye damage.
Precautionary statements	P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves, Eyes/Face protection. P302+P352 - IF ON SKIN: Wash with plenty of water/... P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER/doctor. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Note	The P321 is recommended only in exceptional cases where specific treatment is known and required. This is not the case for the product, which does not require any special measures in addition to the application

### 2.1.13.4 Authorised use(s)

#### 2.1.13.4.1 Use 1 – Hard surface disinfection in Food and feed industry

<b>Product Type</b>	PT4 - Food and Feed area
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	Indoor – in Food/Feed industry + Public field : Disinfection of hard/non-porous surfaces by spraying or soaking with prior cleaning
<b>Application method(s)</b>	By spraying or immersion.
<b>Application rate(s) and frequency</b>	Active against bacteria and yeasts at room temperature: 100 mL/m <sup>2</sup> <ul style="list-style-type: none"> <li>➤ 3% (with 0.72% Lactic acid) in 2 min contact time</li> <li>➤ 1% (with 0.24% Lactic acid) in 15 min contact time</li> </ul>
<b>Category of users</b>	Professional use

<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)
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#### 2.1.13.4.2 Use-specific instructions for use

See general directions for use for Meta SPC 11

#### 2.1.13.4.3 Use-specific risk mitigation measures

See general directions for use for Meta SPC 11

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

See general directions for use for Meta SPC 11

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

See general directions for use for Meta SPC 11

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

See general directions for use for Meta SPC 11

#### 2.1.13.4.7 Use 2 – Equipment disinfection by soaking in Food and feed industry

<b>Product Type</b>	PT4 - Food and Feed area
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	Indoor – in Food/Feed industry + Public field : Disinfection of hard/non-porous surfaces (e.g. processing machines)) by spraying or soaking without prior cleaning
<b>Application method(s)</b>	By spraying or immersion
<b>Application rate(s) and frequency</b>	Active against bacteria and yeasts at +7°C: ➤ By soaking : 15% (with 3.6 % Lactic acid) in 30 sec. contact time

	➤ By spraying : 8% (with 1.92 % Lactic acid) in 2 min contact time; 100 ml/m <sup>2</sup>
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

#### 2.1.13.4.8 Use-specific instructions for use

See general directions for use for Meta SPC 11

#### 2.1.13.4.9 Use-specific risk mitigation measures

See general directions for use for Meta SPC 11

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

See general directions for use for Meta SPC 11

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

See general directions for use for Meta SPC 11

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

See general directions for use for Meta SPC 11

#### 2.1.13.4.13 Use 3 – Hard surfaces disinfection for veterinary hygiene

<b>Product Type</b>	PT3 – Veterinary hygiene
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	Indoor - Veterinary field: Disinfection of hard/non-porous surfaces by spraying or soaking with prior cleaning
<b>Application method(s)</b>	By spraying

	By immersion
<b>Application rate(s) and frequency</b>	Active against bacteria and yeasts at +10°C: 4% (with 0.96% Lactic acid) in 30 min contact time
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

#### 2.1.13.4.14 Use-specific instructions for use

Animal houses must be empty of animals during disinfection. The product is used to disinfect animal housings of pigs, cows, poultry. Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water.

Mixing and loading: container is opened manually and emptied into the reservoir or connected to a pump, which pumps the product into the reservoir of the spraying device which is then filled up with water in order to achieve the correct concentration of use. Apply the product by spraying or immersion. Use as many solution to keep the surfaces wet during the complete contact time. It's not necessary to spray during the complete contact time.

#### 2.1.13.4.15 Use-specific risk mitigation measures

See general directions for use for Meta SPC 11

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

See general directions for use for Meta SPC 11

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

See general directions for use for Meta SPC 11

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

See general directions for use for Meta SPC 11



## 2.1.13.5 General directions for use for Meta SPC 11

### 2.1.13.5.1 Instructions for use

Disinfection procedures by spraying: The surfaces to be disinfection must be wet enough in order to keep them wet during the preconised contact time for optimal disinfection. The following precautionary sentence will be added on the product label : "Make sure to wet surfaces completely".  
Products must be diluted in potable water before use.

### 2.1.13.5.2 Risk mitigation measures

Gloves and goggles are needed during mixing and loading.

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

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  
IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor. If skin irritation occurs: Get medical advice.  
IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. 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

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

The packing and content must be eliminated as dangerous waste product under the whole responsibility of the possessor of this waste product. Do not throw wastes into sewers and watercourses. Dispose in a safe manner in accordance with local/national regulations.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.  
The shelf-life of the products is 2 years.

### 2.1.13.5.6 Other information

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### 2.1.13.6 Third information level: individual products in the meta SPC

<b>Trade name(s)</b>	<b>Kenosan Lactic Lacto Des Bio Des 100 Bio Lac</b>				
<b>Common name</b>	<b>IUPAC name</b>	<b>Function</b>	<b>CAS number</b>	<b>EC number</b>	<b>Content (%)</b>
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	24.0
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	12.0
Isopropanol	Propan-2-ol	Solvent / Processing aid	67-63-0	200-661-7	5.0

Please see the confidential annex for further details on composition.

### 2.1.14 Meta SPC 12

#### 2.1.14.1 Meta SPC administrative information

##### 2.1.14.1.1 Meta SPC identifier

<b>Identifier</b>	Meta SPC 12
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##### 2.1.14.1.2 Suffix to the authorisation number

<b>Number</b>	
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##### 2.1.14.1.3 Product type

<b>Product type</b>	PT4 – Food and Feed area
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#### 2.1.14.2 Meta SPC composition

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	22.0	22.0
C6 alkyl glucoside	Hexyl D-Glucoside	Nonionic surfactant	54549-24-5	259-217-6	2.4	2.4
Methanesulfonic acid	Methanesulfonic acid	Acidifier	75-75-2	200-898-6	0.0	10.5
Sulphuric acid	Sulphuric acid	Acidifier	7664-93-9	231-639-5	0.0	10.5

Please see the confidential annex for further details on composition of products in MetaSPC 12.

Type(s) of formulation of the meta SPC

SL – soluble concentrate
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### 2.1.14.3 Hazard and precautionary statements

<b>Classification: metaSPC 12</b>	
Hazard category	Met. Corr. 1 Skin Corr. 1 Eye Dam. 1
Hazard statement	H290 H314 H318
<b>Labelling</b>	
Signal words	Danger
Hazard statements	H290 - May be corrosive to metals. H314 - Causes severe skin burns and eye damage
Precautionary statements	P234: Keep only in original packaging. P260 - Do not breathe dust/fume/gas/mist/vapours/spray P264 - Wash hands thoroughly after handling P280 - Wear protective gloves, protective clothing, Eyes/Face protection. P301+P330+P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER/doctor P390: Absorb spillage to prevent material damage. P363 - Wash contaminated clothing before reuse. P405 - Store locked up P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Note	The P321 is recommended only in exceptional cases where specific treatment is known and required. This is not the case for the product, which does not require any special measures in addition to the application.

## 2.1.14.4 Authorised use(s)

### 2.1.14.4.1 Use 1 – Inner surface disinfection by CIP with circulation

<b>Product Type</b>	PT4 – Food and Feed area
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	Indoor – in Food and feed industry : Disinfection of hard/non-porous inner surfaces by CIP procedures (with circulation)
<b>Application method(s)</b>	CIP procedures
<b>Application rate(s) and frequency</b>	At +50°C Active against bacteria and yeasts : <ul style="list-style-type: none"> <li>• <u>with prior cleaning</u>: 2% (0.44% Lactic acid) in 2 min contact time / 1% in 30 min contact time</li> <li>• <u>without prior cleaning</u> : 4% (0.88 % Lactic acid) in 2 min contact time Or 1% (0.22 % Lactic acid) in 30 min contact time</li> <li>• <u>in milky conditions</u> : 2% (0.44% Lactic acid) in 15 min contact time</li> </ul>
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

### 2.1.14.4.2 Use-specific instructions for use

See general directions for use for Meta SPC 12

### 2.1.14.4.3 Use-specific risk mitigation measures

See general directions for use for Meta SPC 12

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

See general directions for use for Meta SPC 12

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

See general directions for use for Meta SPC 12

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

See general directions for use for Meta SPC 12

2.1.14.4.7 Use 2 – Inner surface disinfection by CIP without circulation

<b>Product Type</b>	PT4 – Food and Feed area
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	Indoor – in Food and feed industry : Disinfection of hard/non-porous inner surfaces by CIP procedures (without circulation)
<b>Application method(s)</b>	CIP procedures
<b>Application rate(s) and frequency</b>	At +50°C Active against bacteria and yeasts : <ul style="list-style-type: none"> <li>• <u>with prior cleaning</u>: 2% (0.44% Lactic acid) in 2 min contact time</li> <li>• <u>without prior cleaning</u> : 4% (0.88 % Lactic acid) in 2 min contact time Or 2% (0.44 % Lactic acid) in 30 min contact time</li> </ul>
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

2.1.14.4.8 Use-specific instructions for use

See general directions for use for Meta SPC 12

2.1.14.4.9 Use-specific risk mitigation measures

See general directions for use for Meta SPC 12

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

See general directions for use for Meta SPC 12

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

See general directions for use for Meta SPC 12

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

See general directions for use for Meta SPC 12

2.1.14.4.13 Use 3 – Crate wash

<b>Product Type</b>	PT4 – Food and Feed area
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	Indoor – in Food and feed industry disinfection of hard/non-porous surfaces in crate washers
<b>Application method(s)</b>	Crate wash
<b>Application rate(s) and frequency</b>	At +50°C <ul style="list-style-type: none"> <li>• <u>With prior cleaning</u> Active against bacteria and yeasts : 2% (0.44 % Lactic acid) in 2 min contact</li> <li>• <u>without prior cleaning</u> Active against bacteria and yeasts : 4% (0.88 % Lactic acid) in 2 min contact</li> </ul>
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

2.1.14.4.14 Use-specific instructions for use

See general directions for use for Meta SPC 12

#### 2.1.14.4.15 Use-specific risk mitigation measures

See general directions for use for Meta SPC 12

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

See general directions for use for Meta SPC 12

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

See general directions for use for Meta SPC 12

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

See general directions for use for Meta SPC 12

### **2.1.14.5 General directions for use for Meta SPC 12**

#### 2.1.14.5.1 Instructions for use

Products must be diluted in potable water before use.

#### 2.1.14.5.2 Risk mitigation measures

Gloves and goggles are needed during mixing and loading.  
Wear protective coverall (to be specified by the authorisation holder within the product information).

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

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.  
IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.  
IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. 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

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

The packing and content must be eliminated as dangerous waste product under the whole responsibility of the possessor of this waste product. Do not throw wastes into sewers and watercourses. Dispose in a safe manner in accordance with local/national regulations.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.  
The shelf-life of the products is 2 years.

#### 2.1.14.5.6 Other information

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### 2.1.14.6 Third information level: individual products in the meta SPC

Trade name(s)	Pho cid L Tornax 100 Tornax Des Lacto CIP Pho Cid Eco				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	22.0
C6 alkyl glucoside	Hexyl D-Glucoside	Nonionic surfactant	54549-24-5	259-217-6	2.4
Methanesulfonic acid	Methanesulfonic acid	Acidifier	75-75-2	200-898-6	10.5

Trade name(s)	Phocid LS				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	22.0
C6 alkyl glucoside	Hexyl D-Glucoside	Nonionic surfactant	54549-24-5	259-217-6	2.4
Sulphuric acid	Sulphuric acid	Acidifier	7664-93-9	231-639-5	10.5

Please see the confidential annex for further details on composition.



## 2.1.15 Meta SPC 13

### 2.1.15.1 Meta SPC administrative information

#### 2.1.15.1.1 Meta SPC identifier

<b>Identifier</b>	Meta SPC 13
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#### 2.1.15.1.2 Suffix to the authorisation number

<b>Number</b>	
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#### 2.1.15.1.3 Product type

<b>Product type</b>	PT2– Disinfectants and algacides not intended for direct application to humans or animals PT4 – Food and Feed area
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### 2.1.15.2 Meta SPC composition

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	11.0	11.0
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	4.5	4.5
Methanesulfonic acid	Methanesulfonic acid	Acidifier	75-75-2	200-898-6	10.5	19.5

Please see the confidential annex for further details on composition of products in MetaSPC 13.

Type(s) of formulation of the meta SPC

SL – Soluble concentrate
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### 2.1.15.3 Hazard and precautionary statements

<b>Classification: metaSPC 13</b>	
Hazard category	Met. Corr. 1 Skin Corr. 1 Eye Dam. 1
Hazard statement	H290 H314 H318
<b>Labelling</b>	

Signal words	Danger
Hazard statements	H290 - May be corrosive to metals H314 - Causes severe skin burns and eye damage
Precautionary statements	P234: Keep only in original packaging. P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves, protective clothing, Eyes/Face protection. P301+P330+P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER/doctor. P390: Absorb spillage to prevent material damage. P363 - Wash contaminated clothing before reuse. P405 - Store locked up P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Note	The P321 is recommended only in exceptional cases where specific treatment is known and required. This is not the case for the product, which does not require any special measures in addition to the application.

### 2.1.15.4 Authorised use(s)

#### 2.1.15.4.1 Use 1 – Hard surface disinfection (PT4)

<b>Product Type</b>	PT4 - Food and Feed area
<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	Indoor – Food/feed areas Disinfection of hard/non-porous surfaces by foaming
<b>Application method(s)</b>	By foaming
<b>Application rate(s) and frequency</b>	At room temperature in 30 min contact time Active against bacteria and yeasts : <ul style="list-style-type: none"> <li>• <u>with</u> prior cleaning : 1% (0.11% Lactic acid)</li> <li>• <u>without</u> prior cleaning : 5% (0.55% Lactic acid)</li> </ul>

<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

#### 2.1.15.4.2 Use-specific instructions for use

See general directions for use for Meta SPC 13

#### 2.1.15.4.3 Use-specific risk mitigation measures

See general directions for use for Meta SPC 13

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

See general directions for use for Meta SPC 13

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

See general directions for use for Meta SPC 13

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

See general directions for use for Meta SPC 13

### 2.1.15.5 General directions for use for Meta SPC 13

#### 2.1.15.5.1 Instructions for use

The surfaces to be disinfection must be wet enough in order to keep them wet during the preconised contact time for optimal disinfection.

The following precautionary sentence will be added on the product label : "Make sure to wet surfaces completely".

Products must be diluted in potable water before use.

#### 2.1.15.5.2 Risk mitigation measures

Gloves and goggles are needed during mixing and loading.

Wear protective coverall (to be specified by the authorisation holder within the product information).

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

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. 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

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

The packing and content must be eliminated as dangerous waste product under the whole responsibility of the possessor of this waste product. Do not throw wastes into sewers and watercourses. Dispose in a safe manner in accordance with local/national regulations.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.  
The shelf-life of the products is 2 years.

### 2.1.15.5.6 Other information

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## 2.1.15.6 Third information level: individual products in the meta SPC

Trade name(s)	Tornax L Lacto Cid				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	11.0
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	4.5
Methanesulfonic acid	Methanesulfonic acid	Acidifier	75-75-2	200-898-6	10.5

Please see the confidential annex for further details on composition.

## 2.1.16 Meta SPC 14

### 2.1.16.1 Meta SPC administrative information

#### 2.1.16.1.1 Meta SPC identifier

<b>Identifier</b>	Meta SPC 14
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#### 2.1.16.1.2 Suffix to the authorisation number

<b>Number</b>	no authorisation number due to non-authorisation
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#### 2.1.16.1.3 Product type

<b>Product type</b>	PT3 – Veterinay hygiene
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### 2.1.16.2 Meta SPC composition

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	32.0	32.0
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	10.5	10.5

Please see the confidential annex for further details on composition of products in MetaSPC 14.

Type(s) of formulation of the meta SPC

SL – Soluble concentrate
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### 2.1.6.3 Hazard and precautionary statements

<b>Classification: metaSPC 14</b>	
Hazard category	Skin Corr.1 Eye Dam. 1
Hazard statement	H314 H318
<b>Labelling</b>	
Signal words	Danger
Hazard statements	H314 - Causes severe skin burns and eye damage
Precautionary statements	P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves, protective clothing, Eyes/Face protection.

	<p>P301+P330+P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting.</p> <p>P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].</p> <p>P302+P352 - IF ON SKIN: Wash with plenty of water/....</p> <p>P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P310 - Immediately call a POISON CENTER/doctor.</p> <p>P363 - Wash contaminated clothing before reuse.</p> <p>P405 - Store locked up</p> <p>P501 - Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non hazardous waste.</p>
Note	The P321 is recommended only in exceptional cases where specific treatment is known and required. This is not the case for the product, which does not require any special measures in addition to the application.

#### 2.1.16.4 Authorised use(s)

2.1.16.4.1 Use 1 – Hoof bath disinfectant, for professional use (PT3)

**Authorization not granted.**

#### 2.1.17 Meta SPC 15

##### 2.1.16.1 Meta SPC administrative information

###### 2.1.16.1.1 Meta SPC identifier

<b>Identifier</b>	Meta SPC 15
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###### 2.1.16.1.2 Suffix to the authorisation number

<b>Number</b>	
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###### 2.1.16.1.3 Product type

<b>Product type</b>	PT1 – Human hygiene
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### 2.1.16.2 Meta SPC composition

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	3.6	3.6
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	2.0	2.0
Isopropanol	Propan-2-ol	Solvent / Processing aid	67-63-0	200-661-7	4.0	4.0
Butyldiglycol	2-(2-butoxyethoxy)ethanol	Solvent	112-34-5	203-961-6	10.0	10.0

Please see the confidential annex for further details on composition of products in MetaSPC 15.

Type(s) of formulation of the meta SPC

AL – Any other liquid
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### 2.1.16.3 Hazard and precautionary statements

<b>Classification: metaSPC 15</b>	
Hazard category	Eye Dam. 1
Hazard statement	H318
<b>Labelling</b>	
Signal words	Danger
Hazard statements	H318 - Causes serious eye damage
Precautionary statements	P280 - Wear Eyes/Face protection. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER or doctor.
Note	

### 2.1.17.4 Authorised use(s)

2.1.17.4.1 Use 1 – Hygienic handrub, for professional use (PT1)

<b>Product Type</b>	PT1 – Human hygiene
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<b>Where relevant, an exact description of the authorised use</b>	Not relevant
<b>Target organism (including development stage)</b>	Bacteria Yeasts
<b>Field of use</b>	Indoor – in Food/ feed industry; Public field; Kitchens Hygienic handrub, on visibly clean hands
<b>Application method(s)</b>	By rubbing the hands
<b>Application rate(s) and frequency</b>	Active against bacteria and yeasts : RTU (with 3.6 % Lactic acid) – 6 mL (i.e. 3 pushes for both hands together) – 1 min contact time
<b>Category of users</b>	Professional use
<b>Pack sizes and packaging material</b>	50 mL, 75 mL, 100 mL, 150 mL, 500 mL, 1L, 5L, 10L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000L, 1100 L HDPE (High Density Polyethylene)

#### 2.1.17.4.2 Use-specific instructions for use

See general directions for use for Meta SPC 15

#### 2.1.17.4.3 Use-specific risk mitigation measures

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

See general directions for use for Meta SPC 15

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

See general directions for use for Meta SPC 15

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

See general directions for use for Meta SPC 15

#### 2.1.17.4.7 Use 2 – Hygienic handrub, for non-professional use (PT1)

**Authorization not granted.**



## 2.1.17.5 General directions for use for Meta SPC 15

### 2.1.17.5.1 Instructions for use

Apply 6 ml of the product undiluted. Respect a contact time of 1 minute. Rinse thoroughly after disinfection.  
For professional use only

### 2.1.17.5.2 Risk mitigation measures

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

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.  
IF INHALED: If symptoms occur 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

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

The packing and content must be eliminated as dangerous waste product under the whole responsibility of the possessor of this waste product. Do not throw wastes into sewers and watercourses. Dispose in a safe manner in accordance with local/national regulations.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.

The shelf-life of the products is 2 years.

### 2.1.17.5.6 Other information

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**2.1.17.6 Third information level: individual products in the meta SPC**

<b>Trade name(s)</b>	<b>Kenosan Hand Rub</b>				
<b>Common name</b>	<b>IUPAC name</b>	<b>Function</b>	<b>CAS number</b>	<b>EC number</b>	<b>Content (%)</b>
Lactic acid	L-(+)-lactic acid	Active substance	79-33-4	201-196-2	3.6
Sodium Lauryl sulphate	Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	Anionic surfactant	85586-07-8	287-809-4	2.0
Isopropanol	Propan-2-ol	Solvent / Processing aid	67-63-0	200-661-7	4.0
Butyldiglycol	2-(2-butoxyethoxy)ethanol	Solvent	112-34-5	203-961-6	10.0

*Please see the confidential annex for further details on composition*

### 2.1.18 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	50 mL	HDPE (High Density polyethylene)	Cap in HDPE (High Density polyethylene)	Professional and non-professional	Yes
Bottle	75 mL	HDPE	Cap in HDPE	Professional and non-professional	Yes
Bottle	100 mL	HDPE	Cap in HDPE	Professional and non-professional	Yes
Bottle	150 mL	HDPE	Cap in HDPE	Professional and non-professional	Yes
Bottle	300 mL	HDPE	Cap in HDPE	Professional	Yes
Bottle	500 mL	HDPE	Cap in HDPE	Professional and non-professional	Yes
Bottle	1 L	HDPE	Cap in HDPE	Professional and non-professional	Yes
Drum	5 L	HDPE	Cap in HDPE	Professional and non-professional	Yes
Drum	10 L	HDPE	Cap in HDPE	Professional and non-professional	Yes
Drum	20 L	HDPE	Cap in HDPE	Professional	Yes
Drum	25 L	HDPE	Cap in HDPE	Professional	Yes
Drum	30 L	HDPE	Cap in HDPE	Professional	Yes
Drum	60 L	HDPE	Cap in HDPE	Professional	Yes
Drum	200 L	HDPE	Cap in HDPE	Professional	Yes
Drum	220 L	HDPE	Cap in HDPE	Professional	Yes
Container	600 L	HDPE	Cap in HDPE	Professional	Yes
Container	1000 L	HDPE	Cap in HDPE	Professional	Yes
Container	1100 L	HDPE	Cap in HDPE	Professional	Yes
Bottle	1 kg	HDPE	Cap in HDPE	Professional and non-professional	Yes
Drum	5 kg	HDPE	Cap in HDPE	Professional and non-professional	Yes

Drum	10 kg	HDPE	Cap in HDPE	Professional and non-professional	Yes
Drum	20 kg	HDPE	Cap in HDPE	Professional	Yes
Drum	25 kg	HDPE	Cap in HDPE	Professional	Yes
Drum	30 kg	HDPE	Cap in HDPE	Professional	Yes
Drum	60 kg	HDPE	Cap in HDPE	Professional	Yes
Drum	200 kg	HDPE	Cap in HDPE	Professional	Yes
Drum	220 kg	HDPE	Cap in HDPE	Professional	Yes
Container	600 kg	HDPE	Cap in HDPE	Professional	Yes
Container	1000 kg	HDPE	Cap in HDPE	Professional	Yes
Container	1100 kg	HDPE	Cap in HDPE	Professional	Yes
Box with wipes type 2 - 10L	500 wipes	HDPE	Lid in HDPE	Professional	Yes
Box with wipes type 3 - 10L	500 wipes	HDPE	Lid in HDPE	Professional	Yes
Box with wipes type 4 - 2L	105 wipes	HDPE	Lid in HDPE	Professional	Yes
Box with wipes type 4 - 5L	280 wipes	HDPE	Lid in HDPE	Professional	Yes
Box with wipes type 5 - 1.5L	200 wipes	HDPE	Lid in HDPE	Professional	Yes
Toilet duck	500 mL	HDPE	Cap in HDPE	Professional and non-professional	Yes
Toilet duck	700 mL	HDPE	Cap in HDPE	Professional and non-professional	Yes
Toilet duck	750 mL	HDPE	Cap in HDPE	Professional and non-professional	Yes
Toilet duck	1 L	HDPE	Cap in HDPE	Professional and non-professional	Yes
Toilet duck	1.5 L	HDPE	Cap in HDPE	Professional and non-professional	Yes
Toilet duck	2 L	HDPE	Cap in HDPE	Professional and non-professional	Yes

## **2.1.19 Documentation**

### 2.1.19.4 Data submitted in relation to product application

For a list of studies made available for the evaluation of this BPR, please refer to Annex 3.1.

### 2.1.19.5 Access to documentation

A letter of access to the European file of L-(+)-Lactic acid has been attached in section 13 of the Iuclid file. Therefore we have access to the complete dossier for the approval of the biocidals active substance L-(+)-Lactic acid.

## 2.2 Assessment of the biocidal product (family)

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

Table 1. Use # 1.1 – Hygienic handwash for professional use (PT1)

<b>Product Type</b>	PT1
<b>Where relevant, an exact description of the authorised use</b>	Hygienic handwash
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Food and feed industry Public field Kitchens Indoor
<b>Application method(s)</b>	By rubbing the hands
<b>Application rate(s) and frequency</b>	Application rate: 10 mL of product Frequency: daily use
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	50 mL, 75 mL, 100 mL, 150 mL, 500 mL, 1L, 5L, 10L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000L, 1100 L HDPE (High Density Polyethylene)

Table 2. Use # 1.2 – Hygienic handwash for non-professional use (PT1)

<b>Product Type</b>	PT1
<b>Where relevant, an exact description of the authorised use</b>	Hygienic handwash
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Households Public field Kitchens Indoor
<b>Application method(s)</b>	By rubbing the hands
<b>Application rate(s) and frequency</b>	Application rate: 10 mL of product Frequency: daily use
<b>Category(ies) of users</b>	non-professional use
<b>Pack sizes and packaging material</b>	50 mL, 75 mL, 100 mL, 150 mL, 500 mL, 1L, 5L, 10L HDPE (High Density Polyethylene)

Table 3. Use # 2.1 – Ready to use Green remover for professional use

<b>Product Type</b>	PT2
<b>Where relevant, an exact description of the authorised use</b>	Ready to use Green remover on all kind of surfaces
<b>Target organism (including development stage)</b>	Bacteria, yeast and algae
<b>Field of use</b>	Food and feed industry Public field Outdoor Indoor
<b>Application method(s)</b>	Green remover by brushing, by spraying (low pressure) or pouring on all kind of surfaces.
<b>Application rate(s) and frequency</b>	Application rate is 1L product per 10m <sup>2</sup> . Frequency: daily use
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

Table 4. Use # 2.2 – Ready to use Green remover for non-professional use

<b>Product Type</b>	PT2
<b>Where relevant, an exact description of the authorised use</b>	Ready to use Green remover on all kind of surfaces
<b>Target organism (including development stage)</b>	Bacteria, yeast and algae
<b>Field of use</b>	Food and feed industry Public field Outdoor Indoor
<b>Application method(s)</b>	Green remover by brushing, by spraying (low pressure) or pouring on all kind of surfaces.
<b>Application rate(s) and frequency</b>	Application rate is 1L product per 10m <sup>2</sup> . Frequency: monthly use
<b>Category(ies) of users</b>	non-professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L 1 kg, 5 kg, 10 kg HDPE (High Density Polyethylene)

Table 5. Use # 3.1 – Concentrated Green remover

<b>Product Type</b>	PT2
<b>Where relevant, an exact description of the authorised use</b>	Green remover on all kind of surfaces
<b>Target organism (including development stage)</b>	Bacteria, yeast and algae
<b>Field of use</b>	Food and feed industry Public field Outdoor Indoor
<b>Application method(s)</b>	Green remover by brushing, by spraying (low pressure) or pouring on all kind of surfaces.
<b>Application rate(s) and frequency</b>	Mixing and loading: The product should be diluted to 2.5% (250 ml of product, add water up to 10L).  Application rate is 1L diluted product per 10m <sup>2</sup> . Frequency: daily use
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

Table 6. Use # 3.2 – Processing machines in food industry

<b>Product Type</b>	PT4
<b>Where relevant, an exact description of the authorised use</b>	Disinfection of processing machines, including carcass saws and cutting machines.
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Food industry Indoor
<b>Application method(s)</b>	Spraying or soaking
<b>Application rate(s) and frequency</b>	Application rate: 100 ml/m <sup>2</sup> Frequency: Daily, during each intermediate disinfection step
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)



Table 7. Use # 4.1 – Hard surface disinfection for sanitary hygiene, other than in healthcare, for professional use (PT2)

<b>Product Type</b>	PT2
<b>Where relevant, an exact description of the authorised use</b>	Hard surface disinfection for sanitary hygiene, other than in healthcare
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Public field Indoor
<b>Application method(s)</b>	By wiping with a towel By spraying By spraying and wiping afterwards
<b>Application rate(s) and frequency</b>	Application rate: 250 ml/m <sup>2</sup> Frequency: daily use
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

Table 8. Use # 4.2 – Hard surface disinfection for sanitary hygiene, other than in healthcare, for non-professional use (PT2)

<b>Product Type</b>	PT2
<b>Where relevant, an exact description of the authorised use</b>	Hard surface disinfection for sanitary hygiene, other than in healthcare
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Public field Households Indoor
<b>Application method(s)</b>	By wiping with a towel By spraying By spraying and wiping afterwards
<b>Application rate(s) and frequency</b>	Application rate: 250 ml/m <sup>2</sup> Frequency: daily use
<b>Category(ies) of users</b>	Non-professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L 1 kg, 5 kg, 10 kg HDPE (High Density Polyethylene)

Table 9. Use # 4.3 – Hard surface disinfection for hygiene in kitchens, for professional use (PT4)

<b>Product Type</b>	PT4
<b>Where relevant, an exact description of the authorised use</b>	Hard surface disinfection for hygiene in kitchens
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Food and feed industry Indoor
<b>Application method(s)</b>	By wiping with a towel By spraying By spraying and wiping afterwards
<b>Application rate(s) and frequency</b>	Application rate: 100 ml/m <sup>2</sup> Frequency: daily use
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

Table 10. Use # 4.4 – Hard surface disinfection for hygiene in kitchens, for non-professional use (PT4)

<b>Product Type</b>	PT4
<b>Where relevant, an exact description of the authorised use</b>	Hard surface disinfection for hygiene in kitchens
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Households Indoor
<b>Application method(s)</b>	By wiping with a towel By spraying By spraying and wiping afterwards
<b>Application rate(s) and frequency</b>	Application rate: 100 ml/m <sup>2</sup> Frequency: daily use
<b>Category(ies) of users</b>	Non-professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L 1 kg, 5 kg, 10 kg HDPE (High Density Polyethylene)

Table 11. Use # 4.5 – Disinfection of toilet bowls, for professional use (PT2)

<b>Product Type</b>	PT2
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<b>Where relevant, an exact description of the authorised use</b>	Disinfection of toilet bowls
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Public field Indoor
<b>Application method(s)</b>	By pouring and toilet brush
<b>Application rate(s) and frequency</b>	Application rate: 250 ml/m <sup>2</sup> Frequency: daily use
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	500 mL, 700 mL, 750 mL, 1L, 1.5 L, 2 L HDPE (High Density Polyethylene) Toilet Duck

Table 12. Use # 4.6 – Disinfection of toilet bowls, for non-professional use (PT2)

<b>Product Type</b>	PT2
<b>Where relevant, an exact description of the authorised use</b>	Disinfection of toilet bowls
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Households Public field Indoor
<b>Application method(s)</b>	By pouring and toilet brush
<b>Application rate(s) and frequency</b>	Application rate: 250 ml/m <sup>2</sup> Frequency: daily use
<b>Category(ies) of users</b>	Non-professional use
<b>Pack sizes and packaging material</b>	500 mL, 700 mL, 750 mL, 1L, 1.5 L, 2 L HDPE (High Density Polyethylene) Toilet Duck

Table 13. Use # 5.1 –

<b>Product Type</b>	PT3
<b>Where relevant, an exact description of the authorised use</b>	Concentrated pre-dip
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Veterinary field

	Indoor
<b>Application method(s)</b>	By dipping By spraying with spray flacon or spray installation By wiping with a towel
<b>Application rate(s) and frequency</b>	Application rate: 5 mL per cow per application for use by dipping 7,5 mL per cow per application for use by spray flacon 15 mL per cow per application for use by spray installation For use by wiping with a towel: prepare 10 L working solution for 25 towels. Use one towel per cow.  Apply the product before each milking, two or three times per day.
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

Table 14. Use # 5.2 – Skin wash and skin disinfection

<b>Product Type</b>	PT3
<b>Where relevant, an exact description of the authorised use</b>	Concentrated skin wash and skin disinfection for cows and sows: <ul style="list-style-type: none"> <li>- Dairy and beef cattle on the udder before calving. Once, one day before calving and once, one day after calving</li> <li>- Sows on the udder before farrowing. Once, one day before farrowing and once every day during 4 days after farrowing</li> </ul>
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Veterinary field Indoor
<b>Application method(s)</b>	By spraying with spray flacon or spray installation
<b>Application rate(s) and frequency</b>	-dairy and beef cattle on the udder before calving: 1 spray on each teat (approx 5 mL per application per animal). Disinfection takes place once per day, seven day before calving. The animals should be kept standing on a clean floor for at least 5 minutes. -sows on the udder before farrowing: Assume 20 mL per animal, once per day, seven days before farrowing. The animals should be kept standing on a clean floor for at least 5 minutes to let the product dry.
<b>Category(ies) of users</b>	Professional use

<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)
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Table 15. Use # 6.1 – Pre-dip

<b>Product Type</b>	PT3
<b>Where relevant, an exact description of the authorised use</b>	Ready to use Pre-dip
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Veterinary field Indoor
<b>Application method(s)</b>	By dipping By spraying with spray flacon or spray installation
<b>Application rate(s) and frequency</b>	Application rate: 5 mL per cow per application for use by dipping 7,5 mL per cow per application for use by spray flacon 15 mL per cow per application for use by spray installation  Apply the product before each milking, two or three times per day.
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

Table 16. Use # 7.1 – Hard surface disinfection in Food and Feed industry, for professional use (PT4)

<b>Product Type</b>	PT4
<b>Where relevant, an exact description of the authorised use</b>	Used for disinfection of surfaces and objects in kitchens or other areas where food and feed are prepared.
<b>Target organism (including development stage)</b>	Bacteria, yeast and virus
<b>Field of use</b>	Food and Feed industry Indoor
<b>Application method(s)</b>	Wipes
<b>Application rate(s) and frequency</b>	Application rate: 100 ml/m <sup>2</sup> Frequency: daily use

<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	Box with 80 wipes, 100 wipes, 150 wipes, 200 wipes, 250 wipes, 500 wipes, 1000 wipes

Table 17. Use # 7.2 – Hard surface disinfection in food and feed area, for non-professional use (PT4)

<b>Product Type</b>	PT4
<b>Where relevant, an exact description of the authorised use</b>	Used for disinfection surfaces and objects in kitchens or other areas where food is prepared, such as countertops, cutting boards, knives, etc.
<b>Target organism (including development stage)</b>	Bacteria, yeast and virus
<b>Field of use</b>	Households Indoor
<b>Application method(s)</b>	Wipes
<b>Application rate(s) and frequency</b>	Application rate: 100 ml/m <sup>2</sup> Frequency: daily use
<b>Category(ies) of users</b>	Non-professional use
<b>Pack sizes and packaging material</b>	Box with 80 wipes, 100 wipes, 150 wipes, 200 wipes, 250 wipes, 500 wipes, 1000 wipes

Table 18. Use # 7.3 – Hard surface disinfection, use in healthcare, for professional use (PT2)

<b>Product Type</b>	PT2
<b>Where relevant, an exact description of the authorised use</b>	Used for disinfection of walls, floors and other surfaces in indoor spaces, including bathrooms and toilets.
<b>Target organism (including development stage)</b>	Bacteria, yeast and virus
<b>Field of use</b>	Public field Indoor
<b>Application method(s)</b>	Wipes
<b>Application rate(s) and frequency</b>	Application rate: 250 ml/m <sup>2</sup> Frequency: daily use
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	Box with 80 wipes, 100 wipes, 150 wipes, 200 wipes, 250 wipes, 500 wipes, 1000 wipes

Table 19. Use # 7.4 – Hard surface disinfection, use in healthcare, for non-professional use (PT2)

<b>Product Type</b>	PT2
<b>Where relevant, an exact description of the authorised use</b>	Used for disinfection of walls, floors and other surfaces in indoor spaces, including bathrooms and toilets.

<b>Target organism (including development stage)</b>	Bacteria, yeast and virus
<b>Field of use</b>	Public field Indoor
<b>Application method(s)</b>	Wipes
<b>Application rate(s) and frequency</b>	Application rate: 250 ml/m <sup>2</sup> Frequency: daily use
<b>Category(ies) of users</b>	Non-professional use
<b>Pack sizes and packaging material</b>	Box with 80 wipes, 100 wipes, 150 wipes, 200 wipes, 250 wipes, 500 wipes, 1000 wipes

Table 20. Use # 7.5 – Hard surface disinfection, use other than in healthcare, for professional use (PT2)

<b>Product Type</b>	PT2
<b>Where relevant, an exact description of the authorised use</b>	Used for disinfection of walls, floors and other surfaces in indoor spaces, including bathrooms and toilets.
<b>Target organism (including development stage)</b>	Bacteria, yeast and virus
<b>Field of use</b>	Public field Indoor
<b>Application method(s)</b>	Wipes
<b>Application rate(s) and frequency</b>	Application rate: 250 ml/m <sup>2</sup> Frequency: daily use
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	Box with 80 wipes, 100 wipes, 150 wipes, 200 wipes, 250 wipes, 500 wipes, 1000 wipes

Table 21. Use # 7.6 – Hard surface disinfection, use other than in healthcare, for non-professional use (PT2)

<b>Product Type</b>	PT2
<b>Where relevant, an exact description of the authorised use</b>	Used for disinfection of walls, floors and other surfaces in indoor spaces, including bathrooms and toilets.
<b>Target organism (including development stage)</b>	Bacteria, yeast and virus
<b>Field of use</b>	Public field Indoor
<b>Application method(s)</b>	Wipes
<b>Application rate(s) and frequency</b>	Application rate: 250 ml/m <sup>2</sup> Frequency: daily use
<b>Category(ies) of users</b>	Non-professional use

<b>Pack sizes and packaging material</b>	Box with 80 wipes, 100 wipes, 150 wipes, 200 wipes, 250 wipes, 500 wipes, 1000 wipes
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Table 22. Use # 8.1 – Post-dip

<b>Product Type</b>	PT3
<b>Where relevant, an exact description of the authorised use</b>	Ready to use post-dip by dipping
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Veterinary field Indoor
<b>Application method(s)</b>	By dipping
<b>Application rate(s) and frequency</b>	Apply the product immediately after each milking, two or three times per day. Assume 5 mL per cow per treatment.
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

Table 23. Use # 9.1 – Post-dip

<b>Product Type</b>	PT3
<b>Where relevant, an exact description of the authorised use</b>	Ready to use post-dip by spraying and dipping
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Veterinary field Indoor
<b>Application method(s)</b>	By dipping By spraying with spray flacon or spray installation (including robot)
<b>Application rate(s) and frequency</b>	Apply the product immediately after each milking, two or three times per day. Dipping: 5 mL per cow per application. Spray flacon: 7,5 mL per cow per application. Spraying installation and robot: 15 mL per cow per application.
<b>Category(ies) of users</b>	Professional use



<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)
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Table 24. Use # 10.1 – Post-dip

<b>Product Type</b>	PT3
<b>Where relevant, an exact description of the authorised use</b>	Ready to use post-dip by spraying and dipping
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Veterinary field Indoor
<b>Application method(s)</b>	By dipping By spraying with spray flacon or spray installation (including robot)
<b>Application rate(s) and frequency</b>	Apply the product immediately after each milking, two or three times per day. Dipping: 5 mL per cow per application. Spray flacon: 7,5 mL per cow per application. Spraying installation and robot: 15 mL per cow per application.
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

Table 25. Use # 11.1 – Hard surface disinfection in Food and feed industry

<b>Product Type</b>	PT4
<b>Where relevant, an exact description of the authorised use</b>	Hard surface disinfection in Food and feed industry. Disinfection of knives and other small material for intermediate use in Food industry.
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Food and Feed industry Public field Indoor
<b>Application method(s)</b>	By spraying By immersion

<b>Application rate(s) and frequency</b>	Application rate: 100 ml/m <sup>2</sup> Frequency: daily use
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

Table 26. Use # 11.2 – Equipment disinfection by soaking in Food and feed industry

<b>Product Type</b>	PT4
<b>Where relevant, an exact description of the authorised use</b>	Disinfection of knives and other small material for intermediate use
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Food and Feed industry Indoor
<b>Application method(s)</b>	By spraying or immersion
<b>Application rate(s) and frequency</b>	Application rate: 100 ml/m <sup>2</sup> Frequency: daily use
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

Table 27. Use # 11.3 – Hard surfaces disinfection for veterinary hygiene

<b>Product Type</b>	PT3
<b>Where relevant, an exact description of the authorised use</b>	/
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Veterinary field Indoor and outdoor
<b>Application method(s)</b>	By spraying or immersion  By spraying, apply the product with a back pulverisator or an automatic sprayer in order to cover the surfaces. By dipping, equipment is dipped/immersed into the bath and is removed after 30 minutes.

<b>Application rate(s) and frequency</b>	0.25 l /m <sup>2</sup> by spraying By dipping or immersion: equipment is immersed into a bath during 30 minutes Frequency: between animal growth cycles. Equipment is disinfected when necessary (max. 13 times per year).
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

Table 28. Use # 12.1 – Inner surface disinfection by CIP with circulation

<b>Product Type</b>	PT4
<b>Where relevant, an exact description of the authorised use</b>	Inner surface disinfection by CIP with circulation
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Food and feed industry Indoor
<b>Application method(s)</b>	CIP
<b>Application rate(s) and frequency</b>	Application rate: 100 ml/m <sup>2</sup> Frequency: daily use
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

Table 29. Use # 12.2 – Inner surface disinfection by CIP without circulation

<b>Product Type</b>	PT4
<b>Where relevant, an exact description of the authorised use</b>	Inner surface disinfection by CIP without circulation
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Food and feed industry Indoor
<b>Application method(s)</b>	CIP
<b>Application rate(s) and frequency</b>	Application rate: 100 ml/m <sup>2</sup> Frequency: daily use

<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

Table 30. Use # 12.3 – Crate wash

<b>Product Type</b>	PT4
<b>Where relevant, an exact description of the authorised use</b>	Inner surface disinfection by CIP without circulation
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Food and feed industry Indoor
<b>Application method(s)</b>	Crate wash
<b>Application rate(s) and frequency</b>	Application rate: 100 ml/m <sup>2</sup> Frequency: daily use
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

Table 31. Use # 13.1 – Hard surface disinfection (PT4)

<b>Product Type</b>	PT4
<b>Where relevant, an exact description of the authorised use</b>	Hard surface disinfection
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Food and feed industry Indoor
<b>Application method(s)</b>	By foaming
<b>Application rate(s) and frequency</b>	Application rate: 100 ml/m <sup>2</sup> Frequency: daily use
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L

	1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)
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Table 32. Use # 14.1 – Coronary band disinfection

<b>Product Type</b>	PT3
<b>Where relevant, an exact description of the authorised use</b>	-Disinfection on coronary band and interdigital skin of hooves for cattle, sheep, goats and pigs when a new animal is joining the herd -Disinfection of coronary band and frog for horses when a new animal is joining the herd -Disinfection of coronary band for sows when changing from gestation pen to maternity pen on the entire body once before farrowing -Cattle washing before exhibitions (entire body; maximum 3-5 cows to treat per herd; 1-2 times per year)
<b>Target organism (including development stage)</b>	Bacteria and Yeast
<b>Field of use</b>	Veterinary field Indoor and outdoor
<b>Application method(s)</b>	By spraying or brushing
<b>Application rate(s) and frequency</b>	To be defined
<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	300 ml, 500 ml, 1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000 L, 1100 L 1 kg, 5 kg, 10 kg, 20 kg, 25 kg, 30 kg, 60 kg, 200 kg, 220 kg, 600 kg, 1000 kg, 1100 kg HDPE (High Density Polyethylene)

Table 33. Use # 15.1 – Hygienic handrub, for professional use (PT1)

<b>Product Type</b>	PT1
<b>Where relevant, an exact description of the authorised use</b>	Hygienic handrub
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Food and feed industry Public field Kitchens Indoor
<b>Application method(s)</b>	By rubbing the hands
<b>Application rate(s) and frequency</b>	Application rate: 6 mL of product Frequency: daily use

<b>Category(ies) of users</b>	Professional use
<b>Pack sizes and packaging material</b>	50 mL, 75 mL, 100 mL, 150 mL, 500 mL, 1L, 5L, 10L, 20 L, 25 L, 30 L, 60 L, 200 L, 220 L, 600 L, 1000L, 1100 L HDPE (High Density Polyethylene)

Table 34. Use # 15.2 – Hygienic handrub, for non-professional use (PT1)

<b>Product Type</b>	PT1
<b>Where relevant, an exact description of the authorised use</b>	Hygienic handrub
<b>Target organism (including development stage)</b>	Bacteria and yeast
<b>Field of use</b>	Households Public field Kitchens Indoor
<b>Application method(s)</b>	By rubbing the hands
<b>Application rate(s) and frequency</b>	Application rate: 6 mL of product Frequency: daily use
<b>Category(ies) of users</b>	non-professional use
<b>Pack sizes and packaging material</b>	50 mL, 75 mL, 100 mL, 150 mL, 500 mL, 1L, 5L, 10L HDPE (High Density Polyethylene)

## 2.2.2 Physical, chemical and technical properties

The BPF is composed by 15 meta-SPCs. The tables below are filled in for each meta-SPC.

**META-SPC1**: representative product is Kenosan Hand Scrub (L1 formulation). Only fixed concentration of active substance content and excipients is intended in the mSPC1.

**META-SPC2**: representative products are RTU algaecide (L2 formulation) with minimum concentrated excipients and L4 formulation with maximum concentrated excipients. The active substance content remains the same (no variation possible in the meta-SPC)

**META-SPC3**: representative product is Concentrated algaecide (L5 formulation). Only fixed concentration of active substance content and excipients is intended in the mSPC3.

**META-SPC4**: representative product is Sanifresh (L6 formulation). Only fixed concentration of active substance content and excipients is intended in the mSPC4.

**META-SPC5**: representative products are L7 formulation with minimum concentrated excipients and Kenopure (L8 formulation) with maximum concentrated excipients. The active substance content remains the same (no variation possible in the meta-SPC)

**META-SPC6**: representative product is Kenopure R or Kenopure RTU (same formulation: L36 formulation). Only fixed concentration of active substance content and excipients is intended in the mSPC6.

**META-SPC7**: representative product is Kenopure wipes (wipes impregnated with formulations from meta-SPC 2).

**META-SPC8**: representative products are Kenolac, Kenolac Red, Kenodip 200 and Stalosan Lac Dip (same formulations L13 formulation with minimum concentrated excipients and minimum active substance) and Kenolac Forte W (L14 formulation with maximum excipients and active substance). The applicant has also submitted tests with formulations L15, L16, L17 and L18, with the combination of minimum and maximum concentrations of a.s. and excipients.

**META-SPC9**: representative products are Kenolac SD, HCP Spray, Lacto Spray, Zitzentop, Lactosilk, Milchsäure Spray, Buhning, Lacto SP (same formulations L19 with minimum active substance) and Kenolac Forte SD (L20 formulation with maximum active substance). The applicant has also submitted tests with formulations L21, L22, L23 and L24, with the combination of minimum and maximum concentrations of a.s. and excipients.

**META-SPC10**: representative product is Kenocool (L25 formulation). Only fixed concentration of active substance content and excipients is intended in the mSPC10.

**META-SPC11**: representative product is Kenosan Lactic (L26 formulation). Only fixed concentration of active substance content and excipients is intended in the mSPC11.

**META-SPC12**: representative products are Phocid L (formulation L29) and Phocid LS (formulation L35). The composition of the different formulations is the same, except the identity of acidifier.

**META-SPC13:** representative product is Tornax L (L31 formulation with minimum excipients). The applicant has also submitted tests on the formulation L32 with maximum excipients (the active substance content is fixed).

**META-SPC14:** representative product is Pediline A (L34 formulation). Only fixed concentration of active substance content and excipients is intended in the mSPC14.

**META-SPC15:** representative product is Kenosan Hand Rub (L33 formulation). Only fixed concentration of active substance content and excipients is intended in the mSPC15.

The exact composition of products and tested formulations can be found in conf. annex.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state, colour and odour at 20 °C and 101.3 kPa	Organoleptic method	L1 product - mSPC1	Green – yellow viscous liquid with grapefruit flowery odour	Ref. 1 , Ref. 49
		L2 product - mSPC2	Clear colourless liquid with no odour	Ref. 5 , Ref. 49
		L4 product - mSPC2	Clear colourless liquid with no odour	Ref. 6 , Ref. 49
		L5 product - mSPC3	Clear colourless liquid with no odour	Ref. 7 , Ref. 49
		L6 product - mSPC4	Pink – red - coloured liquid with eucalyptus odour	Ref. 10 , Ref. 49
		L7 product - mSPC5	Green – yellow -blue - coloured liquid with eucalyptus odour	Ref. 11 , Ref. 49
		L8 product - mSPC5	Green – yellow -blue - coloured liquid with eucalyptus odour	Ref. 12 , Ref. 49



Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		L36 product – mSPC6	Green – yellow -blue - coloured liquid with eucalyptus odour	Ref. 13 , Ref. 49
		L2 impregnated wipes – mSPC7	Blue, white, or blue and white wipes. Composition: 70%viscose - 30%polyester; 50%viscose – 50%polyester; 100%polypropylene; 70%viscose – 30%polyester ; 50%viscose 50%polyester  Impregnation liquid (clear liquid with no odour) mass : 265 to 300% of the mass of the wipes	Ref. 14 , Ref. 49
		L13 product – mSPC8	Clear colourless – yellow – red – green – white – blue – orange - Viscous liquid with no odour	Ref. 15 , Ref. 49
		L14 product – mSPC8	Clear colourless – yellow – red – green – white – blue – orange - Viscous liquid with no odour	Ref. 16 , Ref. 49
		L15 product – mSPC8	Clear colourless viscous liquid with no odour	Ref. 17 , Ref. 49

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		L16 product – mSPC8	Clear colourless – yellow – red – green – white – blue – orange - Viscous liquid with no odour	Ref. 18 , Ref. 49
		L17 product – mSPC8	Clear colourless – yellow – red – green – white – blue – orange - Viscous liquid with no odour	Ref. 19 , Ref. 49
		L18 product – mSPC8	Clear colourless viscous liquid with no odour	Ref. 20 , Ref. 49
		L19 product – mSPC9	Clear colourless – yellow – red – green – white – blue – orange – liquid with no odour	Ref. 21 , Ref. 49
		L20 product – mSPC9	Clear colourless – yellow – red – green – white – blue – orange - liquid with no odour	Ref. 22 , Ref. 49
		L21 product – mSPC9	Clear colourless liquid with no odour	Ref. 23 , Ref. 49
		L22 product – mSPC9	Clear colourless – yellow – red – green – white – blue – orange - liquid with no odour	Ref. 24 , Ref. 49
		L23 product – mSPC9	Clear colourless – yellow – red – green – white – blue – orange	Ref. 25 , Ref. 49

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		L24 product – mSPC9	- liquid with no odour Clear colourless liquid with no odour	Ref. 26 , Ref. 49
		L25 product – mSPC10	Orange - coloured liquid with mint odour	Ref. 27 , Ref. 49
		L26 product – mSPC11	Clear colourless liquid with no odour	Ref. 28 , Ref. 49
		L29 product – mSPC12	Clear colourless liquid with no odour	Ref. 30 , Ref. 49
		L35 product – mSPC12	Clear colourless liquid with no odour	Ref. 31 , Ref. 49
		L31 product – mSPC13	Clear colourless liquid with no odour	Ref. 32 , Ref. 49
		L32 product – mSPC13	Clear colourless liquid with no odour	Ref. 33 , Ref. 49
		L34 product – mSPC14	Clear colourless liquid with no odour	Ref. 34 , Ref. 49
		L33 product – mSPC15	Clear colourless liquid with citrus-ginger odour	Ref. 35 , Ref. 49
Acidity / alkalinity	OECD 122 @ 20 – 25°C	L1 product - mSPC1	pH = 2.49 % m/m H <sub>2</sub> SO <sub>4</sub> = 2.48	Ref. 2

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		L2 product – mSPC2	pH = 2.35 % m/m H <sub>2</sub> SO <sub>4</sub> = 1.97	
		L4 product – mSPC2	pH = 2.43 % m/m H <sub>2</sub> SO <sub>4</sub> = 1.78	
		L5 product – mSPC3	pH = 0.84 % m/m H <sub>2</sub> SO <sub>4</sub> = 34.53	
		L6 product – mSPC4	pH = 1.62 % m/m H <sub>2</sub> SO <sub>4</sub> = 8.96	
		L7 product – mSPC5	pH = 3.05 % m/m H <sub>2</sub> SO <sub>4</sub> = 4.17	
		L8 product – mSPC5	pH = 2.50 % m/m H <sub>2</sub> SO <sub>4</sub> = 4.59	
		L36 product – metaSPC6	pH = 2.25 % m/m H <sub>2</sub> SO <sub>4</sub> = 3.78	
		L2 impregnated wipes – mSPC7	See L2 formulation	
		L13 product – mSPC8	pH = 3.98 % m/m H <sub>2</sub> SO <sub>4</sub> = 2.91	
		L14 product – mSPC8	pH = 3.78 % m/m H <sub>2</sub> SO <sub>4</sub> = 4.63	
		L15 product – mSPC8	pH = 3.99 % m/m H <sub>2</sub> SO <sub>4</sub> = 2.57	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		L16 product – mSPC8	pH = 3.71 % m/m H <sub>2</sub> SO <sub>4</sub> =4.64	
		L17 product – mSPC8	pH = 4.02	
		L18 product – mSPC8	pH = 3.76 % m/m H <sub>2</sub> SO <sub>4</sub> =4.59	
		L19 product – mSPC9	pH = 3.73 % m/m H <sub>2</sub> SO <sub>4</sub> =1.65	
		L20 product – mSPC9	pH = 3.55 % m/m H <sub>2</sub> SO <sub>4</sub> =2.69	
		L21 product – mSPC9	pH = 3.97 % m/m H <sub>2</sub> SO <sub>4</sub> =0.94	
		L22 product – mSPC9	pH = 3.74 % m/m H <sub>2</sub> SO <sub>4</sub> =2.62	
		L23 product – mSPC9	pH = 4.45	
		L24 product – mSPC9	pH = 3.37 % m/m H <sub>2</sub> SO <sub>4</sub> =3.70	
		L25 product – mSPC10	pH = 3.89 % m/m H <sub>2</sub> SO <sub>4</sub> =1.86	
		L26 product – mSPC11	pH = 1.95 % m/m H <sub>2</sub> SO <sub>4</sub> =11.71	
		L29 product – mSPC12	pH = 0.30 % m/m H <sub>2</sub> SO <sub>4</sub> =24.41	
			pH = 0.06	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		L35 product – mSPC12	% m/m H <sub>2</sub> SO <sub>4</sub> =25.06	
		L31 product – mSPC13	pH = 0.41 % m/m H <sub>2</sub> SO <sub>4</sub> =12.04	
		L32 product – mSPC13	pH = -0.14 % m/m H <sub>2</sub> SO <sub>4</sub> =16.67	
		L34 product – mSPC14	pH = 1.64 % m/m H <sub>2</sub> SO <sub>4</sub> =15.78	
		L33 product – mSPC15	pH = 1.78 % m/m H <sub>2</sub> SO <sub>4</sub> =2.81	
Relative density / bulk density	OECD 109: Density of liquids and solids	L1 product - mSPC1	1.0152 kg/l	Ref. 50
		L2 product – mSPC2	1.0063 kg/l	
		L4 product – mSPC2	1.0089 kg/l	
		L5 product - mSPC3	1.1772 kg/l	
		L6 product – mSPC4	1.0435 kg/l	
		L7 product – mSPC5	1.0656 kg/l	
		L8 product – mSPC5	1.0612 kg/l	
		L36 product – metaSPC6	1.0279 kg/l	
		L2 impregnated wipes – mSPC7	Liquid of impregnation density: see L2 formulation	
		L15 product – mSPC8	1.0079 kg/l	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		L16 product – mSPC8	1.0550 kg/l	
		L21 product – mSPC9	1.0276 kg/l	
		L22 product – mSPC9	1.0584 kg/l	
		L25 product – mSPC10	1.0044 kg/l	
		L26 product – mSPC11	1.0698 kg/l	
		L29 product – mSPC12	1.1410 kg/l	
		L31 product – mSPC13	1.0673 kg/l	
		L32 product – mSPC13	1.1277 kg/l	
		L34 product – mSPC14	1.0943 kg/l	
		L33 product – mSPC15	1.0196 kg/l	
Storage stability test – <b>accelerated storage</b>	2 weeks 54°C +- 2°C	L1 product - mSPC1	See below	Ref. 1
	8weeks 40°C +-2°C / 75% RH +- 5%	L2 product – mSPC2		Ref. 5
	Lactic acid content measured via HPLC-UV validated method	L4 product – mSPC2		Ref.6
		L5 product - mSPC3		Ref. 7
		L6 product – mSPC4		Ref. 10
	Performed on the commercial	L7 product- mSPC5		Ref. 11
				Ref. 12

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	(HDPE ) packaging	L8 product – mSPC5		Ref. 13
		L36 product – metaSPC6		Ref. 14
		L2 impregnated wipes – mSPC7		Ref. 15
		L13 product – mSPC8		Ref. 16
		L14 product – mSPC8		Ref. 17
		L15 product – mSPC8		Ref. 18
		L16 product – mSPC8		Ref. 19
		L17 product – mSPC8		Ref. 20
		L18 product – mSPC8		Ref. 21
		L19 product – mSPC9		Ref. 22
		L20 product – mSPC9		Ref. 23
		L21 product – mSPC9		Ref. 24
		L22 product – mSPC9		Ref. 25
		L23 product – mSPC9		Ref. 26
	L24 product – mSPC9		Ref. 27	
	L25 product – mSPC10		Ref. 28	
	L26 product – mSPC11			



Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		L29 product – mSPC12		Ref. 30
		L35 product – mSPC12		Ref. 31
		L31 product – mSPC13		Ref. 32
		L32 product – mSPC13		Ref. 33
		L34 product – mSPC14		Ref. 34
		L33 product – mSPC15		Ref. 35

2weeks, 54°C

Time	Formulation & meta-SPC	Initial	2 weeks
Appearance	L1 – meta-SPC 1	Viscous liquid	Complies
pH		2.49	2.12
Density		1.020	1.021
[Lactic acid] % (variation %)		3.70	3.63 (-1.89)
Appearance	L2 – meta-SPC 2	Clear colourless liquid	Complies
pH		2.18	2.37
Density		1.004	1.004
[Lactic acid] % (variation %)		2.03	2.04 (+0.49)
Appearance	L4 – meta-SPC 2	Clear colourless liquid	Complies
pH		2.29	2.07
Density		1.006	1.007
[Lactic acid] % (variation %)		2.02	1.99 (-1.49)
Appearance	L5 – meta-SPC 3	Clear colourless liquid	Complies
pH		2.13	2.45
Density		1.170	1.182
[Lactic acid] % (variation %)		68.70	69.90 (+1.75)
Appearance	L6 – meta-SPC 4	Coloured liquid	Complies
pH		1.65	1.82
Density		1.038	1.040
[Lactic acid] %		15.39	16.31

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
(variation %)				(+5.98)
Appearance	L7 – meta-SPC 5		Coloured liquid	Complies
pH			3.00	3.02
Density			1.062	1.062
[Lactic acid] % (variation %)			8.47	8.85 (+4.49)
Appearance	L8 – meta-SPC 5		Coloured liquid	Complies
pH			2.33	2.30
Density			1.058	1.060
[Lactic acid] % (variation %)			7.97	7.91 (-0.75)
Appearance	L36 – meta-SPC 6		Coloured liquid	Complies
pH			2.25	2.00
Density			1.022	1.022
[Lactic acid] % (variation %)			3.77	3.45 (-8.49)
Appearance	L13 – meta-SPC 8		Viscous liquid	Complies
pH			3.98	3.73
Density			1.046	1.037
[Lactic acid] % (variation %)			3.57	3.71 (+3.92)
Appearance	L14 – meta-SPC 8		Viscous liquid	Complies
pH			3.96	4.00
Density			1.043	1.044
[Lactic acid] % (variation %)			7.76	7.95 (+2.45)
Appearance	L15 – meta-SPC 8		Viscous liquid	Complies
pH			4.18	4.11
Density			1.018	1.014
[Lactic acid] % (variation %)			3.82	3.85 (+0.79)
Appearance	L16 – meta-SPC 8		Viscous liquid	Complies
pH			3.97	3.99
Density			1.039	1.043
[Lactic acid] % (variation %)			7.67	7.84 (+2.22)
Appearance	L17 – meta-SPC 8		Viscous liquid	Complies
pH			4.20	4.09
Density			1.025	1.032
[Lactic acid] % (variation %)			3.68	3.65 (-0.82)
Appearance	L18 – meta-SPC 8		Viscous liquid	Complies
pH			3.97	3.86
Density			1.027	1.028
[Lactic acid] % (variation %)			7.59	7.73 (+1.84)
Appearance	L19 – meta-SPC 9		Coloured liquid	Complies
pH			3.90	3.90

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Density			1.039	1.036
[Lactic acid] % (variation %)			3.64	3.60 (-1.10)
Appearance	L20 – meta-SPC 9		Coloured liquid	Complies
pH			3.36	3.42
Density			1.050	1.049
[Lactic acid] % (variation %)			7.68	7.97 (+3.78)
Appearance	L21 – meta-SPC 9		Colourless liquid	Complies
pH			3.83	4.29
Density			1.023	1.020
[Lactic acid] % (variation %)			3.72	4.04 (+8.60)
Appearance	L22 – meta-SPC 9		Coloured liquid	Complies
pH			3.44	3.88
Density			1.052	1.052
[Lactic acid] % (variation %)			7.51	7.50 (-0.13)
Appearance	L23 – meta-SPC 9		Coloured liquid	Complies
pH			4.46	3.88
Density			1.043	1.042
[Lactic acid] % (variation %)			3.75	3.63 (-3.20)
Appearance	L24 – meta-SPC 9		Colourless liquid	Complies
pH			3.19	3.63
Density			1.032	1.032
[Lactic acid] % (variation %)			7.96	7.77 (-2.39)
Appearance	L25 – meta-SPC 10		Coloured liquid	Complies
pH			3.79	3.05
Density			1.000	0.991
[Lactic acid] % (variation %)			3.61	3.69 (+2.22)
Appearance	L26 – meta-SPC 11		Clear colourless liquid	Complies
pH			1.85	1.67
Density			1.066	1.062
[Lactic acid] % (variation %)			24.39	24.57 (+0.74)
Appearance	L29 – meta-SPC 12		Clear colourless liquid	Complies
pH			1.71	1.98
Density			1.136	1.134
[Lactic acid] % (variation %)			23.08	24.50 (+6.15)
Appearance	L35 – meta-SPC 12		Clear colourless liquid	Complies
pH			1.73	1.69
Density			1.131	1.142

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
[Lactic acid] % (variation %)		22.72		23.05 (+1.45)
Appearance	L31 – meta-SPC 13	Clear colourless liquid		Complies
pH		1.61		2.13
Density		1.078		1.089
[Lactic acid] % (variation %)		10.91		10.99 (+0.73)
Appearance	L32 – meta-SPC 13	Clear colourless liquid		Complies
pH		1.29		1.59
Density		1.114		1.122
[Lactic acid] % (variation %)		11.12		10.99 (-1.17)
Appearance	L34 – meta-SPC 14	Clear colourless liquid		Complies
pH		1.48		1.22
Density		1.087		1.092
[Lactic acid] % (variation %)		32.83		31.99 (-2.56)
Appearance	L33 – meta-SPC 15	Clear colourless liquid		Complies
pH		2.23		2.14
Density		1.016		1.017
[Lactic acid] % (variation %)		3.65		3.82 (+4.66)

The applicant has also provided dilution stability results on formulation that are to be diluted before use: L5 (meta-SPC 3), L6 (meta-SPC 4), L8 (meta-SPC 5), L26 (meta-SPC 11), L29 (meta-SPC 12), L31 (meta-SPC 13) and L34 (meta-SPC 14) after the storage during 2 weeks at 54°C. The aspect complies with the observations before storage, meaning that these formulations form stable dilutions.(Ref. 51)

Product	Tested concentration (V/V %)	Specification	Before stability			After stability		
			Aspect			Aspect		
			At start	After 30	After 24	At start	After 30	After 24
Concentrated green remover MetaSPC 3 L5	8	Clear liquid without flocculation, precipitate ...	Complies	Complies	Complies	Complies	Complies	Complies
Sanifresh MetaSPC 4 L6	80	Pink liquid without flocculation, precipitate ...	Complies	Complies	Complies	Complies	Complies	Complies
Kenopure MetaSPC 5 L8	40	Green liquid without flocculation, precipitate ...	Complies	Complies	Complies	Complies	Complies	Complies
Kenosan lactic MetaSPC 11 L26	15	Clear liquid without flocculation, precipitate ...	Complies	Complies	Complies	Complies	Complies	Complies
Phocid L MetaSPC 12 L29	8	Milky liquid without flocculation, precipitate...	Complies	Complies	Complies	Complies	Complies	Complies
Thornax L MetaSPC 13 L31	5	Clear liquid without flocculation, precipitate ...	Complies	Complies	Complies	Complies	Complies	Complies
Pediline A MetaSPC 14 L34	6	Clear liquid without flocculation, precipitate ...	Complies	Complies	Complies	Complies	Complies	Complies

8 weeks, 40°C, 75% RH

Time	Formulation & meta-SPC	Initial	8 weeks
Appearance	L1 – meta-SPC 1	Viscous liquid	Complies
pH		2.49	2.37
Density		1.020	1.021

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
[Lactic acid] % (variation %)		3.70		3.64 (-1.62)
Appearance	L2 – meta-SPC 2	Clear colourless liquid		Complies
pH		2.18		2.14
Density		1.004		1.004
[Lactic acid] % (variation %)		2.03		1.99 (+1.97)
Appearance	L4 – meta-SPC 2	Clear colourless liquid		Complies
pH		2.29		2.47
Density		1.006		1.006
[Lactic acid] % (variation %)		2.02		2.05 (+1.49)
Appearance	L5 – meta-SPC 3	Clear colourless liquid		Complies
pH		2.13		2.50
Density		1.170		1.174
[Lactic acid] % (variation %)		68.70		68.11 (-0.86)
Appearance	L6 – meta-SPC 4	Coloured liquid		Complies
pH		1.65		1.92
Density		1.038		1.040
[Lactic acid] % (variation %)		15.39		15.84 (+2.92)
Appearance	L7 – meta-SPC 5	Coloured liquid		Complies
pH		3.00		3.07
Density		1.062		1.060
[Lactic acid] % (variation %)		8.47		8.04 (-5.08)
Appearance	L8 – meta-SPC 5	Coloured liquid		Complies
pH		2.33		2.39
Density		1.058		1.060
[Lactic acid] % (variation %)		7.97		8.35 (-4.77)
Appearance	L36 – meta-SPC 6	Coloured liquid		Complies
pH		2.25		2.28
Density		1.022		1.023
[Lactic acid] % (variation %)		3.77		3.64 (-3.45)
Packaging aspect	L2 impregnated wipes – meta-SPC 7	Conform		Conform
Wipes aspect		Conform		Conform
Wipes moistening		Soaked		Soaked
Mass of the complete Packaging (g) and weight loss (%)		5 different wipes packagings have been tested. 2 types of tests have been performed: "closed bottle test", where	Packaging from 577 g to 4037.8 g	
[Lactic acid] % (variation %)		1.96 to 2.30		1.91 to 2.40 (-6.50 to +4.35)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	the weight loss of the packaging has been evaluated; and "in use test", where the aspect and content in a.s. have been evaluated			
Appearance	L13 – meta-SPC 8	Viscous liquid	Complies	
pH			3.98	3.92
Density			1.046	1.040
[Lactic acid] % (variation %)			3.57	3.83 (+7.28)
Appearance	L14 – meta-SPC 8	Viscous liquid	Complies	
pH			3.96	4.09
Density			1.043	1.042
[Lactic acid] % (variation %)			7.76	7.75 (-0.13)
Appearance	L15 – meta-SPC 8	Viscous liquid	Complies	
pH			4.18	4.34
Density			1.018	1.020
[Lactic acid] % (variation %)			3.82	3.85 (+0.79)
Appearance	L16 – meta-SPC 8	Viscous liquid	Complies	
pH			3.97	4.28
Density			1.039	1.044
[Lactic acid] % (variation %)			7.67	7.43 (-3.13)
Appearance	L17 – meta-SPC 8	Viscous liquid	Complies	
pH			4.20	4.45
Density			1.025	1.034
[Lactic acid] % (variation %)			3.68	3.71 (+0.82)
Appearance	L18 – meta-SPC 8	Viscous liquid	Complies	
pH			3.97	4.08
Density			1.027	1.023
[Lactic acid] % (variation %)			7.59	7.64 (+0.66)
Appearance	L19 – meta-SPC 9	Coloured liquid	Complies	
pH			3.90	4.06
Density			1.039	1.040
[Lactic acid] % (variation %)			3.64	3.69 (+1.37)
Appearance	L20 – meta-SPC 9	Coloured liquid	Complies	
pH			3.36	4.09
Density			1.050	1.042
[Lactic acid] % (variation %)			7.68	7.75 (-2.34)
Appearance	L21 – meta-SPC 9	Colourless liquid	Complies	
pH			3.83	3.74

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	
Density			1.023	1.022	
[Lactic acid] % (variation %)			3.72	3.67 (-1.34)	
Appearance			L22 – meta-SPC 9	Coloured liquid	Complies
pH				3.44	3.48
Density	1.052	1.052			
[Lactic acid] % (variation %)	7.51	7.34 (-2.26)			
Appearance	L23 – meta-SPC 9		Coloured liquid	Complies	
pH			4.46	4.18	
Density			1.043	1.042	
[Lactic acid] % (variation %)			3.75	3.56 (-5.07)	
Appearance	L24 – meta-SPC 9		Colourless liquid	Complies	
pH			3.19	3.23	
Density			1.032	1.032	
[Lactic acid] % (variation %)			7.96	7.61 (-4.40)	
Appearance	L25 – meta-SPC 10		Coloured liquid	Complies	
pH			3.79	3.79	
Density			1.000	0.997	
[Lactic acid] % (variation %)			3.61	3.69 (+2.22)	
Appearance	L26 – meta-SPC 11		Clear colourless liquid	Complies	
pH			1.85	2.09	
Density			1.066	1.067	
[Lactic acid] % (variation %)			24.39	24.02 (-1.52)	
Appearance	L29 – meta-SPC 12		Clear colourless liquid	Complies	
pH			1.71	1.80	
Density			1.136	1.135	
[Lactic acid] % (variation %)			23.08	22.60 (-2.08)	
Appearance	L35 – meta-SPC 12		Clear colourless liquid	Complies	
pH			1.73	2.23	
Density			1.131	1.141	
[Lactic acid] % (variation %)			22.72	22.30 (-1.85)	
Appearance	L31 – meta-SPC 13		Clear colourless liquid	Complies	
pH			1.61	1.73	
Density			1.078	1.084	
[Lactic acid] % (variation %)			10.91	11.43 (+4.77)	
Appearance	L32 – meta-SPC 13		Clear colourless liquid	Complies	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
pH		1.29	2.08	
Density		1.114	1.127	
[Lactic acid] % (variation %)		11.12	10.76 (-3.24)	
Appearance	L34 – meta-SPC 14	Clear colourless liquid	Complies	
pH		1.48	1.56	
Density		1.087	1.085	
[Lactic acid] % (variation %)		32.83	32.16 (-2.04)	
Appearance	L33 – meta-SPC 15	Clear colourless liquid	Complies	
pH		2.23	2.50	
Density		1.016	1.015	
[Lactic acid] % (variation %)		3.65	3.51 (-3.84)	
Storage stability test – long term storage at ambient temperature	25°C ±2°C/ 60% RH ±5%  Lactic acid content measured via HPLC-UV validated method  1L HDPE packaging  Performed on the commercial (HDPE ) packaging	L1 product - mSPC1  L2 product - mSPC2  L4 product - mSPC2  L5 product - mSPC3  L6 product - mSPC4  L7 product - mSPC5  L8 product - mSPC5  L36 product - mSPC6  L2 impregnated wipes - mSPC7  L13 product - mSPC 8  L14 product - mSPC8	<b><u>Study ongoing for the results at 36 months.</u></b>  <u>See below</u>	Ref. 1, 1a  Ref. 5, 5a  Ref. 6, 6a  Ref. 7, 7a  Ref. 10, 10a  Ref. 11, 11a  Ref. 12, 12a  Ref. 13, 13a  Ref. 14  Ref. 15  Ref. 16, 16a



Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		L15 product – mSPC8		Ref. 17, 17a
		L16 product – mSPC8		Ref. 18, 18a
		L17 product – mSPC8		Ref. 19, 19a
		L18 product – mSPC8		Ref. 20, 20a
		L19 product – mSPC9		Ref. 21, 21a
		L20 product – mSPC9		Ref. 22, 22a
		L21 product – mSPC9		Ref. 23, 23a
		L22 product – mSPC9		Ref. 24, 24a
		L23 product – mSPC9		Ref. 25, 25a
		L24 product – mSPC9		Ref.26, 26a
		L25 product – mSPC10		Ref. 27, 27a
		L26 product – mSPC11		Ref. 28, 28a
		L29 product – mSPC12		Ref. 30, 30a
		L35 product – mSPC12		Ref. 31, 31a
		L31 product – mSPC13		Ref. 32, 32a
		L32 product – mSPC13		Ref. 33, 33a
				Ref. 34, 34a

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		L34 product – mSPC14		Ref. 35, 35a
		L33 product – mSPC15		

At time of manufacturing and at shelf life the weight of the test item is determined. If the weight loss is less than 10%, it is noted as "compliant". The result for all meta-SPCs at all intermediate points is "compliant". For sake of clarity intermediate results for only 12 and 18 months are shown here, without mentioning inferior durations.

Time	Formulation & meta-SPC	Initial	12 months	18 months	24 months	36 months
Appearance	L1 – meta-SPC 1	Viscous liquid	Complies			
pH		2.49	2.29			
Density		1.020	1.021			
[Lactic acid] % (variation %)		3.70	3.67 (-0.8)			
Appearance	L2 – meta-SPC 2	Clear colourless liquid	Complies	Complies		
pH		2.18	2.18	2.25		
Density		1.004	1.005	1.005		
[Lactic acid] % (variation %)		2.03	2.02 (-0.5)	2.06 (+1.2)		
Appearance	L4 – meta-SPC 2	Clear colourless liquid	Complies	Complies		
pH		2.29	2.19	2.19		
Density		1.006	1.007	1.008		
[Lactic acid] % (variation %)		2.02	2.03 (+0.5)	2.07 (+2.4)		
Appearance	L5 – meta-SPC 3	Clear colourless liquid	Complies	Complies		
pH		2.13	2.37	2.40		
Density		1.170	1.173	1.171		

Property		Guideline and Method	Purity of the test substance (% (w/w))		Results	Reference
[Lactic acid] % (variation %)		68.70	68.72 (+0.00)	71.62 (+4.3)		
Appearance	L6 – meta-SPC 4	Coloured liquid	Complies	Complies		
pH		1.65	1.75	1.93		
Density		1.038	1.041	1.041		
[Lactic acid] % (variation %)		15.39	15.81 (+2.7)	16.19 (+5.2)		
Appearance	L7 – meta-SPC 5	Coloured liquid	Complies			
pH		3.00	3.00			
Density		1.062	1.064			
[Lactic acid] % (variation %)		8.47	8.01 (-5.5)			
Appearance	L8 – meta-SPC 5	Coloured liquid	Complies	Complies	Complies	Complies
pH		2.33	2.28	2.37	2.35	2.51
Density		1.058	1.059	1.061	1.060	1.062
[Lactic acid] % (variation %)		7.97	8.53 (+7.03)	8.40 (+5.40)	7.99 (+0.25)	7.85 (-1.51)
Appearance	L36 – meta-SPC 6	Coloured liquid	Complies			
pH		2.25	1.96			
Density		1.022	1.025			
[Lactic acid] % (variation %)		3.77	3.64 (-3.4)			
Packaging aspect	L2 impregnated wipes – meta-SPC 7 5 differen	Conform	Conform			
Wipes aspect		Conform	Conform			
Wipes moistening		Soaked	Soaked			

Property		Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference																																				
Mass of the complete Packaging (g) and weight loss (%)	t wipes packaging have been tested. 2 types of tests have been	Packaging from 553.6 g to 3789.6 g	Weight loss 0.29 % to 9.50 % according to different packagings																																						
[Lactic acid] % (variation %)	performed: "closed bottle test", where the weight loss of the packaging has been evaluated; and "in use test", where the aspect and content in a.s. have been evaluated	1.98 to 2.29	1.90 to 2.68 (-5.1 to +34.6)	<p>Two packagings show a variation higher than authorised 10% variations. all the rest of packagings (5) falls within the 10% variation.</p> <p>Different samples of different volumes have been tested:</p> <ul style="list-style-type: none"> <li>- wipes 1 from packaging of 2L and 10L</li> <li>- wipes 2 from packaging of 2L and 10L</li> <li>- wipes 3 from packaging of 2L and 10L</li> <li>- wipes 4 from packaging of 2L and 5L</li> <li>- wipes 5 from packaging of 1.5L</li> </ul> <p>WIPE 1: No determination of lactic acid content has been performed (but all other parameters are compliant).</p> <p>WIPE 2 : has shown a stability of 9 months. At 12 months the variation in lactic acid content was 18.5% for the 2L packaging. The 10 L packaging was compliant with lactic acid variation (5.1% variation).</p> <p>WIPE 3 : shows also an unacceptable variation at 12 months for the packaging of volume 2 L; but acceptable variation for volume of 10 L.</p> <p>WIPE 4: is stable over 12 months.</p> <p>WIPE 5 : is also stable over 12 months.</p> <table border="1"> <thead> <tr> <th></th> <th>Volume</th> <th>Lactic acid variation after 9 months</th> <th>Lactic acid variation after 12 months</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Wipe1</td> <td>2 L</td> <td colspan="2">Not determined</td> </tr> <tr> <td>10 L</td> <td colspan="2">Not determined</td> </tr> <tr> <td rowspan="2">Wipe 2</td> <td>2 L</td> <td>- 9.7 %</td> <td><b>+18.5 %</b></td> </tr> <tr> <td>10 L</td> <td>- 4.4 %</td> <td>- 5.1 %</td> </tr> <tr> <td rowspan="2">Wipe 3</td> <td>2 L</td> <td>+ 0.1%</td> <td><b>+34.6%</b></td> </tr> <tr> <td>10 L</td> <td>-1.4%</td> <td>-2.4%</td> </tr> <tr> <td rowspan="2">Wipe 4</td> <td>2 L</td> <td>+2.8%</td> <td>+1.0%</td> </tr> <tr> <td>5 L</td> <td>-3.8%</td> <td>-5.6%</td> </tr> <tr> <td>Wipe 5</td> <td>1.5 L</td> <td>-7.6%</td> <td>+4.8%</td> </tr> </tbody> </table> <p>Because of issues with intermediate results of stability test, the applicant has decided to remove the packagings presenting</p>			Volume	Lactic acid variation after 9 months	Lactic acid variation after 12 months	Wipe1	2 L	Not determined		10 L	Not determined		Wipe 2	2 L	- 9.7 %	<b>+18.5 %</b>	10 L	- 4.4 %	- 5.1 %	Wipe 3	2 L	+ 0.1%	<b>+34.6%</b>	10 L	-1.4%	-2.4%	Wipe 4	2 L	+2.8%	+1.0%	5 L	-3.8%	-5.6%	Wipe 5	1.5 L	-7.6%	+4.8%
	Volume	Lactic acid variation after 9 months	Lactic acid variation after 12 months																																						
Wipe1	2 L	Not determined																																							
	10 L	Not determined																																							
Wipe 2	2 L	- 9.7 %	<b>+18.5 %</b>																																						
	10 L	- 4.4 %	- 5.1 %																																						
Wipe 3	2 L	+ 0.1%	<b>+34.6%</b>																																						
	10 L	-1.4%	-2.4%																																						
Wipe 4	2 L	+2.8%	+1.0%																																						
	5 L	-3.8%	-5.6%																																						
Wipe 5	1.5 L	-7.6%	+4.8%																																						

Property		Guideline and Method	Purity of the test substance (% (w/w))		Results	Reference
			<p>indications of instability. Therefore, the following packagings are removed :</p> <p>Wipe 1, 2L and 10 L Wipe 2, 2L Wipe 3, 2L</p> <p>The following packaging can be authorized based on the stability results :</p> <p>Wipe 2, 10 L - 500 wipes Wipe 3, 10 L - 500 wipes Wipe 4, 2 L - 105 wipes Wipe 4, 5 L - 280 wipes Wipe 5, 1.5 L - 200 wipes</p>			
Appearance	L13 – meta-SPC 8	Viscous liquid	Complies	Complies	Complies	Complies
pH		3.98	3.86	3.85	3.87	3.92
Density		1.046	1.045	1.048	1.047	1.046
[Lactic acid] % (variation %)		3.57	3.76 (+7.03)	3.55 (+5.40)	3.64 (+0.25)	3.73 (-1.51)
Appearance	L14 – meta-SPC 8	Viscous liquid	Complies	Complies		
pH		3.96	3.64	3.63		
Density		1.043	1.043	1.053		
[Lactic acid] % (variation %)		7.76	8.13 (+4.8)	7.95 (+2.4)		
Appearance	L15 – meta-SPC 8	Viscous liquid	Complies	Complies		
pH		4.18	3.81	3.96		
Density		1.018	1.017	1.022		
[Lactic acid] % (variation %)		3.82	3.66 (-4.2)	3.53 (-7.6)		
Appearance	L16 – meta-SPC 8	Viscous liquid	Complies	Complies		
pH		3.97	3.92	3.99		
Density		1.039	1.037	1.058		
[Lactic acid] % (variation %)		7.67	7.33 (-4.4)	7.56 (-1.5)		

Property		Guideline and Method	Purity of the test substance (% (w/w))		Results	Reference
Appearance	L17 – meta-SPC 8	Viscous liquid	Complies	Complies		
pH		4.20	3.77	3.82		
Density		1.025	1.027	1.040		
[Lactic acid] % (variation %)		3.68	3.77 (-0.3)	3.76 (+2.2)		
Appearance	L18 – meta-SPC 8	Viscous liquid	Complies	Complies		
pH		3.97	3.70	3.64		
Density		1.027	1.041	1.040		
[Lactic acid] % (variation %)		7.59	7.86 (+3.6)	7.55 (-0.5)		
Appearance	L19 – meta-SPC 9	Coloured liquid	Complies	Complies		
pH		3.90	3.81	3.98		
Density		1.039	1.040	1.041		
[Lactic acid] % (variation %)		3.64	3.44 (-5.5)	3.45 (-5.1)		
Appearance	L20 – meta-SPC 9	Coloured liquid	Complies	Complies		
pH		3.36	3.47	3.67		
Density		1.050	1.051	1.050		
[Lactic acid] % (variation %)		7.68	8.21 (+6.9)	7.85 (+2.1)		
Appearance	L21 – meta-SPC 9	Colourless liquid	Complies	Complies		
pH		3.83	3.81	3.76		
Density		1.023	1.025	1.025		
[Lactic acid] % (variation %)		3.72	3.69 (-0.8)	3.55 (-4.5)		
Appearance	L22 – meta-SPC 9	Coloured liquid	Complies	Complies		
pH		3.44	3.50	3.46		
Density		1.052	1.054	1.053		
[Lactic acid] % (variation %)		7.51	7.58 (+1.0)	7.28 (-9.2)		

Property		Guideline and Method	Purity of the test substance (% (w/w))		Results	Reference
Appearance	L23 – meta-SPC 9	Coloured liquid	Complies	Complies		
pH		4.46	4.19	4.13		
Density		1.043	1.044	1.044		
[Lactic acid] % (variation %)		3.75	3.69 (-1.6)	3.46 (-7.6)		
Appearance	L24 – meta-SPC 9	Colourless liquid	Complies	Complies		
pH		3.19	3.27	3.18		
Density		1.032	1.034	1.034		
[Lactic acid] % (variation %)		7.96	7.68 (-3.5)	7.39 (-7.2)		
Appearance	L25 – meta-SPC 10	Coloured liquid	Complies	Complies		
pH		3.79	3.88	3.93		
Density		1.000	0.999	0.998		
[Lactic acid] % (variation %)		3.61	3.53 (-2.2)	3.44 (-4.6)		
Appearance	L26 – meta-SPC 11	Clear colourless liquid	Complies	Complies		
pH		1.85	1.67	1.80		
Density		1.066	1.067	1.068		
[Lactic acid] % (variation %)		24.39	22.23 (-8.9)	22.16 (-9.1)		
Appearance	L29 – meta-SPC 12	Clear colourless liquid	Complies	Complies		
pH		1.71	1.55	1.62		
Density		1.136	1.137	1.136		
[Lactic acid] % (variation %)		23.08	22.10 (-4.2)	21.41 (-7.2)		
Appearance	L35 – meta-SPC 12	Clear colourless liquid	Complies			

Property		Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
pH		1.73	1.75		
Density		1.131	1.143		
[Lactic acid] % (variation %)		22.72	21.53 (-5.2)		
Appearance		L31 - meta-SPC 13	Clear colourless liquid	Complies	Complies
pH		1.61	2.09	2.11	
Density		1.078	1.081	1.050	
[Lactic acid] % (variation %)		10.91	10.82 (-0.8)	10.88 (-0.3)	
Appearance		L32 - meta-SPC 13	Clear colourless liquid	Complies	
pH		1.29	1.65		
Density		1.114	1.129		
[Lactic acid] % (variation %)		11.12	12.12 (+9.1)		
Appearance		L34 - meta-SPC 14	Clear colourless liquid	Complies	Complies
pH		1.48	1.35	1.38	
Density		1.087	1.091	1.093	
[Lactic acid] % (variation %)		32.83	33.10 (+0.8)	31.00 (-5.6)	
Appearance		L33 - meta-SPC 15	Clear colourless liquid	Complies	
pH		2.23	2.21		
Density		1.016	1.019		
[Lactic acid] % (variation %)		3.65	3.89 (+6.4)		
Appearance					



Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	
Storage stability test – <b>low temperature stability test for liquids</b>	5°C +- 3°C, 8 weeks	L1 product - mSPC1	See below	Ref. 1	
	0°C +-2°C, 1 week	L2 product - mSPC2		Ref. 5	
	Lactic acid content measured via HPLC-UV validated method	L4 product - mSPC2		Ref. 6	
		L5 product - mSPC3		Ref. 7	
	1L HDPE packaging	L6 product - mSPC4		Ref. 10	
		L7 product - mSPC5		Ref. 11	
	Freeze thaw stability during 3 cycles.	L8 product - mSPC5		Ref. 12	
		L36 product - mSPC6		Ref. 13	
	1 cycl = 24 hours +- 1 hour stored at <= 18°C alternated with 24 hours +- 1 hour at 20°C +-5°C  Performed on the commercial (HDPE ) packaging	L2 impregnated wipes - mSPC7		No test has been provided. Please indicate on the labelling "Store at ambient temperature. Do not store below 0°C"	-
		L13 product - mSPC8		Ref. 15	
		L14 product - mSPC8		Ref. 16	
		L15 product - mSPC8		Ref. 17	
		L16 product - mSPC8	Ref. 18		
	L17 product - mSPC8	Ref. 19			

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		L18 product – mSPC8		Ref. 20
		L19 product – mSPC9		Ref. 21
		L20 product – mSPC9		Ref. 22
		L21 product – mSPC9		Ref. 23
		L22 product – mSPC9		Ref. 24
		L23 product – mSPC9		Ref. 25
		L24 product – mSPC9		Ref. 26
		L25 product – mSPC10		Ref. 27
		L26 product – mSPC11		Ref. 28
		L29 product – mSPC12		Ref. 30
		L35 product – mSPC12		Ref. 31
		L31 product – mSPC13		Ref. 32
		L32 product – mSPC13		Ref. 33
		L34 product – mSPC14		Ref. 34
		L33 product – mSPC15		Ref. 35

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
<b>8 week, 5°C</b>				
Time	Formulation & meta-SPC	Initial		8 weeks
Appearance	L1 – meta-SPC 1	Viscous liquid		Viscous liquid
pH		2.49		2.41
Density		1.020		1.021
[Lactic acid] % (variation %)		3.70		3.63 (-1.89)
Appearance	L2 – meta-SPC 2	Clear colourless liquid		Clear colourless liquid
pH		2.18		2.37
Density		1.004		1.005
[Lactic acid] % (variation %)		2.03		2.03 (+0.00)
Appearance	L4 – meta-SPC 2	Clear colourless liquid		Clear colourless liquid
pH		2.29		2.34
Density		1.006		1.007
[Lactic acid] % (variation %)		2.02		2.04 (+0.99)
Appearance	L5 – meta-SPC 3	Clear colourless liquid		Clear colourless liquid
pH		2.13		2.45
Density		1.170		1.173
[Lactic acid] % (variation %)		68.70		67.19 (+2.20)
Appearance	L6 – meta-SPC 4	Coloured liquid		Coloured liquid
pH		1.65		2.02
Density		1.038		1.041
[Lactic acid] % (variation %)		15.39		16.28 (+5.78)
Appearance	L7 – meta-SPC 5	Coloured liquid		Coloured liquid
pH		3.00		3.07
Density		1.062		1.063
[Lactic acid] % (variation %)		8.47		8.04 (-5.08)
Appearance	L8 – meta-SPC 5	Coloured liquid		Coloured liquid
pH		2.33		2.37
Density		1.058		1.059
[Lactic acid] % (variation %)		7.97		7.87 (-1.25)
Appearance	L36 – meta-SPC 6	Coloured liquid		Coloured liquid
pH		2.25		2.50
Density		1.022		1.022
[Lactic acid] % (variation %)		3.77		3.62 (-3.98)
Appearance	L13 – meta-SPC 8	Viscous liquid		Viscous liquid
pH		3.98		3.82

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Density			1.046	1.044
[Lactic acid] % (variation %)			3.57	3.77 (+5.60)
Appearance	L14 – meta-SPC 8		Viscous liquid	Viscous liquid
pH			3.96	4.21
Density			1.043	1.049
[Lactic acid] % (variation %)			7.76	7.69 (-0.90)
Appearance	L15 – meta-SPC 8		Viscous liquid	Viscous liquid
pH			4.18	4.26
Density			1.018	1.020
[Lactic acid] % (variation %)			3.82	3.79 (-0.79)
Appearance	L16 – meta-SPC 8		Viscous liquid	Viscous liquid
pH			3.97	4.43
Density			1.039	1.044
[Lactic acid] % (variation %)			7.67	7.26 (-5.35)
Appearance	L17 – meta-SPC 8		Viscous liquid	Viscous liquid
pH			4.20	4.48
Density			1.025	1.032
[Lactic acid] % (variation %)			3.68	3.71 (+0.82)
Appearance	L18 – meta-SPC 8		Viscous liquid	Viscous liquid
pH			3.97	4.08
Density			1.027	1.032
[Lactic acid] % (variation %)			7.59	7.52 (-0.92)
Appearance	L19 – meta-SPC 9		Coloured liquid	Coloured liquid
pH			3.90	3.90
Density			1.039	1.043
[Lactic acid] % (variation %)			3.64	3.67 (+0.82)
Appearance	L20 – meta-SPC 9		Coloured liquid	Coloured liquid
pH			3.36	3.46
Density			1.050	1.053
[Lactic acid] % (variation %)			7.68	7.54 (-1.82)
Appearance	L21 – meta-SPC 9		Colourless liquid	Colourless liquid
pH			3.83	3.78
Density			1.023	1.023
[Lactic acid] % (variation %)			3.72	3.66 (-1.61)
Appearance	L22 – meta-SPC 9		Coloured liquid	Coloured liquid
pH			3.44	3.49
Density			1.052	1.053
[Lactic acid] % (variation %)			7.51	7.42 (-1.20)
Appearance	L23 – meta-SPC 9		Coloured liquid	Coloured liquid

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
pH		4.46		4.32
Density		1.043		1.044
[Lactic acid] % (variation %)		3.75		3.59 (-4.27)
Appearance			Colourless liquid	Colourless liquid
pH	L24 – meta-SPC 9	3.19		3.21
Density		1.032		1.033
[Lactic acid] % (variation %)		7.96		7.55 (-5.15)
Appearance	L25 – meta-SPC 10		Coloured liquid	Coloured liquid
pH		3.79		3.84
Density		1.000		1.001
[Lactic acid] % (variation %)		3.61		3.67 (+1.66)
Appearance	L26 – meta-SPC 11		Clear colourless liquid	Clear colourless liquid
pH		1.85		1.82
Density		1.066		1.071
[Lactic acid] % (variation %)		24.39		24.01 (-1.56)
Appearance	L29 – meta-SPC 12		Clear colourless liquid	Clear colourless liquid
pH		1.71		1.83
Density		1.136		1.136
[Lactic acid] % (variation %)		23.08		22.56 (-2.25)
Appearance	L35 – meta-SPC 12		Clear colourless liquid	Clear colourless liquid
pH		1.73		2.27
Density		1.131		1.140
[Lactic acid] % (variation %)		22.72		22.12 (-2.64)
Appearance	L31 – meta-SPC 13		Clear colourless liquid	Clear colourless liquid
pH		1.61		1.85
Density		1.078		1.082
[Lactic acid] % (variation %)		10.91		10.99 (+0.73)
Appearance	L32 – meta-SPC 13		Clear colourless liquid	Clear colourless liquid
pH		1.29		2.08
Density		1.114		1.115
[Lactic acid] % (variation %)		11.12		10.89 (-2.07)
Appearance	L34 – meta-SPC 14		Clear colourless liquid	Clear colourless liquid
pH		1.48		1.55
Density		1.087		1.094
[Lactic acid] %		32.83		32.09

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
(variation %)				(-2.25)
Appearance	L33 – meta-SPC 15		Clear colourless liquid	Clear colourless liquid
pH			2.23	2.40
Density			1.016	1.016
[Lactic acid] % (variation %)			3.65	3.51 (-3.84)
<u>1 week, 0°C</u>				
Time	Formulation & meta-SPC	Initial		1 week
Appearance	L1 – meta-SPC 1		Viscous liquid	Viscous liquid
pH			2.49	2.44
Density			1.020	1.022
[Lactic acid] % (variation %)			3.70	3.79 (+2.43)
Appearance	L2 – meta-SPC 2		Clear colourless liquid	Clear colourless liquid
pH			2.18	2.20
Density			1.004	1.004
[Lactic acid] % (variation %)			2.03	2.06 (+1.48)
Appearance	L4 – meta-SPC 2		Clear colourless liquid	Clear colourless liquid
pH			2.29	2.28
Density			1.006	1.006
[Lactic acid] % (variation %)			2.02	2.04 (+0.99)
Appearance	L5 – meta-SPC 3		Clear colourless liquid	Clear colourless liquid
pH			2.13	2.34
Density			1.170	1.169
[Lactic acid] % (variation %)			68.70	69.55 (+1.24)
Appearance	L6 – meta-SPC 4		Coloured liquid	Coloured liquid
pH			1.65	1.67
Density			1.038	1.038
[Lactic acid] % (variation %)			15.39	16.52 (+7.34)
Appearance	L7 – meta-SPC 5		Coloured liquid	Coloured liquid
pH			3.00	3.01
Density			1.062	1.061
[Lactic acid] % (variation %)			8.47	7.92 (-6.49)
Appearance	L8 – meta-SPC 5		Coloured liquid	Coloured liquid
pH			2.33	2.40
Density			1.058	1.060
[Lactic acid] %			7.97	8.05

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
(variation %)				(+1.00)
Appearance	L36 – meta-SPC 6		Coloured liquid	Coloured liquid
pH			2.25	2.14
Density			1.022	1.023
[Lactic acid] % (variation %)			3.77	3.63 (-3.71)
Appearance	L13 – meta-SPC 8		Viscous liquid	Viscous liquid
pH			3.98	3.83
Density			1.046	1.042
[Lactic acid] % (variation %)			3.57	3.62 (+1.40)
Appearance	L14 – meta-SPC 8		Viscous liquid	Viscous liquid
pH			3.96	4.05
Density			1.043	1.048
[Lactic acid] % (variation %)			7.76	8.21 (+5.80)
Appearance	L15 – meta-SPC 8		Viscous liquid	Viscous liquid
pH			4.18	4.23
Density			1.018	1.021
[Lactic acid] % (variation %)			3.82	3.82 (+0.00)
Appearance	L16 – meta-SPC 8		Viscous liquid	Viscous liquid
pH			3.97	3.96
Density			1.039	1.032
[Lactic acid] % (variation %)			7.67	7.59 (-1.04)
Appearance	L17 – meta-SPC 8		Viscous liquid	Viscous liquid
pH			4.20	4.24
Density			1.025	1.024
[Lactic acid] % (variation %)			3.68	3.72 (+1.09)
Appearance	L18 – meta-SPC 8		Viscous liquid	Viscous liquid
pH			3.97	4.04
Density			1.027	1.028
[Lactic acid] % (variation %)			7.59	7.48 (-1.45)
Appearance	L19 – meta-SPC 9		Coloured liquid	Coloured liquid
pH			3.90	3.91
Density			1.039	1.039
[Lactic acid] % (variation %)			3.64	3.59 (-1.37)
Appearance	L20 – meta-SPC 9		Coloured liquid	Coloured liquid
pH			3.36	3.47
Density			1.050	1.051
[Lactic acid] % (variation %)			7.68	7.60 (-1.04)
Appearance	L21 – meta-SPC 9		Colourless liquid	Colourless liquid
pH			3.83	3.80

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Density			1.023	1.023
[Lactic acid] % (variation %)			3.72	3.60 (-3.23)
Appearance	L22 – meta-SPC 9		Coloured liquid	Coloured liquid
pH			3.44	3.47
Density			1.052	1.053
[Lactic acid] % (variation %)			7.51	7.35 (-2.13)
Appearance	L23 – meta-SPC 9		Coloured liquid	Coloured liquid
pH			4.46	4.30
Density			1.043	1.043
[Lactic acid] % (variation %)			3.75	3.63 (-3.20)
Appearance	L24 – meta-SPC 9		Colourless liquid	Colourless liquid
pH			3.19	3.18
Density			1.032	1.033
[Lactic acid] % (variation %)			7.96	7.30 (-8.29)
Appearance	L25 – meta-SPC 10		Coloured liquid	Coloured liquid
pH			3.79	3.87
Density			1.000	0.996
[Lactic acid] % (variation %)			3.61	3.70 (+2.49)
Appearance	L26 – meta-SPC 11		Clear colourless liquid	Clear colourless liquid
pH			1.85	1.78
Density			1.066	1.066
[Lactic acid] % (variation %)			24.39	23.64 (-3.08)
Appearance	L29 – meta-SPC 12		Clear colourless liquid	Clear colourless liquid
pH			1.71	1.59
Density			1.136	1.136
[Lactic acid] % (variation %)			23.08	21.88 (-5.20)
Appearance	L35 – meta-SPC 12		Clear colourless liquid	Clear colourless liquid
pH			1.73	1.71
Density			1.131	1.140
[Lactic acid] % (variation %)			22.72	21.97 (-3.30)
Appearance	L31 – meta-SPC 13		Clear colourless liquid	Clear colourless liquid
pH			1.61	2.13
Density			1.078	1.078
[Lactic acid] % (variation %)			10.91	11.94 (+9.44)
Appearance	L32 – meta-SPC 13		Clear colourless liquid	Clear colourless liquid



Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
pH			1.29	1.86
Density			1.114	1.115
[Lactic acid] % (variation %)			11.12	10.51 (-5.49)
Appearance	L34 – meta-SPC 14		Clear colourless liquid	Clear colourless liquid
pH			1.48	1.81
Density			1.087	1.088
[Lactic acid] % (variation %)			32.83	32.79 (-0.12)
Appearance	L33 – meta-SPC 15		Clear colourless liquid	Clear colourless liquid
pH			2.23	2.20
Density			1.016	1.017
[Lactic acid] % (variation %)			3.65	3.50 (-4.11)
<u>3 freeze thaw cycles</u>				

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Time	Formulation & meta-SPC 1	Initial	After 3 cycles	
Appearance			Viscous liquid	Viscous liquid
pH			2.49	2.19
Density			1.020	1.020
[Lactic acid] % (variation %)			3.70	3.78 (+2.16)
Appearance	L2 – meta-SPC 2	Clear colourless liquid	Clear colourless liquid	
pH			2.18	2.32
Density			1.004	1.004
[Lactic acid] % (variation %)			2.03	1.84 (-9.36)
Appearance	L4 – meta-SPC 2	Clear colourless liquid	Clear colourless liquid	
pH			2.29	2.39
Density			1.006	1.006
[Lactic acid] % (variation %)			2.02	2.05 (+1.49)
Appearance	L5 – meta-SPC 3	Clear colourless liquid	Clear colourless liquid	
pH			2.13	2.44
Density			1.170	1.172
[Lactic acid] % (variation %)			68.70	71.09 (+3.48)
Appearance	L6 – meta-SPC 4	Coloured liquid	Coloured liquid	
pH			1.65	1.73
Density			1.038	1.037
[Lactic acid] % (variation %)			15.39	16.28 (+5.78)
Appearance	L7 – meta-SPC 5	Coloured liquid	Coloured liquid	
pH			3.00	2.95
Density			1.062	1.062
[Lactic acid] % (variation %)			8.47	8.86 (-4.60)
Appearance	L8 – meta-SPC 5	Coloured liquid	Coloured liquid	
pH			2.33	2.41
Density			1.058	1.059
[Lactic acid] % (variation %)			7.97	8.70 (+9.16)
Appearance	L36 – meta-SPC 6	Coloured liquid	Coloured liquid	
pH			2.25	2.09
Density			1.022	1.023
[Lactic acid] % (variation %)			3.77	3.82 (+1.33)
Appearance	L13 – meta-SPC 8	Viscous liquid	Viscous liquid	
pH			3.98	3.82
Density			1.046	1.032
[Lactic acid] %			3.57	3.81

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
(variation %)				(+6.72)
Appearance	L14 – meta-SPC 8	Viscous liquid		Viscous liquid
pH			3.96	4.06
Density			1.043	1.048
[Lactic acid] % (variation %)			7.76	8.21 (+5.80)
Appearance	L15 – meta-SPC 8	Viscous liquid		Viscous liquid
pH			4.18	4.19
Density			1.018	1.020
[Lactic acid] % (variation %)			3.82	3.80 (-0.52)
Appearance	L16 – meta-SPC 8	Viscous liquid		Viscous liquid
pH			3.97	3.83
Density			1.039	1.034
[Lactic acid] % (variation %)			7.67	7.87 (+2.61)
Appearance	L17 – meta-SPC 8	Viscous liquid		Viscous liquid
pH			4.20	4.23
Density			1.025	1.028
[Lactic acid] % (variation %)			3.68	3.70 (+0.54)
Appearance	L18 – meta-SPC 8	Viscous liquid		Viscous liquid
pH			3.97	4.14
Density			1.027	1.022
[Lactic acid] % (variation %)			7.59	8.08 (+6.46)
Appearance	L19 – meta-SPC 9	Coloured liquid		Coloured liquid
pH			3.90	3.90
Density			1.039	1.038
[Lactic acid] % (variation %)			3.64	3.60 (-1.10)
Appearance	L20 – meta-SPC 9	Coloured liquid		Coloured liquid
pH			3.36	3.52
Density			1.050	1.052
[Lactic acid] % (variation %)			7.68	8.21 (+6.90)
Appearance	L21 – meta-SPC 9	Colourless liquid		Colourless liquid
pH			3.83	4.37
Density			1.023	1.023
[Lactic acid] % (variation %)			3.72	3.56 (-4.30)
Appearance	L22 – meta-SPC 9	Coloured liquid		Coloured liquid
pH			3.44	3.87
Density			1.052	1.052
[Lactic acid] % (variation %)			7.51	7.57 (+0.80)
Appearance	L23 – meta-SPC 9	Coloured liquid		Coloured liquid
pH			4.46	4.71

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Density			1.043	1.043
[Lactic acid] % (variation %)			3.75	3.60 (-4.00)
Appearance	L24 – meta-SPC 9		Colourless liquid	Colourless liquid
pH			3.19	3.60
Density			1.032	1.031
[Lactic acid] % (variation %)			7.96	7.48 (-6.03)
Appearance	L25 – meta-SPC 10		Coloured liquid	Coloured liquid
pH			3.79	3.81
Density			1.000	0.993
[Lactic acid] % (variation %)			3.61	3.65 (+1.11)
Appearance	L26 – meta-SPC 11		Clear colourless liquid	Clear colourless liquid
pH			1.85	1.90
Density			1.066	1.063
[Lactic acid] % (variation %)			24.39	25.27 (+3.61)
Appearance	L29 – meta-SPC 12		Clear colourless liquid	Clear colourless liquid
pH			1.71	1.99
Density			1.136	1.135
[Lactic acid] % (variation %)			23.08	22.16 (-3.99)
Appearance	L35 – meta-SPC 12		Clear colourless liquid	Clear colourless liquid
pH			1.73	1.72
Density			1.131	1.141
[Lactic acid] % (variation %)			22.72	2.61 (-0.48)
Appearance	L31 – meta-SPC 13		Clear colourless liquid	Clear colourless liquid
pH			1.61	2.18
Density			1.078	1.079
[Lactic acid] % (variation %)			10.91	11.06 (+1.37)
Appearance	L32 – meta-SPC 13		Clear colourless liquid	Clear colourless liquid
pH			1.29	1.73
Density			1.114	1.115
[Lactic acid] % (variation %)			11.12	10.89 (-2.07)
Appearance	L34 – meta-SPC 14		Clear colourless liquid	Clear colourless liquid
pH			1.48	1.55
Density			1.087	1.089
[Lactic acid] % (variation %)			32.83	32.97 (+0.43)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Appearance	L33 – meta-SPC 15		Clear colourless liquid	Clear colourless liquid
pH			2.23	2.16
Density			1.016	1.016
[Lactic acid] % (variation %)			3.65	3.70 (+1.37)
Effects on content of the active substance and technical characteristics of the biocidal product - <b>light</b>	Waived	Intended to be stored in non-transparent packaging – to be indicated on the SPC		
Effects on content of the active substance and technical characteristics of the biocidal product – <b>temperature and humidity</b>	Please see the storage stability studies			
Effects on content of the active substance and technical characteristics of the biocidal product - <b>reactivity towards container material</b>	Please see the storage stability studies: Packaging bottle is not degraded (no leakage, no ballooning, no paneling of the packaging, no deformations)			
Wettability	Waived	The product is not a solid preparation to be dispersed in water		
Suspensibility, spontaneity and dispersion stability	Waived	All products of this biocidal product family are soluble liquid products (SL) or ready to use liquid products (AL). Wettability data is required for solid preparations which are to be dispersed in water.		
Wet sieve analysis and dry sieve test	Waived	The product is not a wettable powder		
Emulsifiability, re-emulsifiability and emulsion stability	Waived	None of products of the BPF is emulsifiable concentrate or suspo-emulsion		
Disintegration time	Waived	Inappropriate for the formulation type of the product		
Particle size distribution, content of dust/fines, attrition, friability	Waived	<p>The products of meta - SPC 1, 7, 8, 12, 13, 15 are not intended to be applied via spraying equipment.</p> <p>For the meta-SPCs 2, 3, 4, 5, 6, 9, 10, 11 and 14 the applicant has submitted the following waiver (accepted by BE eCA):</p> <p>To comply with the obligations under the Biocidal Products Regulation (BPR) CID LINES NV provides</p>		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		<p>this justification explaining why the data on the size of droplets and other features of the spray and MMAD is not provided for the LA BPF dossier with case number BC-RC051007-54.</p> <p>a) Products are sold separately from the spraying cans. The spraying can is not part of the authorization.</p> <p>b) The MMAD is not an input parameter in human exposure assessment. MMAD has only a consequence on the inhalation absorption of aerosol droplets, so when the product is applied by spraying. Products intended to be applied for spraying are products of metaSPC 2, 3, 4, 5, 6, 9, 10, 11, 14. For these products the exposure to aerosol generated during the application was assessed by Spraying Model 1, Spraying Model 2 or Consumer spraying &amp; dusting Model 2 for all substances (active substance or substances of concern). Exposure to vapours of the SoCs propan-2-ol and Butyldiglycol is assessed by ConsExpo. For the active substances, exposure to vapours is not relevant as these are no volatile substances. So, it can be concluded that the inhalation exposure assessed in the HHRA takes into account all the possible states of the product. Furthermore, the MMAD would only be useful if it would be directly used in the exposure assessment. But it is not the case in this dossier. So, there is no indication to measure the MMAD.</p> <p>c) The MMAD is not relevant for efficacy assessment.</p>		
Persistent foaming	Waived for meta-SPC 1, 2, 6, 7, 8, 9, 10, 15	No dilution is foreseen for the normal use of the products		
	CIPAC MT 47.1	L5 product - mSPC3 <sup>1</sup> [L5] = 0.5 %  [L5] = 2.5 %	Volume foam <sub>1min</sub> : 25 ml Volume foam <sub>12min</sub> : 0 ml	Ref. 8

<sup>1</sup> For the product L5 (meta-SPC 3), the highest dilution claimed is 4% for carcass saws, based on efficacy tests output. Initially, the highest dilution tested for the persistent foaming was 2.5%, and for the dilution stability and surface tension : 8%. The applicant would like to refer to 2.5% results for the persistent foaming: As the maximum allowed level of 60 ml after 1 and 12 minutes is already exceeded at 2.5% concentration, the maximum allowed level of 60 ml will also be exceeded after 1 and 12 minutes at 4% dilution. BE eCA agrees with this read across.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		L6 product – mSPC4 [L6] = 30 %	Volume foam <sub>1min</sub> : 150 ml Volume foam <sub>12min</sub> : 75 ml	
		[L6] = 80 %	Volume foam <sub>1min</sub> : 120 ml Volume foam <sub>12min</sub> : 40 ml	
		L8 product – mSPC5 [L8] = 40 %	Volume foam <sub>1min</sub> : 65 ml Volume foam <sub>12min</sub> : 60 ml	
		L26 product – mSPC11 [L26] = 15 %	Volume foam <sub>1min</sub> : 120 ml Volume foam <sub>12min</sub> : 110 ml	
		[L26] = 1 %	Volume foam <sub>1min</sub> : 56 ml Volume foam <sub>12min</sub> : 36 ml	
		L29 product – mSPC12 [L29] = 8 %	Volume foam <sub>1min</sub> : 0 ml Volume foam <sub>12min</sub> : 0 ml	
		[L29] = 1 %	Volume foam <sub>1min</sub> : 6 ml Volume foam <sub>12min</sub> : 4 ml	
		L31 product – mSPC13		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		[L31] = 5 %  [L31] = 1 %  L34 product – mSPC14 [L34] = 6 %	Volume foam <sub>1min</sub> : 75 ml Volume foam <sub>12min</sub> : 75 ml  Volume foam <sub>1min</sub> : 24 ml Volume foam <sub>12min</sub> : 20 ml  Volume foam <sub>1min</sub> : 110 ml Volume foam <sub>12min</sub> : 110 ml  Since the proper use of products needs PPEs such as gloves and goggles, the exposure to foam is covered by the risk assessment.	
Flowability/Pourability/Dustability	Waived	Inappropriate for the formulation type of the product		
Burning rate — smoke generators	Waived	The product is not a smoke generator		
Burning completeness — smoke generators	Waived	The product is not a smoke generator		
Composition of smoke — smoke generators	Waived	The product is not a smoke generator		
Spraying pattern — aerosols	Waived	None of the products of the BPF are aerosols		
Physical compatibility	Waived	None of the products of this biocidal product family are recommended to be used in combination with other products.		
Chemical compatibility	Waived	None of the products of this biocidal product family are recommended to be used in combination with other products.		
Degree of dissolution and dilution stability	Waived	The products of meta-SPC 1, 2, 6, 7, 8, 9, 10, 15 are a ready-to-use product		



Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	CIPAC MT 41.1	L5 product – mSPC3 <sup>2</sup> [L5] = 8.0 %	After 30 min: Clear liquid without flocculation, precipitate  After 24 h: Clear liquid without flocculation, precipitate	Ref. 9
		L6 product – mSPC4 [L6] = 80.0 %	After 30 min: Pink liquid without flocculation, precipitate  After 24 h: Pink liquid without flocculation, precipitate	
		L8 product – mSPC5 [L8] = 40.0 %	After 30 min: Green liquid without flocculation, precipitate  After 24 h: Green liquid without flocculation, precipitate	
		L26 product – mSPC11 [L26] = 15 %	After 30 min: Clear liquid without flocculation, precipitate	

<sup>2</sup> For the product L5 (meta-SPC 3), the highest dilution claimed is 4% for carcass saws, based on efficacy tests output. Initially, the highest dilution tested for the persistent foaming was 2.5%, and for the dilution stability and surface tension : 8%. The applicant would like to refer to 8% results for the dilution stability: At 8%, the solution is stable, and it should be the same for the less concentrated solutions. BE eCA agrees with this read across.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		L29 product - mSPC12 [L29] = 8 %	After 24 h: Clear liquid without flocculation, precipitate  After 30 min: Clear liquid without flocculation, precipitate	
		L31 product - mSPC13 [L31] = 5 %	After 24 h: Clear liquid without flocculation, precipitate  After 30 min: Clear liquid without flocculation, precipitate	
		L34 product - mSPC14 [L34] = 6 %	After 24 h: Clear liquid without flocculation, precipitate  After 30 min: Clear liquid without flocculation, precipitate	
Surface tension	OECD 115  Nouy ring method for liquid products L2, L5, L6, L7, L8, L36, L19, L20,	L1 product - mSPC1, undiluted  L2 product - mSPC2, undiluted	30.32 mN/m St. Dev.: 0.12 mN/m  24.29 mN/m St. Dev.: 0.07 mN/m	Ref. 3 Ref. 3a

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	L25, L26, L29, L31, L34, L33	L5 product - mSPC3, 8% diluted	34.27 mN/m St. Dev.: 0.23 mN/m	
	Wilhelmy plate method for viscous liquids: L1, L13, L14, L33	4% diluted	29.80 mN/m St. Dev.: 0.001 mN/m	
		L6 product - mSPC4, 80% diluted	27.91 mN/m St. Dev.: 0.07 mN/m	
		L7 product - mSPC5, 40% diluted	27.57 mN/m St. Dev.: 0.31 mN/m	
		L8 product - mSPC5, 40% diluted	26.11 mN/m St. Dev.: 0.21 mN/m	
		L36 product - mSPC6, undiluted	28.57 mN/m St. Dev.: 0.17 mN/m	
		L2 impregnated wipes - mSPC7	Please see the L2 formulation	
		L13 product - mSPC8, undiluted	28.81 mN/m St. Dev.: 0.76 mN/m	
		L14 product - mSPC8, undiluted	27.30 mN/m St. Dev.: 0.68 mN/m	
		L19 product - mSPC9, undiluted	29.34 mN/m St. Dev.: 0.13 mN/m	
		L20 product - mSPC9, undiluted	29.14 mN/m St. Dev.: 0.33 mN/m	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		L25 product – mSPC10, undiluted	29.02 mN/m St. Dev.: 0.40 mN/m	
		L26 product – mSPC11, 15% diluted	31.29 mN/m St. Dev.: 0.30 mN/m	
		L29 product – mSPC12, 8% diluted	32.46 mN/m St. Dev.: 0.35 mN/m	
		L31 product – mSPC13, 5% diluted	20.96 mN/m St. Dev.: 0.37 mN/m	
		L34 product – mSPC14, 6% diluted	32.37 mN/m St. Dev.: 0.58 mN/m	
		L33 product – mSPC15, undiluted	31.80 mN/m St. Dev.: 0.23 mN/m	
Viscosity <sup>3</sup>	OECD 114 : Viscosity of liquids  20°C & 40°C	L1 product - mSPC1	452 cP at 20°C 192 cP at 40°C	Ref. 4
		L4 product – mSPC2	<10 cP at 20°C <10 cP at 40°C	
		L5 product – mSPC3	30 cP at 20°C 22 cP at 40°C	
		L6 product – mSPC4	336 cP at 20°C 292 cP at 40°C	
		L7 product – mSPC5	<10 cP at 20°C 11 cP at 40°C	

<sup>3</sup> The values of viscosity lower than 10 cP mean that the product is not viscous at 20 or 40 °C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		L8 product – mSPC5	88 cP at 20°C 32 cP at 40°C	
		L36 product – mSPC6	<10 cP at 20°C <10 cP at 40°C	
		L2 impregnated wipes – mSPC7	Please see the L2 formulation	
		L15 product – mSPC8	242 cP at 20°C 244 cP at 40°C	
		L16 product – mSPC8	1033 cP at 20°C 1528 cP at 40°C	
		L21 product – mSPC9	<10 cP at 20°C <10 cP at 40°C	
		L22 product – mSPC9	<10 cP at 20°C <10 cP at 40°C	
		L25 product – mSPC10	15 cP at 20°C <10 cP at 40°C	
		L26 product – mSPC11	<10 cP at 20°C 13 cP at 40°C	
		L29 product – mSPC12	<10 cP at 20°C <10 cP at 40°C	
		L31 product – mSPC13	44 cP at 20°C 30 cP at 40°C	
		L32 product – mSPC13	31 cP at 20°C <10 cP at 40°C	
		L34 product – mSPC14	11 cP at 20°C <10 cP at 40°C	
		L33 product – mSPC15	<10 cP at 20°C <10 cP at 40°C	

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

The BPF is composed by 15 meta-SPCs, with all products ready-to-use or concentrate-to-dilute liquids, except the meta-SPC 7, containing impregnated wipes.

Meta – SPCs 1 and 8 are viscous liquids, the rest of meta-SPCs contains colourless to coloured clear liquids. The pH of the products of the BPF is in the range -0.14 to 4.45. The relative density of the products is in the range 1.0044 to 1.1772.

The accelerated storage tests (54°C at 2 weeks and 40°C, 75% RH at 8 weeks) and tests in cold conditions (5°C at 8 weeks, 0°C at 1 week and freeze thaw stability) show that all products are stable concerning their content in a.s., as well as important properties. For the meta-SPC 7, it is to be indicated: "do not store at temperatures below 0°C" and "store below 40°C". The long term storage tests are still ongoing, but the first intermediate results (at least for 12 months for all of the products, going up to final 36 months for some of them) also show a good stability. In conclusion, 2 years of shelf life could be granted, pending a submission of long term storage results as soon as available. This proposal is supported based on the accelerated storage tests. It should be made clear if the long term storage tests at 24 (36) months fail to demonstrate stability of the products at 24 (36) months, the shelf life will be decreased to the last acceptable shelf life regarding the variation of active substance."

Persistent foaming tests on products to be used diluted (meta-SPC 3, 4, 5, 11, 13 and 14) show a volume exceeding 60 ml. However, for the use of the products, PPE are needed and they cover the risk brought by the excessive foaming. The dilution stability of the products to be diluted is shown to be acceptable. The surface tension is between 20.96 mN/m and 34.27 mN/m for the highest in use concentrations of products. The viscosity is in the range < 10 cP and 1033 cP at 20 °C and very similar at 40 °C.

### 2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Explosives	Waived	The explosivity hazard is waived based on structural considerations. For more details, please see the extended waiver in the confidential annex.		
Flammable gases	Waived	Not relevant for the formulation type of the BPF products		
Flammable aerosols	Waived	Not relevant for the formulation type of the BPF products		
Oxidising gases	Waived	Not relevant for the formulation type of the BPF products		
Gases under pressure	Waived	Not relevant for the formulation type of the BPF products		
Flammable liquids	Abel closed cup method IP 170  Tested on mixtures containing █████ and isopropanol (considered as worst case for the BPF regarding this hazard)  For sustained combustibility, test performed in accordance with the Recommendations on the Transport of Dangerous Goods (Manual of Tests and Criteria, test L.2).	L1 product - mSPC1: Kenosan Hand Scrub  L7 product - mSPC5: Kenopure  L16 product - mSPC8  L22 product - mSPC9	Flash point > 75°C → <b>no classification</b>  Flash point > 75°C → <b>no classification</b>  Flash point > 75°C → <b>no classification</b>  Flash point = 56°C Sustained combustibility test: no combustion up to and including 75°C → <b>no classification</b> as flam. Liq. According to the Annex I: 2.6.4.5.: <i>Liquids with a flash point of more than 35 °C and not more than 60 °C need not be classified in Category 3 if negative results</i>	Ref. 36  Ref. 37  Ref. 38  Ref. 39 Ref. 52

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		L25 product – mSPC10: Kenocool	<i>have been obtained in the sustained combustibility test L.2, Part III, section 32 of the UN RTDG, Manual of Tests and Criteria.</i> Flash point = 29°C → <b>Flam liq 3</b>	Ref. 40
		L26 product – mSPC11: Kenosan Lactic	Flash point = 52°C Sustained combustibility test: no combustion up to and including 75°C → <b>no classification</b> as flam. Liq.	Ref. 41 Ref. 53
		L33 product – mSPC15: Kenosan Hand Rub	Flash point = 52.5°C Sustained combustibility test: no combustion up to and including 75°C → <b>no classification</b> as flam. Liq.	Ref. 42 Ref. 52
Flammable solids	Waived	Not relevant for the formulation type of the BPF products		
Self-reactive substances and mixtures	Waived	The self-reactivity hazard is waived based on structural considerations. For more details, please see the extended waiver in the confidential annex.		
Pyrophoric liquids	Waived	Due to high water content and known experience none of the formulations of the biocidal product family is expected to have pyrophoric properties.		
Pyrophoric solids	Waived	Not relevant for the formulation type of the BPF products		





Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		0.55% weight loss	1.13% weight loss	
3	L5	No 0.87% weight loss	No 1.18% weight loss	No
4	L6	No 1.20% weight loss	No 3.39% weight loss	No
5	L7	No 1.34% weight loss	No 2.35% weight loss	No
	L8	No 1.00% weight loss	No 2.76% weight loss	No
6	L36	No 0.72% weight loss	No 2.50% weight loss	No
8	L15	No 0.32% weight loss	No 1.95% weight loss	No
	L16	No 0.25% weight loss	No 2.72% weight loss	No
9	L21	No 0.74% weight loss	No 1.03% weight loss	No
	L22	No 1.00% weight loss	No 2.85% weight loss	No
10	L25	No 0.51% weight loss	No 1.19% weight loss	No
11	L26	No 0.96% weight loss	No 1.92% weight loss	No
12	L29	No 7.36% weight loss	Yes 16.10% weight loss	No
13	L28	No 0.11% weight loss	Yes 100% weight loss	No
	L32	No 7.62% weight loss	Yes 21.36% weight loss	Yes
14	L34	No 1.16% weight loss	No 2.55% weight loss	No
15	L33	No	No	No

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		0.76% weight loss	3.77% weight loss	
	Meta-SPCs 12 and 13 are considered as metal corrosive as > 13.5% mass loss (corresponding to the criterion of 6.25 mm/year) is observed after 7 days exposure..			
Auto-ignition temperatures of products (liquids and gases)	Waived	A study addressing the auto ignition temperature for the products of the BPF is not available. This end-point is waived based on the composition of different meta-SPCs and the flammability of different formulations. Moreover, the applicant has performed a screening of each ingredient regarding the auto-ignition temperature. More detailed information can be found in the confidential annex.		
Relative self-ignition temperature for solids	Waived	Not relevant for the formulation type of the BPF products		
Dust explosion hazard	Waived	Not relevant for the formulation type of the BPF products		

### Conclusion on the physical hazards and respective characteristics of the product

The products from the meta-SPCs 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 14, 15 do not present any physical hazards.  
The products from the following meta-SPCs should be classified for the corresponding physical hazard::

m-SPC10: Flam. Liq. 3,  
m-SPC12: Corr. to metals 1  
m-SPC13: Corr. to metals 1

## 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									
Meta-SPCs 1, 6, 7, 15									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
<i>Lactic acid</i>	HPLC - UV	3 fortification ranges with triplicates  (Conc. Lactic acid = 0.8%; 5%; 10%)	0.8 % to 10% w/w lactic acid concentration  5 calibration solutions  $R^2 = 1$	At the retention time of lactic acid there was no peak (or a small peak observed with an area that can be neglected at sample level)	For 0.8%: 96 to 102  For 5%: 99 to 101  For 10%: 99 to 101	For 0.8%: 100  For 5%: 101  For 10%: 100	For 0.8%: 3.15  For 5%: 0.73  For 10%: 0.58	-	Ref. 44

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Meta-SPCs 2, 3									
Analyte (type of analyte e.g. active)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		

substance)									
<i>Lactic acid</i>	HPLC - UV	3 fortification ranges with triplicates  (Conc. Lactic acid = 0.8%; 5%; 10%)	0.8 % to 10% w/w lactic acid concentration  5 calibration solutions  $R^2 = 1$	At the retention time of lactic acid there was no peak (or a small peak observed with an area that can be neglected at sample level)	For 0.8%: 96 to 101  For 5%: 99 to 101  For 10%: 98 to 101	For 0.8%: 99  For 5%:100  For 10%:99	For 0.8%: 2.21  For 5%: 0.67  For 10%: 1.13	-	Ref. 45

**Analytical methods for the analysis of the product as such including the active substance, impurities and residues**

**Meta-SPCs 4, 12, 13**

Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
<i>Lactic acid</i>	HPLC - UV	3 fortification ranges with triplicates  (Conc. Lactic acid = 0.8%; 5%; 10%)	0.8 % to 10% w/w lactic acid concentration  5 calibration solutions	At the retention time of lactic acid there was no peak (or a small peak	For 0.8%: 99 to 102  For 5%: 99 to 101  For 10%:	For 0.8%: 100  For 5%:100	For 0.8%: 1.22  For 5%: 0.96	-	Ref. 46

			$R^2 = 1$	observed with an area that can be neglected at sample level)	99 to 100	For 10%:99	For 10%: 0.88		
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**Analytical methods for the analysis of the product as such including the active substance, impurities and residues  
Meta-SPCs 5, 8, 9**

Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
<i>Lactic acid</i>	HPLC - UV	3 fortification ranges with triplicates  (Conc. Lactic acid = 0.8%; 5%; 10%)	0.8 % to 10% w/w lactic acid concentration  5 calibration solutions  $R^2 = 1$	At the retention time of lactic acid there was no peak (or a small peak observed with an area that can be neglected at sample level)	For 0.8%: 100 to 104  For 5%: 99 to 103  For 10%: 98 to 102	For 0.8%: 102  For 5%:102  For 10%:101	For 0.8%: 1.83  For 5%: 1.86  For 10%: 1.93	-	Ref. 47

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Meta-SPCs 10, 11, 14									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
<i>Lactic acid</i>	HPLC - UV	3 fortification ranges with triplicates  (Conc. Lactic acid = 0.8%; 5%; 10%)	0.8 % to 10% w/w lactic acid concentration  5 calibration solutions  $R^2 = 1$	At the retention time of lactic acid there was no peak (or a small peak observed with an area that can be neglected at sample level)	For 0.8%: 97 to 101  For 5%: 99 to 100  For 10%: 98 to 100	For 0.8%: 98  For 5%: 99  For 10%:99	For 0.8%: 1.33  For 5%: 0.8  For 10%: 0.80	-	Ref. 48

The HPLC-UV instrument parameters are the following:

- Pressure limit: Min = 0 bar; Max = 320 bar
- Isocratic, Flow 1.5mL/min
- Injection volume: 5  $\mu$ L
- Column oven temperature: 40°C
- Wavelength: 210nm

In order to enclose different values of the lactic acid concentrations, placebos C, D, E are first diluted 10 times, and then another dilution factor is applied in order to reach the range where the method is linear. Typically these dilution factors are 25, 10, 4, 3 and 2 times.

The precision has been tested in terms of repeatability and intermediate precision in all 5 test reports. For all of these reports the relative standard deviations obtained on three different levels comply to the modified Horwitz equation and relative standard deviations obtained on three different levels comply to the unmodified Horwitz equation.

The BPF contains 8 SoCs identified below:

- Sodium Lauryl Sulphate
- Sodium Lauryl Ether Sulfate
- Sulfonic acids, C14-17-sec-alkane, sodium salts
- C6 alkyl glucoside
- Isopropanol
- Methanesulfonic acid
- Sulphuric acid
- Butyldiglycol

The applicant has not submitted any validated method for detection of the SoCs. The waiver is the following: *"We did not provide a validated method of analysis for the substances of concern as the family does not contain substances of concern that may be formed upon storage of the biocidal product (cfr. Guidance on the BPR Volume I parts A+B+C version 2.0, May 2018).*

*As the substances of concern are not formed upon storage, the substances of concern will never exceed the percentage at which calculations were done for risk assessment.*

*Moreover the substances of concern have no influence on the efficacy of the products and as they are not formed upon storage, monitoring of the substances of concern during stability is not required.*

*As there are no relevant impurities, also no data was provided here."*

This argumentation is also in line with the TAB from February 2020:

*"Analytical methods for the determination of substances of concern present in biocidal products is an information requirement according to Annex III Title 1 to the BPR and has to be addressed when submitting an application of product authorisation. The following considerations should be addressed:*

*- analytical methods are not required for SoC that cannot be formed during storage and their concentration remains unchanged;*

*- analytical methods are required for SoC that are formed during storage or the concentration(s) of known SoC is/are increased during storage;*

*- explanations should be provided in cases where the formation of SoC is not expected during storage."*

However, this TAB entry not applicable for this dossier, since it has been submitted in April 2019.

If we have a deeper view on the SoCs, we can see that the most of the SoCs are Band A or B , except isopropanol and butyldiglycol. For Band A or B SoCs, only qualitative risk assessment is performed, and therefore BE eCA has accepted a non-submission of a method.



For the Band C SoCs: isopropanol and butyldiglycol, the precise concentration is used in the risk assessment. Therefore it is important to be able to detect correctly the content of the substances. It is why the eCA disagrees with the waiver. The applicant has provided the following validated analytical methods for the SoCs isopropanol and butyldiglycol.

Analytical methods for the analysis of the SoCs									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantificati on (LOQ) or other limits	Referen ce
					Range	Mean	RSD		
<i>Isopropanol (in meta-SPCs 1, 8, 9 formulations)</i>	GC-FID	3 fortification ranges with triplicates	1 % to 10% w/w  5 calibration solutions  R <sup>2</sup> = 1	To demonstrate the specificity of the method a placebo of the mSPC's were analyzed. A very small peak was observed. This peak is a fraction of the lowest standard area and can thus be neglected.	For 1%: 96 to 101  For 5%: 98 to 104  For 10%: 98 to 102	For 1%: 99  For 5%: 102  For 10%: 101	For 1%: 2.22  For 5%: 3.53  For 10%: 0.99	-	Ref. 55
<i>Isopropanol (in meta-SPCs 11 formulation)</i>	GC-FID	3 fortification ranges with triplicates	1 % to 10% w/w  5 calibration solutions  R <sup>2</sup> = 1	To demonstrate the specificity of the method a placebo of the mSPC's were analyzed. A very small peak was observed. This peak is a fraction of the lowest standard area and can thus be neglected.	For 1%: 97 to 98  For 5%: 96 to 102  For 10%: 97 to 105	For 1%: 98  For 5%: 99  For 10%: 102	For 1%: 0.27  For 5%: 3.20  For 10%: 2.58	-	Ref. 55

<i>Isopropanol (in meta-SPCs 15 formulation)</i>	GC-FID	3 fortification ranges with triplicates	1 % to 10% w/w  5 calibration solutions  $R^2 = 1$	To demonstrate the specificity of the method a placebo of the mSPC's were analyzed. A very small peak was observed. This peak is a fraction of the lowest standard area and can thus be neglected.	For 1%: 97 to 102  For 5%: 101 to 106  For 10%: 99 to 104	For 1%: 100  For 5%: 104  For 10%: 103	For 1%: 2.11  For 5%: 2.32  For 10%: 0.44	-	Ref. 55
<i>Butyldiglycol (in meta- SPC15 formulation)</i>	GC-FID	3 fortification ranges with triplicates	4% w/w to 40% w/w  5 calibration solutions  $R^2 = 1$	To demonstrate the specificity of the method a placebo of mSPC 15 was analyzed. A very small peak was observed. This peak is a fraction of the lowest standard area and can thus be neglected.	For 4%: 100 to 104  For 20%: 102 to 104  For 40%: 101 to 104	For 4%: 103  For 20%: 103  For 40%:102	For 4%: 1.17  For 20%: 0.96  For 40%: 0.72	-	Ref. 54

According to the CAR of the active substance, relevant residues in food of plant and animal origin and in the environmental compartments arising from the application of L(+) lactic acid are not expected. Therefore, residue analytical methods for L(+) lactic acid in food of plant and animal origin, in soil, air, drinking and surface water are not required. Since L(+) lactic acid is not classified as toxic or very toxic, analytical methods in body fluids and tissues are not required.

**Conclusion on the methods for detection and identification of the product**

The validated method is HPLC-UV. The validation of the method was performed on three fortifications with triplicates. The method is accurate, precise and specific for the determination of lactic acid. The mean recovery is between 98 and 99%.

The applicant has also provided validated methods for SoCs: butyldiglycol and isopropanol. Both methods are accurate, precise and specific.

## 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 :

- PT1 (Human hygiene)
- PT2 (*Disinfectants and algacides not intended for direct applications to humans or animals*)
- PT3 (*Veterinary Hygiene*)
- PT4 (*Food & feed Area*)

The biocidal products within the **FAMILY** contain L-(+)-lactic acid as active substance.

The **FAMILY** is divided into 15 Meta SPCs.

According to the product and the intended uses, the following main use procedures are Considered :

#### Meta SPC 1

Use 1.1: Hygienic handwash for professional use (PT1)

Use 1.2: Hygienic handwash for non-professional use (PT1)

#### Meta SPC 2

Use 2.1: Ready to use algicide, for professional use (PT2)

Use 2.2: Ready to use algicide, for non-professional use (PT2)

#### Meta SPC 3

Use 3.1: Concentrated algicide (PT2)

Use 3.2: Disinfection of hard/non-porous surfaces in the food industry (e.g. processing machines)

#### Meta SPC 4

Use 4.1: Hard surface disinfection for sanitary hygiene, other than in healthcare, for professional use (PT2)

Use 4.2: Hard surface disinfection for sanitary hygiene, other than in healthcare, for non-professional use (PT2)

Use 4.3: Hard surface disinfection, for professional use (PT4)

Use 4.4: Hard surface disinfection, for non-professional use (PT4)

Use 4.5: Disinfection of toilet bowls, for professional use (PT2)

Use 4.6: Disinfection of toilet bowls, for non-professional use (PT2)

#### Meta SPC 5

Use 5.1: Teat disinfection before milking (PT3)

Use 5.2: Intact skin disinfection (PT3)

#### Meta SPC 6

Use 6.1: Teat disinfection before milking (PT3)

#### Meta SPC 7

Use 7.1 – Hard surface disinfection in Food and Feed industry, for professional use (PT4)

Use 7.2 – Hard surface disinfection in food and feed area, for non-professional use (PT4)

Use 7.3 – Hard surface disinfection, use in healthcare, for professional use (PT2)

Use 7.4 – Hard surface disinfection, use in healthcare, for non-professional use (PT2)

Use 7.5 – Hard surface disinfection, use other than in healthcare, for professional use (PT2)

Use 7.6 – Hard surface disinfection, use other than in healthcare, for non-professional use (PT2)

#### Meta SPC 8

Use 8.1: Teat disinfection after milking by dipping (PT3)

#### Meta SPC 9

Use 9.1: Teat disinfection after milking by spraying & dipping (PT3)

#### Meta SPC 10

Use 10.1: Teat disinfection after milking by spraying or dipping (PT3)

#### Meta SPC 11

Use 11.1: Hard surface disinfection in Food and feed industry (PT4)

Use 11.2: Disinfection of hard/non-porous surfaces in the food industry (e.g. processing machines)

Use 11.3: Hard surface disinfection for veterinary hygiene (PT3)

#### Meta SPC 12

Use 12.1: Inner surface disinfection by CIP with circulation (PT4)

Use 12.2: Inner surface disinfection by CIP without circulation (PT4)

Use 12.3: Crate wash (PT4)

#### Meta SPC 13

Use 13.1: Hard surface disinfection in Food and feed industry (PT4)

#### Meta SPC 14

Use 14.1: Coronary band disinfection (PT3)

#### Meta SPC 15

Use 15.1: Hygienic handrub, for professional use (PT1)

Use 15.2: Hygienic handrub, for non-professional use (PT1)

The biocidal products within the **FAMILY** are intended to be used by professional or non-professional users and are presented as :

- Liquid concentrates that need to be diluted with tap water
- Liquid RTU
- RTU pre-saturated wipes

Target organisms may include bacteria, yeasts (as mandatory target organisms), viruses and algae, relevant to the products' areas of use and in-use conditions.

All the product of the **FAMILY** are intended to be used to control microorganisms responsible for infectious diseases and to avoid contamination of food/feed (PT4 applications).

For PT1 & PT2 applications, the "organisms to be protected" is human beings. For PT4 applications, the "organisms to be protected" are human beings and animals. For PT3

applications, the "organisms to be protected" are first animals and second human beings as animal consumers.

#### 2.2.5.2 Mode of action, including time delay

##### Information from the L-(+)-Lactic acid CAR:

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.

#### 2.2.5.3 Efficacy data

Efficacy tests performed according to suspension and surface standards have been submitted

##### ➤ **Potential active substances**

An overview of the potential actives is presented in section 3.3.6 of the confidential annex. Most of the co-formulants used in the formulations of the products are not in the Review Program.

However, for clarity purposes, the Applicant provided many efficacy tests to prove that the co-formulants have no impact on the efficacy of the products.

**CONCLUSION** : According to the results of the efficacy tests presented in section 3.3.6 of the confidential annex, none of the co-formulants have an impact on the efficacy of the formulations

## 2.2.5.4 Efficacy data

➤ **Efficacy of the products for each Meta-SPC :**

<b>Meta SPC-1 (3.60% LA)</b>				
<b>Experimental data on the efficacy of the biocidal product against target organisms</b>				
<b>Field of use envisaged</b>	<b>PT1</b>	Use #1 : Hygienic Handwash – <i>PROF (but not for medical uses)</i> Use #2 : Hygienic Handwash ( <i>but not for medical uses</i> )		
<b>Test product</b>	<b>Function &amp; Test organism(s)</b>	<b>Test method / Test system / concentrations applied / exposure time</b>	<b>Test results : effects</b>	<b>Reference &amp; R.I.</b>
<b>MetaSPC1 (L1) with 3.7% Lactic Acid</b>  Batch N°5119090005 (Doc. "Certificate of analysis L1 MetaSPC 1")	<b>Bactericidal activity</b>  <i>Enterococcus hirae</i> <i>E.coli</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i>	<b>EN 1276 (2010)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 1 min</li> <li>• Concentrations tested : 5 – 40 – 80%</li> <li>• I.S. : 3g/L BSA (dirty conditions)</li> </ul>	Bactericidal activity at 40% in 1 min at +20°C in dirty conditions.	Doc. "RP_2019-04-007_metaSPC1_L1_EN1276_20°C_1min_dirty_v2"  <b>R.I. 1 Key study</b>
<b>MetaSPC1 (L1) with 3.7% Lactic Acid</b>  Batch N°5119090005 (Doc.	<b>Yeasticidal activity</b>  <i>Candida albicans</i>	<b>EN 1650 (2013)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 1 min</li> <li>• Concentrations tested : 80%</li> <li>• I.S. : 3g/L BSA (dirty conditions)</li> </ul>	Yeasticidal activity at 80% in 1 min at +20°C in dirty conditions.	Doc. « RP_2019-03-053_metaSPC1_L1_EN1650_1min_20°C_dirty »  <b>R.I. 1 Key study</b>



"Certificate of analysis L1 MetaSPC 1")				
<b>MetaSPC1 (L1) with 3.58% Lactic Acid</b>  Batch N°5119150001 (Doc. "Certificate of analysis L1 MetaSPC 1.2")	<i>E. coli</i> K12	<b>EN 1499 (2013)</b>  <ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 1 min</li> <li>• Concentrations tested : 100% - 10 mL</li> </ul>	The test-product is in compliance with the current requirements of the EN 1499 standard => This product, intended to be used as a hygienic handwash, allows the reduction of "transient microbial flora" (bacterial organisms) on hands when used undiluted with 10 mL & water at RT in 1 min.	Doc. « STULV19AA2681-1_AAE21505_v1.000_Report_EN1499_metaSPC1_10ml_1 min »  <b>R.I. 1 Key study</b>

<b>META-SPC 1 (representative product with 3.60% LA) : Summary of the test results validated after evaluation</b>	
<b>EN 1276</b>	40% - 1 min - +20°C - DIRTY
<b>EN 1650</b>	80% - 1 min - +20°C - DIRTY (Y only)
<b>EN 1499</b>	RTU with 10 mL & water at RT in 1 min

Meta SPC1 - EFF CONCLUSIONS	
<b>PT1</b>	<p><b>Use #1.1</b> : Hygienic Handwash – <i>PROF (not for medical uses)</i></p> <p><b>Use #1.2</b> : Hygienic Handwash (<i>not for medical uses</i>)</p> <p>This RTU product (3.6% LA), intended to be used as a hygienic handwash, allows the reduction of "transient bacteria flora" on hands when used undiluted with 10 mL (i.e. 4 pushes for both hands together <u>or</u>, if applicable, adjustment of the dosing device to 10 mL per application) &amp; water at RT in 1 min wash.</p>

Meta SPC-2 (RTU formulations) (2% LA)				
Experimental data on the efficacy of the biocidal product against target organisms				
Field of use envisaged	PT2	Use #2.1 : RTU algicide – PROF Use #2.2 : RTU algicide		
Test product	Function & Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results : effects	Reference & R.I.
<b>MetaSPC3 (L5) with 68.7% Lactic Acid</b>  Batch N°5119030005 (Doc. "Certificate of analysis L5 MetaSPC 3")	<b>Bactericidal activity</b> <i>Enterococcus hirae</i> <i>E.coli</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i>  <i>Enterococcus faecium</i>	<b>EN 1276 (2010)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature/contact time : +20 ± 1°C in 60 min</li> <li>• Concentrations tested : 1 – 1.5 – 2 – 3 – 4%</li> <li>• I.S. : 3g/L BSA (dirty conditions)</li> </ul>	Bactericidal activity at 2% in 60 min at +20°C in dirty conditions.	Doc. "RP_2019-04-008_metaSPC3_EN1276_20°C_60min_dirty"  <b>R.I. 1 Key study</b>
<b>MetaSPC3 (L5) with 68.7% Lactic Acid</b>  Batch N°5119030005 (Doc. "Certificate of analysis L5 MetaSPC 3")	<b>Yeasticidal activity</b> <i>Candida albicans</i>	<b>EN 1650 (2013)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature/contact time : +20 ± 1°C in 60 min</li> <li>• Concentrations tested : 1 – 1.5 – 2 – 3 – 4%</li> <li>• I.S. : 3g/L BSA (dirty conditions)</li> </ul>	Yeasticidal activity at 2.5% in 60 min at +20°C in dirty conditions.	Doc. « RP_2019-04-013_metaSPC3_EN1650_20°C_60min_dirty»  <b>R.I. 1 Key study</b>
<b>MetaSPC3 (L5)</b>	<b>Bactericidal activity + Yeasticidal activity</b>	<b>EN 13697 (2015)</b> Quantitative carrier test – hard & non-porous surfaces	Bactericidal & yeasticidal activity	Doc. "RP_2019-04-039_metaSPC3_EN13697_18-25°C_60min_dirty"

<p><b>with 68.7% Lactic Acid</b></p> <p>Batch N°5119030005 (Doc. "Certificate of analysis L5 MetaSPC 3")</p>	<p><i>Enterococcus hirae</i> <i>E.coli</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Candida albicans</i></p> <p><i>Enterococcus faecium</i> <i>Candida albicans</i></p>	<ul style="list-style-type: none"> <li>• Temperature/contact time : +20 ± 1°C in 60 min</li> <li>• Concentrations tested : 1 - 1.5 - 2 - 3 - 4%</li> <li>I.S. : 3g/L BSA (dirty conditions)</li> <li>•</li> </ul>	<p>at 2.5% in 60 min at +20°C on hard/non-porous surfaces without prior cleaning.</p>	<p><b>R.I. 1</b> <b>Key study</b></p>
<p><b>MetaSPC3 (L5) with 68.7% Lactic Acid</b></p> <p>Batch N°5119030005 (Doc. "Certificate of analysis L5 MetaSPC 3")</p>	<p><b>Algaecidal activity</b> <i>Chlorella vulgaris</i> <i>Anabaena flos-aquae</i></p> <p>One species from each group (green algae and cyanobacteria) was tested to demonstrate the algaecidal efficacy of products : The APP have chosen these strains based on the expertise of Eurofins, since the guidance doesn't describe which strains to test and since there is no clear requirements/protocols for demonstrating the algicidal efficacy in main group 1. Arguments accepted by the Eff-WG members.</p>	<p><b>EN 1276 (2010) modified</b> Quantitative suspension test</p> <ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 3 hours</li> <li>• Concentrations tested : 0.5 - 2 - 2.9%</li> <li>• I.S. : 3g/L BSA (dirty conditions)</li> </ul>	<p>Log ↓ &gt; 99.29 % at 0.5% in 3h (2 replicates).</p> <p>Algaecidal activity at 0.5% in 3h at +20°C on hard/non-porous surfaces without prior cleaning.</p>	<p>Doc. "EVALUATION OF ALGAECIDAL ACTIVITY DIRTY Meta 3"</p> <p><b>R.I. 1</b> <b>Key study</b></p>
<p><b>MetaSPC3 (L5)</b></p>	<p><b>Algaecidal activity</b> <i>Chlorella vulgaris</i> <i>Anabaena flos-aquae</i></p>	<p><b>EN 13697 (2015) adapted</b> Quantitative carrier test – hard &amp; non-porous surfaces</p>	<p>Log ↓ &gt; 99.29 % at 0.5% in 3h (2 replicates).</p>	<p>Doc. "STULV19AA2682-1_AAE14729_v1.000" &amp;</p>

<p><b>with 68.7% Lactic Acid</b></p> <p>Batch N°5119030005 (Doc. "Certificate of analysis L5 MetaSPC 3")</p>	<p>One species from each group (green algae and cyanobacteria) was tested to demonstrate the algaecidal efficacy of products : The APP have chosen these strains based on the expertise of Eurofins, since the guidance doesn't describe which strains to test and since there is no clear requirements/protocols for demonstrating the algicidal efficacy in main group 1. Arguments accepted by the Eff-WG members.</p>	<ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 3 hours</li> <li>• Concentrations tested : 0.5 - 2 - 2.9%</li> </ul> <p>I.S. : 3g/L BSA (dirty conditions)</p>	<p>Algaecidal activity at 0.5% in 3h at +20°C on hard/non-porous surfaces without prior cleaning.</p>	<p>"STULV19AA2684-1_AAE33446_v1.000"</p> <p><b>R.I. 1</b></p> <p><b>Key study</b></p>
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<b>META-SPC 2 (representative product with 2% LA) : Summary of the test results validated after evaluation</b>	
<b>EN 1276</b>	2% (with product at 70% LA) ⇔ 1.4% LA - 60 min - +20°C - DIRTY On algae only : 0.5% (⇔ 0.35 % Lactic Acid) - 3h - +20°C - DIRTY
<b>EN 13697 – B + Y</b>	B+Y : 2.5% (⇔ 1.75 % Lactic Acid) - 60 min - +20°C - DIRTY
<b>EN 1650 – Yeasts only</b>	2.5% (with product at 70% LA) ⇔ 1.75% LA - 60 min - +20°C - DIRTY
<b>EN 13697 On ALGAE only</b>	0.5% (⇔ 0.35 % Lactic Acid) - 3h - +20°C - DIRTY
<b>EN 1276</b>	2% (with product at 70% LA) ⇔ 1.4% LA - 60 min - +20°C - DIRTY On algae only : 0.5% (⇔ 0.35 % Lactic Acid) - 3h - +20°C - DIRTY
<b>EN 13697 – B + Y</b>	B+Y : 2.5% (⇔ 1.75 % Lactic Acid) - 60 min - +20°C - DIRTY

**Meta SPC2 - EFF CONCLUSIONS****PT2**

**Use #2.1** : RTU algicide – *PROF*

**Use #2.2** : RTU algicide

Active against unicellular green algae and blue-green algae (cyanobacteria) : with RTU product (2% LA) at +20-25°C (indoor/outdoor) in 3h contact time on hard/non-porous surfaces without previous cleaning

By spraying or pouring: be sure to wet surfaces completely. The required contact time has to be respected until further treatments (e.g. brushing the surfaces).

<b>Meta SPC-3 (concentrated formulations) (70% LA)</b>				
<b>Experimental data on the efficacy of the biocidal product against target organisms</b>				
<b>Field of use envisaged</b>		<b>PT2</b>	Use #1 : concentrated algicide	
		<b>PT4</b>	Use #2 : disinfection of hard/non-porous surfaces in the food industry (e.g. processing machines)	
<b>Test product</b>	<b>Function &amp; Test organism(s)</b>	<b>Test method / Test system / concentrations applied / exposure time</b>	<b>Test results : effects</b>	<b>Reference &amp; R.I.</b>
<b>MetaSPC3 (L5) with 68.7% Lactic Acid</b>  Batch N°5119030005 (Doc. "Certificate of analysis L5 MetaSPC 3")	<b>Bactericidal activity</b> <i>Enterococcus hirae</i> <i>E.coli</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i>  <i>Enterococcus faecium</i>	<b>EN 1276 (2010)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature/contact time : +20 ± 1°C in 60 min +40 ± 1°C in 5 sec.</li> <li>• Concentrations tested : 1 - 1.5 - 2 - 3 - 4%</li> <li>• I.S. : 3g/L BSA (dirty conditions)</li> </ul>	Bactericidal activity at 2% in 60 min at +20°C in dirty conditions.  Active against <i>Enterococcus faecium</i> at 4% in 5 sec. at +40°C in dirty conditions.	Doc. "RP_2019-04-008_metaSPC3_EN1276_20°C_60min_dirty"  Doc. "RP_2019-04-008_metaSPC3_EN1276_20°C_60min_dirty"  <p style="text-align: center;"><b>R.I. 1 Key study</b></p>
<b>MetaSPC3 (L5) with 68.7% Lactic Acid</b>  Batch N°5119030005 (Doc. "Certificate of analysis L5 MetaSPC 3")	<b>Yeasticidal activity</b> <i>Candida albicans</i>	<b>EN 1650 (2013)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature/contact time : +20 ± 1°C in 60 min +40 ± 1°C in 5 sec.</li> <li>• Concentrations tested : 1 - 1.5 - 2 - 3 - 4%</li> <li>• I.S. : 3g/L BSA (dirty conditions)</li> </ul>	Yeasticidal activity at 2.5% in 60 min at +20°C in dirty conditions.  Yeasticidal activity at 4% in 5 sec. at +40°C in dirty conditions.	Doc. « RP_2019-04-013_metaSPC3_EN1650_20°C_60min_dirty»  <p style="text-align: center;"><b>R.I. 1 Key study</b></p>
<b>MetaSPC3 (L5) with 68.7% Lactic Acid</b>	<b>Bactericidal activity + Yeasticidal activity</b>  <i>Enterococcus hirae</i>	<b>EN 13697 (2015)</b> Quantitative carrier test – hard & non-porous surfaces	Bactericidal & yeasticidal activity at 2.5% in 60 min at +20°C on hard/non-porous surfaces without prior cleaning.	Doc. "RP_2019-04-039_metaSPC3_EN13697_18-25°C_60min_dirty"

<p>Batch N°5119030005 (Doc. "Certificate of analysis L5 MetaSPC 3")</p>	<p><i>E.coli</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Candida albicans</i>  <i>Enterococcus faecium</i> <i>Candida albicans</i></p>	<ul style="list-style-type: none"> <li>• Temperature/contact time : +20 ± 1°C in 60 min +40 ± 1°C in 5 sec.</li> <li>• Concentrations tested : 1 - 1.5 - 2 - 3 - 4%</li> <li>• I.S. : 3g/L BSA (dirty conditions)</li> </ul>	<p>Active against <i>Enterococcus faecium</i> at 4% in 5 sec. at +40°C on hard/non-porous surfaces without prior cleaning. Yeasticidal activity at 4% in 5 sec. at +40°C on hard/non-porous surfaces without prior cleaning.</p>	<p>Doc. RP_2019-08-154_metaSPC3_L5_EN13697_40°C_5sec_dirty</p> <p><b>R.I. 1 Key study</b></p>
<p><b>MetaSPC3 (L5) with 68.7% Lactic Acid</b></p> <p>Batch N°5119030005 (Doc. "Certificate of analysis L5 MetaSPC 3")</p>	<p><b>Field trial – Comparative tests*</b> <b>On carcass saw/splitter</b></p> <ul style="list-style-type: none"> <li>- Water at ≥ +82°C</li> <li>- LA solution – 4% (via automatic dosage) at +40°C in 5 sec. – by spraying</li> </ul> <p>With total aerobic bacterial load used to validate the efficacy of the tested product. Samples taken on at least 3 different days per week, during 2 weeks in 2 different (pork or cattle) slaughterhouses.</p> <p>* According to Reg. EU 853/2004, slaughterhouses should have the required installation to disinfect tools with hot water at least at +82°C or an alternative system with a similar effect.</p>		<p>Log ↓ with LA solution = 97.73 % Log ↓ with +82°C water = 96.88 %</p> <p>The test-product is in compliance with the current requirements of the Reg. EU 853/2004 =&gt; The LA product, when used at 4% (water at +40°C) in 5 sec., has an equivalent effect as +82°C water to be used as an alternative to disinfect dirty slaughterhouse tools <u>by spraying/soaking</u>.</p>	<p>Doc. « FDLDR201908123 - LA MSPC 3 F L5»</p> <p><b>R.I. 1 Key study</b></p>
<p><b>MetaSPC3 (L5) with 68.7% Lactic Acid</b></p> <p>Batch N°5119030005 (Doc. "Certificate of analysis L5 MetaSPC 3")</p>	<p><b>Algaecidal activity</b> <i>Chlorella vulgaris</i> <i>Anabaena flos-aquae</i></p> <p>One species from each group (green algae and cyanobacteria) was tested to demonstrate the algaecidal efficacy of products : The APP have chosen these strains</p>	<p><b>EN 1276 (2010) modified</b> Quantitative suspension test</p> <ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 3 hours</li> <li>• Concentrations tested : 0.5 - 2 - 2.9%</li> <li>• I.S. : 3g/L BSA (dirty conditions)</li> </ul>	<p>Log ↓ &gt; 99.29 % at 0.5% in 3h (2 replicates).</p> <p>Algaecidal activity at 0.5% in 3h at +20°C on hard/non-porous surfaces without prior cleaning.</p>	<p>Doc. "EVALUATION OF ALGAECIDAL ACTIVITY DIRTY Meta 3"</p> <p><b>R.I. 1 Key study</b></p>

	based on the expertise of Eurofins, since the guidance doesn't describe which strains to test and since there is no clear requirements/protocols for demonstrating the algicidal efficacy in main group 1. Arguments accepted by the Eff-WG members.			
<p><b>MetaSPC3 (L5) with 68.7% Lactic Acid</b></p> <p>Batch N°5119030005 (Doc. "Certificate of analysis L5 MetaSPC 3")</p>	<p><b>Algaecidal activity</b> <i>Chlorella vulgaris</i> <i>Anabaena flos-aquae</i></p> <p>One species from each group (green algae and cyanobacteria) was tested to demonstrate the algaecidal efficacy of products : The APP have chosen these strains based on the expertise of Eurofins, since the guidance doesn't describe which strains to test and since there is no clear requirements/protocols for demonstrating the algicidal efficacy in main group 1. Arguments accepted by the Eff-WG members.</p>	<p><b>EN 13697 (2015) adapted</b> Quantitative carrier test – hard &amp; non-porous surfaces</p> <ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 3 hours</li> <li>• Concentrations tested : 0.5 – 2 – 2.9%</li> <li>• I.S. : 3g/L BSA (dirty conditions)</li> </ul>	<p>Log ↓ &gt; 99.29 % at 0.5% in 3h (2 replicates).</p> <p>Algaecidal activity at 0.5% in 3h at +20°C on hard/non-porous surfaces without prior cleaning.</p>	<p>Doc. "STULV19AA2682-1_AAE14729_v1.000" &amp; "STULV19AA2684-1_AAE33446_v1.000"</p> <p><b>R.I. 1 Key study</b></p>



<b>META-SPC 3 (representative product with 68.7% LA) : Summary of the test results validated after evaluation</b>			
<b>EN 1276</b>	2% - 60 min - +20°C - DIRTY	<b>EN 13697</b>	B+Y : 2.5% (⇔ 1.7175 % Lactic Acid) - 60 min - +20°C - DIRTY
	4% - 5 sec. - +40°C - DIRTY		B+Y : 4% - 5 sec. - +40°C - DIRTY
<b>EN 1650</b>	2.5% - 60 min - +20°C - DIRTY	<b>FIELD</b>	Algae : 0.5% (⇔ 0.3435 % Lactic Acid) - 3h - +20°C - DIRTY
	4% - 5 sec. - +40°C - DIRTY		4% - 5 sec. - +40°C - DIRTY

### Meta SPC3 - EFF CONCLUSIONS

#### PT2

**Use #3.1** : concentrated algicide

Active against unicellular green algae and blue-green algae (cyanobacteria) : with 0.5% diluted product (0.3435 % LA) at +20-25°C (indoor/outdoor) in 3h contact time on hard/non-porous surfaces without previous cleaning

By spraying or pouring: be sure to wet surfaces completely. The required contact time has to be respected until further treatments (e.g. brushing the surfaces).

#### PT4

**Use #3.2** : disinfection of hard/non-porous surfaces in the food industry (e.g. processing machines)

B + Y : 4% (2.748 % LA) at +40°C in 5 sec. contact time on hard/non-porous surfaces without previous cleaning (by spraying or soaking)

<b>Meta SPC-4 (16% LA)</b>				
<b>Experimental data on the efficacy of the biocidal product against target organisms</b>				
<b>Field of use envisaged</b>	<b>PT2</b>	Use #1 : Hard surface disinfection for sanitary hygiene - <i>NOT healthcare</i>		
		Use #2 : Hard surface disinfection for sanitary hygiene - <i>NOT healthcare</i>		
		Use #5 : RTU Toilet bowl disinfection - <i>PROF</i>		
		Use #6 : RTU Toilet bowl disinfection		
	<b>PT4</b>	Use #3 : Hard surface disinfection - <i>PROF</i>		
		Use #4 : Hard surface disinfection		
<b>Test product</b>	<b>Function &amp; Test organism(s)</b>	<b>Test method / Test system / concentrations applied / exposure time</b>	<b>Test results : effects</b>	<b>Reference &amp; R.I.</b>
<b>MetaSPC4 (L6)</b> <b>With 15.39%</b> <b>Lactic Acid</b>  Batch N°5119080004 (Doc. "Certificate of analysis L6 MetaSPC 4.2")	<b>Bactericidal activity</b> <i>Enterococcus hirae</i> <i>E.coli</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i>	<b>EN 1276 (2010)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 5 or 15 min</li> <li>• Concentrations tested : 1 - 2.5 - 5 %</li> <li>• I.S. : 3g/L BSA (dirty conditions)</li> </ul>	Bactericidal activity at 5% in 5 or 15 min at +20°C in dirty conditions.	Doc. "RP_2019-02-082_mSPC4_L6_EN1276_20°C_15min_dirty"  Doc. "RP_2019-02-091_mSPC4_L6_EN1276_20°C_5min_dirty"  <p style="text-align: center;"><b>R.I. 1</b> <b>Key study</b></p>
<b>MetaSPC4 (L6)</b> <b>With 15.39%</b> <b>Lactic Acid</b>  Batch N°5119080004 (Doc. "Certificate of analysis L6 MetaSPC 4.2")	<b>Yeasticidal activity</b> <i>Candida albicans</i>	<b>EN 1650 (2013)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 5 or 15 min</li> <li>• Concentrations tested : 1 - 2.5 - 5 - 10 %</li> <li>• I.S. : 3g/L BSA (dirty conditions)</li> </ul>	Yeasticidal activity at 5% in 5 or 15 min at +20°C in dirty conditions.	Doc. "RP_2019-02-090_mSPC4_L6_EN1650_20°C_15min_dirty"  Doc. « RP_2019-03-005_mSPC4_L6_EN1650_20°C_5min_dirty »  <p style="text-align: center;"><b>R.I. 1</b> <b>Key study</b></p>
<b>MetaSPC4 (L6)</b> <b>With 15.39%</b> <b>Lactic Acid</b>	<b>Bactericidal activity + Yeasticidal activity</b> <i>Enterococcus hirae</i>	<b>EN 13697 (2015)</b> Quantitative carrier test – hard & non-porous surfaces	Bactericidal activity	Doc. "RP_2019-02-096_metaSPC4_L6_EN13697_18-25°C_15min_dirty"

<p>Batch N°5119080004 (Doc. "Certificate of analysis L6 MetaSPC 4.2")</p>	<p><i>E.coli</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Candida albicans</i></p>	<ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 5 or 15 min</li> <li>• Concentrations tested : 1 - 5 - 7.5 - 15 - 20 - 30 - 40 - 60 - 70 - 80%</li> <li>• I.S. : 3g/L BSA (dirty conditions)</li> </ul>	<p>at 7.5% in 15 min at +20°C on hard/non-porous surfaces without prior cleaning. Yeasticidal activity at 20% in 15 min at +20°C on hard/non-porous surfaces without prior cleaning.</p> <p>Bactericidal activity at 40% in 5 min at +20°C on hard/non-porous surfaces without prior cleaning. Yeasticidal activity at 80% in 5 min at +20°C on hard/non-porous surfaces without prior cleaning.</p>	<p>Doc. "RP_2019-02-097_metaSPC4_L6_EN13697_18-25°C_5min_dirty"</p> <p><b>R.I. 1</b> <b>Key study</b></p>
<p><b>SANIFRESH - MetaSPC4 (L6) With 15.39% Lactic Acid</b></p> <p>Batch N°5119030004 (Doc. "Certificate of analysis L6 MetaSPC 4")</p>	<p><b>Permanence of the product SANIFRESH on surfaces</b></p>	<p>For the experiment, pure <b>SANIFRESH</b> is poured at room temperature on a toilet bowl surface. The amount of liquid remaining on the surface was determined by taking pictures (after 0 and 25 min).</p>	<p>The products does stay at least 25 min on the surface of the toilet bowl.</p>	<p>Doc. "Toilet test BPF Lactic acid Sanifresh"</p> <p><b>R.I. 1</b> <b>Key study</b></p>

<b>META-SPC 4 (representative product with 16% LA) : Summary of the test results validated after evaluation</b>			
<b>EN 1276</b>	5% - 5 min - +20°C - DIRTY	<b>EN 13697</b>	B+Y : 20% - 15 min - +20°C - DIRTY
	5% - 15 min - +20°C - DIRTY		B+Y : RTU - 5 min - +20°C - DIRTY
<b>EN 1650</b>	5% - 15 min - +20°C - DIRTY		

**Meta SPC4 - EFF CONCLUSIONS****PT2**

**Use #4.1** : Hard surface disinfection for sanitary hygiene – *PROF (not in healthcare areas)*

**Use #4.2** : Hard surface disinfection for sanitary hygiene (*not in healthcare areas*)

**PT4**

**Use #4.3** : Hard surface disinfection for sanitary hygiene – *PROF (not in healthcare areas)*

**Use #4.4** : Hard surface disinfection for sanitary hygiene (*not in healthcare areas*)

B + Y : 20% at +20°C in 15 min contact time on hard/non-porous surfaces wo previous cleaning

By spraying, pouring or brushing : be sure to wet surfaces completely. The required contact time has to be respected until further treatments (e.g. brushing the surfaces).

**PT2**

**Use #4.5** : RTU Toilet bowl disinfection – *PROF*

**Use #4.6** : RTU Toilet bowl disinfection

B + Y : 100% at +20°C in 5 min contact time on hard/non-porous surfaces wo previous cleaning

By pouring - A test (Doc. "BPF LA Toilet Test") was done on the formulation to prove that that vertical surfaces stay wet at least 5 minutes during contact time.

<b>Meta SPC-5 (8% LA)</b>				
<b>Experimental data on the efficacy of the biocidal product against target organisms</b>				
<b>Field of use envisaged</b>				
		<b>PT3</b>	Use #1 : Teat disinfection (pre-milking)	
			Use #2 : Intact skin wash/disinfection (of the udder of dairy and beef cattle before calving and of the udder of sows before farrowing)	
<b>Test product</b>	<b>Function &amp; Test organism(s)</b>	<b>Test method / Test system / concentrations applied / exposure time</b>	<b>Test results : effects</b>	<b>Reference &amp; R.I.</b>
<b>MetaSPC5 (L7)</b> <b>With 8.14% Lactic Acid</b>  Batch N°5119121118 (Doc. "Certificate of analysis L7 MetaSPC 5")	<b>Bactericidal activity</b> <i>E.coli</i> <i>Staphylococcus aureus</i> <i>Streptococcus uberis</i>	<b>EN 1656 (2009)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature : +30 ± 1°C</li> <li>• Contact time : 1 or 5 min</li> <li>• Concentrations tested : 10 - 12 - 15 - 20 - 25 %</li> <li>• I.S. : 10g/L YE + 10g/L BSA (dirty conditions)</li> </ul>	Bactericidal activity (for teat disinfection) at 25% in 1 min at +30°C in High-level soiling conditions	Doc. "RP_2019-06-019_metaSPC5_L7_EN1656_30°C_1min_dirty"  <p style="text-align: center;"><b>R.I. 1</b> <b>Key study</b></p>
<b>MetaSPC5 (L7)</b> <b>With 8.14% Lactic Acid</b>  Batch N°5119121118 (Doc. "Certificate of analysis L7 MetaSPC 5")	<b>Bactericidal activity</b> <i>E.coli</i> <i>Staphylococcus aureus</i> <i>Proteus vulgaris</i> <i>Pseudomonas aeruginosa</i>	<b>EN 1656 (2009)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature : +30 ± 1°C</li> <li>• Contact time : 5 min</li> <li>• Concentrations tested : 10 - 12 - 15%</li> </ul> I.S. : 10g/L YE + 10g/L BSA (dirty conditions)	Bactericidal activity (for surface disinfection) at 15% in 5 min at +30°C in High-level soiling conditions	Doc. "RP_2019-07-005_mSPC5_L7_EN1656_30°C_5min_dirty"  <p style="text-align: center;"><b>R.I. 1</b> <b>Key study</b></p>
<b>██████ 25%</b>	<b>Bactericidal activity</b> <i>E.coli</i> <i>Staphylococcus aureus</i> <i>Streptococcus uberis</i>	<b>EN 1656 (2009)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> </ul>	Log ↓ = 2.12 at 40% in 5 min	Doc. "RP_2019-08-008_██████_EN1656_30°C_5min_dirty_metaSPC 5"

	<i>Pseudomonas aeruginosa</i>	<ul style="list-style-type: none"> <li>Contact time : 5 min</li> <li>Concentrations tested : 15 – 25 - 40%</li> <li>I.S. : 10g/L YE + 10g/L BSA (dirty conditions)</li> </ul>	No bactericidal activity of ██████ 25% at 40% in 5 min at +20°C in dirty conditions.	<b>R.I. 1 Key study</b>
██████████ <b>30% + Allantoin 0.05% + ██████ 1.875%</b>	<b>Bactericidal activity</b> <i>Streptococcus uberis</i> <i>Proteus vulgaris</i>	<b>EN 1656 (2009)</b> Quantitative suspension test <ul style="list-style-type: none"> <li>Temperature : +20 ± 1°C</li> <li>Contact time : 5 min</li> <li>Concentrations tested : 80%</li> <li>I.S. : 10g/L YE + 10g/L BSA (dirty conditions)</li> </ul>	<i>Proteus vulgaris</i> Log ↓ = 2.18 at 80% in 5 min <i>Streptococcus uberis</i> Log ↓ = 2.15 at 80% in 5 min  No bactericidal activity of "██████████ 30% + Allantoin 0.05% + ██████ 1.875%" at 80% in 5 min at +20°C in dirty conditions	Doc. "RP_2019-08-023_Emollients+██████████_EN1656_30°C_min_dirty_metaSP C 5-6"  <b>R.I. 1 Key study</b>
<b>MetaSPC5 (L7) With 8.14% Lactic Acid</b>  Batch N°5119121118 (Doc. "Certificate of analysis L7 MetaSPC 5")	<b>Yeasticidal activity</b> <i>Candida albicans</i>	<b>EN 1657 (2016)</b> Quantitative suspension test <ul style="list-style-type: none"> <li>Temperature : +30 ± 1°C</li> <li>Contact time : 1 or 5 min</li> <li>Concentrations tested : 30 – 40 - 50 %</li> <li>I.S. : 10g/L YE + 10g/L BSA (dirty conditions)</li> </ul>	Yeasticidal activity at 40% in 1 min at +30°C in High-level soiling conditions	Doc. "RP_2019-03-045_mSPC5_EN1657_30°C_1min_dirty"  <b>R.I. 1 Key study</b>
<b>MetaSPC5 (L7) With 8.14% Lactic Acid</b>  Batch N°511915000 2 (Doc.	<b>Bactericidal activity</b> <b>E.coli</b> <b>Staphylococcus aureus</b> <b>Streptococcus uberis</b>	<b>EN 16437 (2014) modified</b> <b>Bactericidal activity when applied to synthetic skin (VITRO-SKIN)</b> <ul style="list-style-type: none"> <li>Temperature : +30 ± 1°C</li> <li>Contact time : 1 min</li> <li>Concentrations tested : 15 – 20 - 25%</li> </ul>	Bactericidal activity (for teat disinfection) at 20% in 1 min at +30°C on skin without prior cleaning by spraying/dipping.	Doc. "RP_2019-07-032_metaSPC 5_L7_skin test_30°C_1min_dirty"  R.I. 1 Key study

"Certificate of analysis L7 MetaSPC 5.2")		<ul style="list-style-type: none"> <li><b>I.S. : 10g/L YE + 10g/L BSA (dirty conditions)</b></li> </ul>		
<b>MetaSPC5 (L7)</b> <b>With 8.14% Lactic Acid</b>  <b>Batch N°511915000 2 (Doc. "Certificate of analysis L7 MetaSPC 5.2")</b>	<b>Bactericidal activity</b> <b>Enterococcus hirae</b> <b>Proteus vulgaris</b> <b>Pseudomonas aeruginosa</b> <b>Staphylococcus aureus</b>	<b>EN 16437 (2014) modified</b> <b>Bactericidal activity when applied to synthetic skin (VITRO-SKIN)</b>  <ul style="list-style-type: none"> <li><b>Temperature : +30 ± 1°C</b></li> <li><b>Contact time : 5 min</b></li> <li><b>Concentrations tested : 1 - 5 - 8 %</b></li> </ul> <b>I.S. : 10g/L YE + 10g/L BSA (dirty conditions)</b>	Bactericidal activity at 5% in 5 min at +30°C on skin without prior cleaning by spraying/dipping.	Doc. "RP_2019-07-033_metaSPC 5_L7_skin test_30°C_5min_dirty"  R.I. 1 Key study

<b>META-SPC 5 (representative product with 8% LA) : Summary of the test results validated after evaluation</b>			
<b>EN 1656</b>	25% - 1 min - +30°C - DIRTY	<b>EN 16437 Modified</b>	B : 20% - 1 min - +30°C - DIRTY
<b>EN 1657</b>	40% - 1 min - +30°C - DIRTY		

<b>Meta SPC5 - EFF CONCLUSIONS</b>
<p><b>PT3</b></p> <p><b>Use #5.1</b> : Teat disinfection (pre-milking)  B + Y : 40% (3.2 % LA) at +30°C in 1 min contact time wo previous cleaning  Since the product has been tested at +30°C, if the product is stored at +4-7°C (fridge) a precautionary sentence will be added in the PAR in order to mention that the product must "return" to RT before use &amp; must be diluted with RT potable water.</p> <p><b>Use #5.2</b> : Intact skin wash/disinfection (of the udder of dairy and beef cattle before calving and of the udder of sows before farrowing)  B + Y : 40% (3.2 % LA) at +30°C in 1 min contact time wo previous cleaning  Since the product has been tested at +30°C, if the product is stored at +4-7°C (fridge) a precautionary sentence will be added in the PAR in order to mention that the product must "return" to RT before use &amp; must be diluted with RT potable water.</p>

<b>Meta SPC-6 (3.6% LA)</b>				
<b>Experimental data on the efficacy of the biocidal product against target organisms</b>				
Field of use envisaged	PT3	Use #1 : Teat disinfection (pre-milking)		
Test product	Function & Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results : effects	Reference & R.I.
<b>MetaSPC6 (L36)</b> <b>With 3.69% Lactic Acid</b>  Batch N°4119071139 (Doc. "Certificate of analysis L36 MetaSPC 6")	<b>Bactericidal activity</b> <i>E.coli</i> <i>Staphylococcus aureus</i> <i>Streptococcus uberis</i>	<b>EN 1656 (2009)</b> Quantitative suspension test <ul style="list-style-type: none"> <li>• Temperature : +30 ± 1°C</li> <li>• Contact time : 1 min</li> <li>• Concentrations tested : 10 – 40 – 80%</li> <li>• I.S. : 10g/L YE + 10g/L BSA (dirty conditions)</li> </ul>	Bactericidal activity (for teat disinfection) at 40% in 1 min at +30°C in High-level soiling conditions	Doc. "RP_2019-04-004_metaSPC 6_EN1656_30°C_60s_dirty"  <b>R.I. 1</b> <b>Key study</b>
<b>MetaSPC6 (L36)</b> <b>With 3.69% Lactic Acid</b>  Batch N°4119071139 (Doc. "Certificate of analysis L36 MetaSPC 6")	<b>Yeasticidal activity</b> <i>Candida albicans</i>	<b>EN 1657 (2016)</b> Quantitative suspension test <ul style="list-style-type: none"> <li>• Temperature : +30 ± 1°C</li> <li>• Contact time : 1 min</li> <li>• Concentrations tested : 80%</li> <li>• I.S. : 10g/L YE + 10g/L BSA (dirty conditions)</li> </ul>	Yeasticidal activity at 80% in 1 min at +30°C in High-level soiling conditions	Doc. "RP_2019-03-055_metaSPC 6_L36_EN1657_30°C_1min_dirty"  <b>R.I. 1</b> <b>Key study</b>
<b>MetaSPC6 (L36)</b> <b>With 3.69% Lactic Acid</b>	<b>Bactericidal activity</b> <i>E.coli</i> <i>Staphylococcus aureus</i> <i>Streptococcus uberis</i>	<b>EN 16437 (2014) modified</b> Bactericidal activity when applied to synthetic skin (VITRO-SKIN) <ul style="list-style-type: none"> <li>• Temperature : +30 ± 1°C</li> <li>• Contact time : 1 min</li> </ul>	Bactericidal activity (for teat disinfection) at 100% in 1 min at +30°C on skin without prior cleaning.	Doc. "RP_2019-07-034_metaSPC 6_L36_skin test_30°C_1min_dirty"  <b>R.I. 1</b> <b>Key study</b>



Batch N°4119071139 (Doc. "Certificate of analysis L36 MetaSPC 6")		<ul style="list-style-type: none"> <li>• Concentrations tested : 100%</li> <li>• I.S. : 10g/L YE + 10g/L BSA (dirty conditions)</li> </ul>		
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**META-SPC 6 (representative product with 3.60% LA) : Summary of the test results validated after evaluation**

<b>EN 1656</b>	40% - 1 min - +30°C - DIRTY	<b>EN 16437 Modified</b>	B : 100% - 1 min - +30°C - DIRTY
<b>EN 1657</b>	80% - 1 min - +30°C - DIRTY		

**Meta SPC6 - EFF CONCLUSIONS**
**PT3**

**Use #6.1** : Teat disinfection (pre-milking with wipes)

B + Y : RTU at +30°C in 1 min contact time wo previous cleaning

Since the product has been tested at +30°C, if the product is stored at +4-7°C (fridge) a precautionary sentence will be added in the PAR in order to mention that the product must "return" to RT before use & must be diluted with RT potable water.

<b>Meta SPC-7 (2% LA)</b>				
<b>Experimental data on the efficacy of the biocidal product against target organisms</b>				
<b>Field of use envisaged</b>	<b>PT4</b>	Use #1 : Hard surface disinfection - <i>PROF</i>		
		Use #2 : Hard surface disinfection		
	<b>PT2</b>	Use #3 : Hard surface disinfection - <i>healthcare</i> - <i>PROF</i>		
		Use #4 : Hard surface disinfection - <i>healthcare</i>		
		Use #5 : Hard surface disinfection - <i>PROF</i>		
		Use #6 : Hard surface disinfection		
<b>Test product</b>	<b>Function &amp; Test organism(s)</b>	<b>Test method / Test system / concentrations applied / exposure time</b>	<b>Test results : effects</b>	<b>Reference &amp; R.I.</b>
<b>MetaSPC2 (L2) with 2.03% Lactic Acid</b>  Batch N°5119030001 (Doc. "Certificate of analysis L2 MetaSPC 2")	<b>Bactericidal activity</b> <i>Enterococcus hirae</i> <i>E.coli</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i>	<b>EN 1276 (2010)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 1 min</li> <li>• Concentrations tested : 80 %</li> <li>• I.S. : 0.3g/L BSA (clean conditions)</li> </ul>	Bactericidal activity at 80% in 1 min at +20°C in clean conditions.	Doc. "RP_2019-07-041_metaSPC2_L2_EN1276_1min_clean"  <p style="text-align: center;"><b>R.I. 1</b> <b>Key study</b></p>
<b>MetaSPC2 (L2) with 2.03% Lactic Acid</b>  Batch N°5119030001 (Doc. "Certificate of analysis L2 MetaSPC 2")	<b>Yeasticidal activity</b> <i>Candida albicans</i>	<b>EN 1650 (2013)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 2 min</li> <li>• Concentrations tested : 10 - 40 - 80 %</li> <li>• I.S. : 0.3g/L BSA (clean conditions)</li> </ul>	Yeasticidal activity at 80% in 2 min at +20°C in clean conditions.	Doc. « RP_2019-09-004_metaSPC2_L2_EN1650_20°C_2min_clean»  <p style="text-align: center;"><b>R.I. 1</b> <b>Key study</b></p>

<p><b>MetaSPC3 (L5) with 68.7% Lactic Acid</b></p> <p>Batch N°5119030005 (Doc. "Certificate of analysis L5 MetaSPC 3")</p>	<p><b>Virucidal activity</b> Adenovirus Murine norovirus Poliovirus</p>	<p><b>EN 14476 (2013 + AC 2015) Quantitative suspension test</b></p> <ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 2 min</li> <li>• Concentrations tested : 0.5 – 2 – 2.9%</li> <li>• I.S. : 0.3g/L BSA (clean conditions)</li> </ul>	<p>Virucidal activity at 2 % in 2 min at +20°C in clean conditions.</p>	<p>Doc. "Test report R-LVCIR003"</p> <p><b>R.I. 2</b></p>
<p><b>MetaSPC7 (L2) With 2% Lactic Acid</b></p> <p>Batch N°5119310001 (Doc. "Certificate of analysis L2 MetaSPC 2 whipe")</p>	<p><b>Bactericidal activity</b> <i>E.coli</i> <i>E.coli</i> K12 <i>Enterococcus hirae</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Candida albicans</i></p>	<p><b>EN 16615 (2013)</b> Quantitative carrier test – hard &amp; non-porous surfaces – Wipes with mechanical action</p> <ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 1 min</li> <li>• 5 wipe types tested : <b>Wipe 1</b> – blue/white tissue (200x300 mm) - 70% viscose/30% polyester <b>Wipe 2</b> – blue tissue (200x200 mm) - 50% viscose/50% polyester <b>Wipe 3</b> – blue tissue (200x200 mm) - 100% polypropylene <b>Wipe 4</b> – blue tissue (200x200 mm) – 40g/m<sup>2</sup> <b>Wipe 5</b> – white tissue (200x300 mm) – 24g/m<sup>2</sup></li> <li>• I.S. : 0.3g/L BSA (clean conditions)</li> </ul>	<p>Bactericidal (LgR &gt; 5.10 with all the 5 types of wipes) &amp; yeasticidal (LgR &gt; 4.77 with all the 5 types of wipes) activity in 1 min at +20°C on hard/non-porous surfaces with prior cleaning.</p>	<p>Doc. "EN 16615 Meta7"</p> <p><b>R.I. 1 Key study</b></p>

<b>META-SPC 7 (representative product with 2% LA) : Summary of the test results validated after evaluation</b>			
<b>EN 1276</b>	80% - 1 min - +20°C - CLEAN	<b>EN 16615</b>	B + Y : 1 min - +30°C - CLEAN
<b>EN 1650</b>	80% - 2 min - +20°C - CLEAN		
<b>EN 14476</b>	2% (from 68.7% ⇔ 1.374% ) - 2 min - +20°C - CLEAN		

<b>Meta SPC7 - EFF CONCLUSIONS</b>
<p><b>PT2</b>  <b>Use #7.3</b> : Hard surface disinfection – <i>PROF</i>  <b>Use #7.4</b> : Hard surface disinfection  <b>Use #7.5</b> : Hard surface disinfection – <i>PROF (in healthcare)</i>  <b>Use #7.6</b> : Hard surface disinfection (<i>in healthcare</i>)</p> <p><b>PT4</b>  <b>Use #7.1</b> : Hard surface disinfection – <i>PROF</i>  <b>Use #7.2</b> : Hard surface disinfection</p> <p>B + Y + V<sub>FULL</sub> : at +20°C in 2 min contact time on hard/non-porous surfaces with prior cleaning  <i>Wipe the surface to be disinfected. Make sure to wet surfaces completely.</i></p>

<b>Meta SPC-8 (min. 3.60% LA)</b>				
<b>Experimental data on the efficacy of the biocidal product against target organisms</b>				
<b>Field of use envisaged</b>	<b>PT3</b>	Use #1 : RTU Teat disinfection (post-milking)		
Test product	<b>Function &amp; Test organism(s)</b>	<b>Test method / Test system / concentrations applied / exposure time</b>	<b>Test results : effects</b>	<b>Reference &amp; R.I.</b>
MetaSPC8 (L15) With 3.82% Lactic Acid  Batch N°5119020007 (Doc. "Certificate of analysis L15 MetaSPC 8")	<b>Bactericidal activity</b> <i>E.coli</i> <i>Staphylococcus aureus</i> <i>Streptococcus uberis</i>	<b>EN 1656 (2009)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature : +30 ± 1°C</li> <li>• Contact time : 5 min</li> <li>• Concentrations tested : 10 - 40 - 80%</li> <li>• I.S. : Skimmed Milk 10g/L</li> </ul>	Bactericidal activity (for teat disinfection) at 40% in 5 min at +30°C in presence of milk.	Doc. "RP_2020-02_037_mSPC8_EN1656_30°C_5min_milk"  <b>R.I. 1 Key study</b>
MetaSPC8 (L15) With 3.82% Lactic Acid  Batch N°5119020007 (Doc. "Certificate of analysis L15 MetaSPC 8")	<b>Yeasticidal activity</b> <i>Candida albicans</i>	<b>EN 1657 (2016)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature : +30 ± 1°C</li> <li>• Contact time : 5 min</li> <li>• Concentrations tested : 10 - 40 - 80%</li> <li>• I.S. : Skimmed Milk 10g/L</li> </ul>	Yeasticidal activity at 40% in 5 min at +30°C in presence of milk.	Doc. "RP_2019-01-012_mSPC8_EN1657_30°C_5min_milk"  <b>R.I. 1 Key study</b>
MetaSPC8 (L15) With 3.82% Lactic Acid  Batch N°5119020007 (Doc. "Certificate of	<b>Bactericidal activity</b> <i>E.coli</i> <i>Staphylococcus aureus</i> <i>Streptococcus uberis</i>	<b>EN 16437 (2014) modified</b> Bactericidal activity when applied to synthetic skin (VITRO-SKIN)  <ul style="list-style-type: none"> <li>• Temperature : +30 ± 1°C</li> <li>• Contact time : 5 min</li> <li>• Concentrations tested : 10 - 40 - 100%</li> <li>• I.S. : Skimmed Milk 10g/L</li> </ul>	Bactericidal activity (for teat disinfection) at 100% in 5 min at +30°C on skin in presence of milk.	Doc. "RP_2019-01-025_mSPC8_skin test_30°C_5min_milk"  <b>R.I. 1 Key study</b>

analysis L15 MetaSPC 8")				
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<b>META-SPC 8 (representative product with 3.60% LA) : Summary of the test results validated after evaluation</b>			
<b>EN 1656</b>	40% - 5 min - +30°C - MILK	<b>EN 16437 Modified</b>	100% - 5 min - +30°C - MILK
<b>EN 1657</b>	40% - 5 min - +30°C - MILK		

<b>Meta SPC8 - EFF CONCLUSIONS</b>	
<b>PT3</b>	<p><b>Use #8.1</b> : Teat disinfection (post-milking)            B + Y : RTU (3.6 % LA) at +30°C in 5 min contact time            Since the product has been tested at +30°C, if the product is stored at +4-7°C (fridge) a precautionary sentence will be added in the PAR in order to mention that the product must "return" to RT before use.            Moreover, in order to ensure optimal teat disinfection, the following sentence should be added in the general conditions of use "<i>the animals should be kept standing for at least 5 min</i>".</p>

<b>Meta SPC-9 (min. 3.6% LA)</b>				
<b>Experimental data on the efficacy of the biocidal product against target organisms</b>				
<b>Field of use envisaged</b>	<b>PT3</b>	Use #1 : RTU Teat disinfection (post-milking)		
<b>Test product</b>	<b>Function &amp; Test organism(s)</b>	<b>Test method / Test system / concentrations applied / exposure time</b>	<b>Test results : effects</b>	<b>Reference &amp; R.I.</b>
<b>Read-across from META-SPC 8</b>				

<b>META-SPC 9 (representative product with 3.60% LA) : Summary of the test results validated after evaluation</b>				
<b>EN 1656</b>	40% - 5 min - +30°C - MILK	<b>EN 16437 Modified</b>	100% - 5 min - +30°C - MILK	
<b>EN 1657</b>	40% - 5 min - +30°C - MILK			

<b>Meta SPC9 - EFF CONCLUSIONS</b>	
<b>PT3</b>	<p><b>Use #9.1</b> : Teat disinfection (post-milking)            B + Y : RTU (3.6 % LA) at +30°C in 5 min contact time            Since the product has been tested at +30°C, if the product is stored at +4-7°C (fridge) a precautionary sentence will be added in the PAR in order to mention that the product must "return" to RT before use.            Moreover, in order to ensure optimal teat disinfection, the following sentence should be added in the general conditions of use "<i>the animals should be kept standing for at least 5 min</i>".</p>

<b>Meta SPC-10 (3.6% LA)</b>				
<b>Experimental data on the efficacy of the biocidal product against target organisms</b>				
<b>Field of use envisaged</b>	<b>PT3</b>	<b>Use #1 : RTU Teat disinfection (post-milking)</b>		
<b>Test product</b>	<b>Function &amp; Test organism(s)</b>	<b>Test method / Test system / concentrations applied / exposure time</b>	<b>Test results : effects</b>	<b>Reference &amp; R.I.</b>
<b>MetaSPC10 (L25)</b> With 3.61% Lactic Acid  Batch N°5119020011 (Doc. "Certificate of analysis L25 MetaSPC 10")	<b>Bactericidal activity</b> <i>E.coli</i> <i>Staphylococcus aureus</i> <i>Streptococcus uberis</i>	<b>EN 1656 (2009)</b> Quantitative suspension test <ul style="list-style-type: none"> <li>• Temperature : +30 ± 1°C</li> <li>• Contact time : 5 min</li> <li>• Concentrations tested : 10 - 40 - 80%</li> <li>• I.S. : Skimmed Milk 10g/L</li> </ul>	Bactericidal activity (for teat disinfection) at 80% in 5 min at +30°C in presence of milk.	Doc. "RP_2019-01-013_metaSPC 10_L25_EN1656_30°C_5min_milk"  <b>R.I. 1 Key study</b>
<b>MetaSPC10 (L25)</b> With 3.61% Lactic Acid  Batch N°5119020011 (Doc. "Certificate of analysis L25 MetaSPC 10")	<b>Yeasticidal activity</b> <i>Candida albicans</i>	<b>EN 1657 (2016)</b> Quantitative suspension test <ul style="list-style-type: none"> <li>• Temperature : +30 ± 1°C</li> <li>• Contact time : 5 min</li> <li>• Concentrations tested : 10 - 40 - 80%</li> <li>• I.S. : Skimmed Milk 10g/L</li> </ul>	Yeasticidal activity at 80% in 5 min at +30°C in presence of milk.	Doc. "RP_2019-01-027_metaSPC 10_L25_EN1657_30°C_5min_milk"  <b>R.I. 1 Key study</b>
<b>MetaSPC10 (L25)</b> With 3.61% Lactic Acid	<b>Bactericidal activity</b> <i>E.coli</i> <i>Staphylococcus aureus</i> <i>Streptococcus uberis</i>	<b>EN 16437 (2014) modified</b> Bactericidal activity when applied to synthetic skin (VITRO-SKIN)	Bactericidal activity (for teat disinfection) at 100% in 5 min at +30°C on skin in presence of milk.	Doc. "RP_2019-01-026_metaSPC 10_L25_skin test_30°C_5min_milk"



Batch N°5119020011 (Doc. "Certificate of analysis L25 MetaSPC 10")		<ul style="list-style-type: none"> <li>• Temperature : +30 ± 1°C</li> <li>• Contact time : 5 min</li> <li>• Concentrations tested : 10 - 40 - 100%</li> <li>• I.S. : Skimmed Milk 10g/L</li> </ul>		<b>R.I. 1</b> <b>Key study</b>
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<b>META-SPC 10 (representative product with 3.60% LA) : Summary of the test results validated after evaluation</b>			
<b>EN 1656</b>	80% - 5 min - +30°C - MILK	<b>EN 16437</b> <b>Modified</b>	100% - 5 min - +30°C - MILK
<b>EN 1657</b>	40% - 5 min - +30°C - MILK		

<b>Meta SPC10 - EFF CONCLUSIONS</b>
<p><b>PT3</b>  <b>Use #10.1</b> : Teat disinfection (post-milking)            B + Y : RTU (3.6 % LA) at +30°C in 5 min contact time on teats (post-milking)            Since the product has been tested at +30°C, if the product is stored at +4-7°C (fridge) a precautionary sentence will be added in the PAR in order to mention that the product must "return" to RT before use.            Moreover, in order to ensure optimal teat disinfection, the following sentence should be added in the general conditions of use "<i>the animals should be kept standing for at least 5 min</i>".</p>

<b>Meta SPC-11 (24% LA)</b>				
<b>Experimental data on the efficacy of the biocidal product against target organisms</b>				
<b>Field of use envisaged</b>		<b>PT3</b>	Use #1 : Hard surface disinfection	
		<b>PT4</b>	Use #2 : Hard surface disinfection	
			Use #3 : Disinfection of hard/non-porous surfaces in the food industry (e.g. processing machines)	
<b>Test product</b>	<b>Function &amp; Test organism(s)</b>	<b>Test method / Test system / concentrations applied / exposure time</b>	<b>Test results : effects</b>	<b>Reference &amp; R.I.</b>
<b>MetaSPC11 (L26)</b> With 23.99% Lactic Acid  Batch N°5119121116 (Doc. "Certificate of analysis L26 MetaSPC 11.2")	<b>Bactericidal activity</b> <i>Enterococcus hirae</i> <i>E.coli</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i>	<b>EN 1656 (2009)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature : +10 ± 1°C</li> <li>• Contact time : 30 min</li> <li>• Concentrations tested : 1 – 2 - 3%</li> <li>• I.S. : 3g/L BSA (clean conditions)</li> </ul>	Bactericidal activity at 2% in 30 min at +10°C in clean conditions	Doc. "RP_2019-07-008_metaSPC11_L26_EN1656_10°C_30min_clean" + Doc. "EN 1656 Meta11" (including certificate of analysis of batch N°5120073305)  <p style="text-align: center;"><b>R.I. 1 Key study</b></p>
<b>MetaSPC11 (L26)</b> With 23.99% Lactic Acid  Batch N°5119121116 (Doc. "Certificate of analysis L26 MetaSPC 11.2")	<b>Yeasticidal activity</b> <i>Candida albicans</i>	<b>EN 1657 (2016)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature : +10 ± 1°C</li> <li>• Contact time : 30 min</li> <li>• Concentrations tested : 1 – 2 - 3%</li> <li>• I.S. : 3g/L BSA (clean conditions)</li> </ul>	Yeasticidal activity at 3% in 30 min at +10°C in clean conditions.	Doc. "RP_2019-06-020_mSPC11_L26_EN1657_10°C_30min_clean"  <p style="text-align: center;"><b>R.I. 1 Key study</b></p>
<b>MetaSPC11 (L26)</b> With 23.99% Lactic Acid	<b>Bactericidal activity</b> <i>Enterococcus hirae</i> <i>P. vulgaris</i>	<b>EN 14349 (2012)</b> Quantitative carrier test – hard & non-porous surfaces	Bactericidal activity at 2% in 30 min at +10°C on hard/non-porous surfaces with prior cleaning.	Doc. "RP_2019-07-011_metaSPC_11_L26_EN14349_10°C_30min_clean_v2"

<p>Batch N°511901102 (Doc. "Certificate of analysis L26 MetaSPC 11.2")</p>	<p><i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i></p>	<ul style="list-style-type: none"> <li>• Temperature : +10 ± 1°C</li> <li>• Contact time : 30 min</li> <li>• Concentrations tested : 1 – 2 - 3%</li> <li>• I.S. : 3g/L BSA (clean conditions)</li> </ul>		<p><b>R.I. 1</b> <b>Key study</b></p>
<p><b>MetaSPC11 (L26)</b> With 23.99% Lactic Acid</p> <p>Batch N°5119121116 (Doc. "Certificate of analysis L26 MetaSPC 11.2")</p>	<p><b>Yeasticidal activity</b> <i>Candida albicans</i></p>	<p><b>EN 16438 (2014)</b> Quantitative carrier test – hard &amp; non- porous surfaces</p> <ul style="list-style-type: none"> <li>• Temperature : +10 ± 1°C</li> <li>• Contact time : 30 min</li> <li>• Concentrations tested : 3 – 4 - 5%</li> <li>• I.S. : 3g/L BSA (clean conditions)</li> </ul>	<p>Yeasticidal activity at 4% in 30 min at +10°C on hard/non- porous surfaces with prior cleaning.</p>	<p>Doc. "RP_2019-07- 027_mSPC 11_L26_EN16438_10°C_ 30min_clean"</p> <p style="text-align: center;"><b>R.I. 1</b> <b>Key study</b></p>
<p><b>MetaSPC11 (L26)</b> With 23.99% Lactic Acid</p> <p>Batch N°5119121116 (Doc. "Certificate of analysis L26 MetaSPC 11.2")</p>	<p><b>Bactericidal activity</b> <i>Enterococcus hirae</i> <i>E.coli</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i></p>	<p><b>EN 1276 (2010)</b> Quantitative suspension test</p> <p>+7 ± 1°C 2 min 2 – 4 – 5% 3g/L BSA (dirty conditions)</p> <p>+7 ± 1°C 30 sec. 4 – 5 - 15% 3g/L BSA (dirty conditions)</p> <p>+20 ± 1°C 2 min</p>	<p>Bactericidal activity - at 4% in 2 min at +7°C in dirty conditions. - at 15% in 30 sec. at +7°C in dirty conditions. - at 0.5% in 2 min at +20°C in clean conditions. - at 0.25% in 15 min at +20°C in clean conditions.</p>	<p>Docs "RP_2019-04-115_mSPC 11_L26_EN1276_7°C_2 min_dirty" "RP_2019-04-116_mSPC 11_L26_EN1276_7°C_30 sec_dirty" "RP_2019-07-004_mSPC 11_L26_EN1276_20°C_2 min_clean" "RP_2019-07-002_mSPC 11_L26_EN1276_20°C_1 5min_clean"</p> <p style="text-align: center;"><b>R.I. 1</b></p>

		<p>0.1 – 0.25 – 0.5% 0.3g/L BSA (clean conditions)</p> <p>+20 ± 1°C 15 min 0.1 – 0.25 – 0.5% 0.3g/L BSA (clean conditions)</p>		<b>Key study</b>
<p><b>MetaSPC11 (L26)</b> With 23.99% Lactic Acid</p> <p>Batch N°5119121116 (Doc. "Certificate of analysis L26 MetaSPC 11.2")</p>	<p><b>Yeasticidal activity</b> <i>Candida albicans</i></p>	<p><b>EN 1650 (2013)</b> Quantitative suspension test</p> <p>+7 ± 1°C 2 min 4 – 5 - 8% 3g/L BSA (dirty conditions)</p> <p>+7 ± 1°C 30 sec. 8 – 10 - 15% 3g/L BSA (dirty conditions)</p> <p>+20 ± 1°C 2 min 0.5 – 1 - 2% 0.3g/L BSA (clean conditions)</p> <p>+20 ± 1°C 15 min 0.25 – 0.5 - 1% 0.3g/L BSA (clean conditions)</p>	<p>Yeasticidal activity</p> <ul style="list-style-type: none"> <li>- at 8% in 2 min at +7°C in dirty conditions.</li> <li>- at 15% in 30 sec. at +7°C in dirty conditions.</li> <li>- at 2% in 2 min at +20°C in clean conditions.</li> <li>- at 1% in 15 min at +20°C in clean conditions.</li> </ul>	<p>Docs</p> <p>"RP_2019-04-118_mSPC 11_L26_EN1650_7°C_2 min_dirty"</p> <p>"RP_2019-04-122_metaSPC 11_L26_EN1650_7°C_30 sec_dirty"</p> <p>"RP_2019-04-024_mSPC 11_EN1650_20°C_2min_clean"</p> <p>"RP_2019-04-023_mSPC 11_EN1650_20°C_15min_clean"</p> <p><b>R.I. 1</b> <b>Key study</b></p>
<p><b>MetaSPC11 (L26)</b> With 23.99% Lactic Acid</p>	<p><b>Bactericidal activity + Yeasticidal activity</b> <i>Enterococcus hirae</i> <i>E.coli</i></p>	<p><b>EN 13697 (2015)</b> Quantitative carrier test – hard &amp; non-porous surfaces</p>	<p>Bactericidal &amp; Yeasticidal activity</p> <ul style="list-style-type: none"> <li>- at 8% in 2 min at +7°C on hard/non-porous surfaces wo prior cleaning.</li> </ul>	<p>Docs</p> <p>"RP_2019-04-150_metaSPC</p>

<p>Batch N°5119121116 (Doc. "Certificate of analysis L26 MetaSPC 11.2")</p>	<p><i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Candida albicans</i></p>	<p>+7 ± 1°C 2 min 1 - 2 - 8% 3g/L BSA (dirty conditions)</p> <p>+7 ± 1°C 30 sec. 8 - 10 - 15% 3g/L BSA (dirty conditions)</p> <p>+20 ± 1°C 2 min 1 - 1.5 - 2 - 3% 0.3g/L BSA (clean conditions)</p> <p>+20 ± 1°C 15 min 0.25 - 0.5 - 1 - 2% 0.3g/L BSA (clean conditions)</p>	<p>- at 15% in 30 sec. at +7°C on hard/non-porous surfaces wo prior cleaning.</p> <p>- at 3% in 2 min at +20°C on hard/non- porous surfaces with prior cleaning.</p> <p>- at 1% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning.</p>	<p>11_L26_EN13697_7°C_2 min_dirty" "RP_2019-04- 151_metaSPC 11_L26_EN13697_7°C_3 0sec_dirty" "RP_2019-05- 011_metaSPC 11_L26_EN13697_20°C_ 2min_clean" "RP_2019-05- 010_metaSPC 11_L26_EN13697_20°C_ 15min_clean"</p> <p style="text-align: center;"><b>R.I. 1 Key study</b></p>
<p><b>MetaSPC11 (L26)</b> With 23.99% Lactic Acid</p> <p>Batch N°5119121116 (Doc. "Certificate of analysis L26 MetaSPC 11.2")</p>	<p><b>Field trial – Comparative tests*</b> <b>On carcass saw/splitter</b></p> <ol style="list-style-type: none"> <li>1) Water at ≥ +82°C</li> <li>2) LA solution (via automatic dosage) – by spraying : Rinse the knives before disinfection</li> </ol> <p>- 15% at +7°C in 30 sec. - 8% at +7°C in 2 min</p> <p>With total aerobic bacterial load used to validate the efficacy of the tested product. Samples taken on at least 3 different days per week, during 2 weeks in 2 different (pork or cattle) slaughterhouses.</p>	<p><u>15% at +7°C in 30 sec. :</u> Log ↓ with LA solution = 99.94 % Log ↓ with +82°C water = 94.41 %</p> <p>The test-product is in compliance with the current requirements of the Reg. EU 853/2004 =&gt; The LA product, when used at 15% (water at +7°C) in 30 sec., has an equivalent effect as +82°C water to be used as an alternative to disinfect dirty slaughterhouse tools <u>by spraying</u>. According to the challenge test provided by bthe Applicant, the concentration of</p>	<p>Docs « FDLDR2019061711 LA MSPC 11 F L26 - 15% 30 sec» + « ADDENDUM - Field Trial - Challenge test data » « FDLDR2019080511 LA MSPC 11 F L26 - 8% 2 min»</p> <p style="text-align: center;"><b>R.I. 1 Key study</b></p>	

	<p>* According to Reg. EU 853/2004, slaughterhouses should have the required installation to disinfect tools with hot water at least at +82°C or an alternative system with a similar effect.</p>	<p>Lactic Acid remains stable after the slaughter of 6928 pigs.</p> <p><u>8% at +7°C in 2 min :</u>  Log ↓ with LA solution = 99.85 %  Log ↓ with +82°C water = 99.35 %</p> <p>The test-product is in compliance with the current requirements of the Reg. EU 853/2004  =&gt; The LA product, when used at 8% (water at +7°C) in 2 min, has an equivalent effect as +82°C water to be used as an alternative to disinfect dirty slaughterhouse tools <u>by spraying</u>.</p>	
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<b>META-SPC 11 (representative product with 24% LA) : Summary of the test results validated after evaluation</b>					
<b>EN 1656</b>	2% - 30 min - +10°C - CLEAN	<b>EN 14349</b>	2% - 30 min - +10°C - CLEAN		
<b>EN 1657</b>	3% - 30 min - +10°C - CLEAN	<b>EN 16438</b>	4% - 30 min - +10°C - CLEAN		
<b>EN 1276</b>	0.5% - 2 min - +20°C - CLEAN	<b>EN 13697 B+L</b>	3% - 2 min - +20°C - CLEAN 1% - 15 min - +20°C - CLEAN 15% - 30 sec. - +7°C - DIRTY 8% - 2 min - +7°C - DIRTY		
	0.25% - 15 min - +20°C - CLEAN				
	15% - 30 sec. - +7°C - DIRTY				
	4% - 2 min - +7°C - DIRTY				
<b>EN 1650</b>	2% - 2 min - +20°C - CLEAN			<b>FIELD</b>	15% - 30 sec. - +7°C - DIRTY 8% - 2 min - +7°C - DIRTY
	1% - 15 min - +20°C - CLEAN				
	15% - 30 sec. - +7°C - DIRTY				
	8% - 2 min - +7°C - DIRTY				

**Meta SPC11 - EFF CONCLUSIONS****PT3**

**Use #11.3** : Hard surface disinfection

B + Y : 4% (0.96 % LA) at +10°C in 30 min contact time on hard/non-porous surfaces with prior cleaning

**PT4**

**Use #11.1** : Hard surface disinfection

B + Y: 3% (0.72 % LA) in 2 min contact time or 1% (0.24 % LA) in 15 min contact time - at +20°C on hard/non-porous surfaces with prior cleaning

**Use #11.2** : Disinfection of hard/non-porous surfaces in the food industry (e.g. processing machines)

B + Y : 15% (3.6 % LA) in 30 sec. contact time - by DIPPING - at +7°C on hard/non-porous surfaces without prior cleaning

B + Y : 8% (1.92 % LA) in 2 min contact time - by SPRAYING - at +7°C on hard/non-porous surfaces without prior cleaning

<b>Meta SPC-12 (22% LA)</b>				
<b>Experimental data on the efficacy of the biocidal product against target organisms</b>				
<b>Field of use envisaged</b>		<b>PT4</b>		
		Use #1 : inner surface disinfection – CIP with circulation		
		Use #2 : inner surface disinfection – CIP wo circulation		
		Use #3 : Crate wash		
<b>Test product</b>	<b>Function &amp; Test organism(s)</b>	<b>Test method / Test system / concentrations applied / exposure time</b>	<b>Test results : effects</b>	<b>Reference &amp; R.I.</b>
<b>MetaSPC12 (L29)</b> With 22.05% Lactic Acid  Batch N°5119141111 (Doc. "Certificate of analysis L29 MetaSPC 12")	<b>Bactericidal activity</b> <i>Enterococcus faecium</i>	<b>EN 1276 (2010)</b> Quantitative suspension test  +50 ± 1°C 15 - 30 min 0.25 – 0.5 – 1% 0.3g/L BSA (clean conditions)  +50 ± 1°C 15 min 0.5 – 1 – 2 % Skimmed Milk 10g/L  +50 ± 1°C 2 min 0.5 – 1 – 2 % 0.3g/L BSA (clean conditions)  +50 ± 1°C 2 - 30 min 0.25 – 0.5 – 1% 3g/L BSA (dirty conditions)	Active against <i>Enterococcus faecium</i> :  - at 0.5% in 15 & 30 min at +50°C in clean conditions.  - at 1% in 15 min at +50°C in presence of milk.  - at 1% in 2 min at +50°C in clean conditions.  - at 1% in 2 & 30 min at +50°C in dirty conditions.	Docs "RP_2019-04-009_metaSPC12_L29_EN1276_50°C_15min_clean" "RP_2019-04-010_metaSPC12_L29_EN1276_50°C_15min_milk" "RP_2019-04-011_metaSPC12_L29_EN1276_50°C_30min_clean" "RP_2019-07-009_metaSPC12_L29_EN1276_50°C_2min_clean_E.f." "RP_2019-07-010_metaSPC12_L29_EN1276_50°C_30min_dirty_E.f." "RP_2019-07-018_metaSPC12_L29_EN1276_50°C_2min_dirty"
				<b>R.I. 1</b> <b>Key study</b>



<p><b>MetaSPC12 (L29)</b> With 22.05% Lactic Acid</p> <p>Batch N°5119141111 (Doc. "Certificate of analysis L29 MetaSPC 12")</p>	<p><b>Yeasticidal activity</b> <i>Candida albicans</i></p>	<p><b>EN 1650 (2013)</b> Quantitative suspension test</p> <p>+50 ± 1°C 15 min 1 - 1.5 - 2 % 0.3g/L BSA (clean conditions)</p> <p>+50 ± 1°C 30 min 0.5 - 1 - 2 % 0.3g/L BSA (clean conditions)</p> <p>+50 ± 1°C 15 min 1 - 1.5 - 2 % Skimmed Milk 10g/L</p> <p>+50 ± 1°C 2 min 0.5 - 1 - 2 % 0.3g/L BSA (clean conditions)</p> <p>+50 ± 1°C 2 min 2 - 3 - 4 % 3g/L BSA (dirty conditions)</p> <p>+50 ± 1°C 30 min 0.5 - 1 - 2 % 3g/L BSA (dirty conditions)</p>	<p>Yeasticidal activity :</p> <p>- at 2% in 15 min at +50°C in clean conditions.</p> <p>- at 1% in 30 min at +50°C in clean conditions.</p> <p>- at 2% in 15 min at +50°C in presence of milk.</p> <p>- at 2% in 2 min at +50°C in clean conditions.</p> <p>- at 4% in 2 min at +50°C in dirty conditions.</p> <p>- at 1% in 30 min at +50°C in dirty conditions</p>	<p>Docs</p> <p>"RP_2019-04-025_metaSPC12_L29_EN1650_50°C_15min_clean" « RP_2019-04-027_metaSPC12_L29_EN1650_50°C_30min_clean» « RP_2019-05-047_metaSPC12_L29_EN1650_50°C_15min_milk » « RP_2019-07-020_mSPC12_L29_EN1650_50°C_2min_clean » « RP_2019-07-022_mSPC12_L29_EN1650_50°C_2min_dirty » « RP_2019-06-001_metaSPC12_L29_EN1650_50°C_30min_dirty »</p> <p><b>R.I. 1 Key study</b></p>
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<p><b>MetaSPC12 (L29)</b> With 22.05% Lactic Acid</p> <p>Batch N°5119141111 (Doc. "Certificate of analysis L29 MetaSPC 12")</p>	<p><b>Bactericidal activity + Yeastocidal activity</b> <i>Enterococcus faecium</i> <i>Candida albicans</i></p>	<p><b>EN 13697 (2015)</b> Quantitative carrier test – hard &amp; non-porous surfaces</p> <p>+50 ± 1°C 2 min 1 - 2 – 3 % 0.3g/L BSA (clean conditions)</p> <p>+50 ± 1°C 2 min 2 – 3 – 4 % 3g/L BSA (dirty conditions)</p> <p>+50 ± 1°C 30 min 0.25 – 0.5 – 0.75 % 3g/L BSA (dirty conditions)</p>	<p>Bactericidal &amp; Yeastocidal activity :</p> <p>- at 2% in 2 min at +50°C on hard/non-porous surfaces with prior cleaning</p> <p>- at 4% in 2 min at +50°C on hard/non-porous surfaces wo prior cleaning</p> <p>- at 2% in 30 min at +50°C on hard/non-porous surfaces wo prior cleaning</p>	<p>Docs "RP_2019-07-031_mSPC12_L29_EN13697_50°C_2min_clean" "RP_2019-07-024_mSPC12_L29_EN13697_50°C_2min_dirty" "RP_2019-04-049_metaSPC12_L29_EN13697_50°C_30min_dirty"</p> <p><b>R.I. 1 Key study</b></p>
<p><b>MetaSPC12 (L29)</b> With 22.05% Lactic Acid</p> <p>Batch N°5119141111 (Doc. "Certificate of analysis L29 MetaSPC 12")</p>	<p><b>Bactericidal activity</b> <i>Enterococcus faecium</i></p>	<p><b>DIN SPEC 10534 (2012)</b> Field trial – Disinfection in cratwashers</p> <p>During the washing phase With an automatic product dosing pump. On 8 crates At 2% or 4% - 2 min - +50°C Using a mixture of 0.6% BSA + 1% mucin + 3% maize starch as I.S. (dirty conditions)</p>	<p>Active against <i>Enterococcus faecium</i> at 2% or 4% in 2 min on hard/non-porous surfaces in presence of a mixture of 0.6% BSA + 1% mucin + 3% maize starch as I.S.</p>	<p>Docs "Binder CLEAN - metaSPC 12" "Binder Dirty - metaSPC 12"</p> <p><b>R.I. 1 Key study</b></p>
<p><b>MetaSPC12 (L29)</b> With 22.05% Lactic Acid</p>	<p><b>Yeastocidal activity</b> <i>Saccharomyces cerevisiae</i></p>	<p><b>DIN SPEC 10534 (2012)</b> Field trial – Disinfection in cratwashers</p> <p>During the washing phase</p>	<p>Active against <i>Saccharomyces cerevisiae</i> at 2% in 2 min on hard/non-porous surfaces in dirty conditions.</p>	<p>Docs "FIELD TRIAL META 12"</p> <p><b>R.I. 2</b></p>

Batch N°5119141111 (Doc. "Certificate of analysis L29 MetaSPC 12")		With an automatic product dosing pump. On 8 crates At 2% - 2 min - +50°C Using a mixture of 0.6% BSA + 1% mucin + 3% maize starch as I.S. (dirty conditions)		
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<b>META-SPC 12 (representative product with 22% LA) : Summary of the test results validated after evaluation</b>				
<b>EN 1276</b>	0.5% - 15 min - +50°C - CLEAN	<b>EN 13697 B+L</b>		2% - 2 min - +50°C - CLEAN 4% - 2 min - +50°C - DIRTY 2% - 30 min - +50°C - DIRTY
	1% - 2 min - +50°C - CLEAN			
	1% - 2 min - +50°C - DIRTY			
	1% - 15 min - +50°C - MILK			
<b>EN 1650 Y</b>	2% - 2 min - +50°C - CLEAN			
	2% - 15 min - +50°C - CLEAN			
	1% - 30 min - +50°C - CLEAN			
	4% - 2 min - +50°C - DIRTY			
	1% - 30 min - +50°C - DIRTY			
2% - 15 min - +50°C - MILK				
		<b>CRATE</b>		B + Y : 2% - 2 min - +50°C - DIRTY

**Meta SPC12 - EFF CONCLUSIONS****PT4****Use #12.1** : inner surface disinfection – CIP with circulation

B + Y :

- CLEAN conditions at +50°C : 2% (0.44 % LA) in minimum 2 min contact time // 1% (0.22 % LA) in 30 min contact time
- DIRTY conditions at +50°C : 4% (0.88 % LA) in minimum 2 min contact time // 1% (0.22 % LA) in 30 min contact time
- In Dairy industry : 2% (0.44 % LA) in 15 min contact time

**Use #12.2** : inner surface disinfection – without circulation

B + Y :

- CLEAN conditions at +50°C : 2% (0.44 % LA) in 2 min contact time
- DIRTY conditions at +50°C : 4% (0.88 % LA) in 2 min contact time // 2% (0.44 % LA) in 30 min contact time

**Use #12.3** : Crate wash

B + Y :

- CLEAN conditions at +50°C : 2% (0.44 % LA) in minimum 2 min contact time
- DIRTY conditions at +50°C : 4% (0.88 % LA) in minimum 2 min contact time

<b>Meta SPC-13 (11% LA)</b>				
<b>Experimental data on the efficacy of the biocidal product against target organisms</b>				
Field of use envisaged	PT4	Use #1 : Hard surface disinfection		
Test product	Function & Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results : effects	Reference & R.I.
<b>MetaSPC13 (L31)</b> With 10.91 % Lactic Acid  Batch N°5119700013 (Doc. "Certificate of analysis L31 MetaSPC 13 – 2019-11-023 revised")	<b>Bactericidal activity</b> <i>Enterococcus hirae</i> <i>E.coli</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i>	<b>EN 1276 (2010)</b> Quantitative suspension test  +20 ± 1°C 30 min 0.25 – 0.5 - 1% 0.3g/L BSA (clean conditions)  +20 ± 1°C 30 min 2 – 3 – 4 % 3g/L BSA (dirty conditions)	Bactericidal activity - at 0.5% in 30 min at +20°C in clean conditions. - at 2% in 30 min at +20°C in dirty conditions.	Docs "RP_2019-03-008_mSPC13_L31_EN1276_20°C_30min_clean" "RP_2019-03-009_mSPC13_L31_EN1276_20°C_30min_dirty"  <b>R.I. 1 Key study</b>
<b>MetaSPC13 (L31)</b> With 10.91 % Lactic Acid  Batch N°5119700013 (Doc. "Certificate of analysis L31 MetaSPC 13 – 2019-11-023 revised")	<b>Yeasticidal activity</b> <i>Candida albicans</i>	<b>EN 1650 (2013)</b> Quantitative suspension test  +20 ± 1°C 30 min 0.5 – 1 – 1.5% 0.3g/L BSA (clean conditions)  +20 ± 1°C 30 min 0.5 – 1 - 2% 3g/L BSA (dirty conditions)	Yeasticidal activity : - at 1% in 30 min at +20°C in clean conditions. - at 4% in 30 min at +20°C in dirty conditions.	Docs "RP_2019-02-092_mSPC13_L31_EN1650_20°C_30min_clean" "RP_2019-02-093_mSPC13_L31_EN1650_20°C_30min_dirty"  <b>R.I. 1 Key study</b>
<b>MetaSPC13 (L31)</b>	<b>Bactericidal activity + Yeasticidal activity</b>	<b>EN 13697 (2015)</b>	Bactericidal & Yeasticidal activity :	Docs

With 10.91 % Lactic Acid	<i>Enterococcus hirae</i> <i>E.coli</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Candida albicans</i>	Quantitative carrier test – hard & non-porous surfaces  +20 ± 1°C 30 min 0.25 - 0.5 – 1 % 0.3g/L BSA (clean conditions)  +20 ± 1°C 30 min 0.5 - 1 - 2 - 3 - 4 - 5 % 3g/L BSA (dirty conditions)	- at 1% in 30 min at +20°C on hard/non-porous surfaces with prior cleaning - at 5% in 30 min at +20°C on hard/non-porous surfaces wo prior cleaning.	"RP_2019-03-012_mSPC13_L31_EN13697_18-25°C_30min_clean" "RP_2019-03-013_mSPC13_L31_EN13697_18-25°C_30min_dirty"  <b>R.I. 1</b> <b>Key study</b>
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<b>META-SPC 13 (representative product with 11% LA) : Summary of the test results validated after evaluation</b>			
<b>EN 1276</b>	0.5% - 30 min - +20°C - CLEAN	<b>EN 13697</b> <b>B + Y</b>	1% - 30 min - +20°C - CLEAN 5% - 30 min - +20°C - DIRTY
	2% - 30 min - +20°C - DIRTY		
<b>EN 1650</b>	1% - 30 min - +20°C - CLEAN		
	4% - 30 min - +20°C - DIRTY		

### Meta SPC13 - EFF CONCLUSIONS

#### PT4

**Use #13.1** : Hard surface disinfection (by foaming)

B + Y : 1% (0.11 % LA) at +20°C in 30 min contact time on hard/non-porous surfaces with previous cleaning

B + Y : 5% (0.55 % LA) at +20°C in 30 min contact time on hard/non-porous surfaces without previous cleaning

By foaming : be sure to wet surfaces completely. The required contact time has to be respected until further treatments.

<b>Meta SPC-14 (32% LA)</b>				
<b>Experimental data on the efficacy of the biocidal product against target organisms</b>				
<b>Field of use envisaged</b>		<b>PT3</b>	Use #1 : Coronary band & interdigital skin of hooves disinfection	
<b>Test product</b>	<b>Function &amp; Test organism(s)</b>	<b>Test method / Test system / concentrations applied / exposure time</b>	<b>Test results : effects</b>	<b>Reference &amp; R.I.</b>
<b>MetaSPC14 (L34)</b> With 32.07 % Lactic Acid  Batch N°5119090013 (Doc. "Certificate of analysis L34 MetaSPC 14.2")	<b>Bactericidal activity</b> <i>Enterococcus hirae</i> <i>P. vulgaris</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i>	<b>EN 1656 (2009)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature : +30 ± 1°C</li> <li>• Contact time : 5 min</li> <li>• Concentrations tested : 3 - 4 - 5%</li> <li>• I.S. : 10g/L BSA + 10g/L YE</li> </ul>	Bactericidal activity at 5% in 5 min at +30°C in dirty conditions	Doc. "RP_2019-04-001_mSPC14_EN1656_30°C_5min_dirty"  <p style="text-align: center;"><b>R.I. 1</b></p>
<b>MetaSPC14 (L34)</b> With 32.07 % Lactic Acid  Batch N°5119090013 (Doc. "Certificate of analysis L34 MetaSPC 14.2")	<b>Yeasticidal activity</b> <i>Candida albicans</i>	<b>EN 1657 (2016)</b> Quantitative suspension test  <ul style="list-style-type: none"> <li>• Temperature : +30 ± 1°C</li> <li>• Contact time : 5 min</li> <li>• Concentrations tested : 5 - 6 - 7%</li> <li>• I.S. : 10g/L BSA + 10g/L YE</li> </ul>	Yeasticidal activity at 6% in 5 min at +30°C in dirty conditions.	Doc. "RP_2019-03-006_mSPC14_EN1657_30°C_5min_dirty"  <p style="text-align: center;"><b>R.I. 1</b></p>
<b>MetaSPC14 (L34)</b> With 32.07 % Lactic Acid	<b>Bactericidal activity</b> <i>Enterococcus hirae</i> <i>P. vulgaris</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i>	<b>EN 16437 (2014) modified</b> Bactericidal activity when applied to synthetic skin (VITRO-SKIN)  <ul style="list-style-type: none"> <li>• Temperature : +30 ± 1°C</li> <li>• Contact time : 5 min</li> </ul>	Bactericidal activity (for teat disinfection) at 5% in 5 min at +30°C on dirty skin.  According to the ECHA EFF guidance (Annex IV p.270), the required T°C for	Doc. "RP_2019-07-035_metaSPC 14_L34_skin test_30°C_5min_dirty"  <p style="text-align: center;"><b>R.I. 1</b></p>

Batch N°5119090013 (Doc. "Certificate of analysis L34 MetaSPC 14.2")		<ul style="list-style-type: none"> <li>• Concentrations tested : 4 - 5 - 6%</li> <li>• I.S. : 10g/L BSA + 10g/L YE</li> </ul>	hoof disinfection is +10°C, but since the product is intended to be used for skin disinfection, your justification seems acceptable. Then as the conclusion, I'm of the opinion to validate the use as proposed. However, this way-to-proceed may be brought into question by other MS during the peer-review.	
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**META-SPC 14 (representative product with 32% LA) : Summary of the test results validated after evaluation**

<b>EN 1656</b>	5% - 5 min - +30°C - DIRTY	<b>EN</b>	
<b>EN 1657</b>	6% - 5 min - +30°C - DIRTY	<b>EN 16437 Modified</b>	B+Y : 6% - 5 min - +30°C - DIRTY

**Meta SPC14 - EFF CONCLUSIONS**
**PT3**
**Use #14.1** : Coronary band & interdigital skin of hooves disinfection

B+Y : 6% (1.92 % LA) at +30°C- 5 min – on hooves not cleaned prior disinfection.



<b>Meta SPC-15 (3.60% LA)</b>					
<b>Experimental data on the efficacy of the biocidal product against target organisms</b>					
<b>Field of use envisaged</b>		<b>PT1</b>	Use #1 : Hygienic hand rub		
<b>Test product</b>	<b>Function &amp; Test organism(s)</b>	<b>Test method / Test system / concentrations applied / exposure time</b>		<b>Test results : effects</b>	<b>Reference &amp; R.I.</b>
<b>MetaSPC15 (L33)</b> With 3.65 % Lactic Acid  Batch N°511916006 (Doc. "Certificate of analysis L33 MetaSPC 15")	<b>Bactericidal activity</b> <i>Enterococcus hirae</i> <i>E.coli</i> K12 <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i>	<b>EN 13727 (2013)</b> Quantitative suspension test <ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 1 min</li> <li>• Concentrations tested : 1 - 20 – 80%</li> <li>• I.S. : 0.3g/L BSA (clean conditions)</li> </ul>		Bactericidal activity at 20% in 1 min at +20°C in clean conditions.	Doc. "RP_2019-06-005_metaSPC15_L33_EN13727_20°C_1min_clean"  <b>R.I. 1</b> <b>Key study</b>
<b>MetaSPC15 (L33)</b> With 3.65 % Lactic Acid  Batch N°511916006 (Doc. "Certificate of analysis L33 MetaSPC 15")	<b>Yeasticidal activity</b> <i>Candida albicans</i>	<b>EN 13624 (2013)</b> Quantitative suspension test <ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 1 min</li> <li>• Concentrations tested : 80%</li> <li>• I.S. : 0.3g/L BSA (clean conditions)</li> </ul>		Yeasticidal activity at 80% in 1 min at +20°C in clean conditions.	Doc. "RP_2019-05-019_metaSPC15_L33_EN13624_20°C_1min_clean"  <b>R.I. 1</b> <b>Key study</b>
<b>MetaSPC15 (L33)</b> With 3.65 % Lactic Acid	<b>Bactericidal activity</b> <i>E. coli</i> K12	<b>EN 1500 (2013)</b> <ul style="list-style-type: none"> <li>• Temperature : +20 ± 1°C</li> <li>• Contact time : 30 sec.</li> </ul>		The test-product is in compliance with the current requirements of the EN 1500 standard	Doc. « STULV19AA2783-1_AAE32085_v1.000»  <b>R.I. 1</b>

Batch N°511916006 (Doc. "Certificate of analysis L33 MetaSPC 15")		<ul style="list-style-type: none"> <li>Concentrations tested : 100% - 6 mL</li> </ul>	=> This product, intended to be used as a hygienic handrub, allows the reduction of "transient microbial flora" (bacterial organisms) on hands when used undiluted with 6 mL in 30 sec.	<b>Key study</b>
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<b>META 15 (3.6% Lactic Acid) : Summary of the test results validated after evaluation</b>	
<b>EN 13727</b>	20% - 1 min - +20°C - CLEAN
<b>EN 13624</b>	80% - 1 min - +20°C - CLEAN (Y only)
<b>EN 1500</b>	RTU (3.6 % LA) with 6 mL & water at RT in 30 sec.

<b>Meta SPC15 - EFF CONCLUSIONS</b>
<p><b>PT1</b>  <b>Use #15.1</b> : Hygienic hand rub – Prof  <b>Use #15.2</b> : Hygienic hand rub  B+Y : RTU (3.6 % LA) – 6 mL – 1 min - +20°C – on visibly clean hands</p>

<b>CID lines Lactic acid-based products BPF</b>		
<b>SUMMARY</b> of the conclusions on efficacy of the products of the <i>Family</i> and <b>validated label claims</b>		
<b>Meta SPC-1</b>		<b>Validated label claims</b>
<b>Representative product with 3.60% LA</b>		
<b>PT1</b>	<b>Use #1.1</b> : Hygienic Handwash – <i>PROF (not for medical uses)</i>	This product, intended to be used as a hygienic handwash, allows the reduction of “transient bacteria flora” on hands when used undiluted with 10 mL & water at RT in 1 min.
	<b>Use #1.2</b> : Hygienic Handwash ( <i>not for medical uses</i> )	
<b>Meta SPC-2</b>		<b>Validated label claims</b>
<b>Representative product with 2% LA</b>		
<b>PT2</b>	Use #2.1 : RTU algicide – PROF	On hard/non-porous surfaces <u>without</u> prior cleaning Active against unicellular green algae and blue-green algae (cyanobacteria) : at 100% at +20-25°C in 3h contact time
	Use #2.2 : RTU algicide	
<b>Meta SPC-3</b>		<b>Validated label claims</b>
<b>Representative product with 68.7% LA</b>		
<b>PT2</b>	<b>Use #3.1</b> : concentrated algicide	On hard/non-porous surfaces <u>without</u> prior cleaning Active against unicellular green algae and blue-green algae (cyanobacteria) : at 0.5% at +20°C in 3h contact time
<b>PT4</b>	<b>Use #3.2</b> : disinfection of hard/non-porous surfaces in the food industry (e.g. processing machines)	On hard/non-porous surfaces <u>without</u> prior cleaning Active against bacteria and yeasts : at 4% at +40°C in 5 sec. contact time
<b>Meta SPC-4</b>		<b>Validated label claims</b>
<b>Representative product with 16% LA</b>		
<b>PT2</b>	<b>Use #4.1</b> : Hard surface disinfection for sanitary hygiene – <i>PROF (not in healthcare areas)</i>	On hard/non-porous surfaces <u>without</u> prior cleaning Active against bacteria and yeasts : at 20% at +20°C in 15 min contact time
	<b>Use #4.2</b> : Hard surface disinfection for sanitary hygiene ( <i>not in healthcare areas</i> )	
	<b>Use #4.5</b> : RTU Toilet bowl disinfection – <i>PROF</i>	On hard/non-porous surfaces <u>without</u> prior cleaning Active against bacteria and yeasts : at 100% at +20°C in 5 min contact time
	<b>Use #4.6</b> : RTU Toilet bowl disinfection	
<b>PT4</b>	<b>Use #4.3</b> : Hard surface disinfection for sanitary hygiene – <i>PROF (not in healthcare areas)</i>	On hard/non-porous surfaces <u>without</u> prior cleaning Active against bacteria and yeasts :

	<b>Use #4.4</b> : Hard surface disinfection for sanitary hygiene ( <i>not in healthcare areas</i> )	at 20% at +20°C in 15 min contact time
<b>Meta SPC-5</b> <b>Representative product with 8% LA</b>		<b>Validated label claims</b>
<b>PT3</b>	<b>Use #5.1</b> : Teat disinfection (pre-milking)	<u>Without</u> prior cleaning Active against bacteria and yeasts : at 40% at +30°C in 1 min contact time
	<b>Use #5.2</b> : Intact skin wash/disinfection (of the udder of dairy and beef cattle before calving and of the udder of sows before farrowing)	
<b>Meta SPC-6</b> <b>Representative product with 3.6% LA</b>		<b>Validated label claims</b>
<b>PT3</b>	<b>Use #6.1</b> : Teat disinfection (pre-milking with wipes)	<u>Without</u> prior cleaning Active against bacteria and yeasts : at 100% at +30°C in 1 min contact time
<b>Meta SPC-7</b> <b>Representative product with 2% LA</b>		<b>Validated label claims</b>
<b>PT2</b>	<b>Use #7.3</b> : Hard surface disinfection – <i>PROF</i>	<u>On hard/non-porous surfaces with</u> prior cleaning Active against bacteria, yeasts and viruses : With pre-impregnated wipes at +20°C in 2 min contact time
	<b>Use #7.4</b> : Hard surface disinfection	
	<b>Use #7.5</b> : Hard surface disinfection – <i>PROF (in healthcare)</i>	
	<b>Use #7.6</b> : Hard surface disinfection ( <i>in healthcare</i> )	
<b>PT4</b>	<b>Use #7.1</b> : Hard surface disinfection – <i>PROF</i>	
	<b>Use #7.2</b> : Hard surface disinfection	
<b>Meta SPC-8</b> <b>Representative product with 3.6% LA</b>		<b>Validated label claims</b>
<b>PT3</b>	<b>Use #8.1</b> : Teat disinfection (post-milking)	On teats - Active against bacteria and yeasts : At 100% at +30°C in 5 min contact time
<b>Meta SPC-9</b> <b>Representative product with 3.6% LA</b>		<b>Validated label claims</b>
<b>PT3</b>	<b>Use #9.1</b> : Teat disinfection (post-milking)	On teats - Active against bacteria and yeasts : At 100% at +30°C in 5 min contact time

Meta SPC-10 Representative product with 3.6% LA		Validated label claims
PT3	Use #10.1 : Teat disinfection (post-milking)	On teats - Active against bacteria and yeasts : At 100% at +30°C in 5 min contact time
Meta SPC-11 Representative product with 24% LA		Validated label claims
PT3	Use #11.3 : Hard surface disinfection	On hard/non-porous surfaces <u>with</u> prior cleaning Active against bacteria and yeasts : 4% at +10°C in 30 min contact time
PT4	Use #11.1 : Hard surface disinfection (spraying/immersion)	On hard/non-porous surfaces <u>with</u> prior cleaning Active against bacteria and yeasts : 3% at +20°C in 2 min contact time / 1% at +20°C in 15 min contact time
	Use #11.2 : disinfection of hard/non-porous surfaces in the food industry (e.g. processing machines)	On hard/non-porous surfaces <u>without</u> prior cleaning Active against bacteria and yeasts : at +7°C - 15% in 30 sec. contact time by DIPPING at +7°C - 8% in 2 min contact time by SPRAYING
Meta SPC-12 Representative product with 22% LA		Validated label claims
PT4	Use #12.1 : inner surface disinfection – CIP with circulation	At +50°C - On hard/non-porous surfaces Active against bacteria and yeasts : <ul style="list-style-type: none"> <li><u>with</u> prior cleaning : 2% in 2 min contact time / 1% in 30 min contact time</li> <li><u>without</u> prior cleaning : 4% in 2 min contact time / 1% in 30 min contact time</li> <li>In Dairy industry : 2% in 15 min contact time</li> </ul>
	Use #12.2 : inner surface disinfection – without circulation	At +50°C - On hard/non-porous surfaces Active against bacteria and yeasts : <ul style="list-style-type: none"> <li><u>with</u> prior cleaning : 2% in 2 min contact time</li> <li><u>without</u> prior cleaning : 4% in 2 min contact time / 2% in 30 min contact time</li> </ul>

	<b>Use #12.3 : Crate wash</b>	At +50°C - On hard/non-porous surfaces <u>Without</u> prior cleaning : Active against bacteria and yeasts : 4% in 2 min contact
<b>Meta SPC-13 Representative product with 11% LA</b>		<b>Validated label claims</b>
<b>PT4</b>	<b>Use #13.1</b> : Hard surface disinfection (foaming)	At +20°C in 30 min - On hard/non-porous surfaces Active against bacteria and yeasts : <ul style="list-style-type: none"> <li>• <u>with</u> prior cleaning : 1%</li> <li>• <u>without</u> prior cleaning : 5%</li> </ul>
<b>Meta SPC-14 Representative product with 32% LA</b>		<b>Validated label claims</b>
<b>PT3</b>	<b>Use #14.1</b> : Coronary band & interdigital skin of hooves disinfection	At +30°C in 5 min - Active against bacteria and yeasts : <ul style="list-style-type: none"> <li>• <u>without</u> prior cleaning : 6%</li> </ul>
<b>Meta SPC-15 Representative product with 3.2% LA</b>		<b>Validated label claims</b>
<b>PT1</b>	<b>Use #15.1</b> : Hygienic hand rub - Prof	Active against bacteria and yeasts : RTU – 6 mL – 1 min - +20°C – on clean hands
	<b>Use #15.2</b> : Hygienic hand rub	

#### 2.2.5.5 Occurrence of resistance and resistance management

Information from the L-(+)-Lactic acid CAR:

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.

#### 2.2.5.6 Known limitations

Note of the applicant: not applicable.

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

The products in this product family are not intended to be used in combination with other biocidal products.

## 2.2.6 Risk assessment for human health

For the human health hazard assessment, **new information (in vitro skin irritation and corrosion tests)** is provided on the biocidal products of this biocidal product family. The others endpoints are assessed on the basis of the properties of the individual ingredients of the concerned biocidal products.

### 2.2.6.1 Assessment of effects on Human Health

#### ***Skin corrosion and irritation***

Skin corrosion tests are performed on the maximum concentrations of metaSPCs 2, 4 and 11.

Skin irritation tests are performed on the maximum concentrations of metaSPCs 1, 2, 4, 5, 6, 8, 9, 10, 11 and 15.

The skin corrosion/irritation tests performed on metaSPC 2 are also representative for metaSPC 7 as the wipes of metaSPC 7 are impregnated with the solution of metaSPC 2.



Summary table of in vitro studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	Test substance, Doses	Relevant information about the study	Results	Remarks (e.g. major deviations)	Reference
OECD guideline n°439, In vitro skin: reconstructed human epidermis (RHE) test method  Reliability: 1	Formula with maximum concentrations of Meta SPC 1 (Kenosan Hand Scrub)  Dose: 16 µL of product  batch 5119344405	Undiluted product  Skin irritation test	<b>Skin irritant</b> potential of tests chemicals is predicted by the mean tissue viability of tissues exposed to a test chemical. For tissues treated with Meta SPC 1, the mean tissue viabilities are > 50%. Based on these results, Meta SPC 1 must be considered as <b>non-irritant</b> to skin, in accordance with UN GHS.		SKINIRR_2019-09-01-mSPC1, D. Skopinski, 2019, 8.1.1
OECD guideline n°431, In vitro skin: reconstructed human epidermis (RHE) test method  Reliability: 1	Formula with maximum concentrations of Meta SPC 2 (RTU algaecide)  Dose: 40 µL of product (L4)  batch 5119030003	Undiluted product  Skin corrosion test	<b>Skin corrosive</b> potential of tests chemicals is predicted by the mean tissue viability of tissues exposed to a test chemical. For tissues treated with Meta SPC 2 for 3 minutes, the mean tissue viabilities are > 50%. For tissues treated with Meta SPC 2 for 60 minutes, the mean tissue viabilities are > 50%. Based on these results, Meta SPC 2 must be considered as <b>non-corrosive</b> to skin, in accordance with UN GHS.		SKINCORR_2019-05-01-mSPC2, D. Skopinski, 2019, 8.1.1

<p>OECD guideline n°439, In vitro skin: reconstructed human epidermis (RHE) test method</p> <p>Reliability: 1</p>	<p>Formula with maximum concentrations of Meta SPC 2 (RTU algaecide)</p> <p>Dose: 16 µL of product (L2)</p> <p>batch 5119420001</p>	<p>Undiluted product</p> <p>Skin irritation test</p>	<p><b>Skin irritant</b> potential of tests chemicals is predicted by the mean tissue viability of tissues exposed to a test chemical. For tissues treated with Meta SPC 2, the mean tissue viabilities are &gt; 50%. Based on these results, Meta SPC 2 must be considered as <b>non-irritant</b> to skin, in accordance with UN GHS.</p>		<p>SKINIRR_2019-10-01-mSPC2, D. Skopinski, 2019, 8.1.1</p>
<p>OECD guideline n°431, In vitro skin: reconstructed human epidermis (RHE) test method</p> <p>Reliability: 1</p>	<p>Formula with maximum concentrations of Meta SPC 4 (Sanifresh)</p> <p>Dose: 40 µL of product (L6)</p> <p>batch 5119030004</p>	<p>Undiluted product</p> <p>Skin corrosion test</p>	<p><b>Skin corrosive</b> potential of tests chemicals is predicted by the mean tissue viability of tissues exposed to a test chemical. For tissues treated with Meta SPC 4 for 3 minutes, the mean tissue viabilities are ≥ 50%. For tissues treated with Meta SPC 4 for 60 minutes, the mean tissue viabilities are ≥ 15%. Based on these results, Meta SPC 4 must be considered as <b>non-corrosive</b> to skin, in accordance with UN GHS.</p>		<p>SKINCORR_2019-05-02-mSPC4, M. Degraeve, 2019, 8.1.1</p>

<p>OECD guideline n°439, In vitro skin: reconstructed human epidermis (RHE) test method</p> <p>Reliability: 1</p>	<p>Formula with maximum concentrations of Meta SPC 5 (Kenopure)</p> <p>Dose: 16 µL of product (L8)</p> <p>batch 5119344406</p>	<p>Undiluted product</p> <p>Skin irritation test</p>	<p><b>Skin irritant</b> potential of tests chemicals is predicted by the mean tissue viability of tissues exposed to a test chemical. For tissues treated with Meta SPC 5, the mean tissue viabilities are &gt; 50%. Based on these results, Meta SPC 5 must be considered as <b>non-irritant</b> to skin, in accordance with UN GHS.</p>		<p>SKINIRR_2019-09-01-mSPC5, D. Skopinski, 2019, 8.1.1</p>
<p>OECD guideline n°439, In vitro skin: reconstructed human epidermis (RHE) test method</p> <p>Reliability: 1</p>	<p>Formula with maximum concentrations of Meta SPC 6 (Kenopure R)</p> <p>Dose: 16 µL of product (L36)</p> <p>batch 5119344407</p>	<p>Undiluted product</p> <p>Skin irritation test</p>	<p><b>Skin irritant</b> potential of tests chemicals is predicted by the mean tissue viability of tissues exposed to a test chemical. For tissues treated with Meta SPC 6, the mean tissue viabilities are &gt; 50%. Based on these results, Meta SPC 6 must be considered as <b>non-irritant</b> to skin, in accordance with UN GHS.</p>		<p>SKINIRR_2019-09-01-mSPC6, D. Skopinski, 2019, 8.1.1</p>

<p>OECD guideline n°439, In vitro skin: reconstructed human epidermis (RHE) test method</p> <p>Reliability: 1</p>	<p>Formula with maximum concentrations of Meta SPC 8 (Kenolac)</p> <p>Dose: 16 µL of product (L16)</p> <p>batch 5119020008</p>	<p>Undiluted product</p> <p>Skin irritation test</p>	<p><b>Skin irritant</b> potential of tests chemicals is predicted by the mean tissue viability of tissues exposed to a test chemical. For tissues treated with Meta SPC 8, the mean tissue viabilities are &gt; 50%. Based on these results, Meta SPC 8 must be considered as <b>non-irritant</b> to skin, in accordance with UN GHS.</p>		<p>SKINIRR_2019-06-01-mSPC8, D. Skopinski, 2019, 8.1.1</p>
<p>OECD guideline n°439, In vitro skin: reconstructed human epidermis (RHE) test method</p> <p>Reliability: 1</p>	<p>Formula with maximum concentrations of Meta SPC 9 (Kenolac SD)</p> <p>Dose: 16 µL of product (L22)</p> <p>batch 5119344408</p>	<p>Undiluted product</p> <p>Skin irritation test</p>	<p><b>Skin irritant</b> potential of tests chemicals is predicted by the mean tissue viability of tissues exposed to a test chemical. For tissues treated with Meta SPC 9, the mean tissue viabilities are &gt; 50%. Based on these results, Meta SPC 9 must be considered as <b>non-irritant</b> to skin, in accordance with UN GHS.</p>		<p>SKINIRR_2019-09-01-mSPC9, D. Skopinski, 2019, 8.1.1</p>

<p>OECD guideline n°439, In vitro skin: reconstructed human epidermis (RHE) test method</p> <p>Reliability: 1</p>	<p>Formula with maximum concentrations of Meta SPC 10 (Kenocool)</p> <p>Dose: 16 µL of product (L25)</p> <p>batch 5119020011</p>	<p>Undiluted product</p> <p>Skin irritation test</p>	<p><b>Skin irritant</b> potential of tests chemicals is predicted by the mean tissue viability of tissues exposed to a test chemical. For tissues treated with Meta SPC 10, the mean tissue viabilities are &gt; 50%. Based on these results, Meta SPC 10 must be considered as <b>non-irritant</b> to skin, in accordance with UN GHS.</p>		<p>SKINIRR_2019-06-02-mSPC10, D. Skopinski, 2019, 8.1.1</p>
<p>OECD guideline n°431, In vitro skin: reconstructed human epidermis (RHE) test method</p> <p>Reliability: 1</p>	<p>Formula with maximum concentrations of Meta SPC 11 (Kenosan Lactic)</p> <p>Dose: 40 µL of product (L26)</p> <p>batch 3091828203</p>	<p>Undiluted product</p> <p>Skin corrosion test</p>	<p><b>Skin corrosive</b> potential of tests chemicals is predicted by the mean tissue viability of tissues exposed to a test chemical. For tissues treated with Meta SPC 11 for 3 minutes, the mean tissue viabilities are ≥ 50%. For tissues treated with Meta SPC 11 for 60 minutes, the mean tissue viabilities are ≥ 15%. Based on these results, Meta SPC 11 must be considered as <b>non-corrosive</b> to skin, in accordance with UN GHS.</p>		<p>SKINCORR_2019-05-02-mSPC11, M. Degraeve, 2019, 8.1.1</p>

OECD guideline n°439, In vitro skin: reconstructed human epidermis (RHE) test method  Reliability: 1	Formula with maximum concentrations of Meta SPC 15 – (Kenosan Hand Rub)  Dose: 16 µL of product (L33)  batch 5119344409	Undiluted product  Skin irritation test	<b>Skin irritant</b> potential of tests chemicals is predicted by the mean tissue viability of tissues exposed to a test chemical. For tissues treated with Meta SPC 15, the mean tissue viabilities are > 50%. Based on these results, Meta SPC 15 must be considered as <b>non-irritant</b> to skin, in accordance with UN GHS.		SKINIRR_2019-09-01-mSPC15, D. Skopinski, 2019, 8.1.1
OECD guideline n°439, In vitro skin: reconstructed human epidermis (RHE) test method  Reliability: 1	Formula with maximum concentrations of Meta SPC 4 – (Sanifresh) batch 5119030004  Dose: 40 µL of product (L26)  Formula with maximum concentrations of Meta SPC 11 – (Kenosan Lactic) batch 3091828203	Undiluted product  Skin corrosion test	MetaSPCs 4 and 11 of the BPF of lactic acid must be considered as <b>irritant to skin</b> , in accordance with UN GHS.		2020-03-035_mSPC4 and 11_irritation test, I. Verschaeve, 2020, 8.1.1

### Conclusion used in Risk Assessment – Skin corrosion and irritation

Value / conclusion	<ul style="list-style-type: none"> <li>metaSPC 1: products are <u>not</u> considered as irritant for skin according to the CLP regulation.</li> </ul>
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	<ul style="list-style-type: none"> <li>• metaSPC 2: products are <u>not</u> considered as irritant for skin according to the CLP regulation.</li> <li>• metaSPC 3: products are <u>corrosive</u> for skin according to the CLP regulation.</li> <li>• metaSPC 4: products are <u>irritant</u> for skin according to the CLP regulation.</li> <li>• metaSPC 5: products are <u>not</u> considered as irritant for skin according to the CLP regulation.</li> <li>• metaSPC 6: products are <u>not</u> considered as irritant for skin according to the CLP regulation.</li> <li>• metaSPC 7: products are <u>not</u> considered as irritant for skin according to the CLP regulation.</li> <li>• metaSPC 8: products are <u>not</u> considered as irritant for skin according to the CLP regulation.</li> <li>• metaSPC 9: products are <u>not</u> considered as irritant for skin according to the CLP regulation.</li> <li>• metaSPC 10: products are <u>not</u> considered as irritant for skin according to the CLP regulation.</li> <li>• metaSPC 11: products are <u>irritant</u> for skin according to the CLP regulation.</li> <li>• metaSPC 12: products are <u>corrosive</u> for skin according to the CLP regulation.</li> <li>• metaSPC 13: products are <u>corrosive</u> for skin according to the CLP regulation.</li> <li>• metaSPC 14: products are <u>corrosive</u> for skin according to the CLP regulation.</li> <li>• metaSPC 15: products are <u>not</u> considered as irritant for skin according to the CLP regulation.</li> </ul>
Justification for the value / conclusion	<p>According to the RAC opinion of L-(+)-Lactic acid (CAS 79-33-4), the active substance is classified as H314.</p> <p>MetaSPC 1 contains 3,6%<i>m/m</i> lactic acid and pH&gt;2 and pH&lt;11,5. The product(s) of metaSPC 1 have no extreme low or high pH. The SCL to have H314 classification is 5%. The product(s) contain 3,6% lactic acid and don't contain other ingredients classified as H314. Therefore the product(s) of metaSPC 1 should not be classified as H314.</p>

<p>The SCL for lactic acid to have H315 classification is 1%. The product(s) contain 3,6% lactic acid therefore the product(s) of metaSPC 1 should be classified as H315.</p> <p>Skin irritation test has been done on the maximum concentrations of metaSPC 1. This OECD439 test resulted in non-irritant to skin.</p> <p>Therefore the products of metaSPC 1 can be considered as non-irritant to skin</p> <p>MetaSPC 2 contains 2%<i>m/m</i> lactic acid and pH&gt;2 and pH&lt;11,5.</p> <p>The product(s) of metaSPC 2 have no extreme low or high pH.</p> <p>The SCL to have H314 classification is 5%. The product(s) contain 2% lactic acid and don't contain other ingredients classified as H314. Therefore the product(s) of metaSPC 2 should not be classified as H314.</p> <p>The SCL to have H315 classification is 1% because of L-(+)-Lactic acid, therefore the product(s) of metaSPC 2 should be classified as H315.</p> <p>Skin irritation test has been done on the maximum concentrations of metaSPC 2. This OECD439 test resulted in non-irritant to skin.</p> <p>Therefore the products of metaSPC 2 can be considered as non-irritant to skin. In case a "no classification" for dermal effects is based on studies, please also refer to the WG HH I – 2021.</p> <p>MetaSPC 3 contains 70%<i>m/m</i> lactic acid and pH&gt;2 and pH&lt;11,5.</p> <p>The product(s) of metaSPC 3 have no extreme low or high pH.</p> <p>The SCL for lactic acid to have H314 classification is 5%. The product(s) contain 70% lactic acid, therefore the product(s) of metaSPC 3 should be classified as H314 (Skin Corr 1C according to the ATP15).</p> <p>No skin corrosion test has been done as the products of metaSPC 3 contain 70%<i>m/m</i> lactic acid. Therefore, the products of metaSPC 3 should be classified as H314 (Skin Corr 1C according to the ATP15).</p> <p>MetaSPC 4 contains 16%<i>m/m</i> lactic acid and pH between 1 and 3.</p> <p>The product(s) of metaSPC 4 can have extreme low pH.</p> <p>The SCL to have H314 classification is 5%. The product(s) contain 16% lactic acid. Therefore the product(s) of metaSPC 4 should be classified as H314.</p> <p>Skin corrosion test has been done on the maximum concentrations of metaSPC 4. This OECD431 test resulted in non-corrosion.</p> <p>Skin irritation test has been done on the maximum concentrations of metaSPC 4. This OECD439 test resulted in irritant to skin.</p> <p>Therefore the H314 can be removed and the H315 can be added to the classification.</p> <p>MetaSPC 5 contains 8%<i>m/m</i> lactic acid and pH&gt;2 and pH&lt;11,5.</p> <p>The product(s) of metaSPC 5 have no extreme low or high pH.</p> <p>The SCL to have H314 classification is 5%. The product(s) contain 8% lactic acid. Therefore the product(s) of metaSPC 5 should be classified as H314.</p> <p>Skin irritation test has been done on the maximum concentrations of metaSPC 5. This OECD439 test resulted in non-irritant to skin.</p> <p>Therefore the products of metaSPC 5 can be considered as non-irritant to skin.</p> <p>MetaSPC 6 contains 3,6%<i>m/m</i> lactic acid and pH&gt;2 and pH&lt;11,5.</p> <p>The product(s) of metaSPC 6 have no extreme low or high pH.</p> <p>The SCL to have H314 classification is 5%. The product(s) contain 3,6% lactic acid and don't contain other ingredients classified as H314. Therefore the product(s) of metaSPC 6 should not be classified as H314.</p>
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The SCL to have H315 classification is 1% because of L-(+)-Lactic acid, therefore the product(s) of metaSPC 6 should be classified as H315. Skin irritation test has been done on the maximum concentrations of metaSPC 6. This OECD439 test resulted in non-irritant to skin. Therefore the products of metaSPC 6 can be considered as non-irritant to skin.

MetaSPC 7 are wipes impregnated with the solution of metaSPC 2. Therefore we refer to the above justification of metaSPC 2 and the products of metaSPC 7 can be considered as non-irritant to skin.

MetaSPC 8 contains 3,6%*m/m* to 7,5%*m/m* lactic acid and  $\text{pH} > 2$  and  $\text{pH} < 11,5$ .

The product(s) of metaSPC 8 have no extreme low or high pH. The SCL for lactic acid to have H314 classification is 5%. The product(s) of this metaSPC contain 3,6 to 7,5% lactic acid.

The SCL for [REDACTED] to have H314 classification is 2%. The product(s) of this metaSPC contain 0,5 to 1% [REDACTED].

Therefore the product(s) of metaSPC 8 should be classified as H314.

Skin irritation test has been done on the maximum concentrations of metaSPC 8. This OECD439 test resulted in non-irritant to skin.

Therefore the products of metaSPC 8 can be considered as non-irritant to skin

MetaSPC 9 contains 3,6%*m/m* to 7,5%*m/m* lactic acid and  $\text{pH} > 2$  and  $\text{pH} < 11,5$ .

The product(s) of metaSPC 9 have no extreme low or high pH.

The SCL for lactic acid to have H314 classification is 5%. The product(s) of this metaSPC contain 3,6 to 7,5% lactic acid.

The SCL for [REDACTED] to have H314 classification is 2%. The product(s) of this metaSPC contain 0,5 to 1,3% [REDACTED].

Therefore the product(s) of metaSPC 9 should be classified as H314.

Skin irritation test has been done on the maximum concentrations of metaSPC 9. This OECD439 test resulted in non-irritant to skin.

Therefore the products of metaSPC 9 can be considered as non-irritant to skin

MetaSPC 10 contains 3,6%*m/m* lactic acid and  $\text{pH} > 2$  and  $\text{pH} < 11,5$ .

The product(s) of metaSPC 10 have no extreme low or high pH.

The SCL for lactic acid to have H314 classification is 5%. The product(s) of this metaSPC contain 3,6% lactic acid.

The SCL for [REDACTED] to have H314 classification is 2%. The product(s) of this metaSPC contain 0,4% [REDACTED].

Accumulating both ingredients results in a value  $< 1 ((3,6/5) + (0,4/2)) = 8/10$

Therefore the product(s) of metaSPC 10 should not be classified as H314.

The SCL to have H315 classification is 1% because of L-(+)-Lactic acid, therefore the product(s) of metaSPC 10 should be classified as H315.

Skin irritation test has been done on the maximum concentrations of metaSPC 10. This OECD439 test resulted in non-irritant to skin.

Therefore the products of metaSPC 10 can be considered as non-irritant to skin

MetaSPC 11 contains 24%*m/m* lactic acid and pH between 1 and 3.

The product(s) of metaSPC 11 can have extreme low pH.

	<p>The SCL for lactic acid to have H314 classification is 5%. The product(s) of this metaSPC contain 24% lactic acid. Therefore the product(s) of metaSPC 11 should be classified as H314.</p> <p>Skin corrosion test has been done on the maximum concentrations of metaSPC 11. This OECD431 test resulted in non-corrosion.</p> <p>Skin irritation test has been done on the maximum concentrations of metaSPC 11. This OECD439 test resulted in irritant to skin.</p> <p>Therefore the H314 can be removed and the H315 can be added to the classification.</p> <p>MetaSPC 12 contains 22%<i>m/m</i> lactic acid and pH between 1 and 3. The product(s) of metaSPC 12 can have extreme low pH. The product also contains 10.5% <i>m/m</i> of sulfuric acid classified as skin corr.1.</p> <p>According to CLP regulation (additive approach), the concentration is equal to 32.6 % <i>m/m</i> which is higher than the SCL of 5%. Therefore the product(s) of metaSPC 12 should be classified as H314. The product also contains 10.5% of Methane sulfonic acid (CAS 75-75-2), classified as Skin Corr. 1A The substance clearly contributes to the H314 classification of the mixture. Therefore Methanesulfonic acid is a SoC Band B for metaSPC 12</p> <p>MetaSPC 13 contains 11%<i>m/m</i> lactic acid and pH between 1 and 3. The product(s) of metaSPC 13 can have extreme low pH. The SCL to have H314 classification is 5% because of L-(+)-Lactic acid, therefore the product(s) of metaSPC 13 should be classified as H314. No skin corrosion test has been done as we agree to keep the H314 classification for this metaSPC. The product also contains Methane sulfonic acid (CAS 75-75-2), classified as Skin Corr. 1A and present in 13 at a maximal concentration of 19,5%. The substance clearly contributes to the H314 classification of the mixture. Therefore Methanesulfonic acid is a SoC Band B for 13.</p> <p>MetaSPC 14 contains 22%<i>m/m</i> lactic acid and pH between 1 and 3. The product(s) of metaSPC 14 can have extreme low pH. The SCL to have H314 classification is 5% because of L-(+)-Lactic acid, therefore the product(s) of metaSPC 14 should be classified as H314. No skin corrosion test has been done. Therefore, the products of metaSPC 14 should be classified as H314.</p> <p>MetaSPC 15 contains 3,6%<i>m/m</i> lactic acid and pH&gt;2 and pH&lt;11,5. The product(s) of metaSPC 15 have no extreme low or high pH. The SCL to have H314 classification is 5%. The product(s) contain 3,6% lactic acid and don't contain other ingredients classified as H314. Therefore the product(s) of metaSPC 15 should not be classified as H314. The SCL to have H315 classification is 1% because of L-(+)-Lactic acid, therefore the product(s) of metaSPC 15 should be classified as H315. Skin irritation test has been done on the maximum concentrations of metaSPC 15. This OECD439 test resulted in non-irritant to skin. Therefore the products of metaSPC 15 can be considered as non-irritant to skin.</p>
<p>Classification of the product according to CLP and DSD</p>	<p>MetaSPCs 1, 2, 5, 6, 7, 8, 9, 10 and 15 are not classified regarding skin corrosion/irritation.</p> <p>MetaSPCs 3, 12, 13 and 14 are classified as H314.</p> <p>MetaSPCs 4 and 11 are classified as H315.</p>

<b>Data waiving</b>	
Information requirement	Study scientifically unjustified for metaSPCs 3, 12, 13 and 14
Justification	In accordance to the Regulation 1272/2008/EC (CLP) and the RAC opinion of 2019, metaSPCs 3, 12, 13 and 14 are classified regarding skin corrosion/irritation. No further testings are necessary for these metaSPCs.

### **Eye irritation**

No eye irritation tests have been performed.

The RAC opinion of 2019 for Lactic acid has been taken into consideration. No further testings have been performed.

<b>Conclusion used in Risk Assessment – Eye irritation</b>	
Value / conclusion	MetaSPCs 2 and 7 in this family are classified as irritant for the eyes. The other metaSPCs in this family are classified as corrosive for the eyes.
Justification for the value / conclusion	<p>According to the RAC opinion of L-(+)-Lactic acid (CAS 79-33-4), the active substance is classified as H314 and H318</p> <p>MetaSPC 1 contains 3,6% m/m lactic acid classified as Eye dam.1 It also contains 5% m/m of sodium lauryl sulphate classified as Eye dam.1. According to CLP regulation (additive approach), the concentration is equal to 8.6% m/m which is higher than the SCL of 3%. Therefore the product(s) of metaSPC 1 should be classified as H318.</p> <p>MetaSPC 2 contains 2% m/m lactic acid classified as Eye dam.1. According to CLP regulation, the concentration is equal to 2 % m/m which is lower than the SCL of 3%. Therefore metaSPC 4 should be classified as Eye irrit.2</p> <p>MetaSPC 3 contains 70% m/m lactic acid classified as Eye dam.1 It also contains 6% m/m of sodium lauryl sulphate classified as Eye dam.1. According to CLP regulation (additive approach), the concentration is equal to 76 % m/m which is higher than the SCL of 3%. Therefore the product(s) of metaSPC 3 should be classified as H318</p> <p>MetaSPC 4 contains 16% m/m lactic acid classified as Eye dam.1. It also contains 5% m/m sodium of lauryl sulphate classified as Eye dam.1. According to CLP regulation (additive approach), the concentration is equal to 21 % m/m which is higher than the SCL of 3%. Therefore the product(s) of metaSPC 4 should be classified as H318</p> <p>MetaSPC 5 contains 8% m/m lactic acid classified as Eye dam.1. It also contains 8.4% m/m of sodium lauryl ether sulfate and 2.25% m/m of sulfonic acids, C14-17-sec-alkane, sodium salts classified as Eye dam.1. According to CLP regulation (additive approach), the concentration is equal to 18.65 % m/m which is higher than the SCL of 3%. Therefore the product(s) of metaSPC 5 should be classified as H318</p>

MetaSPC 6 contains 3,6%*m/m* lactic acid classified as Eye dam.1. It also contains 5.25% *m/m* of sodium lauryl sulphate classified as Eye dam.1. According to CLP regulation (additive approach), the concentration is equal to 8.85 % *m/m* which is higher than the SCL of 3%. Therefore the product(s) of metaSPC 6 should be classified as H318

MetaSPC 7 are wipes impregnated with the solution of L2 (Meta SPC2). According to CLP regulation , the concentration is equal to 2 % *m/m* which is lower than the SCL of 3%. Therefore the product(s) of metaSPC 7 should be classified as Eyes Irrit.2.

MetaSPC 8 contains 3,6%*m/m* to 7,5%*m/m* lactic acid classified as Eye dam.1. It also contains 1.3% *m/m* of sodium lauryl sulphate classified as Eye dam.1. According to CLP regulation (additive approach), the concentration is equal to 4.9 to 8.8 % *m/m* which is higher than the SCL of 3%. Therefore the product(s) of metaSPC 8 should be classified as H318.

MetaSPC 9 contains 3,6%*m/m* to 7,5%*m/m* lactic acid classified as Eye dam.1. It also contains 1.3% *m/m* of sodium lauryl sulphate classified as Eye dam.1. According to CLP regulation (additive approach), the concentration is equal to 4.9 to 8.8 % *m/m* which is higher than the SCL of 3%. Therefore the product(s) of metaSPC 9 should be classified as H318

MetaSPC 10 contains 3,6%*m/m* lactic acid.  
The SCL to have H318 classification is 3% because of L-(+)-Lactic acid, therefore the product(s) of metaSPC 10 should be classified as H318.

MetaSPC 11 contains 24%*m/m* lactic acid classified as Eye dam.1. It also contains 12 % *m/m* of sodium lauryl sulphate classified as Eye dam.1. According to CLP regulation (additive approach), the concentration is equal to 36 % *m/m* which is higher than the SCL of 3%. Therefore the product(s) of metaSPC 11 should be classified as H318

MetaSPC 12 contains 22%*m/m* lactic acid classified as Eye dam.1. It also contains 2.4 % *m/m* of C6 alkyl glucoside, 10.5 % *m/m* of methanesulfonic acid or 10.5% *m/m* of sulphuric acid classified as Eye dam.1. According to CLP regulation (additive approach), the concentration is equal to 34.9 % *m/m* which is higher than the SCL of 3%. Therefore the product(s) of metaSPC 12 should be classified as H318.

MetaSPC 13 contains 11%*m/m* lactic acid classified as Eye dam.1. It also contains 4.5 % *m/m* of sodium lauryl sulphate and 10.5 or 19.5 % *m/m* of methanesulfonic acid classified as Eye dam.1. According to CLP regulation (additive approach), the concentration is equal to 26 or 35 % *m/m* which is higher than the SCL of 3%. Therefore the product(s) of metaSPC 13 should be classified as H318

MetaSPC 14 contains 32%*m/m* lactic acid classified as Eye dam.1 It also contains 10.5% *m/m* of sodium lauryl sulphate classified as Eye dam.1. According to CLP regulation (additive approach), the concentration is

	<p>equal to 42 % m/m which is higher than the SCL of 3%. Therefore the product(s) of metaSPC 14 should be classified as H318</p> <p>MetaSPC 15 contains 3,6% m/m lactic acid. The SCL to have H318 classification is 3% because of L-(+)-Lactic acid, therefore the product(s) of metaSPC 15 should be classified as H318.</p>
Classification of the product according to CLP and DSD	<p>MetaSPCs 2 and 7 of the family are classified as H319. All other metaSPCs (1, 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14 and 15) of the family are classified as H318.</p>

<b>Data waiving</b>	
Information requirement	Study scientifically unjustified
Justification	In accordance to the Regulation 1272/2008/EC (CLP) and the RAC opinion of 2019, all products are classified regarding eye corrosion/irritation. No further testings are necessary for these metaSPCs.

### ***Respiratory tract irritation***

<b>Conclusion used in the Risk Assessment – Respiratory tract irritation</b>	
Justification for the conclusion	<p><u>Justification for all metaSPCs</u> All metaSPCs contain &lt;20% methane sulfonic acid which is classified as STOT SE 3, H335. Moreover, there are no other ingredients which are classified with H335. The generic concentration limit for STOT SE 3 is 20%. Therefore, no metaSPC are not classified with H335</p>
Classification of the product according to CLP and DSD	No metaSPC is classified with H335

<b>Data waiving</b>	
Information requirement	Study scientifically unjustified.
Justification	The compositions of all the metaSPCs are known and there are sufficient hazard information for each ingredient to be able to use the calculation method in accordance with the CLP.

### ***Skin sensitization***

<b>Conclusion used in Risk Assessment – Skin sensitisation</b>	
Value/conclusion	The BPF is not sensitizing for skin

Justification for the value/conclusion	<p>The Lactic acid Family does not contain any substances leading to the classification of the product as skin sens.1 (above to the SCL equal to 1%).</p> <p>However two substances contained in perfumes triggers the EUH 208 classification of the following products:</p> <ul style="list-style-type: none"> <li>- Eucalyptus globulus oil (CAS No. 8000-48-4) present in the perfume contained in the product listed in the META SPC 4 is sufficient to trigger the product classification as EUH 208 (upper than 1/10 of generic/specific concentration limit).</li> <li>- Menthan-3-one (CAS No. 14073-97-3) present in the perfume contained in the product listed in the META SPC 10 is sufficient to trigger the product classification as EUH 208 (upper than 1/10 of generic/specific concentration limit).</li> </ul>
Classification of the product according to CLP and DSD	<p>No classification as skin sens.1 (H317).</p> <p>For meta SPC 4 and 10 the classification EUH208 is required.</p>

<b>Data waiving</b>	
Information requirement	Study scientifically unjustified.
Justification	The compositions of all the metaSPCs are known and there are sufficient hazard information for each ingredient to be able to use the calculation method in accordance with the CLP.

### ***Respiratory sensitization (ADS)***

<b>Conclusion used in Risk Assessment – Respiratory sensitisation</b>	
Value/conclusion	The BPF is not sensitising for respiratory tract
Justification for the value/conclusion	The Lactic acid Family does not contain any ingredient which is classified as Resp. Sens., H334.
Classification of the product according to CLP and DSD	No classification

<b>Data waiving</b>	
Information requirement	Study scientifically unjustified.
Justification	The compositions of all the metaSPCs are known and there are sufficient hazard information for each ingredient to be able to use the calculation method in accordance with the CLP.

**Acute toxicity**Acute toxicity by oral route

<b>Value used in the Risk Assessment – Acute oral toxicity</b>	
Value	All products in the family are <u>not</u> classified
Justification for the selected value	The ATE (oral) of all formulas in this family are all above 2000 mg/kg. See calculations in the confidential annex.
Classification of the product according to CLP and DSD	All products in the family: no classification

<b>Data waiving</b>	
Information requirement	Study scientifically unjustified.
Justification	The compositions of all the metaSPCs are known and there are sufficient hazard information for each ingredient to be able to use the calculation method in accordance with the CLP.

Acute toxicity by inhalation

<b>Value used in the Risk Assessment – Acute inhalation toxicity</b>	
Value	All products in the family are <u>not</u> classified
Justification for the selected value	The family doesn't contain ingredients which are classified as acute inhalation toxic.
Classification of the product according to CLP and DSD	All products in the family are <u>not</u> classified

<b>Data waiving</b>	
Information requirement	Study scientifically unjustified
Justification	Products of the entire BPF are not classified as acute toxic by inhalation route according to the CLP regulation.

Acute toxicity by dermal route

<b>Value used in the Risk Assessment – Acute dermal toxicity</b>	
Value	All products in the family are <u>not</u> classified

Justification for the selected value	The ATE (dermal) of all formulas in this family are all above 2000 mg/kg. See calculations in the confidential annex.
Classification of the product according to CLP and DSD	All products in the family: no classification

<b>Data waiving</b>	
Information requirement	Study scientifically unjustified
Justification	The compositions of all the metaSPCs are known and there are sufficient hazard information for each ingredient to be able to use the calculation method in accordance with the CLP.

### **Information on dermal absorption**

<b>Value(s) used in the Risk Assessment – Dermal absorption</b>	
Substance	L-lactic acid
Value(s)	Not relevant
Justification for the selected value(s)	According to the WEBEX <sup>3</sup> meetings discussions, only local risk assessment is considered relevant for this active substance. Therefore, a dermal absorption value is not considered relevant.

<sup>3</sup> During the 1st Coordination Webex on UA-APPs on BPs with L-(+)-lactic acid (28/01/2020)

### **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

**Sodium lauryl sulphate (CAS 85586-07-8)** is classified as Eye Dam 1 and is presented in metaSPC 1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 13, 14 and 15 at a maximal concentration of 5%, 6%, 5%, 5,25%, 1,3%, 1,3%, 0,05%, 12%, 4,5%, 10,5% and 2% respectively.

MetaSPC 1, 3, 4, 6, 8, 9, 11, 13, 14 and 15 are classified as Eye Dam 1, H318. For metaSPC 8, 9 and 15 the substance does not trigger the classification of the product by itself but due to the additivity principle for this class of hazard, the substance is considered a SoC contributing to the H318 classification of the mixture. For metaSPC 1, 3, 4, 6, 11, 13 and 14 the substance clearly contributes to the H318 classification of the mixture. **Therefore Sodium lauryl sulphate is a SoC Band B for metaSPC 1, 3, 4, 6, 8, 9, 11, 13, 14 and 15.**

MetaSPC 10 is classified as Eye Dam. 1, H318 but the substance does not contribute to the classification of metaSPC 10 because the concentration is below the generic cut off



value for skin corrosion and eye damage. **Therefore Sodium lauryl sulphate is not a SoC for metaSPC 10.**

**Sodium lauryl ether sulfate (CAS 68891-38-3)** is classified as Eye Dam. 1 and is present in metaSPC 5 at a maximal concentration of 8,4%. MetaSPC 5 is classified as Eye Dam. 1, H318. The substance clearly contributes to the H318 classification of the mixture. **Therefore Sodium lauryl ether sulfate is a SoC Band B for metaSPC 5.**

**Sulfonic acids, C14-17-sec-alkane, sodium salts (CAS 97489-15-1)** is classified as Eye Dam. 1 and is present in metaSPC 5 at a maximal concentration of 2,25%. MetaSPC 5 is classified as Eye Dam. 1, H318. The substance does not trigger the classification of the product by itself but due to the additivity principle for this class of hazard, the substance is considered a SoC contributing to the H318 classification of the mixture. **Therefore Sulfonic acids, C14-17-sec-alkane, sodium salts is a SoC Band B for metaSPC 5.**

**C6 alkyl glucoside (CAS 54549-24-5)** is classified as Eye Dam. 1 and is present in metaSPC 12 at a maximal concentration of 2,4%. MetaSPC 12 is classified as Eye Dam. 1, H318. The substance does not trigger the classification of the product by itself but due to the additivity principle for this class of hazard, the substance is considered a SoC contributing to the H318 classification of the mixture. **Therefore C6 alkyl glucoside is a SoC Band B for metaSPC 12.**

**Methane sulfonic acid (CAS 75-75-2)** is classified as Skin Corr. 1A and is present in metaSPC 12 and 13 at a maximal concentration of 10,5% and 19,5% respectively. MetaSPC 12 and 13 are classified as Skin Corr. 1A, H314. The substance clearly contributes to the H314 classification of the mixture. **Therefore Methanesulfonic acid is a SoC Band B for metaSPC 12 and 13.**

**Sulphuric acid (CAS 7664-93-9)** is classified as Skin Corr. 1A and is present in metaSPC 12 at a maximal concentration of 10,5%. MetaSPC 12 is classified as Skin Corr. 1A, H314. The substance clearly contributes to the H314 classification of the mixture. **Therefore Sulphuric acid is a SoC Band B for metaSPC 12.**

No other co-formulants present meet this criteria.

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)** has a Competent Authority Report for PT1, PT2 and PT4. The substance is present in metaSPC 1, 8, 9, 11 and 15 at a maximal concentration of 4%, 3%, 3%, 5% and 4% respectively. **Therefore Isopropanol is a SoC Band C for metaSPC 1, 8, 9, 11 and 15.**

There are no other co-formulants present that meet this criteria

3. Substances that enhance the effect of the active substance in the product, e.g. synergists.

There are no co-formulants present that meet this criteria (BPR Guidance Vol IV Appendix 11).

4. Substances that have been included in the list (candidate list) established in accordance with the REACH Regulation, Article 59(1) or fulfil the criteria for inclusion in the candidate list, if not already covered by the criteria of Article 3(f) of the BPR. These substances should be considered SoCs if they are present in the biocidal product at a concentration  $\geq 0.1\%$ . It is noted this criterion will ultimately capture, over and above the clearly-defined SoCs specified in Art 3(f) of the BPR, endocrine disruptors (EDs) and substances with hazards of equivalent concern to CMR 1A or 1B (under the CLP Regulation).

There are no co-formulants present that meet this criteria (<https://echa.europa.eu/candidate-list-table> and <https://echa.europa.eu/information-on-chemicals/candidate-list-substances-in-articles-table>). An elaborate screening was performed in order to detect potential endocrine disrupting properties of the co-formulants included in the BPF L-Lactic Acid (L-LA). All steps described in '**Practical guidance - CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants\_applicants**' were followed. Please see confidential annex for more information.

5. Substances for which there are Community workplace exposure limits.

**Butyldiglycol (CAS 112-34-5)** has European Community workplace exposure limits of 67,5 mg/m<sup>3</sup> for 8 hours exposure and 101,2 mg/m<sup>3</sup> for short term exposure. The substance is present in metaSPC 15 at a maximal concentration of 10%. There are only SCOEL values available, without skin notation.

**Therefore Butyldiglycol is a SoC Band C for metaSPC 15.**

There are no other co-formulants present with European workplace exposure limits.

In summary:

metaSPC 1: Sodium lauryl sulphate (Band B), Isopropanol (Band C)  
metaSPC 3: Sodium lauryl sulphate (Band B)  
metaSPC 4: Sodium lauryl sulphate (Band B)  
metaSPC 5: Sodium lauryl ether sulphate (Band B), Sulfonic acids, C14-17-sec-alkane, sodium salts (Band B)  
metaSPC 6: Sodium lauryl sulphate (Band B)  
metaSPC 8: Sodium lauryl sulphate (Band B), Isopropanol (Band C)  
metaSPC 9: Sodium lauryl sulphate (Band B), Isopropanol (Band C)  
metaSPC 11: Sodium lauryl sulphate (Band B), Isopropanol (Band C)  
metaSPC 12: C6 alkyl glucoside (Band B), Methanesulfonic acid (Band B), Sulphuric acid (Band B)  
metaSPC 13: Sodium lauryl sulphate (Band B), Methanesulfonic acid (Band B)  
metaSPC 14: Sodium lauryl sulphate (Band B)  
metaSPC 15: Sodium lauryl sulphate (Band B), Isopropanol (Band C), Butyldiglycol (Band C)

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

Not relevant.

#### 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 WEBEX<sup>4</sup> meetings discussions, only local risk assessment is considered relevant for this active substance. Therefore, only **local dermal risk assessment** would be performed for the active substance 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 these co-formulants, a complete risk assessment has to be performed. These co-formulants are :

- Butyldiglycol (CAS 112-34-5) because it has an EU OEL (MetaSPC15)
- Isopropanol (CAS 67-63-0) because it is an approved biocidal active substance (MetaSPC 1, 8, 9, 11 and 15).

In addition, some others co-formulants are assigned to band B or A. In accordance with the guidance, a qualitative risk assessment is performed (section 2.2.8.3).

<sup>4</sup>During the 1st Coordination Webex on UA-APPs on BPs with L-(+)-lactic acid (28/01/2020)

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	n.r.	Yes**	Yes**	n.r.	n.r.	n.r.	n.r.
Dermal	n.r.	Yes*	Yes*	n.r.	n.r.	n.r.	n.r.
Oral	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.

\*\* For the substances of concern, Isopropanol (67-63-0) and Butyldiglycol (112-34-5) a risk characterization for local effects via the inhalative routes of exposure is performed.

\* Additionally, for the substance of concern, Isopropanol, a systemic risk characterization is performed.

Exposure paths are not considered relevant for the active substance, because of very low systemic effects toxicity of L(+) lactic acid, derivation of any systemic toxicological reference dose was regarded not necessary. Therefore, for this substance and regarding the WG 17 March 2021<sup>4</sup>, a semi-quantitative local risk assessment using the dermal NOAEC of 10% is performed when the metaSPC is not classified in order to prevent some irritating effects triggered by repeated exposure. When the metaSPC are classified for dermal effects (H315, H314), only a qualitative risk assessment has been performed.

Secondary exposure is not considered relevant due to the toxicological profile of the active substance and SoC.

<sup>4</sup>During the 1st Coordination Webex on UA-APPs on BPs with L-(+)-lactic acid (28/01/2020)

<sup>5</sup> Discussion table – WGI2021\_TOX\_6-1; draft CAR on L-(+)-lactic acid – PT 6

**List of scenarios**

This table summaries the potential scenarios to the MetaSPC products of this family.

However, regarding the active substance :

- MetaSPCs 1, 2, 5, 6, 7, 8, 9, 10 and 15 are not classified as skin corrosive/irritants following studies. Therefore, a semi-quantitative risk assessment is performed for these MetaSPC. See section 2.2.6.3 risk characterization for more information.
- MetaSPCs 3, 4, 11, 12, 13 and 14 are classified for skin proprieties as H314 (MetaSPCs 3, 12, 13, 14) and as H315 (MetaSPCs 4, 11). Therefore, a qualitative risk assessment is performed for these MetaSPC. This risk covers potential semi-quantitative risks. See also section 2.2.6.3 risk characterization for more information.
- Please take into consideration that the aerosols are not expected during refilling and loading of concentrates in meta 3, 12-14, and meta 4, 11.

Regarding the Substances of Concern,

- A systemic risk assessment is performed for propan-2-ol (MetaSPCs 15, 1, 8, 9, 11).
- A quantitative inhalation local risk assessment is performed for both propan-2-ol (MetaSPCs 15, 1, 8, 9, 11) and Butyldiglycol (MetaSPC 15).

Summary table: scenarios			
Scenario number	Scenario (e.g. mixing/ loading)	Primary or secondary exposure Description of scenario	Exposed group (e.g. professionals, non- professionals, bystanders)
<b>metaSPC 5: PT3 concentrated pre-milking disinfectants</b>			
1.	Mixing and loading of concentrated pre-milking teat disinfectant	Primary exposure dermal + inhalation (pouring the pure product in a bigger jerrycan to allow dilution step) for manual dilution. Automatic dilution (drawing of pure product) is covered by the manual dilution step.	Professionals  Use 5.1
2.	Application on teats by dipping	Primary exposure dermal + inhalation	Professionals  Use 5.1, 6.1, <b>8.1, 9.1, 10.1</b>
3.	Application on teats by spraying	Primary exposure dermal / inhalation (manual spraying of teats) Automatic spraying with spraying installation is covered by the manual spraying	Professionals  Use 5.1, 6.1, <b>9.1, 10.1</b>
4.	Application on teats by wiping	Primary exposure dermal + inhalation	Professionals  Use 5.1
5.	Cleaning of teats, removal of freshly applied product pre-milking	Primary exposure dermal + inhalation	Professionals  Use 5.1, 6.1
6.	Cleaning of equipment	Primary exposure dermal + inhalation	Professionals  Use 5.1, 6.1, <b>8.1, 9.1, 10.1</b>
<b>metaSPC 6: PT3 RTU pre-milking disinfectants</b>			
<p>Several exposures are already included in previous scenarios.            Application by dipping the teats is included in scenario 2            Application by spraying the teats is included in scenario 3            Cleaning of teats, removal of freshly applied product pre-milking is included in scenario 5            Cleaning of equipment is included in scenario 6</p>			

7.	Loading of RTU teat disinfectant	Primary exposure dermal + inhalation (pouring or pumping working solution in order to fill the application equipment)  This include filling from large containers	Professionals  Use 6.1, <b>8.1, 9.1, 10.1</b>
<b>metaSPC 8, 9, 10: PT3 RTU post-milking disinfectants</b>			
Several exposures are already included in previous scenarios. Loading of RTU teat disinfectant is included in scenario 7 Application by dipping the teats is included in scenario 2 Application by spraying the teats is included in scenario 3 Cleaning of equipment is included in scenario 6			
8.	Loading of RTU disinfectant into milking robot	Primary exposure dermal. Inhalation exposure is not considered relevant.  This include filling from large containers	Professionals  Use <b>9.1, 10.1</b>
9.	Application on teats by robot	No exposure is foreseen.	Professionals  Use <b>9.1, 10.1</b>
10.	Cleaning of teats, removal of dried residues post-milking	Primary exposure dermal. Inhalation exposure can be considered limited as it concerns dried residues	Professionals  Use <b>8.1, 9.1, 10.1</b>
11.	Cleaning of teats by robot	No exposure is foreseen.	Professionals  Use <b>9.1, 10.1</b>
<b>metaSPC 5, 14: PT3 Skin disinfectants</b>			
12.	Mixing and loading of concentrated disinfectant	Primary exposure dermal + inhalation (pouring the pure product in a bigger jerrycan to allow dilution step) for manual dilution.  Automatic dilution (drawing of pure product) is covered by the manual dilution step  This include filling from large containers	Professionals  Use 5.2, 14.1
13.	Application on skin by spraying	Primary exposure dermal / inhalation (manual spraying of skin) Automatic spraying with spraying installation is covered by the manual spraying	Professionals  Use 5.2, 14.1
14.	Application on skin by brushing	Primary exposure dermal + inhalation	Professionals  Use 5.2, 14.1

15.	Cleaning of skin, removal of dried residues	Primary exposure dermal + inhalation can be considered limited as it concerns dried residues	Professionals Use 5.2, 14.1
16.	Cleaning of equipment	Primary exposure dermal + inhalation	Professionals Use 5.2, 14.1
<b>metaSPC 1, 15: PT1 Hands disinfectants</b>			
Scenario 17	Application handwash	Primary exposure (dermal + inhalation) during application of the read-to-use product.	Professionals Use <b>1.1</b>
Scenario 18	Application handrub	Primary exposure (dermal + inhalation) during application of the read-to-use product.	Professionals Use <b>15.1</b>
<b>metaSPC 2, 3, 4, 7, 11, 12, 13 : PT2/3/4 Surface disinfectants</b>			
Scenario 19	Mixing and loading PT2-PT4	Dilution and loading of concentrated products. Primary exposure via dermal and inhalation route. The aerosols are not expected during refilling and loading of concentrates.	Professionals Use 3.1, 3.2
Scenario 20	Preparing bath for knives PT4	Manual preparation of immersion bath for knives or cutting instruments disinfection. Primary exposure via dermal and inhalation route.	Professionals Use 3.2, <b>11.2</b>
Scenario 21	Mixing and loading PT2-PT4	Mixing and loading of concentrated products. Primary exposure via dermal and inhalation route. This step covers toilets disinfection by pouring pure products into the toilets.	Professionals Use <b>11.1</b> , <b>11.2</b> , 13.1, 4.1, 4.3, 4.5, 2.1
Scenario 22	Wiping PT2-PT4	Primary exposure (dermal + inhalation) during wiping/brushing of the working solution (covers wiping with ready-to-use wipes of metaSPC 7)	Professionals Use 4.3, 7.1, 3.1, 2.1
Scenario 23	Spraying P2-PT4	Primary exposure (dermal + inhalation) during spraying of the working solution on surfaces.	Professionals Use 4.1, 4.3, 3.1, 2.1
Scenario 24	Spraying step PT4-PT2	Primary exposure (dermal + inhalation) during spraying of the working solution on surfaces (foaming).	Professionals Use <b>11.1</b> , 13.1
Scenario 25	Immersion of knives and cutting machines PT4	Primary exposure (dermal + inhalation) during immersion of knives in food industry.  This covers the major case when this bath is almost closed with just a hole for the knife (this regular case induce no exposure then).	Professionals Use <b>11.2</b> , 3.2

Scenario 26	Spraying knives and cutting machines PT4	Primary exposure (dermal + inhalation) during spraying of knives in food industry.  This covers the major case when the spraying is normally done in a closed box (this regular case induce no exposure then).  Ths also covers the manual spraying of the metaSPC 2 on small surfaces.	Professionals Use <b>11.2</b> , 3.2, 2.1
Sceanrio 27	Spraying surfaces PT3	Primary exposure (dermal + inhalation) during spraying of the working solution on surfaces.  The scenario covers the mixing and loading step.	Professionals Use <b>11.3</b>
Scenario 28	Cleaning of spray equipment PT3	Primary exposure (dermal + inhalation) during of spray equipment.	Professionals Use <b>11.3</b>
Scenario 29	Mixing and loading prior CIP – PT4	Primary exposure via dermal and inhalation route during mixing and loading step prior to CIP disinfection.	professionals 12.1, 12.2, 12.3
<b>metaSPC 1, 15: PT1 Hands disinfectants</b>			
Scenario 30	Application handwash PT1	Primary exposure (dermal + inhalation) during application of the read-to-use product.	Non-professionals Use <b>1.1</b>
Sceanrio 31	Application handrub PT1	Primary exposure (dermal + inhalation) during application of the read-to-use product.	Non-professionals Use <b>15.1</b>
<b>metaSPC 2, 4, 7 : PT2/3/4 Surface disinfectants</b>			
Scenario 32	Mixing and loading PT2-PT4	Primary exposure (dermal + inhalation) during mixing and laoding of the product. This step covers the loading of product into the toilets for toilet disinfection.	Non-professionals 4.2, 4.4, 4.6, 2.2
Scenario 33	Wiping products PT4-PT2	Primary exposure (dermal + inhalation) during wiping/brushing of the working solution (covers wiping with ready-to-use wipes of metaSPC 7)	Non-professionals 4.2, 4.4, 7.2, 2.2, 7.4, 7.6
Scenario 34	Spraying products PT4-PT2	Primary exposure (dermal + inhalation) during coarse spraying of the working solution	Non-professionals 4.2, 4.4, 2.2
Scenario 35	Hand hel spraying PT4-PT2	Primary exposure (dermal + inhalation) during manual spraying of the working solution	Non-professionals 4.2, 4.4, 2.2



**Industrial exposure**

The products of this family are not intended to be used by industrial users. Therefore, industrial exposure is not relevant.

**Professional exposure****Scenario [1]: Mixing and loading of concentrated pre-milking teat disinfectants – MetaSPC 5**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed.

**Scenario [2]: Application on teats by dipping of teat disinfectants – MetaSPC 5, 6, 8, 9, 10**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed.

Please note that for SoC propan-2-ol present in MetaSPC 8 and 9. A worst case scenario, that is assumed to cover worst case use, is considered in scenario 5.

**Scenario [3]: Application on teats by spraying of teat disinfectants – MetaSPC 5, 6, 9, 10**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed.

Please note that for SoC propan-2-ol present in MetaSPC 8 and 9. A worst case scenario, that is assumed to cover worst case use, is considered in scenario 5.

**Scenario [4]: Application on teats by wiping of pre-milking teat disinfectants – MetaSPC 5**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed.

**Scenario [5]: Cleaning of teats, removal of freshly applied product of pre-milking teat disinfectants – MetaSPC 5, 6**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed.

SoC propan-2-ol is present in MetaSPC 8 and 9. Regarding Recommendation 13, this scenario has been selected as a worst case exposure for a volatile substance and is assumed to cover all others uses for PT3 – teats disinfectant.

**Description of Scenario [5] Cleaning step of teats, removal of freshly applied product – pre-milking teat disinfectants – SoC propan-2-ol.**

In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017) dermal hand exposure is estimated with a worst-case exposure of 0,1% of the amount of biocidal product on the surface area based on the Disinfectant Products Fact Sheet. The same HEAdhoc recommendation no. 13 mentions that inhalation exposure can be estimated by using ConsExpoWeb.

For the assessment of hand exposure, it is assumed that the surface area corresponds to the teats of the cow, with 44 cm<sup>2</sup>/teat and 176 cm<sup>2</sup>/cow. To calculate the amount of the biocidal product on the surface area, the layer thickness of 0,01 cm approach is considered appropriate. This calculation is used to determine the amount of solution used in the ConsExpoWeb calculation for inhalation exposure.

The spraying or dipping time per cow per event is 10 seconds. The farmer milks 82 cows three time (according to the instruction of use) per day all year through. The cows are treated pre and post milking. The exposure duration is 1.5 hour x 3 = 4.5 hours (270 min) per day. The room volume of the parlour is 168 m<sup>3</sup>.

NB: according the efficacy a minimum contact of 5 minutes is required for uses 8.1 and 9.1.

	Parameters	Value
Tier 1	Maximum concentration of propan-2-ol	3%
	Dermal absorption (default value for water-based dilution product)	50%
	Density	1
	Volume of product available for dermal exposure (calculated 44cm <sup>2</sup> * 4teats * 82cows * 0.01 cm layer thickness)	144.32 cm <sup>3</sup>
	Room size (Recom. 13)	168 m <sup>2</sup>
	Ventilation rate (Recom. 13)	4/h
	Application and exposure duration (Recom. 13)	270 min
	Release area (Recom. 13)	1.4432 m <sup>2</sup>
	Molecular weight matrix (water based product)	18 g/mol
	Inhalation rate (Recom. 14)	1.25 m <sup>3</sup> /h (0.021 m <sup>3</sup> /min)
	Emission duration (Efficacy)	5 min
	Vapour pressure (at 20°C) (AR for propan-2-ol)	5780 Pa
	Product amount (calculated 44cm <sup>2</sup> * 4teats * 82cows * 0.01 cm layer thickness*density*3x/d)	433 g

**Calculations for Scenario [5]**

<b>Summary table: systemic exposure from professional uses</b>					
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake</b>	<b>Estimated dermal uptake</b>	<b>Estimated oral uptake</b>	<b>Estimated total uptake</b>
Scenario [5] Propan-2-ol	1	0,403	0,10824	negligibe	0,51124 Mg/kg bw

**Local inhalation risk assessment :**

For Propan-2-ol :

The primary exposure of professional users towards propan-2-ol during application of the products is assessed by ConsExpo Web

For consideration of the local inhalation exposure, the following calculation have been performed:

Inhaled SoC concentration (mg SoC/m<sup>3</sup>)

- during task : Peak concentration (TWA 15 min)

- 8-hr TWA : Peak concentration (TWA 15 min) / (15/60 (hours) / 8 hours)

<b>Summary table: Local inhalation risk assessment</b>					
<b>Exposure scenario</b>	<b>Tier</b>	<b>Estimated inhalation uptake</b>	<b>Estimated dermal uptake</b>	<b>Estimated oral uptake</b>	<b>Estimated total uptake (8h TWA)</b>
Scenario [5] Propan-2-ol	1	45.8 mg/m <sup>3</sup>	n.a.	n.a.	1.43 mg/m <sup>3</sup>

**Scenario [6]: Cleaning of equipment of teat disinfectants – MetaSPC 5, 6, 8, 9, 10**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed.

Please note that for SoC propan-2-ol present in MetaSPC 8 and 9. A worst case scenario, that is assumed to cover worst case use, is considered in scenario 5.

**Scenario [7]: Loading of RTU teat disinfectants – MetaSPC 6, 8, 9, 10**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed.

Please note that for SoC propan-2-ol present in MetaSPC 8 and 9. A worst case scenario, that is assumed to cover worst case use, is considered in scenario 5. This include filling from large containers.

**Scenario [8]: Loading of milking robot with RTU teat disinfectants – MetaSPC 9, 10**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed.

Please note that for SoC propan-2-ol present in MetaSPC 8 and 9. A worst case scenario, that is assumed to cover worst case use, is considered in scenario 5. This include filling from large containers.

**Scenario [9]: Application on teats by robot of teat disinfectants – MetaSPC 9, 10**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed.

Please note that for SoC propan-2-ol present in MetaSPC 8 and 9. A worst case scenario, that is assumed to cover worst case use, is considered in scenario 5.

**Scenario [10]: Cleaning of teats, removal of dreid residues post-milking teat disinfectants – MetaSPC 8, 9, 10**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed.

Please note that for SoC propan-2-ol present in MetaSPC 8 and 9. A worst case scenario, that is assumed to cover worst case use, is considered in scenario 5.

**Scenario [11]: Cleaning of teats by robot of post-milking teat disinfectants – MetaSPC 9, 10**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed.

Please note that for SoC propan-2-ol present in MetaSPC 8 and 9. A worst case scenario, that is assumed to cover worst case use, is considered in scenario 5.

**Scenario [12]: Mixing and loading of concentrated skin disinfectants – MetaSPC 5, 14**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 14 is classified for skin irritation endpoint, a qualitative risk assessment is also performed. This include filling from large containers.

**Scenario [13]: Application on skin by spraying of skin disinfectants – MetaSPC 5, 14**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 14 is classified for skin irritation endpoint, a qualitative risk assessment is also performed.

**Scenario [14]: Application on skin by brushing of skin disinfectants – MetaSPC 5, 14**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 14 is classified for skin irritation endpoint, a qualitative risk assessment is also performed.

**Scenario [15]: Cleaning of skin, removal of dreid residues skin disinfectants – MetaSPC 5, 14**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 14 is classified for skin irritation endpoint, a qualitative risk assessment is also performed.

**Scenario [16]: Cleaning of equipment of skin disinfectants – MetaSPC 5, 14**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 14 is classified for skin irritation endpoint, a qualitative risk assessment is also performed.

**Scenario [17]: Application handwash – metaSPC 1**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed.

Please note that for SoC propan-2-ol present in MetaSPC 1 a quantitative assessment is performed.

**Description of Scenario [17] Application handwash – metaSPC 1**

This task is performed indoors. The task consists of washing the hands with the ready-to-use products of metaSPC 1 (PT1 use) by professionals.

Dermal exposure is estimated according to the ECHA recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure Methods and models to assess exposure to biocidal products in different product types Version 4.

**Dermal exposure:**

1) For volatile compounds: calculation of the evaporation time from skin surface according to the EU Technical Guidance Document (TGD, 2003) (Part I, App. IF, Evaporation rate, p. 216):

$$t (s) = (m T R / M \beta p A) \times K,$$

where:

t = evaporation time (seconds)

m = mass of compound (mg)

R = gas constant (8.314 J  
K/mol)

T = temperature in Kelvin  
(303.15 K, equal to 30 °C )

M = molar mass of compound

$\beta$  = coefficient of mass transfer  
in the vapour phase (8.7 m/h)

p = vapour pressure of  
compound (Pa)

A = applied area (1950 cm<sup>2</sup>, surface of both hands and forearms according to HEAdhoc Recommendation 14 – Default human factor values for use in exposure assessments for biocidal products)

K = conversion factor (3.6 x 10<sup>4</sup> )

2. Calculation of internal dermal exposure based on dermal flux:

Dermal flux (mg/cm<sup>2</sup>/hour) / 60 x evaporation time/60) x 25 applications x total skin surface

**Inhalatory exposure:**

Instant evaporation model (ConsExpo 4.1) for volatile compounds To calculate internal inhalatory exposure: event concentration x 1.25 m<sup>3</sup> /hour x total exposure duration (contact time x 25 applications) / 60 kg bw

	Parameters <sup>1</sup>	Value
Tier 1 Adult	% isopropanol w/w	4 (Meta 1-15)
	% Butyldiglycol w/w	0 (Meta 1) 10 (Meta 15)
	Frequency (Recom. 6)	25/day
	Dermal flux for propan-2-ol (AR for propan-2-ol)	0.85 mg/cm <sup>2</sup> /h
	Molecular mass of propan-2-ol (AR for propan-2-ol)	60.1 g/mol
	vapour pressure of propan-2-ol (Pa) (AR for propan-2-ol)	5780 Pa
	Quantity used per application (efficacy rate)	10 ml/event
	- Quantity of propan-2-ol considering density of 1	400 mg/event
	applied area (Recom 6)	1950 cm <sup>2</sup>
	evaporation time (seconds) calculated	6.17 s
	Body weight (Recom 14)	60 kg
	Exposure duration (Recom 6)	1 min
	Molecular weight matrix (default for water-based product)	18 g/mol
	Room volume (Recom 6)	80 m <sup>3</sup>
	Ventilation rate (Recom 6)	1.5
	Inhalation rate (Recom 14)	1.25 m <sup>3</sup> /h
	Application temperature (default)	20°C
	Release area (Recom 6)	1950 cm <sup>2</sup>
	Emission duration	0.103 min (6.17/60)

### Calculations for Scenario [17]

Summary table: systemic exposure from professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [17] Propan-2-ol	1	0,03546875	1,18341461	negligibe	1,21888336 Mg/kg bw

### Local inhalation risk assessment :

For Propan-2-ol :

The primary exposure of professional users towards propan-2-ol during application of the products is assessed by ConsExpo Web

For consideration of the local inhalation exposure, the following calculation have been performed:

Inhaled SoC concentration (mg SoC/m<sup>3</sup>)

- during task : Peak concentration (TWA 15 min)

- 8-hr TWA : Peak concentration (TWA 15 min) / (15/60 (hours) / 8 hours)

<b>Summary table: Local inhalation risk assessment</b>					
<b>Exposure scenario</b>	<b>Tier</b>	<b>Estimated inhalation uptake</b>	<b>Estimated dermal uptake</b>	<b>Estimated oral uptake</b>	<b>Estimated total uptake (8h TWA)</b>
Scenario [17] Propan-2-ol	1	0.0681 mg/m <sup>3</sup>	n.a.	n.a.	0.002 mg/m <sup>3</sup>

**Scenario [18]: Application handrub – metaSPC 15**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed.

Please note that for SoC propan-2-ol present in MetaSPC 15 a quantitative assessment is performed. The assessment is identical than scenario 17 (MetaSPC 1).

For SoC Butyldiglycol present in MetaSPC 15, a quantitative assessment is performed.

<b>Description of Scenario [18] Application handwash – metaSPC 1</b>
<p>This task is performed indoors. The task consists of washing the hands with the ready-to-use products of metaSPC 15 (PT1 use) by professionals.</p> <p>Dermal exposure is estimated according to the ECHA recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure Methods and models to assess exposure to biocidal products in different product types Version 4.</p> <p>For Butyldiglycol, only a local inhalation risk is performed. No systemic risk are foreseen. However, the evaporation time is needed in order to be able to perform ConsExpo model and it is calculated as follow :</p> <p><b><math>t (s) = (m T R / M \beta p A) \times K,</math></b>            where:            t = evaporation time (seconds)            m = mass of compound (mg)            R = gas constant (8.314 J K/mol)            T = temperature in Kelvin (303.15 K, equal to 30 °C )            M = molar mass of compound            β = coefficient of mass transfer in the vapour phase (8.7 m/h)            p = vapour pressure of</p>

compound (Pa) A = applied area (1950 cm <sup>2</sup> , surface of both hands and forearms according to HEAdhoc Recommendation 14 – Default human factor values for use in exposure assessments for biocidal products) K = conversion factor (3.6 x 10 <sup>4</sup> )		
<b>Inhalatory exposure:</b>		
Instant evaporation model (ConsExpo 4.1) for volatile compounds.		
	Parameters	Value
Tier 1 Adult	% isopropanol w/w	4 (Meta 1-15)
	% Butyldiglycol w/w	0 (Meta 1) 10 (Meta 15)
	Frequency (Recom. 6)	25/day
	Molecular mass of Butyldiglycol (PUBCHEM)	162.23 g/mol
	vapour pressure of Butyldiglycol (Pa) (PUBCHEM)	3 Pa
	Quantity used per application (efficacy rate)	10 ml/event
	- Quantity of Butyldiglycol considering density of 1	1000 mg/event
	applied area (Recom 6)	1950 cm <sup>2</sup>
	evaporation time (seconds) calculated	10989 s = 183.15 min
	Body weight (Recom 14)	60 kg
	Exposure duration (Recom 6)	1 min
	Molecular weight matrix (default for water-based product)	18 g/mol
	Room volume (Recom 6)	80 m <sup>3</sup>
	Ventilation rate (Recom 6)	1.5
	Inhalation rate (Recom 14)	1.25 m <sup>3</sup> /h
	Application temperature (default)	20°C
	Release area (Recom 6)	1950 cm <sup>2</sup>
	Emission duration	183.15 min

### Calculations for Scenario [18]

#### Local inhalation risk assessment :

For Butyldiglycol:



The primary exposure of professional users towards Butyldiglycol during application of the products is assessed by ConsExpo Web

For consideration of the local inhalation exposure, the following calculation have been performed:

Inhaled SoC concentration (mg SoC/m<sup>3</sup>)

- during task : Peak concentration (TWA 15 min)

- 8-hr TWA : Peak concentration (TWA 15 min) / (15/60 (hours) / 8 hours)

<b>Summary table: Local inhalation risk assessment</b>					
<b>Exposure scenario</b>	<b>Tier</b>	<b>Estimated inhalation uptake</b>	<b>Estimated dermal uptake</b>	<b>Estimated oral uptake</b>	<b>Estimated total uptake (8h TWA)</b>
Scenario [18] Butyldiglycol	1	0.0681 mg/m <sup>3</sup>	n.a.	n.a.	0.002 mg/m <sup>3</sup>

**Scenario [19]: Mixing and loading step – metaSPC 3**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 3 is classified for skin irritation endpoint, a qualitative risk assessment is also performed.

**Scenario [20]: Preparation of immersion baths – metaSPC 3, 11**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 3 and MetaSPC 11 are classified for skin irritation endpoint, a qualitative risk assessment is also performed.

In addition, MetaSPC 11 contains the SoC propan-2-ol. As a worst case, a inhalation exposure to vapor from dipping bath has been estimated.

**Description of Scenario [20] Preparation of immersion baths – metaSPC 3, 11**

Based on the efficacy data, MetaSPC 11 could be used at 3% dilution with a contact time of 2 minutes or at 1% dilution with a contact time of 15 min.

15 minutes of exposition to the vapour could be seen as a worst case.

However, there is no indication from the efficacy of the amount of product that would be used. Therefore, the calculation for evaporation of a volatile substance has been used:

$$t (s) = (m T R / M \beta p A) \times K,$$

where:

t = evaporation time (seconds)

m = mass of compound (mg)

R = gas constant (8.314 J

K/mol)

T = temperature in Kelvin

(303.15 K, equal to 30 °C )

M = molar mass of compound

$\beta$  = coefficient of mass transfer

in the vapour phase (8.7 m/h)

p = vapour pressure of

compound (Pa)

A = applied area

K = conversion factor (3.6 x 10 <sup>4</sup> )		
	Parameters <sup>1</sup>	Value
Tier 1	evaporation time (seconds)	900
	A = applied area (expert judgement)	500 cm <sup>2</sup>
	mass of compound (mg) (calculated)	14963.76095 mg = 15g
	Exposure duration (expert judgement – staying in the room)	2 hours
	Molecular weight matrix (default for water-based product)	18 g/mol
	Indicative value for dermal exposure by pouring	101 mg/min
	Room volume (expert judgement – professional users)	80 m <sup>3</sup>
	Ventilation rate (expert judgement – professional users)	1.5 /h
	Application temperature	20°C
	Molecular mass of propan-2-ol (AR for propan-2-ol)	60.1 g/mol
	vapour pressure of propan-2-ol (Pa) (AR for propan-2-ol)	5780 Pa
	Release area (expert judgement)	500 cm <sup>2</sup>
	Emission duration	15 min

### Calculations for Scenario [20]

Summary table: systemic exposure from professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [20] Propan-2-ol	1	2.43	n.r	n.r	2.43 Mg/kg bw

### Local inhalation risk assessment :

For Propan-2-ol :

The primary exposure of professional users towards propan-2-ol during application of the products is assessed by ConsExpo Web

For consideration of the local inhalation exposure, the following calculation have been performed:

Inhaled SoC concentration (mg SoC/m<sup>3</sup>)

- during task : Peak concentration (TWA 15 min)

- 8-hr TWA : Peak concentration (TWA 15 min) / (15/60 (hours) / 8 hours)

<b>Summary table: Local inhalation risk assessment</b>					
<b>Exposure scenario</b>	<b>Tier</b>	<b>Estimated inhalation uptake</b>	<b>Estimated dermal uptake</b>	<b>Estimated oral uptake</b>	<b>Estimated total uptake (8h TWA)</b>
Scenario [20] Propan-2-ol	1	135 mg/m <sup>3</sup>	n.a.	n.a.	4.21875 mg/m <sup>3</sup>

**Scenario [21]: Mixing and loading – metaSPC 2, 4, 11, 13**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 3, MetaSPC 11 and Meta SPC 13 are classified for skin irritation endpoint, a qualitative risk assessment is also performed.

In addition, MetaSPC 11 contains the SoC propan-2-ol. Scenario 20 could be regarded as a worst case situation for this assessment.

**Scenario [22]: Wiping PT2-PT4– metaSPC 2, 3, 4, 7**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 3 and Meta SPC 4 are classified for skin irritation endpoint, a qualitative risk assessment is also performed.

**Scenario [23]: Spraying PT2-PT4– metaSPC 2, 3, 4**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 3 and Meta SPC 4 are classified for skin irritation endpoint, a qualitative risk assessment is also performed.

**Scenario [24]: Spraying (foaming) PT2-PT4– metaSPC 11,13**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 11 and Meta SPC 13 are classified for skin irritation endpoint, a qualitative risk assessment is also performed.

In addition, MetaSPC 11 contains the SoC propan-2-ol. Scenario 20 could be regarded as a worst case situation for this assessment.

**Scenario [25]: Immersion of knives and cutting machines PT4– metaSPC 3, 11**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 3 and Meta SPC 11 are classified for skin irritation endpoint, a qualitative risk assessment is also performed.

In addition, MetaSPC 11 contains the SoC propan-2-ol. Scenario 20 could be regarded as a worst case situation for this assessment.

**Scenario [26]: Spraying knives and cutting machines PT4– metaSPC 2, 3, 11**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 3 and Meta SPC 11 are classified for skin irritation endpoint, a qualitative risk assessment is also performed.

In addition, MetaSPC 11 contains the SoC propan-2-ol. Scenario 20 could be regarded as a worst case situation for this assessment.

**Scenario [27]: Spraying surfaces PT3– metaSPC 11**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as Meta SPC 11 is classified for skin irritation endpoint, a qualitative risk assessment is also performed.

In addition, MetaSPC 11 contains the SoC propan-2-ol. Scenario 20 could be regarded as a worst case situation for this assessment.

**Scenario [28]: Cleaning of spray equipment PT3– metaSPC 11**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as Meta SPC 11 is classified for skin irritation endpoint, a qualitative risk assessment is also performed.

In addition, MetaSPC 11 contains the SoC propan-2-ol. Scenario 20 could be regarded as a worst case situation for this assessment.

**Scenario [29]: Mixing and loading prior CIP – PT4– metaSPC 12**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as Meta SPC 12 is classified for skin irritation endpoint, a qualitative risk assessment is also performed.

***Non-professional exposure*****Scenario [30]: Application handwash – metaSPC 1**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed.

Please note that for SoC propan-2-ol present in MetaSPC 1 a quantitative assessment is performed.

**Description of Scenario [30] Application handwash – metaSPC 1**

This task is performed indoors. The task consists of washing the hands with the ready-to-use products of metaSPC 1 (PT1 use) by non-professionals.

Dermal exposure is estimated according to the ECHA recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure Methods and models to assess exposure to biocidal products in different product types Version 4.

**Dermal exposure:**

1) For volatile compounds: calculation of the evaporation time from skin surface according to the EU Technical Guidance Document (TGD, 2003) (Part I, App. IF, Evaporation rate, p. 216):

$$t (s) = (m T R / M \beta p A) \times K,$$

where:

t = evaporation time (seconds)

m = mass of compound (mg)

R = gas constant (8.314 J  
K/mol)

T = temperature in Kelvin  
(303.15 K, equal to 30 °C )

M = molar mass of compound

$\beta$  = coefficient of mass transfer  
in the vapour phase (8.7 m/h)

p = vapour pressure of  
compound (Pa)

A = applied area (1950 cm<sup>2</sup>, surface of both hands and forearms according to HEAdhoc Recommendation 14 – Default human factor values for use in exposure assessments for biocidal products)

K = conversion factor (3.6 x 10<sup>4</sup> )

2. Calculation of internal dermal exposure based on dermal flux:

Dermal flux (mg/cm<sup>2</sup>/hour) / 60 x evaporation time/60) x 25 applications x total skin surface

#### Inhalatory exposure:

Instant evaporation model (ConsExpo 4.1) for volatile compounds To calculate internal inhalatory exposure: event concentration x 1.25 m<sup>3</sup> /hour x total exposure duration (contact time x 5 applications) / 60 kg bw

	Parameters <sup>1</sup>	Value
Tier 1 Adult	% isopropanol w/w	4 (Meta 1-15)
	% Butyldiglycol w/w	0 (Meta 1) 10 (Meta 15)
	Frequency (expert judgement – non-professional users)	5/day
	Dermal flux for propan-2-ol (AR for propan-2-ol)	0.85 mg/cm <sup>2</sup> /h
	Molecular mass of propan-2-ol (AR for propan-2-ol)	60.1 g/mol
	vapour pressure of propan-2-ol (Pa) (AR for propan-2-ol)	5780 Pa
	Quantity used per application (efficacy rate)	10 ml/event
	- Quantity of propan-2-ol considering density of 1	400 mg/event
	applied area (Recom 6)	1950 cm <sup>2</sup>
evaporation time (seconds) calculated	6.17 s	

	Body weight (Recom 14)	60 kg
	Exposure duration (Recom 6)	1 min
	Molecular weight matrix (default for water-based product)	18 g/mol
	Room volume (expert judgement – non-professional users)	25 m <sup>3</sup>
	Ventilation rate (expert judgement – non-professional users)	0.6
	Inhalation rate adult (Recom 14)	1.25 m <sup>3</sup> /h
	Application temperature (default)	20°C
	Release area (Recom 6)	1950 cm <sup>2</sup>
	Emission duration	0.103 min (6.17/60)
CHILD (2-6y)	Body weight (Recom 14)	15.6 kg
	Inhalation rate (Recom 14)	1.26 m <sup>3</sup> /h
	evaporation time (seconds) calculated	17.11 s
	applied area (Recom 14) (hands and forearms)	703 cm <sup>2</sup>

### Calculations for Scenario [30]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [30] Propan-2-ol ADULT	1	0,0221875	0,236682922	negligibe	0,258870422Mg /kg bw
Scenario [30] Propan-2-ol CHILD	1	0,07875	0,910318931	negligibe	0,989068931Mg /kg bw

### Local inhalation risk assessment :

For Propan-2-ol :

The primary exposure of non-professional users towards propan-2-ol during application of the products is assessed by ConsExpo Web

For consideration of the local inhalation exposure, the following calculation have been performed:

Inhaled SoC concentration (mg SoC/m<sup>3</sup>)

- during task : Peak concentration (TWA 15 min)

- 8-hr TWA : Peak concentration (TWA 15 min) / (15/60 (hours) / 8 hours)

<b>Summary table: Local inhalation risk assessment</b>					
<b>Exposure scenario</b>	<b>Tier</b>	<b>Estimated inhalation uptake</b>	<b>Estimated dermal uptake</b>	<b>Estimated oral uptake</b>	<b>Estimated total uptake (8h TWA)</b>
Scenario [30] Propan-2-ol ADULT	1	0.213 mg/m <sup>3</sup>	n.a.	n.a.	0.006 mg/m <sup>3</sup>
Scenario [30] Propan-2-ol CHILD	1	0.195 mg/m <sup>3</sup>	n.a.	n.a.	0.006 mg/m <sup>3</sup>

**Scenario [31]: Application handrub – metaSPC 15**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed.

Please note that for SoC propan-2-ol present in MetaSPC 15 a quantitative assessment is performed. The assessment is identical to scenario 30 (MetaSPC 1).

For SoC Butyldiglycol present in MetaSPC 15, a quantitative assessment is performed.

<b>Description of Scenario [31] Application handwash – metaSPC 1</b>
<p>This task is performed indoors. The task consists of washing the hands with the ready-to-use products of metaSPC 15 (PT1 use) by non-professionals.</p> <p>Dermal exposure is estimated according to the ECHA recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure Methods and models to assess exposure to biocidal products in different product types Version 4.</p> <p>For Butyldiglycol, only a local inhalation risk is performed. No systemic risk are foreseen. However, the evaporation time is needed in order to be able to perform ConsExpo model and it is calculated as follow :</p> <p><b><math>t (s) = (m T R / M \beta p A) \times K,</math></b>            where:</p> <ul style="list-style-type: none"> <li>t = evaporation time (seconds)</li> <li>m = mass of compound (mg)</li> <li>R = gas constant (8.314 J K/mol)</li> <li>T = temperature in Kelvin (303.15 K, equal to 30 °C )</li> <li>M = molar mass of compound</li> <li><math>\beta</math> = coefficient of mass transfer in the vapour phase (8.7 m/h)</li> <li>p = vapour pressure of compound (Pa)</li> <li>A = applied area (1950 cm<sup>2</sup>, surface of both hands and forearms according to HEAdhoc Recommendation 14 – Default human factor values for use in exposure assessments forbiocidal products)</li> <li>K = conversion factor (3.6 x 10<sup>4</sup> )</li> </ul>

<b>Inhalatory exposure:</b> Instant evaporation model (ConsExpo 4.1) for volatile compounds.		
	Parameters <sup>1</sup>	Value
Tier 1 Adult	% isopropanol w/w	4 (Meta 1-15)
	% Butyldiglycol w/w	0 (Meta 1) 10 (Meta 15)
	Frequency (expert judgement – non-professional users)	5/day
	Molecular mass of Butyldiglycol (PUBCHEM)	162.23 g/mol
	vapour pressure of Butyldiglycol (Pa) (PUBCHEM)	3 Pa
	Quantity used per application (efficacy rate) - Quantity of Butyldiglycol considering density of 1	10 ml/event 1000 mg/event
	applied area (Recom 6)	1950 cm <sup>2</sup>
	evaporation time (seconds) calculated	10989 s = 183.15 min
	Body weight (Recom 14)	60 kg
		Exposure duration (Recom 6)
Molecular weight matrix (default for water-based product)		18 g/mol
Room volume (expert judgement – non-professional users)		25 m <sup>3</sup>
Ventilation rate (expert judgement – non-professional users)		0.6
Inhalation rate (Recom 14)		1.25 m <sup>3</sup> /h
Application temperature (default)		20°C
Release area (Recom 6)		1950 cm <sup>2</sup>
Emission duration		10989,14254sec=183 min
CHILD (2-6y)	Body weight (Recom 14)	15.6 kg
	Inhalation rate (Recom 14)	1.26 m <sup>3</sup> /h
	evaporation time (seconds) calculated	30481,97433s = 508 min
	applied area (Recom 14) (hands and forearms)	703 cm <sup>2</sup>

### Calculations for Scenario [31]

#### Local inhalation risk assessment :

For Butyldiglycol:



The primary exposure of non-professional users towards Butyldiglycol during application of the products is assessed by ConsExpo Web

For consideration of the local inhalation exposure, the following calculation have been performed:

Inhaled SoC concentration (mg SoC/m<sup>3</sup>)

- during task : Peak concentration (TWA 15 min)

- 8-hr TWA : Peak concentration (TWA 15 min) / (15/60 (hours) / 8 hours)

<b>Summary table: Local inhalation risk assessment</b>					
<b>Exposure scenario</b>	<b>Tier</b>	<b>Estimated inhalation uptake</b>	<b>Estimated dermal uptake</b>	<b>Estimated oral uptake</b>	<b>Estimated total uptake (8h TWA)</b>
Scenario [31] Butyldiglycol ADULT	1	0.00157 mg/m <sup>3</sup>	n.a.	n.a.	0.00005 mg/m <sup>3</sup>
Scenario [31] Butyldiglycol CHILD	1	0.006 mg/m <sup>3</sup>	n.a.	n.a.	0.0002 mg/m <sup>3</sup>

**Scenario [32]: Mixing and loading PT2-PT4– metaSPC 2, 4**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 4 is classified for skin irritation endpoint, a qualitative risk assessment is also performed.

**Scenario [33]: Wiping products PT4-PT2 – metaSPC 2,4,7**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 4 is classified for skin irritation endpoint, a qualitative risk assessment is also performed.

**Scenario [34]: Spraying products PT4-PT2– metaSPC 2,4**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 4 is classified for skin irritation endpoint, a qualitative risk assessment is also performed.

**Scenario [35]: Hand hel spraying PT4-PT2– metaSPC 2,4**

Not relevant for lactic acid, as only semi-quantitative local risk assessment would be performed. In addition, as MetaSPC 4 is classified for skin irritation endpoint, a qualitative risk assessment is also performed.

## **Monitoring data**

Please see. Comments below.

### **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). According to the [CLH published on May 2020](#) this substance is 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 logically 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), due to its high vapor pressure, this substance evaporates completely within the time of application of the biocidal products PT4 and PT3. In the case of the residue transfer does occur, the active substance 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.<sup>5</sup>

The isopropanol is also listed in Commission Implementing Regulation (EU) No 872/2012<sup>6</sup> as flavouring substances intended to be used in or on foodstuffs.

<sup>5</sup><https://www.icis.com/explore/resources/news/2007/11/05/9076020/isopropanol-ipa-uses-and-market-data/>

<sup>6</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0872&from=EN>

Regarding the others SOCs bande B (sodium lauryl sulphate, sodium lauryl ether sulphate, sulfonic acids, C14-17-sec-alkane, sodium salts, C6 alkyl glucoside, methanesulfonic acid, Sulphuric acid), only a qualitative risk assessment needs to be performed according to the Echa guidance<sup>7</sup> on risk assessment on human health. None of the SOCs are classified for acute toxicity or sensitization. However, all SOCs, except for C6 alkyl glucoside, are classified as skin irritant or corrosive. Therefore, if residues of these SOCs from diluted or RTU products type 4 are present in our food (i.e. meat, milk or eggs), they could induce an irritating or corrosive effect to the human digestive tract when eating the food.

The SOCs of band B classified as skin irritant or skin corrosive are included in the following metaSPCs of PT4 products: 3, 4, 7, 11, 12 and 13. To qualitatively assess the irritating or corrosive effect to the human digestive tract, the classification of the highest in use concentration of the above mentioned metaSPCs were screened. For metaSPC 7, this screening was not needed as the product is ready-to-use and not classified as skin irritant or skin corrosive. Therefore, the risk of metaSPC 7 is acceptable. For the other metaSPCs (i.e. metaSPC 3, 4, 11, 12 and 13), none of the highest in-use content of SOCs were classified as skin irritant or skin corrosive. As a conclusion, the in-use content of the skin irritant and skin corrosive SOCs band B are too low to induce irritating properties when used in products from metaSPC 3, 4, 7, 11, 12 and 13.

Regarding butyldiglycol, it's a SOC bande C based on available EU workplace exposure limits. This substance is present in the metaSPC 15, it is only classified as eye irrit.2. Therefore no risk for consumers is expected.

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

<b>Summary table of other (non-biocidal) uses</b>			
	<b>Sector of use</b>	<b>Intended use</b>	<b>Reference</b>
1.	Veterinary	Feeding additive (intended for livestock)	Safety of lactic acid and calcium lactate when used as technological additives for all animal species (adopted 12 novembre 219)
3.	Food industry	Food additive	COMMISSION REGULATION (EU) 2015/165 of 3 February 2015)
4.	Food industry	Food additive (flavouring)	COMMISSION IMPLEMENTING REGULATION (EU) 2017/56 of 14 December 2016

<sup>7</sup>Guidance on the Biocidal Products Regulation Volume III Human Health -Assessment & Evaluation (Parts B+C)Version 4.0 December 2017

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

Not relevant. Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR.

***Aggregated exposure***

Not relevant.

## 2.2.6.3 Risk characterisation for human health

**Reference values to be used in Risk Characterisation**

- **L-lactic acid**

<b>Systemic effect</b>					
Not relevant for this substance					
<b>Local effect</b>					
<b>Reference</b>	<b>Study</b>	<b>NOAEC</b>	<b>AF</b>	<b>Correction for oral absorption</b>	<b>Value</b>
NOAEC	concentration of 10% derived from the result of irritation/corrosion studies in rabbits	10%	n.r.	n.r.	10%

- **SoC Propan-2-ol :**

Propan-2-ol is an approved biocidal active substance on its own in PTs 1, 2, and 4.

**Reference values to be used in Risk Characterisation for Propan-2-ol**

<b>Reference</b>	<b>Study</b>	<b>NOAEL/NOAEC</b>	<b>AF<sup>1</sup></b>	<b>Correction for oral absorption</b>	<b>Value</b>
Professional users AEL <sub>acute/medium/long-term</sub> AEC	Human volunteer study (Sethre et al. 2000a)	200 ppm for neurological effects	3.8	n.a.	17.9 mg/kg bw/d
					52.6 ppm* (8 h TWA)
Non-professional users/general public: AEL <sub>acute/medium/long-term</sub> AEC	Human volunteer study (Sethre et al. 2000a)	200 ppm for neurological effects	6.4	n.a.	10.7 mg/kg bw/d
					31.25 ppm** (8 h TWA)
ARfD	ARfD not established.				
ADI	ADI not established.				
* corresponding to ~ 129 mg/m <sup>3</sup> considering a molecular weight of 60 g/mol					
** corresponding to ~ 77 mg/m <sup>3</sup> considering a molecular weight of 60 g/mol					

- **SoC Butyldiglycol :**

Butyldiglycol (112-34-5) has European Community workplace exposure limits of 67,5 mg/m<sup>3</sup> for 8 hours exposure and 101,2 mg/m<sup>3</sup> for short term exposure.

**Reference values to be used in Risk Characterisation for Butyldiglycol**

Reference	Study	NOAEL/NOAEC	AF <sup>1</sup>	Correction for oral absorption	Value
Professional users  European Community workplace exposure limits	n.a.	n.a.	n.a.	n.a.	67,5 mg/m <sup>3</sup> (8 h TWA)
Professional users/general public  European Community workplace exposure limits	n.a.	n.a.	n.a.	n.a.	101,2 mg/m <sup>3</sup> (short term exposure)

**Maximum residue limits or equivalent**

Residue definitions

MRLs or other relevant reference values	Reference	Relevant commodities	Value
Lactic acid is included in the table 1 (allowed substances) with no restriction.	Commission Regulation (EU) N°37/2010 on MRL		No restriction

**Specific reference value for groundwater***Not relevant.***Risk for industrial users**

The products of this family are not intended to be used by industrial users. Therefore, risk for industrial users is not relevant.

**Risk for professional users****Systemic effects (Propan-2-ol)**

Task/Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/ no)

Scenario [5] Propan-2-ol	1	17.9	0,51124	2.9	YES
Scenario [17] Propan-2-ol	1	17.9	1,21888336	6.8	YES
Scenario [20] Propan-2-ol	1	17.9	2.43	13.6	YES

### Combined scenarios

Not relevant.

### Local effects

- For pronan-2-ol

Scenario	Tier	Estimated uptake mg/m <sup>3</sup> (8 h TWA)	AEC mg/m <sup>3</sup>	Estimated exposure/ AEC (%)	Acceptable (yes/no)
Scenario [5] Propan-2-ol	1	1,43125 mg/m <sup>3</sup>	129	1.1	yes
Scenario [17] Propan-2-ol	1	0,00212812 5 mg/m <sup>3</sup>	129	0.0	yes
Scenario [20] Propan-2-ol	1	4,21875	129	3.3	yes

- For Butyldiglycol

Scenario	Tier	Estimated uptake mg/m <sup>3</sup> (8 h TWA)	OEL mg/m <sup>3</sup>	Estimated exposure/ AEC (%)	Acceptable (yes/no)
Scenario [18] Butyldiglycol	1	0,00049093 8 mg/m <sup>3</sup>	67.5	0.0	yes

- For L-Lactic acid

Scenario	Tier	Concentration of L-lactic acid (%)	NOEC dermal (%)	Estimated exposure/ AEC (%)	Acceptable (yes/no)
Scenario [1] Mixing and loading concentrated metaSPC 5	1	8	10	0.8	YES

Scenario [2] Application by dipping metaSPC 5 – 6 – 8 -9 -10	1	Maximum concentration : 7.5%	10	0.75	YES
Scenario [3] Application by spraying metaSPC 5 -6 -9-10	1	Maximum concentration : 7.5%	10	0.75	YES
Scenario [4] Application by wiping metaSPC 5	1	Maximum in use concentration : 3.456%	10	0.3456	YES
Scenario [5] Cleaning of teats, pre-milking metaSPC 5 - 6	1	Maximum concentration : 3.6%	10	0.36	YES
Scenario [6] Cleaning of equipment metaSPC 5 – 6 – 8 -9 -10	1	Maximum concentration : 7.5%	10	0.375	YES
Scenario [7] Mixing and loading RTU metaSPC 6-8 -9 -10	1	Maximum concentration : 7.5%	10	0.75	YES
Scenario [8] Mixing and loading of robot metaSPC 9, 10	1	Maximum concentration : 7.5%	10	0.75	YES
YESYESScenario [9] Application by robot metaSPC 9, 10	1	Maximum concentration : 7.5%	10	0.75	YES
Scenario [10] Cleaning of teats, post-milking metaSPC 8, 9, 10	1	Maximum concentration : 7.5%	10	0.75	YES
Scenario [11] Cleaning of teats by robot metaSPC 9, 10	1	Maximum concentration : 7.5%	10	0.75	YES
Scenario [12] Mixing and loading of concentrated skin disinfectant metaSPC 5	1	Maximum concentration : 8%  NB: for MetaSPC 14, as it is classified a	10	0.8	YES



		qualitative RA is performed.			
Scenario [13] Application by spraying metaSPC 5	1	Maximum concentration : 8%	10	0.8	YES
Scenario [14] Application by brushing metaSPC 5	1	Maximum concentration : 8%	10	0.8	YES
Scenario [15] Cleaning of skin metaSPC 5	1	Maximum concentration : 8%	10	0.8	YES
Scenario [16] Cleaning of equipment metaSPC 5	1	Maximum concentration : 8%	10	0.8	YES
Scenario 17 handwash metaSPC 1	1	3.6	10	0.36	YES
Scenario 18 handrub metaSPC 15	1	3.6	10	0.36	YES
Scenario 21 Mixing and loading PT2-PT4 metaSPC 2	1	2	10	0.2	YES
Scenario 22 Wiping PT2-PT4 metaSPC 2, 7	1	2	10	0.2	YES
Scenario 26 Spraying knives and cutting machines PT4 metaSPC 2	1	2	10	0.2	YES

### Qualitative assessment

<b>Summary table: estimated local exposure from professional uses</b>							
<b>Hazard category</b>	<b>Effects in terms of C&amp;L</b>	<b>Who is exposed</b>	<b>Tasks, uses, processes</b>	<b>Potential exposure route</b>	<b>Frequency and duration of potential exposure</b>	<b>Relevant RMM &amp; PPE</b>	<b>Conclusion on risk</b>
<b>metaSPC 2: PT2 RTU ( by spaying low pressure, direct pouring and brushing), surface disinfectant</b>							
High	Eye irrit. 2 H319	Professional	Spraying or direct pouring or brushing	Eyes (splashes on the eyes)	Minutes during disinfection process,	RMM Professionals	Acceptable

			applicatio n		less than an hour per day	reversible toxicologi cal effect	reversible toxicologi cal effect
<b>metaSPC 5: PT3 Concentrated pre-milking teat disinfectants</b>							
High	Eye Dam. 1 H318	Professio nal	Mixing and loading the product	Skin Eye (splashes hand to eye transfer)	Few minutes per day	RMM Profession als  PPE: Chemica goggles	Acceptable  RMM are achievable and PPE are realistic
<b>metaSPC 7: PT2 and 4 RTU (wipes), surface disinfectant</b>							
High	Eye irrit. 2 H319	Professio nal	Wiping applicatio n	Eyes (hand to eye transfer)	Minutes during disinfection process, less than an hour per day	+ Revirsi ble effect  RMM  Profession als	Acceptable  Reversible toxicologica l effect
<b>metaSPC 6: PT3 RTU pre-milking teat disinfectants</b>							
High	Eye Dam. 1 H318	Professio nal	Loading the product, application by spraying or dipping the product, cleaning of teats, cleaning of equipment	Skin Eye (splashes hand to eye transfer)	Minutes during loading, cleaning of teats and cleaning of equipment  For application less than an hour per day	RMM Profession als  PPE: Chemical goggles	Acceptable  RMM are achievable and PPE are realistic
<b>metaSPC 8, 9, 10: PT3 RTU post-milking teat disinfectants</b>							
High	Eye Dam. 1 H318	Professio nal	Loading the product, application by spraying (+robot) or dipping the product, cleaning of equipment	Skin Eye (splashes hand to eye transfer)	Minutes during loading and cleaning of equipment  For application less than an hour per day	RMM Profession als  PPE: Chemical goggles	Acceptable  RMM are achievable and PPE are realistic
<b>metaSPC 1 and 15: handwash and handrub</b>							
High	Eye Dam. 1 H318	Professio nal	Application	Eye splash of a	Seconds Handwash are rinsed	RMM Profession als	Acceptable

			(regarding mixing and loading phase, taking into account that the product is viscous therefore splashes of the undiluted product to the eyes are unlikely	handwash or a handrub is not common	Handrub: hands are rubbed until the product evaporate/ dries	PPE  + the user may have recourse to glasses or face shield if necessary	RMM are achievable
<b>metaSPC 3: concentrated products</b>							
Very high	H314 skin corrosive 1C  Eye Dam. 1 H318	Professional	Loading the product, dilution, connecting the product to the system/pipeline	Skin Eye (splashes hand to eye transfer)  Aerosols are not expected during refilling and loading of concentrates.	Minutes during loading and cleaning of equipment	RMM Professionals  PPE: Chemical goggles Gloves Wear protective coverall (to be specified by the authorisation holder within the product information).	Acceptable  RMM are achievable and PPE are realistic
<b>metaSPC 12 : concentrated products</b>							
Very high	H314 skin corrosive	Professional	Loading the product, dilution, connecting the product to the system/pipeline	Skin Eye (splashes hand to eye transfer)  Aerosols are not expected during refilling and	Minutes during loading and cleaning of equipment	RMM Professionals  PPE: Chemical goggles Gloves Wear protective coverall (to be specified	Acceptable  RMM are achievable and PPE are realistic

				loading of concentrates.		by the authorisation holder within the product information).	
<b>metaSPC 13: concentrated products</b>							
Very high	H314 skin corrosive	Professional	Loading the product, dilution, connecting the product to the system/pipeline	Skin Eye (splashes hand to eye transfer)  Aerosols are not expected during refilling and loading of concentrates.	Minutes during loading and cleaning of equipment	RMM Professionals  PPE: Chemical goggles Gloves Wear protective coverall (to be specified by the authorisation holder within the product information).	Acceptable  RMM are achievable and PPE are realistic
<b>metaSPC 14: concentrated products</b>							
Very high	H314 skin corrosive	Professional	Loading the product, dilution, connecting the product to the system/pipeline	Skin Eye (splashes hand to eye transfer)  Aerosols are not expected during refilling and loading of concentrates.	Minutes during loading and cleaning of equipment	RMM Professionals  PPE: Chemical goggles Gloves Wear protective coverall (to be specified by the authorisation holder within the product information).	Acceptable  RMM are achievable and PPE are realistic
<b>metaSPC 4, 11: concentrated products</b>							
Low	H315 skin Irrit	Professional	Loading the product,	Skin Eye (splashes	Minutes during loading	RMM Professionals	Acceptable

high	H318 Eye dam		dilution, connecting the product to the system/pi peline	hand to eye transfer) Aerosols are not expected during refilling and loading of concentra tes.	and cleaning of equipment	PPE: Chemical goggles Gloves	RMM are achievable and PPE are realistic
<b>Meta spc 4 : Spraying application</b>							
High	Eye Dam. 1 H318	Professio nal	Sraying brushing application	Eyes (splashes g on the eyes)	Minutes during disinfection process, less than an hour per day	RMM Profession als  PPE: Chemica goggles	Acceptable  RMM are achievable and PPE are realistic.

Please take into consideration that the aerosols are not expected during refilling and loading of concentrates in meta 3, 12-14, and meta 4, 11 in scenario 12 and 19. Therefore, classification with H314 and H315 is not leading to restriction to automatic procedures or to wearing of RPE against particles.

## Conclusion

Acceptable risks are foreseen for professional using products of MetaSPC 1 and MetaSPC 15 for hand disinfection without PPE.

Acceptable risks are foreseen for professional using products of MetaSPC 2 and 7 for general surface disinfection including surface in contact with food, toilet disinfection and algacide without PPE

Acceptable risks are foreseen for professional using products of metaSPC 5, 6, 8, 9 for teats disinfection. However, as metaSPC 5, 6, 8, 9 and 10 are classified H318, eye damage 1, chemical goggles need to be worn.

Acceptable risks are foreseen for professional using products of MetaSPC 4 and 11 for general surface disinfection including surface in contact with food, toilet disinfection and algacide. However, as the products of metaSPC 4 and 11 are irritant for skin/eye gloves and goggles are needed.

Acceptable risks are foreseen for professional using products of MetaSPC 3. As the products of metaSPC 3 are corrosive for skin/eye gloves, goggles and protective coverall are needed. These PPE also cover the exposure to foam.

Acceptable risks are foreseen for professional using products of MetaSPC 12 for CIP. However, as the products of metaSPC 12 are corrosive for skin/eye gloves, goggles and protective coverall are needed.

Acceptable risks are foreseen for professional using products of MetaSPC 13,. As the products of metaSPC 13 are corrosive for skin/eye gloves, goggles and protective coverall are needed. These PPE also cover the exposure to foam.

Acceptable risks are foreseen for professional using products of MetaSPC 14 as animal skin disinfectant when PPE are worn. However, due to the animal health assessment, this use should not be authorized.

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

#### **Systemic effects (Propan-2-ol)**

<b>Task/Scenario</b>	<b>Tier</b>	<b>AEL mg/kg bw/d</b>	<b>Estimated uptake mg/kg bw/d</b>	<b>Estimated uptake/ AEL (%)</b>	<b>Acceptable (yes/ no)</b>
Scenario [30] Propan-2-ol ADULT	1	10.7	0,258870422	2.4	YES
Scenario [30] Propan-2-ol CHILD	1	10.7	0,989068931	9.2	YES

#### **Combined scenarios**

Not relevant

#### **Local effects**

- For pronan-2-ol

<b>Scenario</b>	<b>Tier</b>	<b>Estimated uptake mg/m<sup>3</sup> (8 h TWA)</b>	<b>AEC mg/m<sup>3</sup></b>	<b>Estimated exposure/ AEC (%)</b>	<b>Acceptable (yes/no)</b>
Scenario [30] Propan-2-ol ADULT	1	0.006 mg/m <sup>3</sup>	77	0.0	yes
Scenario [30] Propan-2-ol CHILD	1	0.006 mg/m <sup>3</sup>	77	0.0	yes

- For Butyldiglycol

Scenario	Tier	Estimated uptake mg/m <sup>3</sup> (8 h TWA)	OEL mg/m <sup>3</sup>	Estimated exposure/ AEC (%)	Acceptable (yes/no)
Scenario [31] Butyldiglycol ADULT	1	0.00005 mg/m <sup>3</sup>	101.2	0.0	yes
Scenario [31] Butyldiglycol CHILD	1	0.0002 mg/m <sup>3</sup>	101.2	0.0	yes

- For L-Lactic acid

Scenario	Tier	Concentration of l-lactic acid (%)	NOEC dermal (%)	Estimated exposure/ AEC (%)	Acceptable (yes/no)
Scenario 30 handwash metaSPC 1	1	3.6	10	0.36	YES
Scenario 31 handrub metaSPC 15	1	3.6	10	0.36	YES
Scenario 32 Toilet disinfection metaSPC 2	1	2	10	0.2	YES
Scenario 33 Wiping MetaSPC 2, 7	1	2	10	0.2	YES
Scenario 34 Spraying MetaSPC 2	1	2	10	0.2	YES
Scenario 35 Hand-held Spraying MetaSPC 2	1	2	10	0.2	YES

### Qualitative assessment

Summary table: estimated local exposure from non-professional uses							
Hazard category	Effects in terms of C&L	Who is exposed	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Relevant RMM & PPE	Conclusion on risk
<b>metaSPC 1 and 15: handwash and handrub</b>							
High	Eye Dam. 1 H318	Non-Professional (including	Application	Potential exposure to eye: but eye splash of	1 minute (see efficacy) Handwash are rinsed	No PPE foreseen for general public	No acceptable according to the <a href="#">BPC</a>

		g children)		a handwash or a handrub is not common	Handrub: hands are rubbed until the product evaporate/ dries	+ Labelling  + used with low frequency + used for short duration + proper instructions for use - irreversible and/or severe effect <sup>24</sup> (e.g. Cat. 1 effect)  - risk of exposure by splashing - risk of exposure, especially for children who rub their eyes during the hand-washing process	<a href="#">opinion</a> (PT1, p.9)
<b>metaSPC 2: PT2 RTU ( by spraying low pressure, direct pouring and brushing), surface disinfectant</b>							
	Eye Irrit 2. H319	Non-professional	Spraying or brushing or direct pouring application	Eyes (splashes on the eyes)	Once per day	Low probability of eye exposure + Reversible effect	Acceptable Reversible toxicological effect



							Accidental exposure
<b>metaSPC 4 : PT2/4 Surface disinfectants</b>							
High	Eye Dam. 1 H318	Non-Professional (adult)	Direct pouring Mixing and loading	Eye splash during pouring step (dilution step for spraying application or RTU in toilets bowl)	Once per day	- Irreversible effect + Use by adult only + accidental + exposure duration + Low probability of eye exposure + RMM:  The product must be fitted with a pouring spout, the product must be poured gently on the toilet bowl to avoid the formation of splashes.  Wash hands after application. A child proof	Acceptable (exposure route is considered accidental and infrequent, correct instruction of use, labelling and packaging is sufficient).

						closure is required  The packaging must be comply with tandard EN ISO 11683, therefore, a TWD should be present on the product.	
High	Eye Dam.1 H318 (regarding spraying application, a 20% dilution step is required.)	Non-Professional (adult)	Spraying application	Eye splash during spraying	Once per day	Taking into account of application mode (spraying or brushing) the risk of exposure could be avoid by applying the following:  + Avoid contact with eyes + Wash hands after application + A child proof closure is required + Spray downward to avoid splashing in the eyes.	Taking into account that the biocidal product is intended to be used by non professional by spraying application and the biocidal product present in Meta SPC 4 are classified as eye dam.1 after discussion during the WGIII2021 it has been decided no risk mitigation measures to prevent all risks of ocular exposure could ensure a

						+ Avoid the formation of splashes when handling the product	sufficient level of safety for this class of users, therefore uses requiring spray application cannot be allowed for non-professionals.
Low	Skin irrit. 2 H315	Non-Professional (adult)	Mixing and loading Application	Dermal contact	Once per day	+ Use by adult only + low effect category + short exposure duration + low toxicity of the active substance + reversible effect + Wash hands after application	Acceptable (dermal contact is expected, however since the contact time is low and the hazard category is also considered low, the risk is acceptable)
<b>metaSPC 7: PT2 and 4 RTU (wipes), surface disinfectant</b>							
	Eye Irrit 2. H319	Non-professional	Wiping application	Eyes (hand to eye transfer)	Once per day	Low probability of eye exposure + Reversible effect	Acceptable Reversible toxicological effect Accidental exposure

## Conclusion

Unacceptable risks are foreseen for non-professional using products of MetaSPC 1 and MetaSPC 15 for hand disinfection. Therefore the use #2 will not be allowed for non-professional use as the risk of exposure (eyes contact) to the corrosive product cannot be excluded.

Acceptable risks are foreseen for non-professional using products of MetaSPC 2 and 7 for general surface disinfection including surface in contact with food, toilet disinfection and algacide without PPE (due to the reversible effect).

Taking into account that the biocidal product is intended to be used by non professional by spraying application and the biocidal product present in Meta SPC 4 are classified as eye dam.1 after discussion during the WGIII2021 it has been decided no risk mitigation measures to prevent all risks of ocular exposure could ensure a sufficient level of safety for this class of users, therefore uses requiring spray application cannot be allowed for non-professionals

Regarding direct pouring application acceptable risks are foreseen for non-professional using products of MetaSPC4 for PT2 surface disinfection by applying the following risk mitigation measures:

- Avoid contact with eyes
- The product must be fitted with a pouring spout, the product must be poured gently on the toilet bowl to avoid the formation of splashes.
- Wash hands after application
- A child proof closure is required
- The packaging must be comply with tandard EN ISO 11683, therefore a TWD should be present on the product.

## ***Risk for the general public***

Not relevant

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

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). According to the [CLH published on May 2020](#) this substance is 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 logically 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. dairy product,..). Therefore the intended use does not significantly contribute to consumer exposure to lactic acid. Therefore, no dietary risk assessment of lactic acid is required.

Regarding the dietary exposure of propan-2-ol (SOC), due to its high vapor pressure, this substance evaporates completely within the time of application of the biocidal products PT4 and PT3. In the case of the residue transfer does occur, the active substance 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.<sup>8</sup>

The isopropanol is also listed in Commission Implementing Regulation (EU) No 872/2012<sup>9</sup> as flavouring substances intended to be used in or on foodstuffs.

Regarding the other SOCs band B (sodium lauryl sulphate, sodium lauryl ether sulphate, sulfonic acids, C14-17-sec-alkane, sodium salts, C6 alkyl glucoside, methanesulfonic acid, Sulphuric acid), only a qualitative risk assessment needs to be performed according to the Echa guidance<sup>10</sup> on risk assessment on human health. None of the SOCs are classified for acute toxicity or sensitization. However, all SOCs, except for C6 alkyl glucoside, are classified as skin irritant or corrosive. Therefore, if residues of these SOCs from diluted or RTU products type 4 are present in our food (i.e. meat, milk or eggs), they could induce an irritating or corrosive effect to the human digestive tract when eating the food.

The SOCs of band B classified as skin irritant or skin corrosive are included in the following metaSPCs of PT4 products: 3, 4, 7, 11, 12 and 13. To qualitatively assess the irritating or corrosive effect to the human digestive tract, the classification of the highest in use concentration of the above mentioned metaSPCs were screened. For metaSPC 7, this screening was not needed as the product is ready-to-use and not classified as skin irritant or skin corrosive. Therefore, the risk of metaSPC 7 is acceptable. For the other metaSPCs (i.e. metaSPC 3, 4, 11, 12 and 13), none of the highest in-use content of SOCs were classified as skin irritant or skin corrosive. As a conclusion, the in-use content of the skin irritant and skin corrosive SOCs band B are too low to induce irritating properties when used in products from metaSPC 3, 4, 7, 11, 12 and 13.

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

Not relevant

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<sup>8</sup><https://www.icis.com/explore/resources/news/2007/11/05/9076020/isopropanol-ipa-uses-and-market-data/>

<sup>9</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0872&from=EN>

<sup>10</sup> Guidance on the Biocidal Products Regulation Volume III Human Health -Assessment & Evaluation (Parts B+C) Version 4.0 December 2017

## 2.2.7 Risk assessment for animal health

**Similar to human health assessment, local effects toward the active substance is considered for animal health.**

Local effects are assessed with the NOAEC for L-lactic acid of 10% for dermal exposure for MetaSPC for which a corrosion/irritation testings have been performed in order to prevent some irritating effects triggered by repeated exposure. When the metaSPC are classified for dermal effects (H315, H314), only a qualitative risk assessment has been performed.

MetaSPC 5, 6, 8, 9 and 10 are intended to be used as pre-or-post milking disinfectants. For these MetaSPC, the products could be directly applied on the animals teats and corrosion/irritation test are available. Therefore, a semi-quantitative risk assessment is performed.

In addition, MetaSPC 14 direct application on skin animal is foreseen. However, for this MetaSPC, no corrosion/irritation test is available and therefore, a qualitative risk assessment has been performed.

For others MetaSPC and secondary exposure to family, exposure is not considered relevant due to the toxicological properties of the active substance.

In addition, exposure to pronan-2-ol is possible for MetaSCP 8 and 9. However, no methodology is available. Therefore, the risk may be compared to human and as it shows acceptable risk, no concern is expected for animal health also.

### Local effects

Scenario	Tier	Concentration of l-lactic acid (%)	NOEC dermal (%)	Estimated exposure/ AEC (%)	Acceptable (yes/no)
Application by dipping metaSPC 5	1	Maximum 8%, in use application 3.2% (dilution 40%)	10	0.32	YES
Application by spraying metaSPC 5	1	Maximum 8%, in use application 3.2% (dilution 40%)	10	0.32	YES
Application by wiping metaSPC 5	1	Maximum 8%, in use application 3.2% (dilution 40%)	10	0.8	YES

Application by dipping metaSPC 6	1	3.6	10	0.36	YES
Application by spraying metaSPC 6	1	3.6	10	0.36	YES
Application by dipping metaSPC 8, 9, 10	1	7.5	10	0.75	YES
Application by spraying metaSPC 9, 10	1	7.5	10	0.75	YES
Application by robot metaSPC 9, 10	1	7.5	10	0.75	YES
Cleaning of teats by robot metaSPC 9, 10	1	7.5	10	0.75	YES
Application by spraying metaSPC 5	1	Maximum 8%, in use application 3.2% (dilution 40%)	10	0.32	YES
Cleaning of skin metaSPC 5	1	Maximum 8%, in use application 3.2% (dilution 40%)	10	0.32	YES

### Qualitative assessment

<b>Summary table: estimated local exposure for animals</b>							
<b>Hazard category</b>	<b>Effects in terms of C&amp;L</b>	<b>Who is exposed</b>	<b>Tasks, uses, processes</b>	<b>Potential exposure route</b>	<b>Frequency and duration of potential exposure</b>	<b>Relevant RMM &amp; PPE</b>	<b>Conclusion on risk</b>
<b>metaSPC 5/6/8/9/10 : pre or post-milking teat disinfectants</b>							
High	Eye Dam. 1 H318	Animal	Application of the product (dipping, spraying, brushing)	Skin Eye (low risk)	Few minutes per day	RMM: application done by professional users. Animal are tied during application,	Acceptable

						reducing potential eye exposure	
<b>metaSPC 14 : skin disinfectants</b>							
Very high	H315 skin irritation	Animal (in-use concentration : $32 \times 0.06 = 1.92\%$ )	Loading the product, dilution, connecting the product to the system/pipeline	Skin (direct application) Eye (splashes)	Few minutes	No RMM foreseen	Not Acceptable

\* For MetaSPC 14, the concentration of lactic acid in the in-use product would be of 1.92% ( $32 \times 6\%$  of dilution). Therefore, according CLP regulation, the product would still be classified for skin irritation, H315. Skin irritant products should not be used directly on animal skin.

### Conclusion

A risk is foreseen for products use in MetaSPC 14 as animal skin disinfectants. Therefore, use 14.1 should not be authorized.

For the others MetaSPC of this family, no unacceptable risk for animal health are foreseen.

Please note that no additional RMM is foreseen for animal health.



## 2.2.8 Risk assessment for the environment

### 2.2.8.1 Effects assessment on the environment

**Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required**

No studies have been conducted on the product. Effects are based on data on the active substance. The applied endpoints are taken from the assessment report and summarised below.

PNEC	Lowest endpoint	AF	PNEC	Test/species
<b>L-lactic acid</b>				
STP	NOEC: 100 mg/L	10	10 mg/L	Respiration inhibition test
fresh water	EC50: 3900 mg/L	1000	3.9 mg/L	Algae
sediment	-	-	4.8 mg/kg wwt	Equilibrium partitioning from aquatic data. Calculated according to the Guidance part B, vol. IV.
soil	-	-	1.9 mg/kg wwt	
groundwater	Reference value for groundwater = 0.1 µg/L			
atmosphere	The vapour pressure of L-lactic acid is 0.4 Pa at 20°C and the Henry constant is $3.6 \times 10^{-5}$ indicating that direct evaporation and volatility from water are expected to be insignificant. Furthermore the CAR indicates the L-lactic acid has no global-warming potential. Hence, the concentration in air will be very low and the air is not an environmental compartment of concern.			
birds	Bioconcentration factors estimated with log Kow are found to be low BCF <sub>fish</sub> = 0.048 L/kg and BCF <sub>earthworms</sub> = 6.78 L/kg indicating a low potential for bioaccumulation.			
mammals				

### **Further Ecotoxicological studies**

No further ecotoxicological studies have been conducted on L-lactic acid nor on the products of the BPF supported in this document.

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

No further ecotoxicological studies have been conducted on L-lactic acid nor on the products of the BPF supported in this document.

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

No further ecotoxicological studies have been conducted on L-lactic acid nor on the products of the BPF supported in this document.

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

No further ecotoxicological studies have been conducted on L-lactic acid nor on the products of the BPF supported in this document. Products of the BPF L-lactic acid are not in the form of bait or granules.

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

No further ecotoxicological studies have been conducted on L-lactic acid nor on the products of the BPF supported in this document based on the intended uses.

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

See Fate and distribution in exposed environmental compartments.

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

An additional study is available on the readily biodegradability criteria of L-lactic acid: "Determination of 'Ready' biodegradability: Carbon Dioxide (CO<sub>2</sub>) Evolution Test (Modified Sturm Test) of PURAC Sanilac 80". This study was also provided, evaluated and end points agreed in the frame of another Union Authorisation. The results are reported below.

Summary table on further studies on fate and behaviour in the environment							
Method, Guideline, GLP status, Reliability	Compartment	pH	Temp [°C]	Initial TS concentration, Co[mg/l]	Half-life, DT <sub>50</sub> [d]	Re-marks	Re-fERENCE
OECD Guideline No. 301B, 1992	Aerobic aqueous medium with microbial activity introduced by inoculation with activated sludge	7.6-7.8	23°C	37.5	~7.1 (based on mean %deg bottle A-B)	28 days Readily biodegradable fulfilling the 10 days window criteria	Test Facility Study No. 20194906

Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment	
Value/conclusion	L-lactic acid is found to be readily biodegradable fulfilling the 10-days window criteria. >75% at the end, > 60% within 10d
Justification for the value/conclusion	All criteria for acceptability of the test were met, the study is considered to be valid.
Data waiving	
Information requirement	
Justification	N.A.

***Leaching behaviour (ADS)***

No further ecotoxicological studies have been conducted on L-lactic acid nor on the products of the BPF supported in this document.

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

No further ecotoxicological studies have been conducted on L-lactic acid nor on the products of the BPF supported in this document.

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

No further ecotoxicological studies have been conducted on L-lactic acid nor on the products of the BPF supported in this document.

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

No further ecotoxicological studies have been conducted on L-lactic acid nor on the products of the BPF supported in this document based on the intended uses.

***If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)***

No further ecotoxicological studies have been conducted on L-lactic acid nor on the products of the BPF supported in this document based on the intended uses.

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

No further ecotoxicological studies have been conducted on L-lactic acid nor on the products of the BPF supported in this document based on the intended uses.

### 2.2.8.2 Exposure assessment

Please find an overview of the assessed scenario's for each SPC and the respective worst cases under the General "tab" in the Excell ENV-L-LA BPF v2 files.

#### General information

Assessed PT	PT 1
Assessed scenarios	Scenario PT1-1A: Handwash for professionals Scenario PT1-1B: Handrub for professionals Scenario PT1-2A: Handwash for private use Senario PT1-2B: Handrub for private use
ESD(s) used	Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product Type 1) January 2004
Approach	All scenarios: Consumption based
Distribution in the environment	Calculated based on BPR Guidance, Volume IV Environment – Part B
Groundwater simulation	see annexes
Confidential Annexes	YES: In the confidential Annex excels are provided
Life cycle steps assessed	All scenarios: Production: No Formulation : No Use: Yes Service life: No
Remarks	Excel containing all calculation can be found in IUCLID and confidential annex.

#### Emission estimation

##### Scenario [PT1-1A]: Handwash for professionals (metaSPC 1)

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario PT1-1A: Handwash for professionals (metaSPC 1)			
Number of beds in model hospital Nbedspres	400	-	Default: ESD PT1 table 4.5 page 17
Fraction released to wastewater Fwater	1	-	Default: ESD PT1 table 4.5 page 17
Number of hospital personal per bed NFTE/bed	1,5	FTE.bed-1	Default value ENV43 of TAB v2.0
Efficient dose rate of the hand disinfectant for nursing staff QformN	0,01	L/event	Applicant information
Efficient dose rate of the hand disinfectant for surgical staff QformN	/	L/event	S: Applicant (only use for nursing staff.

			No efficacy claim for surgical staff)
Number of applications Nappl	10	d-1	ENV41 and ENV43 of TAB v2.0 for "soap and liquid soap hand disinfectant"
Active substance in biocidal product Cform_volume	36,72	g/L	Considering worst-case density = 1.02 applied to the concentration of L-lactic acid 3.6% w/w
Consumption of active ingredient per bed for nursing staff QsubstbedN	5,51E-03	kg/bed/d	Formula ENV 41 of TAB v2.0
<b>Output: calculation: Elocalwater= Nbedspres • QsubstbedN • Fwater</b>			
Emission rate to wastewater (standard STP)	2.20	kg/d	Default: ESD PT1 table 4.5 page 17

#### Calculations for Scenario [PT1-1A]

Resulting local emission to relevant environmental compartments		
Compartment	Local emission (Elocal <sub>compartment</sub> ) [kg/d]	Remarks
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	2.20	
Air	Not directly exposed	
Soil	Not directly exposed	
Groundwater	Not directly exposed	

#### Scenario [PT1-1B]: Handrub for professionals (metaSPC 15)

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario PT1-1B: Handwash for professionals (metaSPC 15)			
Number of beds in model hospital Nbedspres	400	-	Default: ESD PT1 table 4.5 page 17
Fraction released to wastewater Fwater	1	-	Default: ESD PT1 table 4.5 page 17

Number of hospital personal per bed NFTE/bed	1,5	FTE.bed-1	Default value ENV43 of TAB v2.0
Efficient dose rate of the hand disinfectant for nursing staff QformN	0,006	L/event	Applicant information
Efficient dose rate of the hand disinfectant for surgical staff QformN	/	L/event	S: Applicant (only use for nursing staff. No efficacy claim for surgical staff)
Number of applications Nappl	25	d-1	ENV41 and ENV43 of TAB v2.0 for "other hand disinfectants"
Active substance in biocidal product Cform_volume	36.936	g/L	Considering worst-case density = 1.026 applied to the concentration of L-lactic acid 3.6% w/w
Consumption of active ingredient per bed for nursing staff QsubstbedN	8.31E-03	kg/bed/d	Formula ENV 41 of TAB v2.0
<b>Output: calculation: Elocalwater= Nbedspres • QsubstbedN • Fwater</b>			
Emission rate to wastewater (standard STP)	3.32	kg/d	Default: ESD PT1 table 4.5 page 17

#### Calculations for Scenario [PT1-1B]

Resulting local emission to relevant environmental compartments		
Compartment	Local emission (Elocal <sub>compartment</sub> ) [kg/d]	Remarks
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	3.32	
Air	Not directly exposed	
Soil	Not directly exposed	
Groundwater	Not directly exposed	

#### Scenario [PT1-2A]: Handwash for private use (metaSPC 1)

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario PT1-2A: Handwash for private use (metaSPC 1)			

Number of inhabitants feeding one STP Nlocal	10000	-	Default: ESD PT1 table 4.2 page 15
Fraction released to wastewater Fwater	1	-	Default: ESD PT1 table 4.2 page 15
Consumption per application D1 Vform_appl	10	mL	Applicant information
Number of applications Nappl	5	d-1	ENV43 of TAB v2.0 for "soap and liquid soap hand disinfectant"
Fraction of inhabitants using product N Finh	0.2	-	ENV42 item of ENV-TAB v2.0
Market share of disinfectant Fpenetr	0.5	-	ESD PT1 table 4.2 page 15
Active substance in biocidal product Cform_volume	36,72	g/L	Considering worst-case density = 1.02 applied to the concentration of L-lactic acid 3.6% w/w
<b>Output: calculation:</b> D1 and A: $E_{localwater} = N_{local} * N_{appl} * F_{inh} * F_{water} * V_{formappl} * 10^{-6} * C_{formvolume} * F_{penetr}$			
Emission rate to wastewater (standard STP)	1.84	kg/d	Default: ESD PT1

#### Calculations for Scenario [PT1-2A]

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ( $E_{local,compartment}$ ) [kg/d]	Remarks
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	1.84	
Air	Not directly exposed	
Soil	Not directly exposed	
Groundwater	Not directly exposed	

#### Scenario [PT1-2B]: Handrub for private use (metaSPC 15)

<b>Input parameters for calculating the local emission</b>			
<b>Input</b>	<b>Value</b>	<b>Unit</b>	<b>Remarks</b>
Scenario PT1-2B: Handwash for private use (metaSPC 15)			
Number of inhabitants feeding one STP Nlocal	10000	-	Default: ESD PT1 table 4.2 page 15
Fraction released to wastewater Fwater	1	-	Default: ESD PT1 table 4.2 page 15
Consumption per application D1 Vform_appl	6	mL	Applicant information
Number of applications Nappl	5	d-1	ENV43 of TAB v2.0 for "soap and liquid soap hand disinfectant"
Fraction of inhabitants using product N Finh	0.5	-	ENV42 item of ENV-TAB v2.0
Market share of disinfectant Fpenetr	0.5	-	ESD PT1 table 4.2 page 15
Active substance in biocidal product Cform_volume	36.936	g/L	Considering worst-case density = 1.026 applied to the concentration of L-lactic acid 3.6% w/w
<b>Output: calculation:</b> D1 and A: $E_{localwater} = N_{local} * N_{appl} * F_{inh} * F_{water} * V_{formappl} * 10^{-6} * C_{formvolume} * F_{penetr}$			
Emission rate to wastewater (standard STP)	2.77	kg/d	Default: ESD PT1

#### Calculations for Scenario [PT1-2B]

<b>Resulting local emission to relevant environmental compartments</b>		
<b>Compartment</b>	<b>Local emission (<math>E_{localcompartment}</math>) [kg/d]</b>	<b>Remarks</b>
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	2.77	
Air	Not directly exposed	
Soil	Not directly exposed	
Groundwater	Not directly exposed	



Assessed PT	PT 2
Assessed scenarios	Scenario PT2-1: algaecide for professionals – release in STP Scenario PT2-2: algaecide for private use – release in STP Scenario PT2-3: algaecide professionals and private use – release outdoor Scenario PT2-4: Institutional areas (lavatory and general) professionals and non-professionals Scenario PT2-5: Industrial areas professionals and non-professionals Scenario PT2-6: Medical sector for disinfection of rooms, furniture and objets
ESD(s) used	Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products, JRC Scientific and Technical Reports, Report nr. EUR 25115 EN, Publications Office of the European Union, Luxembourg, 2011
Approach	All scenarios: Consumption based (worst case according to excell "ENV-L-LA BPF v2)
Distribution in the environment	Calculated based on BPR Guidance, Volume IV Environment – Part B
Groundwater simulation	see <i>annexes</i>
Confidential Annexes	<i>YES: In the confidential Annex excels are provided</i>
Life cycle steps assessed	All scenarios: Production: No Formulation : No Use: Yes Service life: No
Remarks	Excel containing all calculation according to ENV TAB 48 can be found in annex; section 3.2.

### **Emission estimation**

The break-vent point calculation shows that based on provisional production quantities, the consumption based approach should be followed. Please refers to excel "ENV-L-LA BPF- v2 for further details on the calculation.

### **Scenario [PT2-1]: ]: disinfection of indoor fountains (metaSPC 2, 3)**

Default: ESD PT2 consumption approach industrial areas

<b>Input parameters for calculating the local emission</b>			
<b>Input</b>	<b>Value</b>	<b>Unit</b>	<b>Remarks</b>
Scenario PT2-1: Disinfection of indoor fountains			

Fountain volume	10	L	Applicant information (working solution or rtu)
Number of fountains per STP	600	[-]	the worst-case concentration of l-lactic acid is with metaSP 3 considering the density of 1,170, it covers metaSPC 2 (2% l-lactic acid with density of 1,006)
Fraction of water replaced due to product application	1	d <sup>-1</sup>	Large scale application ESD PT2
Concentration of a.s. in fountain	49.98	mg/ml	output: ESD PT2
Fraction of a.s. released to wastewater	1	[-]	Default ESD PT2
Market share	0.5	[-]	Default ESD PT2
<b>Output: calculation:</b> <b><math>E_{\text{local water}} = V_{\text{fountain}} * N_{\text{fountain}} * F_{\text{rep}} * C_{\text{fountain}} * F_{\text{water}} * F_{\text{market}} / 1000000</math></b>			
Emission rate to wastewater (standard STP)	1.50E-01	kg/d	Output

#### Calculations for Scenario [PT2-1]

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ( $E_{\text{local compartment}}$ ) [kg/d]	Remarks
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	1.50E-01	

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ( $E_{\text{local,compartment}}$ ) [kg/d]	Remarks
Air	Not directly exposed	
Soil	Not directly exposed	
Groundwater	Not directly exposed	

### Scenario [PT2-2]: algaecide outdoor –“spray and rinse” (metaSPC 2,3)

Default: ESD PT2 consumption approach institutional areas

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario PT2-2: algaecide outdoor “Spray and rinse”			
Number of houses treated per day in the city scenario	3	-	Default
Number of houses treated per day in the countryside scenario	1	-	Default
Treated area of a façade	2.00E-02	m <sup>2</sup>	Default
Volume of product applied on area (façade) (= application rate of product)	0.1	l/m <sup>2</sup>	S
Fraction of active substance in product	2,08E-02	-	S
Fraction of product lost during rinse	0.7	-	Default
<b>Output: calculation:</b> $E_{\text{localwater,spray+rinse}} = n_{\text{houses\_applic\_city}} * (E_{\text{localspray\_runoff}} + E_{\text{localspray\_drift,tier1}} + E_{\text{localrinse\_drift}} + E_{\text{localrinse\_runoff}})$			
Emission rate to wastewater (standard STP)	7.81E-01	kg/d	Output: ESD PT2 page 16

### Calculations for Scenario [PT2-2]

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ( $E_{\text{local,compartment}}$ ) [kg/d]	Remarks
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ( $E_{\text{local,compartment}}$ ) [kg/d]	Remarks
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	7.81E-01	cityside
Air	Not directly exposed	
Soil	8.59E-03	countryside
Groundwater	Not directly exposed	

### Scenario [PT2-3]: algaecide – release outdoor service life (metaSPC 2, 3)

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario PT2-3: algaecide – release outdoor (service life)			
Fraction of the substance in product	0,020825	-	metaSPC 3 with density 1.170 covers metaSPC 2
Number of houses that are contributing by leaching	4000	[-]	Application information (working solution or RTU)
Cumulative leaching (100%) over the assessment period	6,5E-01	kg	Output
Daily emission to the sewer	8,7E+01	kg.d <sup>-1</sup>	Output
<b>Output: calculation:</b> $N_{\text{houses,leach}} = N_{\text{house}} * f_{\text{house}}$ $Q_{\text{leach}} = \text{AREA} * V_{\text{form}} * F_{\text{form}} * \text{RHO}_{\text{form}} * 0.001$ $E_{\text{local}} = N_{\text{houses,leach}} * Q_{\text{leach}} / T_{\text{servicelife}}$			
Emission rate to wastewater (standard STP)	8.7E+01	kg/d	Output

### Calculations for Scenario [PT2-3]

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ( $E_{\text{local,compartment}}$ ) [kg/d]	Remarks
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	

<b>Resulting local emission to relevant environmental compartments</b>		
<b>Compartment</b>	<b>Local emission (<math>E_{local,compartment}</math>) [kg/d]</b>	<b>Remarks</b>
Seawater sediment	Not directly exposed	
STP	8.7E+01	
Air	Not directly exposed	
Soil	2.71E-06 (country side)	
Groundwater	Not directly exposed	

**Scenario [PT2-4]:** Institutional areas (lavatory and general) professionals and non-professionals

Default: ESD PT2 consumption approach institutional areas

<b>Input parameters for calculating the local emission</b>			
<b>Input</b>	<b>Value</b>	<b>Unit</b>	<b>Remarks</b>
Scenario PT2-4: Institutional areas (lavatory and general) professionals and non-professionals			
Number of inhabitants feeding one STP $N_{local}$	10000	-	Default ESD PT2
Fraction released to wastewater $F_{water}$	1	-	Default ESD PT2
Concentration of active substance in the product $C_{form-surfaces}$	3.32E-02	kg/L	metaSPC 4 in dilution with density 1.038
Concentration of active substance in the product $C_{form-toilets}$ (lavatory)	1.66E-01	kg/L	metaSPC 4 pure with density 1.038
Consumption per capita (general purpose) $V_{form}$	0.005	l.cap-1.d-1	Default ESD PT2
Consumption per capita (lavatory) $V_{form}$	0.002	l.cap-1.d-1	Default ESD PT2
Fraction of substance disintegrated during or after application (before release to the sewer system) $F_{dis}$	0	-	Default ESD PT2
Penetration factor of disinfectant $F_{penetr}$	0.5	-	Default ESD PT2
<b>Output: calculation: <math>E_{local,water} = N_{local} \cdot V_{form} \cdot C_{form} \cdot F_{penetr} \cdot (1 - F_{dis}) \cdot F_{water}</math></b>			
Emission rate to wastewater (standard STP) general purposes	8.3E-01	kg/d	Output
Emission rate to wastewater (standard STP) lavatory	1.66	kg/d	Output

Elocalwater total	2.49	kg/d	Output
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#### Calculations for Scenario [PT2-4]

Resulting local emission to relevant environmental compartments		
Compartment	Local emission (Elocal <sub>compartment</sub> ) [kg/d]	Remarks
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	2.49	
Air	Not directly exposed	
Soil	Not directly exposed	
Groundwater	Not directly exposed	

#### Scenario [PT2-5]: Industrial areas professionals and non-professionals (metaSPC 7)

Default: ESD PT2 consumption approach industrial areas

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario PT2-5: Industrial areas professionals and non-professionals (metaSPC 7)			
Application rate of biocidal product V <sub>form</sub>	0.00655	L/m <sup>2</sup>	Applicant information (worst-case liquid per wipe)
Concentration of active substance in the product C <sub>form</sub>	20.12	g/L	metaSPC 7 (2% l-lactic acid with density of 1,006)
Surface area to be disinfected AREAsurface	25	m <sup>2</sup>	Small scale application (RTU) ESD PT2
Number of applications per day Nappl	1	d-1	ESD PT2
Fraction of substance disintegrated during or after application (before release to the sewer system) F <sub>dis</sub>	0	-	Default ESD PT2
Fraction released to wastewater F <sub>water</sub>	1	-	Default ESD PT2
<b>Output: calculation: Elocalwater= V<sub>form</sub> • C<sub>form</sub> • AREAsurface • Nappl • (1-F<sub>dis</sub>) • F<sub>water</sub> /1000</b>			
Emission rate to wastewater (standard STP)	3.29E-03	kg/d	Output

## Calculations for Scenario [PT2-5]

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ( $E_{\text{local,compartment}}$ ) [kg/d]	Remarks
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	3.29E-03	
Air	Not directly exposed	
Soil	Not directly exposed	
Groundwater	Not directly exposed	

**Scenario [PT2-6]:** Medical sector dor disinfection of rooms, furniture and objects (metaSPC 7)

Default: ESD RIVM 2001, table 3.6 page 20

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario PT2-6: Industrial areas professionals and non-professionals (metaSPC 7)			
Fraction released to waste water (sanitary purposes) $F_{\text{san,water}}$	0.55	-	D ESD RIVM
Concentration of active substance in the product $C_{\text{san}}$	0.02012	kg/L	metaSPC 7 (2% l-lactic acid with density of 1,006)
Amount of water with ative substance for sanitary purposes $Q_{\text{water\_san}}$	25	L/d	D ESD RIVM
<b>Output: calculation: <math>E_{\text{localwater}} = Q_{\text{water\_san}} \cdot C_{\text{san}} \cdot F_{\text{san,water}}</math></b>			
Emission rate to wastewater (standard STP)	2.77E-01	kg/d	

## Calculations for Scenario [PT2-6]

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ( $E_{\text{local,compartment}}$ ) [kg/d]	Remarks
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ( $E_{\text{local,compartment}}$ ) [kg/d]	Remarks
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	2.77E-01	
Air	Not directly exposed	
Soil	Not directly exposed	
Groundwater	Not directly exposed	

Assessed PT	PT 3
Assessed scenarios	Scenario PT3-1: Disinfection of teats (metaSPC 5, 6, 8, 9, 10) Scenario PT3-2: Skin disinfection (metaSPC 5 and 14) Scenario PT3-3: Animal houses disinfection (metaSPC 11)
ESD(s) used	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, 2011
Approach	All scenarios: Consumption based
Distribution in the environment	Calculated based on BPR Guidance, Volume IV Environment – Part B
Groundwater simulation	<i>see annexes</i>
Confidential Annexes	<i>YES: In the confidential Annex excels are provided</i>
Life cycle steps assessed	All scenarios: Production: No Formulation : No Use: Yes Service life: No
Remarks	Excel containing all calculation can be found in annex; section 3.2.

### **Emission estimation**

#### **Scenario [PT3-1]: Teat disinfection**

Scenario 1A describes the disinfection of teats with products of metaSPC 5, 6, 8, 9, 10 with release in the slurry/manure or in waste water released in slurry/manure: Soil, Groundwater, Feed, Surface water, Sediments, Feed.

Scenario 1B describes the disinfection of teats with products of metaSPC 5, 6, 8, 9, 10 with release in waste water linked to a Sewage Treatment Plant.



<b>Input parameters for calculating the local emission</b>			
<b>Input</b>	<b>Value</b>	<b>Unit</b>	<b>Remarks</b>
Scenario PT3-1: Teat disinfection			
Concentration of active substance in the product for PRE-MILKING Fbioc_pre	34.56	g/L	metaSPC 5 contains 8% w/w l-lactic acid and is used at a dilution of 40% (density 1.08) meaning 34.56 g/L. metaSPC 6 is ready-to-use and contains 3.6% l-lactic acid w/w (density 1.04) so 37.44 g/L. metaSPC 6 is used with application rate of max 15 ml/cow when metaSPC 5 is used with maximum "400 ml/cow" (1 bucket of 10 L of working solution per 25 towels). metaSPC 5 is therefore the worst-case
Concentration of active substance in the product for POST-MILKING Fbioc_post	79.5	g/L	metaSPC 9 covers metaSPC 8 and 10
Application rate of biocidal product <i>per animal per treatment</i> for PRE-MILKING Vprod_pre	0.4	L/cow	S applicant
Application rate of biocidal product <i>per animal per treatment</i> for POST-MILKING Vprod_post	0.015	L/cow	S applicant
Dilution factor Fdil	1	-	S applicant (all concentrations above are already converted in working solution)
Frequency of application per day	3	-	S applicant
Fraction of active released in manure/slurry or in waste water	0.5	-	Cf guidance ESD for PT3
Number of days of lactation period	300	d	Cf guidance ESD for PT3
Number of animals in housing Nanimal	100	-	D: TNG ESD PT3 <a href="#"><u>table 3a p.23</u></a>
Number of milk producing animals per day Nmp_animal	82	-	TAB v2 ENV63

Fraction of active ingredient released to the slurry Fmanure	0.5	-	D: TNG ESD PT3 <i>table 3a p.23</i>
Fraction released to waste water Fstp	0.5	-	D: TNG ESD PT3 <i>table 3a p.23</i>
<b>Output: calculation:</b>			
<b>Qai prescr = (0.001*Fbioc_pre*Vprod_pre*Fdil) + (0.001*Fbio_post*Vprod_post*Fdil)</b>			
<b>Qai manure = Fmanure * Qaiprescr*Nmp_animal</b>			
<b>Qai stp = Elocalwastewater = Qaiprescr*Nanimal*Napp-teat * Nday-lact *Fstp /365</b>			
Qai prescr	0.0150165	Kg	ESD PT3
Qai, manure (Scenario PT3-1A)	0.6157	kg	ESD PT3
Qai, stp (Scenario PT3-1B)	3.70	kg/d	ESD PT3

#### Calculations for Scenario [PT3-1]

Resulting local emission to relevant environmental compartments		
Compartment	Local emission (Elocal <sub>compartment</sub> ) [kg/d]	Remarks
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	Qai stp = 3.70 kg/day	Scenario PT3-1B
Manure	Qai manure = 0.61567 kg	Scenario PT3-1A
Air	Not directly exposed	
Soil	Not directly exposed	
Groundwater	Not directly exposed	

#### Scenario [PT3-2]: Skin disinfection

Products of the BPF L-lactic acid are used as skin disinfectants with release in manure.

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario PT3-2: Skin disinfection			
Concentration of active substance in the product	33.984 (metaSPC 5)	g/L	metaSPC 5 contains 8% w/w l-lactic acid and is used at a dilution of 40%

	20.8704 (metaSPC 14)		(density 1.062) meaning 33.984 g/L. metaSPC 14 contains 32% w/w l- lactic acid and is used at a dilution of 6% (density 1.087) meaning 20.8704 g/L.
Quantity of product used for udder disinfection before calving (dairy and beef) metaSPC 5 – working solution	5	<b>mL/animal</b>	<p>it is considered that max 5 mL is necessary to spray the 4 teats before calving.</p> <p>A cow gives birth 1/year. For a herd of 100 cows, there are 100 "births" per year then.</p> <p>5mL/cow during 7 days for 100 cows = <math>5 \times 7 \times 100 = 3,5L</math> per year of working solution used meaning <math>3,5/365 \times 1000 = 9,6</math> mL working solution per day (mean For a herd of 125 beef, there are 125 "births" per year then.</p> <p>5mL/cow during 7 days for 125 cows = <math>5 \times 7 \times 125 = 4,375L</math> per year of working solution used meaning <math>4,375/365 \times 1000 =</math> 12 mL working solution per day (mean)</p>
Quantity of product used for udder of sows before farrowing (metaSPC 5) – working solution  Sows individual	20	<b>mL/animal</b>	it is considered that max 20 mL is necessary to spray the 4 teats before farrowing.

Sows in group			<p>A sow gives birth 2,5/year. For a herd of 132 sows, there are <math>132*2,5=330</math> "births" per year then.</p> <p>20mL/sow during 7 days for 330 births = <math>20*7*330=46,2L</math> per year of working solution used meaning <math>46,2/365*1000 = 127</math> mL working solution per day (mean)</p>
Quantity of working solution used for coronary band disinfection dairy and beef (metaSPC 14)	15	<b>mL/animal</b>	<p>It is considered as worst-case that 15 mL is sufficient per animal for coronary band disinfection.</p> <p>20 new cows can be introduced per year in the herd or the group.</p> <p>It means <math>15mL*20cows = 300</math> mL used per year so <math>300/365=0,82</math> mL/day.</p>
Quantity of working solution used for washing before an exhibition dairy and beef (metaSPC 14)	10	<b>L/animal (1bucket)</b>	<p>before exhibition, the washing of max 3-5 cows, 2 times a year, the same day will require a bucket of 10L of working solution so 50L for 5 cows equivalent to 100L a year so a mean of <math>100/365 = 0,27L/day</math>.</p>
Quantity of working solution used for coronary band disinfection sows and pigs (metaSPC 14)	10	<b>mL/animal</b>	<p>It is considered as worst-case that 10 mL is sufficient per animal for coronary band disinfection.</p> <p>30 new sows can be introduced per year in the herd or the group.</p>

			It means 10 mL*30sows = 300 mL used per year so 300/365=0,82 mL/day.
Quantity of working solution used for body disinfection sows and pigs (metaSPC 14)	200	mL/animal	<p>It is considered that 200 mL is sufficient to disinfected the sow before farrowing (1 day per farrowing and 2,5 farrowing per year).</p> <p>A sow gives birth 2,5/year. For a herd of 132 sows, there are 132*2,5=330 "births" per year then.</p> <p>200mL/sow during 1 day for 330 births = 200*1*330=66L per year of working solution used meaning 66/365*1000 = 181 mL working solution per day (mean)</p>
<p><b>Output: calculation:</b></p> <p><b>Vprod<sub>i1, i2</sub></b> = <math>Q_{prod_{i,1,i2}}/cow*7d*N_{animal}/365</math></p> <p><b>Vprod<sub>i4, i5</sub></b> = <math>Q_{prod_{i,4,i5}}/cow*7d*N_{animal}/365</math></p> <p><b>Qai prescr</b> = <math>0.001*F_{bioc}*V_{prod}*F_{dil}</math></p> <p><b>Qai manure</b> = <math>F_{manure} * Q_{aiprescr}</math></p>			
Qai prescr (worst-case)	0,00439	Kg	ESD PT3
Qai, manure (worst-case)	0,00439	kg	ESD PT3

Calculations for Scenario [PT3-2]

<b>Resulting local emission to relevant environmental compartments</b>		
<b>Compartment</b>	<b>Local emission (<math>E_{\text{local,compartment}}</math>) [kg/d]</b>	<b>Remarks</b>
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	Not exposed	
Manure	Qai manure = 5.65E-03 kg	Worst-case dairy cattle and beef cattle
Air	Not directly exposed	
Soil	Not directly exposed	
Groundwater	Not directly exposed	

### Scenario [PT3-3]: Animal housings disinfection

Scenario 1A describes the disinfection of teats with products of metaSPC 5, 6, 8, 9, 10 with release in the slurry/manure or in waste water released in slurry/manure: Soil, Groundwater, Feed, Surface water, Sediments, Feed.

Scenario 1B describes the disinfection of teats with products of metaSPC 5, 6, 8, 9, 10 with release in waste water linked to a Sewage Treatment Plant.

<b>Input parameters for calculating the local emission</b>			
<b>Input</b>	<b>Value</b>	<b>Unit</b>	<b>Remarks</b>
Scenario PT3-3: Animal housings disinfection			
Concentration of active substance in the product Fbioc	10.2336	g/L	metaSPC 11 contains 24% w/w l-lactic acid and is used at a dilution of 4% (density 1.066) meaning 10.2336 g/L.
Application rate of biocidal product (working solution) $V_{\text{prod}}$	0.25	L/m <sup>2</sup>	S applicant
Area of the housing AREA, Frequency, $F_{\text{stp}}$ , $F_{\text{slurry/manure}}$	See table 8 ESD Guidance PT3	-	Tier 1: all surfaces Default values per animal
<b>Output: calculation:</b>			

<b>Qai prescr = (0.001*Fbioc_pre*Vprod_pre*Fdil)</b>			
<b>Qai manure = Fmanure * Qaiprescr</b>			
<b>Qai stp = Elocalwastewater = Qaiprescr*Fstp</b>			
Qai prescr	20.5695	Kg	ESD PT3
Qai, manure (Scenario PT3-3A)	10.2848	kg	ESD PT3
Qai, stp (Scenario PT3-3B)	4.11391	kg/d	ESD PT3

## Calculations for Scenario [PT3-3]

<b>Resulting local emission to relevant environmental compartments</b>		
<b>Compartment</b>	<b>Local emission (Elocal<sub>compartment</sub>) [kg/d]</b>	<b>Remarks</b>
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	4.11391	Scenario PT3-3B
Manure	10.2848	Scenario PT3-3A
Air	Not directly exposed	
Soil	Not directly exposed	
Groundwater	Not directly exposed	

**Scenario [PT3-4] Dipping bath**

<b>Input parameters for calculating the local emission</b>			
<b>Input</b>	<b>Value</b>	<b>Unit</b>	<b>Remarks</b>
Scenario PT3-4: Dipping bath			
Concentration of active ingredient in product	10,464	g/L	S: applicant
Volume of the reservoir (tub)	100	L	ENV55
Dilution factor	1	-	S: applicant
Fraction of ingredient released (Fstp)	1	-	D: TAB v2 ENV 168
" (Fslurry)	1	-	D: TNG ESD PT3 <u>table 3a p.22</u>
" (Fair)	0	-	
Number of disinfectant applications in 1 year	365	-	D: TNG ESD PT3 App 1: table 9 S: Applicant (ENV 161 of ENV-TAB v2.0)

biocide application interval	1	d	D: TNG ESD PT3 <i>table 3a p.22</i> S: Applicant (ENV 161 of ENV-TAB v2.0)
Number of manure applications for grassland	4	-	D: TNG ESD PT3 <i>table 1a p.13</i>
Number of manure applications for arable land	1	-	D: TNG ESD PT3 <i>table 1a p.13</i>
Manure application time interval for grassland	53	d	S: TNG ESD PT3 appendix 1 table 12 ( <i>table 3a p.22</i> )
Manure application time interval for arable land	1	d	S: TNG ESD PT3 appendix 1 table 12 ( <i>table 3a p.22</i> ) D: ENV 161 of ENV-TAB v2.0 when no degradation in manure
Number of animals in housing	100	-	D: TNG ESD PT3 <i>table 3a p.22</i>
Amount of phosphate per animal for every relevant cat/subcat	0,10466	kg/animal/d	D: TNG ESD PT3 <i>table 3a p.22</i>
Amount of nitrogen per animal for every relevant cat/subcat	0,3389	kg/animal/d	D: TNG ESD PT3 <i>table 3a p.22</i>
Phosphate immission standard for one year in grassland	110	kg/ha/yr	S: TNG ESD PT3 appendix 1 table 13 ( <i>table 3a p.22</i> )
Phosphate immission standard for one year in arable land	85	kg/ha/yr	S: TNG ESD PT3 appendix 1 table 13 ( <i>table 3a p.22</i> )
Nitrogen immission standard for one year in grassland	170	kg/ha/yr	S: TNG ESD PT3 appendix 1 table 13 ( <i>table 3a p.22</i> )
Nitrogen immission standard for one year in arable land	170	kg/ha/yr	S: TNG ESD PT3 appendix 1 table 13 ( <i>table 3a p.22</i> )
Density of wet bulk soil	1700	kg/m <sup>3</sup>	D: TNG ESD PT3 <i>table 3a p.22</i>
Mixing depth with soil, grassland	<b>0,05</b>	m	D: TNG ESD PT3 <i>table 3a p.22</i>
mixing depth with soil, arable land	0,2	m	D: TNG ESD PT3 <i>table 3a p.22</i>
Half-life for biodegradation in soil	30	day	D: ECHA Guidance Vol IV table 6 page 67
Rate constant for biodegradation in soil	2,31E-02	d <sup>-1</sup>	O: table 6 page 67 ECHA Guidance on BPR: Vol IV Environment Parts



			B+C Version 2.0 October 2017
Environmental temperature	285	K	D: table page 56 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
Enthalpy of vapourisation	50000	J/mol	D: table page 33ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
Enthalpy of solution	10000	J/mol	D: table page 33 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
Gas constant	8,314	Pa m <sup>3</sup> /mol/K	D: table page 56 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
Experimental vapour pressure at test temperature	4,00E-01	Pa	S: CAR June 2017
Temperature at which vapour pressures is determined	20	°C	S: CAR June 2017
Vapour pressure at the environmental temperature	0,2	Pa	O: equation 2 page 32 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
Experimental solubility at test temperature	1,00E+03	mg/L	S: CAR June 2017
Test temperature at which solybility is determined	20	°C	S: CAR June 2017
Solubility at the environmental temperature	891,2	mg/L	O: Equation 3 page 33 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
Experimental Henry's law constant	3,60E-05	Pa/m <sup>3</sup> /mol	S: CAR June 2017
Temperature at which Henry's law constant is determined	20	°C	S: CAR June 2017

Henry's constant at the environmental temperature	2,27E-05	Pa m <sup>3</sup> /mol	O: equation 23 page 56 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
Organic carbon-water partitioning coefficient (Koc)	20,00	L/kg	S: CAR June 2017
Air-water partition coefficient	9,58E-09	-	O: equ 24 page 56 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
Density of the solid phase	2,50E+03	-	D: table 3 page 53 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
Volume fraction of water in soils	0,2	-	D: table 3 page 53 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
Volume fraction of solids in soils	0,6	-	D: table 3 page 53 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
Volume fraction of air in soils	0,2	-	D: table 3 page 53 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
Weight fraction of organic carbon in soils	0,02	-	D: table 3 page 53 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
Partition coefficient solid-water in soils	0,40	-	O: equation 26 page 57 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017

Soil-water partitioning coefficient	0,80	-	O: equation 27 page 58 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
Fraction of rain water that infiltrates into soil	0,25	-	D: table page 87 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
Rate of wet precipitation (700 mm/year)	1,92E-03	m/d	D: table page 87 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
First-order rate constant for leaching from soil layer (grassland)	1,20E-02	/d	O: equation 55 page 87 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
First-order rate constant for leaching from soil layer (arable land)	3,00E-03	/d	O: equation 55 page 87 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017
First-order rate constant for removal from top soil layer (grassland)	3,51E-02	d-1	O: equation 56 page 87 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017 Note: kvolat is not considered to be significant so not used
First-order rate constant for removal from top soil layer (arable land)	2,61E-02	d-1	O: equation 56 page 87 ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017 Note: kvolat is not considered to be significant so not used
<b>Output</b>	Please refers to excel "ENV-L-LA BPF- v2)		

## Calculations for Scenario [PT3-4]

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ( $E_{\text{local,compartment}}$ ) [kg/d]	Remarks
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	Not directly exposed	
Air	Not directly exposed	
Soil	#	Please refers to excel "ENV-L-LA BPF- v2) in section 3.2
Groundwater	#	Please refers to excel "ENV-L-LA BPF- v2) in section 3.2

Assessed PT	PT 4
Assessed scenarios	Scenario PT4-1: FDM Scenario PT4-2: Kitchens and slaughterhouses Scenario PT4-3: milking parlour systems (metaSPC 12) Scenario PT4-4: private use in kitchens (metaSPC 4, 7)
ESD(s) used	Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas, JRC Scientific and Technical Reports, Report nr. EUR 25117 EN, Publications Office of the European Union, Luxembourg, 2011
Approach	All scenarios: Consumption based
Distribution in the environment	Calculated based on BPR Guidance, Volume IV Environment – Part B
Groundwater simulation	see annexes
Confidential Annexes	YES: In the confidential Annex excels are provided
Life cycle steps assessed	All scenarios: Production: No Formulation : No Use: Yes Service life: No
Remarks	Excel containing all calculation can be found in IUCLID and confidential annex.

**Emission estimation****Scenario [PT4-1]: FDM**

<b>Input parameters for calculating the local emission</b>			
<b>Input</b>	<b>Value</b>	<b>Unit</b>	<b>Remarks</b>
Scenario PT4-1: FDM (assessment of entire plant)			
Amount of biocidal active substance used per year in the local plant Qai	407	Kg/year	Worst-case value of the pick list. Covers the use of L-lactic acid.
Number of emission days per year Temission	231	d/year	Default value ESD PT4 (2011)
Fraction released to waste water Fwater	1	-	Default value ESD PT4 (2011)
Fraction of substance eliminated due to on-site pre-treatment of the plant waste water Felim	0	-	Default value ESD PT4 (2011)
Fraction of substance disintegrated during or after application (before release to the sewage system) Fdis	0	-	Default value ESD PT4 (2011)
Capacity of on-site STP CAPSTP_on-site	112.7	m <sup>3</sup> .d <sup>-1</sup>	Default value ESD PT4 (2011)
Capacity of Off-site STP CAPSTP_off-site	2000	m <sup>3</sup> .d <sup>-1</sup>	Default value ESD PT4 (2011)
Dilution factor in surface water DIL	160	-	Default value ESD PT4 (2011)
<b>Output: calculation:</b>			
<b>Ceffluent = Clocalwater = (Qai/Temission) * 1000 * (1-Fdis) * (1-Felim) * Fwater / (CAPSTP_on-site * DIL)</b>			
<b>Cinfluent = (Qai/Temission) * 1000 * (1-Fdis) * (1-Felim) * Fwater / CAPSTP_off-site</b>			
Effluent concentration of active substance in the effluent of the on-site STP Ceffluent = Clocalwater	9,77E-02	mg.l <sup>-1</sup>	ESD PT4 page 24
Influent concentration of active substance in the off-site STP Cinfluent	8,81E-01	mg.l <sup>-1</sup>	ESD PT4 page 24

#### Calculations for Scenario [PT4-1]

<b>Resulting local emission to relevant environmental compartments</b>		
<b>Compartment</b>	<b>Local emission (Elocal<sub>compartment</sub>) [kg/d]</b>	<b>Remarks</b>
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ( $E_{\text{local,compartment}}$ ) [kg/d]	Remarks
Seawater sediment	Not directly exposed	
STP	Ceffluent = 9.77e-02 mg/L	Worst-case
Air	Not directly exposed	
Soil	Not directly exposed	
Groundwater	Not directly exposed	

### Scenario [PT4-2]: Kitchens and slaughterhouses

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario PT4-2: surfaces kitchens and slaughterhouses			
Application rate of the active substance $Q_{ai\_appl}$	3.3876	g/m <sup>2</sup>	Considering worst-case dilution of 15% for metaSPC 11 with 24% l-lactic acid and density of 1.066 with application rate of 100 mL/m <sup>2</sup>
Surface area slaughterhouses and butcheries $AREA_{slaught}$	10000	m <sup>2</sup>	Default value ESD PT4 (2011)
Surface area large scale catering kitchens and canteens $AREA_{kitchens}$	2000	m <sup>2</sup>	Default value ESD PT4 (2011)
Number of applications per day $N_{appl}$	1	/d	Default value ESD PT4 (2011)
Fraction of substance disintegrated during or after application $F_{dis}$	0	-	Default value ESD PT4 (2011)
Fraction of substance eliminated due to on-site pre-treatment of the plant waste $F_{elim}$	0	-	Default value ESD PT4 (2011)
Fraction released to waste water $F_{water}$	1	-	Default value ESD PT4 (2011)
<b>Output: calculation:</b>			
<b><math>E_{\text{localwater}} = Q_{ai\_appl} * Volume * N_{appl} * (1-F_{dis}) * (1-F_{elim}) * F_{water} / 1000</math></b>			
Quantity of active ingredient used $Q_{ai}$	3,84E+01	kg/d	ESD PT4 page 17
Emission rate to wastewater (standard STP)	7,68E+00	kg/d	ESD PT4 page 17
total	4,61E+01		

## Calculations for Scenario [PT4-2]

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ( $E_{\text{local compartment}}$ ) [kg/d]	Remarks
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	<b>4,61E+01</b>	
Air	Not directly exposed	
Soil	Not directly exposed	
Groundwater	Not directly exposed	

## Scenario [PT4-3]: Milking parlour systems (metaSPC 12)

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario PT4-3: Milking parlour systems			
Concentration of active substance in the product $C_{\text{form}}$	5.0204	g/L	Highest dilution of metaSPC 12 taking in account density 1.141
Application rate of biocidal product used for cleaning of the milking installation $V_{\text{forminst}}$	130	L/d	Default value ESD PT4 (2011)
Application rate of biocidal product used for cleaning of the milk storage tank $V_{\text{formtank}}$	45	L/d	Default value ESD PT4 (2011)
Fraction of the product disintegrated during application $F_{\text{dis}}$	0	-	Default value ESD PT4 (2011)
Fraction released to waste water $F_{\text{water}}$	1	-	Default value ESD PT4 (2011)
<b>Output: calculation:</b>			
<b><math>Q_{\text{ai}} = C_{\text{form}} \cdot (V_{\text{forminst}} + V_{\text{formtank}})</math></b>			
<b><math>E_{\text{localwater}} = Q_{\text{ai}} \cdot (1 - F_{\text{dis}}) \cdot F_{\text{water}} / 1000</math></b>			
Quantity of active ingredient used $Q_{\text{ai}}$	8.79E+02	g/d	ESD PT4 page 24
Emission rate to wastewater (standard STP)	8.79E-01	kg/d	ESD PT4 page 24

## Calculations for Scenario [PT4-3]

<b>Resulting local emission to relevant environmental compartments</b>		
<b>Compartment</b>	<b>Local emission (<math>E_{\text{local,compartment}}</math>) [kg/d]</b>	<b>Remarks</b>
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	8.79E-01	
Air	Not directly exposed	
Soil	Not directly exposed	
Groundwater	Not directly exposed	

#### Scenario [PT4-4]: Private use in kitchens (metaSPC 4, 7)

<b>Input parameters for calculating the local emission</b>			
<b>Input</b>	<b>Value</b>	<b>Unit</b>	<b>Remarks</b>
Scenario PT4-3: Private use in kitchens			
Application rate of the biocidal product $Q_{\text{appl}}$	0,1	L/m <sup>2</sup>	S applicant info
Concentration of active substance in bioc product $C_{\text{form}}$	33,216	g/L	S applicant info
Number of households feeding 1 STP $N_{\text{houses}}$	4000	-	D ENV70
Fraction of households using product $F_{\text{houses}}$	0,1	-	D ENV70
Disinfected surface area of a private kitchens $AREA_{\text{surface}}$	2	m <sup>2</sup>	D ENV70
Number of applications $N_{\text{appl}}$	1	1/d	D ENV70
Fraction released to waste water $F_{\text{water}}$	1	-	D ENV70
Fraction released to air $F_{\text{air}}$	0	-	D ENV70
Penetration factor of disinfectant $F_{\text{penetr}}$	0.5	-	D ENV70
<b>Output: calculation:</b>			
<b><math>E_{\text{localwater}} = C_{\text{form}} \cdot Q_{\text{appl}} \cdot N_{\text{houses}} \cdot F_{\text{houses}} \cdot N_{\text{appl}} \cdot AREA_{\text{surface}} \cdot F_{\text{penetr}} \cdot F_{\text{water}}/1000</math></b>			
<b><math>E_{\text{localair}} = C_{\text{form}} \cdot Q_{\text{appl}} \cdot N_{\text{houses}} \cdot F_{\text{houses}} \cdot N_{\text{appl}} \cdot AREA_{\text{surface}} \cdot F_{\text{penetr}} \cdot F_{\text{air}}/1000</math></b>			



Local release to waste water	1.3286	kg/d	O ENV70
Local release to air	0	kg/d	O ENV70

#### Calculations for Scenario [PT4-4]

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ( $E_{\text{local,compartment}}$ ) [kg/d]	Remarks
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	1.3286	
Air	Not directly exposed	
Soil	Not directly exposed	
Groundwater	Not directly exposed	

#### Scenario [PT4-5]: dipping or Soaking (meta SPC 3,11)

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario PT4-5: Private use in kitchens			
Concentration of active substance in dipping bath	39,24	g/L	S applicant info
Volume of solution in a dipping bath	100	L	D ENV 217
Number of sites using the disinfection solution connected to the same STP	5	-	D ENV 217
Fraction of substance disintegrated during or after application (before release to the sewage system)	0	-	D ENV 217
Fraction of substance eliminated due to onsite pre-treatment of wastewater	0	-	D ENV 217
Fraction released to waste water	1	-	D ENV 217
<b>Output: calculation:</b>			
<b><math>E_{\text{localwater}} = C_{\text{form}} \cdot V_{\text{bath}} \cdot N_{\text{appl}} \cdot (1 - F_{\text{dis}}) \cdot (1 - F_{\text{elim}}) \cdot F_{\text{water}} / 1000</math></b>			
Local release to waste water	19.62	kg/d	O ENV217

<b>Resulting local emission to relevant environmental compartments</b>		
<b>Compartment</b>	<b>Local emission (E<sub>local,compartment</sub>) [kg/d]</b>	<b>Remarks</b>
Freshwater	Not directly exposed	
Freshwater sediment	Not directly exposed	
Seawater	Not directly exposed	
Seawater sediment	Not directly exposed	
STP	19.62	
Air	Not directly exposed	
Soil	Not directly exposed	
Groundwater	Not directly exposed	

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

<b>Identification of relevant receiving compartments based on the exposure pathway</b>									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
<b>PT1</b>									
Scenario PT1-1A handwash prof (metaSPC 1)	+	+	-	-	++	Q	+	+	-
Scenario PT1-1B handrub prof (metaSPC 15)	+	+	-	-	++	Q	+	+	-
Scenario PT1-2A handwash non-prof (metaSPC 1)	+	+	-	-	++	Q	+	+	-
Scenario PT1-2B handrub	+	+	-	-	++	Q	+	+	-

non-prof (metaSPC 15)									
<b>PT2</b>									
PT2-1 – Disinfection of indoor fountain (TAB ENV 48)	+	+	-	-	++	Q	+	+	-
PT2-2 – algaecide Outdoor “spray and rinse”	+	+	-	-	++	Q	+(+ +)*	+	-
PT2-3 – algaecide release outdoor	-	+	-	-	-	Q	++	+	-
PT2-4 Institutional areas	+	+	-	-	++	Q	+	+	-
PT2-5 Industrial areas	+	+	-	-	++	Q	+	+	-
PT2-6 Med sector and furnitures	+	+	-	-	++	Q	+	+	-
<b>PT3</b>									
PT3-1A - Teat manure	+	+	-	-	-	Q	++	+	-
PT3-1B - Teat STP	+	+	-	-	++	Q	+	+	-
PT3-2 Skin (manure)	+	+	-	-	-	Q	++	+	-
PT3-3A – Animal housings manure	-+	+	-	-	-	Q	++	+	-
PT3-3B – Animal housings STP	+	+	-	-	++	Q	+	+	-
PT3-4	+	+	-	-	++	++	+	+	-

dipping Bath (ENV55)									
<b>PT4</b>									
PT4-1 FDM	+	+	-	-	++	Q	+	+	-
PT4-2 kitchens and slaught	+	+	-	-	++	Q	+	+	-
PT4-3 milking parlours	+	+	-	-	++	Q	+	+	-
PT4-4 private use kitchens	+	+	-	-	++	Q	+	+	-
PT4-5	+	+	-	-	++	Q	+	+	-

++ compartment directly exposed; + compartment indirectly exposed; - compartment not exposed; Q will be assessed qualitatively \* countryside

<b>Input parameters (only set values) for calculating the fate and distribution in the environment</b>			
Input	Value	Unit	Remarks
Molecular weight	90.08	g/mol	
Melting point	53.0	°C	Pure lactic acid
Boiling point	204.2	°C	calculated
Vapour pressure (at 20°C)	0.4	Pa	
Water solubility (at X°C)	Completely miscible	mg/l	
Log Octanol/water partition coefficient	-0.74	Log 10	
Organic carbon/water partition coefficient (Koc)	20	l/kg	
Henry's Law Constant (at 20°C)[if measured data available]	3.6E-05	Pa/m <sup>3</sup> /mol	
Biodegradability	Ready biodegradable fulfilling the 10 days window criteria DT <sub>50</sub> :7.1	d	
Rate constant for STP [if measured data available]	1	h <sup>-1</sup>	
DT <sub>50</sub> for biodegradation in surface water	unknown	d or hr (at 12°C)	
DT <sub>50</sub> for hydrolysis in surface water	No hydrolysis	d or hr (at 12°C /pH)	
DT <sub>50</sub> for photolysis in surface water		d or hr	

DT <sub>50</sub> for degradation in soil	30	d (at 12°C)	Based on table 6 ECHA guidance Vol IV
DT <sub>50</sub> for degradation in air	90	d	

<b>Calculated fate and distribution in the STP [if STP is a relevant compartment]</b>			
Compartment	Percentage [%]		Remarks
	Scenario 1	Scenario n	
Air	9.87E-06%		EUSES Simple Treat method
Water	12.6%		
Sludge	0.2%		
Degraded in STP	87.2%		

### Calculated PEC values

<b>Summary table on calculated PEC values</b>								
	PEC <sub>STP</sub>	PEC <sub>water</sub>	PEC <sub>sed</sub>	PEC <sub>seawater</sub>	PEC <sub>seas ed</sub>	PEC <sub>soil*</sub>	PEC <sub>GW<sup>1</sup>*</sub>	PEC <sub>air</sub>
	[mg/L]	[mg/l]	[mg/kg <sub>w</sub> wt]	[mg/l]	[mg/kg <sub>w</sub> wt]	[mg/kg wwt]	[mg/l]	[mg/m <sup>3</sup> ]
Scenario PT1-1A handwash prof (metaSPC 1)	1,39E- 01	1,39E- 02	1,69E- 02	0	0	5,35E-03	1,14E- 02	0
Scenario PT1-1B handrub prof (metaSPC 15)	2,09E- 01	2,09E- 02	2,55E- 02	0	0	8,07E-03	1,71E- 02	0
Scenario PT1-2A handwash non-prof (metaSPC 1)	1,16E- 01	1,16E- 02	1,41E- 02	0	0	4,46E-03	9,47E- 03	0
Scenario PT1-2B handrub non-prof (metaSPC 15)	1,75E- 01	1,75E- 02	2,12E- 02	0	0	6,72E-03	1,43E- 02	0
PT2-1 – Disinfectio n of	9.45E- 03	9.45E- 04	1,15E- 03	0	0	3.64E-03	7.73E- 04	0

indoor fountain (TAB ENV 48)								
PT2-2 – algaecide outdoor “Spray and rince”	4.92E-02	4.92E-03	5.99E-03	0	0	1.90E-03 (STP sludge) 8.54E+00 (Spray and rince) 3.37E-01 (spray drift)	4.03E-03	0
PT2-3 – algaecide release outdoor (service life)	5.47E+00	5,47E-01	6,65E-01	0	0	2,11E-01 (city STP sludge) 5.89E+00 (country spry and rince) 1.23E-04 (country side leaching)	4.47E-01	0
PT2-4 Institutional areas	1,57E-01	1,57E-02	1,91E-02	0	0	6,05E-03	1,28E-02	0
PT2-5 Industrial areas	8,30E-04	8,30E-05	1,01E-04	0	0	3,20E-05	6,80E-05	0
PT2-6 Med sector and furnitures	1,74E-02	1,74E-03	2,12E-03	0	0	6,71E-04	1,43E-03	0
Scenario PT3-1A - Teat manure	0	2.90E-01	3.53E-01	0	0	1.255E+00	1.97E+00	0
Scenario PT3-1B - Teat STP	2,33E-01	8.42E-03	1.02E-02	0	0	3.24E-03	6.89E-03	0
Scenario PT3-2 - Skin	0	6,87E-03	8,60E-02	0	0	2,72E-02	6,87E-02	0
Scenario PT3-3A -	0	1,23E-01	1,50E-01	0	0	4,87E-01	1,23E+00	0

animal housings manure								
Scenario PT3-3B - animal housings STP	2,59E-01	2,59E-02	3,16E-02	0	0	9,98E-03	2,12E-02	0
Scenario PT3-4	6.59E-02	6.59E-03	8.02E-03	0	0	See ENV-L-LA BPF v2	See ENV-L-LA BPF v2	
PT4-1 FDM	9,77E-02	9,77E-03	1,19E-02	0	0	4,28E-04	9,09E-04	0
PT4-2 kitchens and slaughter	2,90E+00	2,90E-01	3,53E-01	0	0	1,12E-01	2,37E-01	0
PT4-3 milking parlours	5,63E-02	5,63E-03	6,85E-03	0	0	2,17E-03	4,61E-03	0
PT4-4 private use kitchens	8.37E-02	8.37E-03	1.02E-02	0	0	3.22E-03	6.85E-03	0
PT4-5	1.24	1.24E-01	1.50E-01	0	0	4.76E-02	1.01E-01	0
<sup>1</sup> If the PEC <sub>GW</sub> was calculated by using a simulation tool (e.g. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table.* Only for information, since it is agreed that a qualitative assessment is sufficient for this active.								

## **Primary and secondary poisoning**

### Primary poisoning

Direct exposure of birds and mammals other than the target species is considered negligible as there is no significant direct release in the environment. In addition L-lactic acid is a naturally occurring substance found in plants and animals. Furthermore the breakdown products for this active substance are water and carbon dioxide or methane under anaerobic conditions.

### Secondary poisoning

Secondary poisoning is not expected. L-lactic acid is unlikely to bioaccumulate in aquatic or terrestrial environment according to the Assessment Report. It has a low log Kow (-0.74), it is not highly adsorptive, it does not belong to a class of substances known to have a potential to accumulate in living organisms, its structural features does not

indicate accumulation and it is readily biodegradable. The low accumulation potential is supported by low BCF and BMF for fish and earthworms. The bioconcentration factor for fish is 0.048 l/kg and a default BMF of 1. The bioconcentration factor for earthworms is 6.78 l/kg and a default BMF of 1. No further assessment of secondary exposure via the food chain is therefore considered necessary.

### 2.2.8.3 Risk characterisation

#### **Atmosphere**

##### Conclusion:

L-lactic acid is not expected to be used as fumigant. Therefore direct exposure of the air is not relevant. Evaporation and volatilisation from water or the STP is also expected to be unlikely due to the low vapour pressure (0.4 Pa). There are no indications that L-lactic acid contributes to depletion of the ozone layer as it is not listed as 'controlled substance' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. Therefore, the risks for the air compartment are considered acceptable.

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

$Pnec_{sp} = 10\text{mg/l}$

<b>Summary table on calculated PEC/PNEC values</b>	
	<b>PEC/PNEC<sub>STP</sub></b>
Scenario PT1-1A handwash prof (metaSPC 1)	1,39E-02
Scenario PT1-1B handrub prof (metaSPC 15)	2,09E-02
Scenario PT1-2A handwash non-prof (metaSPC 1)	1,16E-02
Scenario PT1-2B handrub non-prof (metaSPC 15)	1,75E-02
PT2-1 Disinfection of indoor fountain (TAB ENV 48)	9.45E-04
PT2-2 – algaecide Outdoor "Spray and rinse	4.92E-03
PT2-3 – algaecide release outdoor (service life)	5.47E-01
PT2-4 Institutional areas	1,57E-02
PT2-5 Industrial areas	8,30E-05
PT2-6 Med sector and furnitures	1,74E-03
Scenario PT3-1A - Teat manure	/
Scenario PT3-1B -Teat STP	2,33E-02
Scenario PT3-2 - Skin	/



Scenario PT3-3A - animal housings manure	/
Scenario PT3-3B – animal housings STP	8.42E-03
Scenario PT3-4	6.59E-03
PT4-1 FDM	9,77E-03
PT4-2 kitchens and slaughter	2,90E-01
PT4-3 milking parlours	5,63E-03
PT4-4 private use kitchens	8.37E-03
PT4-5 soaking	1.24E-01

**Conclusion:** The ratio PEC/PNEC is inferior to 1 so the risk for STP is fully acceptable in first tier for all scenarios when residues are released to the sewer. Because all worst-case PEC:PNEC ratios are well below one, no additional risk mitigation measures are required to protect the municipal STP.

### **Aquatic compartment**

$P_{\text{pec water}} = 3.9 \text{ mg/l}$ ;  $P_{\text{NEC sed}} = 4.8 \text{ mg/kg ww}$

<b>Summary table on calculated PEC/PNEC values</b>				
	<b>PEC/PNEC<sub>water</sub></b>	<b>PEC/PNEC<sub>sed</sub></b>	<b>PEC/PNEC<sub>sea water</sub></b>	<b>PEC/PNEC<sub>sea sed</sub></b>
Scenario PT1-1A handwash prof (metaSPC 1)	3,56E-03	3,52E-03	-	-
Scenario PT1-1B handrub prof (metaSPC 15)	5,37E-03	5,31E-03	-	-
Scenario PT1-2A handwash non-prof (metaSPC 1)	2,97E-03	2,93E-03	-	-
Scenario PT1-2B handrub non-prof (metaSPC 15)	4,47E-03	4,43E-03	-	-
PT2-1 Disinfection of indoor fountain (TAB ENV 48)	2.42E-04	2.40E-04	-	-
PT2-2 – algaecide Outdoor “Spray and rinse”	1.268E-03	1.25E-03	-	-
PT2-3 – algaecide release outdoor (service life)	1,40E-01	1,39E-01	-	-
PT2-4 Institutional areas	4,02E-03	3,98E-03	-	-
PT2-5 Industrial areas	2,13E-05	2,11E-05	-	-

PT2-6 Med sector and furnitures	4,47E-04	4,42E-04	-	-
Scenario PT3-1A – Teat manure	7.43E-02	7.35E-02	-	-
Scenario PT3-1B -Teat STP	2.16E-03	2.14E-03	-	-
Scenario PT3-2 – Skin	1,76E-03	1,79E-02	-	-
Scenario PT3-3A – animal housings manure	2,89E-02	2,86E-02	-	-
Scenario PT3-3B – animal housings STP	6,09E-03	6,03E-03	-	-
Scenario PT3-4 dipping bath (ENV55)	6.59E-03	1.69E-03		
Scenario PT4-1 FDM	2,51E-03	2,48E-03	-	-
Scenario PT4-2 kitchens and slaught.	7,44E-02	7,36E-02	-	-
PT4-3 milking parlours	1,42E-03	1,40E-03	-	-
PT4-4 private use kitchens	2.15E-03	2.12E-03	-	-
PT4-5 soaking	3.17E-02	3.13E-02		

Conclusion: The ratio PEC/PNEC is inferior to 1 so the risk for Surface water and sediments is fully acceptable in first tier for all scenarios when residues are released to the sewer. Because all worst-case PEC:PNEC ratios are well below one, no additional risk mitigation measures are required to protect the surfaces water and sediments.

### **Terrestrial compartment (indicative)**

$P_{nec\ soil} = 1.9 \text{ mg/kg}_{ww}$

Calculated PEC/PNEC values	
	PEC/PNEC <sub>soil</sub>
Scenario PT1-1A handwash prof (metaSPC 1)	2,81E-03
Scenario PT1-1B handrub prof (metaSPC 15)	4,25E-03
Scenario PT1-2A handwash non-prof (metaSPC 1)	2,35E-03
Scenario PT1-2B handrub non-prof (metaSPC 15)	3,54E-03
PT2-1 – Disinfection of indoor fountain (TAB ENV 48)	1.92E-04
PT2-2 – algacide Outdoor “Spray and rince”	9.97E-04 (STP sludge application) <b>6.20E+00 (Spray and rince)</b> 1.77E-01 (Spray drift)

PT2-3 – algacide release outdoor (service life)	1,11E-01(city STP sludge application) 3.100E+00 (country spray and rinse) 6.45E-05 (country side leaching)
PT2-4 Institutional areas	3,18E-03
PT2-5 Industrial areas	1,68E-05
PT2-6 Med sector and furnitures	3,53E-04
Scenario PT3-1A – Teat manure	<b>1.04E+00</b>
Scenario PT3-1B -Teat STP	1.1E-04
Scenario PT3-2 Skin	1,43E-02
Scenario PT3-3A – animal housings manure	4,87E-01
Scenario PT3-3B – animal housings STP	5,25E-03
Scenario PT3-4 dipping bath (ENV55)	8.13E-01
Scenario PT4-1 FDM	2,25E-04
Scenario PT4-2 kitchens and slaught.	5,88E-02
PT4-3 milking parlours	1,12E-03
PT4-4 private use kitchens	1.70E-03
PT4-5 Soaking	2.51E-02

Conclusion: The ratio PEC/PNEC is inferior to 1 so the risk for Soil is fully acceptable in first tier for all scenarios when residues are released to the sewer except for the Scenario's PT2-2 when rincing is taken into account and PT3-1A disinfection of teats with release into the manure. Nevertheless l-lactic acid is a readily biodegradable substance, largely used by living organism such as bacteria as food elements. Considering the same level of degradation in the manure than in the STP, meaning a  $k_{deg}=24\text{ d}^{-1}$ , a  $F_{slurry} = \exp(-24 * T_{bioc-int} * 0.1667d) = 0.0183$  or 1.8% of retention in the manure. Therefore the  $Q_{ai-manure}$  is largely overestimated and the PEC can be refined with  $2.87 * 1.8\% = 0.05166\text{ mg/kg wwt soil}$ . However, this rough estimate is likely an overestimation, as the standard rate constant of  $24\text{ d}^{-1}$  from the STP can hardly be applied directly to manure, especially since aerobic conditions prevail in the aeration tank, whereas anaerobic conditions are found in pig and cattle manure. For a substance such as Lactic acid, BE eCA does not consider that the amount emitted to soil in scenario PT3-1A would lead to a real risk. This position is supported by the following informations provided in responses to comment during the commenting period:

Lactic acid is a naturally occurring substance that may be present in cattle manure at levels up to about 150 mg/kg manure according to study of Miller D.N. "Influence of genotype and diet on steer performance, manure odor, and carriage of pathogenic and other fecal bacteria. III. Odorous compound production" (doi: 10.2527/jas.2005-748): up to 13,3  $\mu\text{mol/g}$  dry matter with manure containing 12,9% dry matter, and molecular weight of Lactic acid = 90 g/mol. It corresponds to the spreading of about 5 mg lactic

acid per kg soil (considering the use of 33g manure/kg soil based on 170 kg nitrogen/hectare).

According to the same authors (see fig 1 for animal fed corn silage), after fermentation, Lactic acid concentration increase up to about 5000  $\mu\text{mol/kg}$  dry matter, which corresponds to about 200 mg lactic acid per kg soil (also considering use of 33 kg manure/kg soil). The maximum amount of l-lactic acid in soil is found for Scenario PT3-1A = 1.97 mg/kg soil arable land - without taking in account degradation of the substance in the manure). Therefore the use of products of the BPF L-lactic acid is not expected to significantly alter the normal concentration of the substance in soil (up to 200 mg/kg soil).

During WG III 2021, it was concluded that a quantitative assessment of Lactic acid (CAS number 200-018-0) and L-(+)-Lactic acid (CAS number 79-33-4) in soil is not necessary such as for ground water. The same argumentation as used for groundwater can be use for soil.

### **Groundwater**

Concentration in groundwater are found for most of the sceanrios, above the limit of 0.1  $\mu\text{g/L}$ . (please refers to Excell ENV-L-LA BPF v2).

A FOCUS PEARL study is found (Sevilla scenario) with a concentration in groundwater inferior to 0.1  $\mu\text{g/L}$ .

Nevertheless, Lactic acid is a naturally occurring substance that may be present in cattle manure at levels up to about 150 mg/kg manure according to study of Miller D.N. "Influence of genotype and diet on steer performance, manure odor, and carriage of pathogenic and other fecal bacteria. III. Odorous compound production" (doi: 10.2527/jas.2005-748): up to 13,3  $\mu\text{mol/g}$  dry matter with manure containing 12,9% dry matter, and molecular weight of Lactic acid = 90 g/mol. It corresponds to the spreading of about 5 mg lactic acid per kg soil (considering the use of 33g manure/kg soil based on 170 kg nitrogen/hectare).

According to the same authors (see fig 1 for animal fed corn silage), after fermentation, Lactic acid concentration increase up to about 5000  $\mu\text{mol/kg}$  dry matter, which corresponds to about 200 mg lactic acid per kg soil (also considering use of 33 kg manure/kg soil). The maximum amount of l-lactic acid in soil is found for Scenario PT3-1A = 5.45 mg/kg soil (without taking in account degradation of the substance in the manure). Therefore the use of products of the BPF L-lactic acid is not expected to significantly alter the normal concentration of the substance in soil (up to 200 mg/kg soil) and subsequently in the groundwater as contamination of the groundwater is done exclusively via leaching from soil. In addition, during WG-II-2020, in an equivalent dossier it was agreed that *Lactic acid* does not cause unacceptable risk for groundwater and that no further calculations are needed *providing that the following justification is added in the PAR:*

*"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 cannot be taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations. Modelling of groundwater exposure 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

Direct exposure of birds and mammals other than the target species is considered negligible as there is no significant direct release in the environment. In addition L-lactic acid is a naturally occurring substance found in plants and animals. Furthermore the breakdown products for this active substance are water and carbon dioxide or methane under anaerobic conditions.

### Secondary poisoning

Secondary poisoning is not expected. L-lactic acid is unlikely to bioaccumulate in aquatic or terrestrial environment according to the Assessment Report. It has a low log Kow (-0.74), it is not highly adsorptive, it does not belong to a class of substances known to have a potential to accumulate in living organisms, its structural features does not indicate accumulation and it is readily biodegradable. The low accumulation potential is supported by low BCF and BMF for fish and earthworms. The bioconcentration factor for fish is 0.048 l/kg and a default BMF of 1. The bioconcentration factor for earthworms is 6.78 l/kg and a default BMF of 1. No further assessment of secondary exposure via the food chain is therefore considered necessary.

Conclusion: Secondary poisoning is unlikely regarding the phys-chem properties of the substance L-lactic acid, the low toxicity of this substance and the low potential for bioaccumulation.

## **Mixture toxicity**

### Screening step

Screening Step 1: Identification of the concerned environmental compartments

As the products of the BPF are all based on 1 active substance only, L-lactic acid, there is no need to perform multiple active assessment. However due to the presence of Substance of Concern in the formulation, the assessment still seems relevant for the mixture toxicity.

Environmental compartments that can be exposed are never directly exposed to the product (concentrates, pure, or working solution). Only the compartment STP is directly exposed to the working solution or rinsing solution (but not to the pure product) or the manure/slurry compartment. Other compartments such as soil, groundwater, surface water and sediments, are exposed to working solutions, rinsing solution, pure products after product has been released to the manure/slurry pit or STP. There is also a risk for primary and secondary poisoning of non-target organisms.

#### Screening Step 2: Identification of relevant substances

An excel added in the conditential annex "ENV-Mixture toxicity L-LA BPF v1" is added in confidential annex.

<b>Summary of relative toxic units</b>		
	Relevant component 1 <i>(active substance)</i>	Relevant Component n
Content in the product [w/w %]	<i>0.005</i>	<i>0.04</i>
Concerned environmental compartment 1 <i>(Aquatic compartment)</i>		
Organism 1 <i>(fish)</i>	<i>99.16</i>	<i>0.84</i>
Organism 2 <i>(daphnia)</i>	<i>99.58</i>	<i>0.42</i>
Organism n <i>(algae)</i>	<i>99.95</i>	<i>0.05</i>
Concerned environmental compartment n <i>(e.g. soil)</i>		
Organism 1 <i>(earthworm)</i>	<i>86.21</i>	<i>13.79</i>

#### Screening Step 3: Screen on synergistic interactions

According to the tables 57 and 58 of Appendix 11 on synergisms of the EHA Guidance Vol IV, synergisms between active substance and SoCs are not expected.

<b>Screening step</b>	
Y	Significant exposure of environmental compartments? (Y/N)
Y	Number of relevant substances >1? (Y/N)
N	Indication for synergistic effects for the product or its constituents in the literature? (Y/N)

According to the BPR guidance (Volume IV Environment (Parts B+C), version 2.0 October 2017) co-formulants are checked for each identification criteria mentioned in the Chapter 8 Assessment of substances of concern.

1. Substance classified as hazardous and that is present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of the Regulation (EC) No 1272/2008

None of the metaSPCs is classified as hazardous for environment. Therefore no co-formulants meet this criteria.

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) if present at a concentration  $\geq 0.1\%$

Isopropanol (67-63-0) has a Competent Authority Report for PT1, PT2 and PT4. The substance is present in metaSPC 1, 8, 9, 11 and 15 at a maximal concentration of 4%, 3%, 3%, 5% and 4% respectively. Therefore Isopropanol is a SoC for metaSPC 1, 8, 9, 11 and 15.

There are no other co-formulants present that meet this criteria (<https://echa.europa.eu/information-on-chemicals/biocidal-active-substances>).

3. Substances that enhance the effect of the active substance in the product, e.g. synergists.

There are no co-formulants present that meet this criteria (BPR Guidance Vol IV Appendix 11).

4. Substances included in the candidate list

There are no co-formulants included in the ECHA candidate list.

5. Substances which meet two of the criteria for being PBT

There are no co-formulants included in the ECHA candidate list.

6. Substances for which an Environmental Quality Standard (EQS) has been derived

None of the co-formulants are contained in the Priority Substances list according to Annex II of Directive 2008/105/EC.

Moreover, an elaborate screening was performed in order to detect potential endocrine disrupting properties of the co-formulants included in the BPF L-Lactic Acid (L-LA)(please refers to confidential annexe).

In summary:

MetaSPC 1: Isopropanol

MetaSPC 8: Isopropanol

MetaSPC 9: Isopropanol

MetaSPC 11: Isopropanol

MetaSPC 15: Isopropanol

Detailed information on SoC is provided in the Confidential Annex. Since this SOC as minor impact on the mixture toxicity, no additional assessment is provided in public PAR for this substance.

## Aggregated exposure (combined for relevant emission sources)

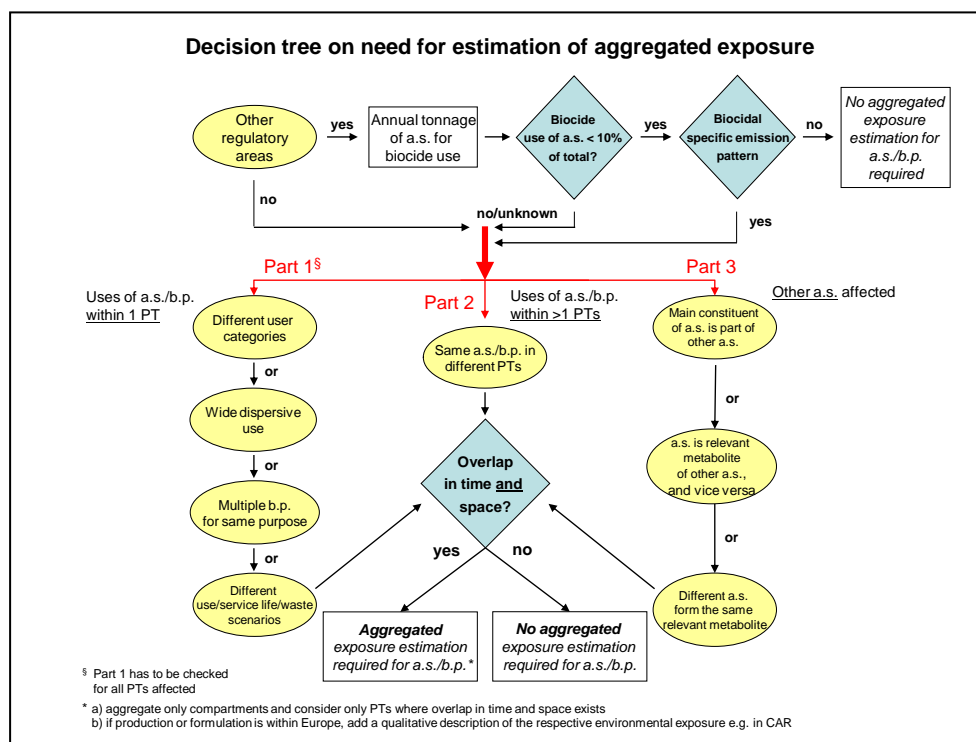


Figure 1: Decision tree on the need for estimation of aggregated exposure

Summary table on calculated $\Sigma$ PEC/PNEC values								
	$\Sigma$ PEC/P NEC <sub>STP</sub>	$\Sigma$ PEC/PN EC <sub>water</sub>	$\Sigma$ PEC/P NEC <sub>sed</sub>	$\Sigma$ PEC/PNE C <sub>seawater</sub>	$\Sigma$ PEC/PN EC <sub>seased</sub>	$\Sigma$ PEC/P NEC <sub>soil</sub>	$\Sigma$ PE C <sub>GW</sub>	$\Sigma$ PE C <sub>air</sub>
Via STP	4,60E-01	1,11E-01	1,10E-01	-	-	8,63E-02		-
Via manure	-	2,13E-01 (dairy)	2,11E-01 (dairy)	-	-	2,99E+00 (dairy)		-

**Conclusion:** The ratio  $\Sigma$ PEC/PNEC is inferior to 1 so the risk for all target compartments is fully acceptable in first tier for all scenarios except for the Soil via manure due to Scenario PT3-1A disinfection of teats with release into the manure. Nevertheless l-lactic acid is a readily biodegradable substance, largely used by living organism such as bacteria as food elements. Considering the same level of degradation in the manure than in the STP, meaning a  $k_{deg}=24 \text{ d}^{-1}$ , a  $F_{slurry} = \exp(-24 \cdot T_{bioc-int} \cdot 0.1667d) = 0.0183$  or 1.8% of retention in the manure. Therefore the  $Q_{ai-manure}$  is largely overestimated in this scenario and the PEC can be refined with  $2.87 \cdot 1.8\% = 0.05166 \text{ mg/kg wwt soil}$ . With the refined PEC/PNEC for scenario PT3-1A, risk acceptable. This raw estimation is probably a bit too favourable and we may admit that the reality is probably somewhere in between. For a substance such as Lactic acid, BE eCA does not consider that the amount emitted to soil in scenario PT3-1A would lead to a real risk.



## 2.2.9 Assessment of Endocrine disrupting properties

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in Lactic acid based products – CID LINES NV:

1. Assessment of the ED properties of the active substances in CID LINES NV:
  - 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 Lactic acid is not part of the list<sup>11</sup> of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review. As stated in the Assessment Report, there is no indication for endocrine properties for L(+) Lactic acid.
  - Therefore, BE eCA considers that there are no concerns regarding ED properties of Lactic acid.
2. Assessment of the ED properties of non-active substances (co-formulants) in Lactic acid based products – CID LINES NV:
  - After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex), one of the co-formulants is subject to an on-going evaluation regarding its ED properties under REACH. Pending the final decision regarding the ED properties of this substance, BE eCA will not request further data or perform further assessment of the ED properties of this co-formulant.
  - None of the other co-formulants has been identified as having ED properties or are subject to an on-going evaluation or a decision regarding their ED properties. Therefore, 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 may be a potential concern regarding the ED properties of one of the co-formulant used in the biocidal product family Lactic acid based products – CID LINES NV.

Pending the final decision regarding the ED properties of this substance, it was not possible to conclude whether the non-active substance should be considered to have ED properties before the expiration of the legal deadline in the BPR and therefore the process will be concluded at the post-authorisation stage (Please refer to section 2.1.2 (34) of CA-March18.Doc.7.b-final).

Currently neither the active substance, nor the co-formulants of these BPs have been identified as endocrine disruptors in line with document CA-March18-Doc.7.3.b-final. Therefore, it could be concluded that the BPF and its products are also not to be considered as having ED properties.

However if one or several components are identified as having ED properties, the conditions for granting the biocidal product/family authorisation will be revised according to CA-March18.Doc.7.b-final, section 2.3 (47).

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<sup>11</sup> Please refer to CA-September18.Doc.7.5.a-final .

### **2.2.9 Measures to protect man, animals and the environment**

See Summary of Product Characteristics (SPC) of the Biocidal Product Family.

### **2.2.10 Assessment of a combination of biocidal products**

The products of the Biocidal Product Family 'CID LINES – Lactic acid based products' are not intended to be used in combination with other biocidal products.

### **2.2.11 Comparative assessment**

Not relevant

### 3 Annexes

#### 3.1 List of studies for the biocidal product (family)

APCP	Title	Author	date
Ref. 1	Stability report: Stability of the product L1 META SPC 1 = Kenosan Hand Scrub Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	19/09/19
Ref. 1a	Stability report: Stability of the product L1 META SPC 1 = Kenosan Hand Scrub Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	07/10/20
Ref. 2	Acidity test report according to OECD122: BPF Lactic acid formulations	██████████	07/05/19
Ref. 3	Surface tension measurement: Lactic acid BPF, study number 2020-01-081	██████████	04/03/20
Ref. 3a	Surface tension of Lactic acid BPF, study number 2020-01-081	██████████	17/09/20
Ref. 4	Viscosity test report of BPF LA formulations according to OECD guidelines for the testing of chemicals, section 1 test 144	██████████	24/09/19
Ref. 5	Stability report: Stability of the product L2 META SPC 2 = RTU Green Remover Minimum active substance, minimum excipients = Maximum active substance, minimum excipients	██████████	19/09/19
Ref. 5a	Stability report: Stability of the product L2 META SPC 2 = Minimum active substance, minimum excipients = Maximum active substance, minimum excipients	██████████	13/10/20
Ref. 6	Stability report: Stability of the product L4 META SPC 2 Maximum active substance, maximum excipients = Minimum active substance, maximum excipients	██████████	19/09/19
Ref. 6a	Stability report: Stability of the product L4 META SPC 2 Maximum active substance, maximum excipients = Minimum active substance, maximum excipients	██████████	07/10/20
Ref. 7	Stability report: Stability of the product L5 META SPC 3 = Concentrated Green Remover Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	19/09/19
Ref. 7a	Stability report: Stability of the product L5 META SPC 3 Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	07/10/20
Ref. 8	Test report: Foam test of BPF LA to CIPAC MT 47.1	██████████	30/08/19
Ref. 9	Test report: Dilution test of BPF lactic acid according to CIPAC MT 41.1	██████████	29/08/19
Ref. 10	Stability report: Stability of the product L6 META SPC 4 = Sanifresh Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	19/09/19
Ref. 10a	Stability report: Stability of the product L6 META SPC 4 Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	07/10/20

Ref. 11	Stability report: Stability of the product L7 META SPC 5 = Dummy 1 Minimum active substance, minimum excipients = Maximum active substance, minimum excipients	██████████	23/09/19
Ref. 11a	Stability report: Stability of the product L7 META SPC 5 Minimum active substance, minimum excipients = Maximum active substance, minimum excipients	██████████	07/10/20
Ref. 12	Stability report: Stability of the product L8 META SPC 5 = Kenopure Maximum active substance, maximum excipients = Minimum active substance, maximum excipients	██████████	19/09/19
Ref. 13	Stability report: Stability of the product L36 META SPC 6 = Kenopure R Minimum active substance= Maximum active substance Minimum excipients = Maximum excipients	██████████	19/09/19
Ref. 13a	Stability report: Stability of the product L36 META SPC 6 Minimum active substance= Maximum active substance Minimum excipients = Maximum excipients	██████████	08/10/20
Ref. 14	Stability report: Stability of the product KENOPURE WIPES = MetaSPC 7	██████████	23/09/19
Ref. 14a	Stability report of the product MetaSPC 7	██████████	14/10/20
Ref. 15	Stability report: Stability of the product L13 META SPC 8 = Kenolac	██████████	23/09/19
Ref. 16	Stability report: Stability of the product L14 META SPC 8 = Kenolac Forte W	██████████	23/09/19
Ref. 16a	Stability report: Stability of the product L14 META SPC 8	██████████	08/10/20
Ref. 17	Stability report: Stability of the product L15 META SPC 8 Minimum active substance, minimum excipients	██████████	23/09/19
Ref. 17a	Stability report: Stability of the product L15 META SPC 8 Minimum active substance, minimum excipients	██████████	08/10/20
Ref. 18	Stability report: Stability of the product L16 META SPC 8 Maximum active substance, maximum excipients	██████████	23/09/19
Ref. 18a	Stability report: Stability of the product L16 META SPC 8 Maximum active substance, maximum excipients	██████████	08/10/20
Ref. 19	Stability report: Stability of the product L17 META SPC 8 Minimum active substance, maximum excipients	██████████	23/09/19
Ref. 19a	Stability report: Stability of the product L17 META SPC 8 Minimum active substance, maximum excipients	██████████	08/10/20
Ref. 20	Stability report: Stability of the product L18 META SPC 8 Maximum active substance, minimum excipients	██████████	23/09/19
Ref. 20a	Stability report: Stability of the product L18 META SPC 8 Maximum active substance, minimum excipients	██████████	08/10/20
Ref. 21	Stability report: Stability of the product L19 META SPC 9 = Kenolac SD	██████████	23/09/19
Ref. 21a	Stability report: Stability of the product L19 META SPC 9	██████████	08/10/20
Ref. 22	Stability report: Stability of the product L20 META SPC 9 = Kenolac Forte SD	██████████	23/09/19
Ref. 22a	Stability report: Stability of the product L20 META SPC 9	██████████	08/10/20

Ref. 23	Stability report: Stability of the product L21 META SPC 9 Minimum active substance, minimum excipients	██████████	23/09/19
Ref. 23a	Stability report: Stability of the product L21 META SPC 9 Minimum active substance, minimum excipients	██████████	08/10/20
Ref. 24	Stability report: Stability of the product L22 META SPC 9 Maximum active substance, maximum excipients	██████████	23/09/19
Ref. 24a	Stability report: Stability of the product L22 META SPC 9 Maximum active substance, maximum excipients	██████████	08/10/20
Ref. 25	Stability report: Stability of the product L23 META SPC 9 Minimum active substance, maximum excipients	██████████	23/09/19
Ref. 25a	Stability report: Stability of the product L23 META SPC 9 Minimum active substance, maximum excipients	██████████	08/10/20
Ref. 26	Stability report: Stability of the product L24 META SPC 9 Maximum active substance, minimum excipients	██████████	23/09/19
Ref. 26a	Stability report: Stability of the product L24 META SPC 9 Maximum active substance, minimum excipients	██████████	08/10/20
Ref. 27	Stability report: Stability of the product L25 META SPC 10 = Kenocool Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	23/09/19
Ref. 27a	Stability report: Stability of the product L25 META SPC 10 Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	08/10/20
Ref. 28	Stability report: Stability of the product L26 META SPC 11 = Kenosan Lactic	██████████	23/09/19
Ref. 28a	Stability report: Stability of the product L26 META SPC 11	██████████	08/10/20
Ref. 30	Stability report: Stability of the product L29 META SPC 12 = Phocid L Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	23/09/19
Ref. 30a	Stability report: Stability of the product L29 META SPC 12 Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	08/10/20
Ref. 30a	Stability report: Stability of the product L29 META SPC 12 = Phocid L Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	04/03/20
Ref. 31	Stability report: Stability of the product L35 META SPC 12 = Phocid LS Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	23/09/19
Ref. 31a	Stability report: Stability of the product L35 META SPC 12 Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	08/10/20
Ref. 32	Stability report: Stability of the product L31 META SPC 13 = Tornax L Minimum active substance, minimum excipients = Maximum active substance, minimum excipients	██████████	23/09/19

Ref. 32a	Stability report: Stability of the product L31 META SPC 13 Minimum active substance, minimum excipients = Maximum active substance, minimum excipients	██████████	08/10/20
Ref. 33	Stability report: Stability of the product L32 META SPC 13 Maximum active substance, maximum excipients = Minimum active substance, maximum excipients	██████████	23/09/19
Ref. 33a	Stability report: Stability of the product L32 META SPC 13 Maximum active substance, maximum excipients = Minimum active substance, maximum excipients	██████████	08/10/20
Ref. 34	Stability report: Stability of the product L34 META SPC 14 = Pediline A Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	23/09/19
Ref. 34a	Stability report: Stability of the product L34 META SPC 14 Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	08/10/20
Ref. 35	Stability report: Stability of the product L33 META SPC 15 = Kenosan Hand Rub Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	23/09/19
Ref. 35a	Stability report: Stability of the product L33 META SPC 15 Minimum active substance = Maximum active substance Minimum excipients = Maximum excipients	██████████	08/10/20
Ref. 36	ANALYTICAL REPORT LA-646085.01.A05	██████████	11/07/19
Ref. 37	ANALYTICAL REPORT LA-646085.01.A04	██████████	11/07/19
Ref. 38	ANALYTICAL REPORT LA-646085.01.A09	██████████	11/07/19
Ref. 39	ANALYTICAL REPORT LA-646085.01.A06	██████████	11/07/19
Ref. 40	ANALYTICAL REPORT LA-646085.01.A07	██████████	11/07/19
Ref. 41	ANALYTICAL REPORT LA-646085.01.A08	██████████	11/07/19
Ref. 42	ANALYTICAL REPORT LA-646085.01.A03	██████████	11/07/19
Ref. 43	Corrosion test report: Determination of corrosion BPF Lactic Acid (LA)	██████████	09/05/19
Ref. 44	Validation report: Determination of lactic acid in MSPC 1, 6, 7 and 15 by HPLC-UV	██████████	29/04/19
Ref. 45	Validation report: Determination of lactic acid in MSPC 2 and 3 by HPLC-UV	██████████	30/04/19
Ref. 46	Validation report: Determination of lactic acid in MSPC 4,12 and 13 by HPLC-UV	██████████	30/04/19
Ref. 47	Validation report: Determination of lactic acid in MSPC 5, 8 and 9 by HPLC-UV	██████████	30/04/19
Ref. 48	Validation report: Determination of lactic acid in MSPC 10, 11 and 14 by HPLC-UV	██████████	30/04/19
Ref. 49	Physical state, colour and odour of Lactic acid BPF, Study number: 2020-02-091	██████████	07/04/20

Ref. 50	Test report : density of BPF lactic, Study 2020-03-019	██████████	31/03/20
Ref. 51	Test report : dilution stability of BPF lactic acid, Study 2019-12-040	██████████	13/02/20
Ref. 52	MetaSPC 9 (L22) & MetaSPC 15 (Kenosan Hand Rub) Combustibility Testing	██████████	14/11/19
Ref. 53	Kenosan Lactic Sustained Combustibility Testing	██████████	26/03/20
Ref. 54	Validation: Substance of Concern Butyldiglycol in mSPC 15	██████████	10/02/21
Ref. 55	Validation: Substance of Concern Isopropanol in mSPC 1, 8, 9, 11 and 15	██████████	18/02/21

Efficacy	IUCLID File
impact of co-formulants	
EN 1276	RP_2019-08-25_emollients+██████████_EN1276_20°_15min_clean_metaSPC 1+11
EN 1276	RP_2019-08-27_emollients+██████████_EN1276_50°_30min_clean_metaSPC 12
EN 13727	RP_2019-08-40_Emollients+██████████_EN13727_20°_1min_clean_metaSPC 15
EN 1656	RP_2019-08-023_Emollients+██████████_EN1656_30°C_min_dirty_metaSPC 5-6
EN 1656	RP_2019-08-020_Emollients+██████████_EN1656_30°C_5min_milk_metaSPC 8-9-10
EN 1276	RP_2019-08-26_IPA_EN1276_20°_15min_clean_metaSPC 1+11
EN 1656	RP_2019-08-021_IPA_EN1656_30°C_5min_milk_metaSPC 8-9
EN 13727	RP_2019-08-41_IPA_EN13727_20°_1min_clean
EN 1656	RP_2019-08-037_██████████_EN1656_30°C_5min_milk_metaSPC 8+10
EN 1656	RP_2019-08-007_██████████_EN1656_30°C_5min_milk_metaSPC 10
EN 1656	RP_2019-08-008_██████████_EN1656_30°C_5min_dirty_metaSPC 5
Meta SPC 1	
EN 1276	RP_2019-04-007_metaSPC1_L1_EN1276_20°C_1min_dirty_v2
EN 1650	RP_2019-03-053_metaSPC1_L1_EN1650_1min_20°C_dirty
EN 1499	STULV19AA2681-1_AAE21505_v1.000_Report_EN1499_metaSPC1_10ml_1min
Meta SPC 2	
EN 1276	RP_2019-07-041_metaSPC2_L2_EN1276_1min_clean
EN 13727	RP_2019-07-041_metaSPC2_L2_EN1276_1min_clean
EN 1650	RP_2019-09-004_metaSPC2_L2_EN1650_20°C_2min_clean
EN 13624	RP_2019-09-003_metaSPC2_L2_EN13624_20°C_2min_clean
Meta SPC 3	
EN 1276	RP_2019-04-008_metaSPC3_EN1276_20°C_60min_dirty
EN 1650	RP_2019-04-013_metaSPC3_EN1650_20°C_60min_dirty
EN 13697	RP_2019-04-039_metaSPC3_EN13697_18-25°C_60min_dirty
	RP_2019-08-154_metaSPC3_L5_EN13697_40°C_5sec_dirty
Field trial	FDLDR201908123 - LA MSPC 3 F L5
EN 1276	EVALUATION OF ALGAECIDAL ACTIVITY DIRTY Meta 3
EN 13697	STULV19AA2682-1_AAE14729_v1.000" & "STULV19AA2684-1_AAE33446_v1.000
Meta SPC 4	
EN 1276	RP_2019-02-082_mSPC4_L6_EN1276_20°C_15min_dirty
	RP_2019-02-091_mSPC4_L6_EN1276_20°C_5min_dirty
EN 1650	RP_2019-02-090_mSPC4_L6_EN1650_20°C_15min_dirty
	RP_2019-03-005_mSPC4_L6_EN1650_20°C_5min_dirty
EN 13697	RP_2019-02-096_metaSPC4_L6_EN13697_18-25°C_15min_dirty
Sanifresh	RP_2019-02-097_metaSPC4_L6_EN13697_18-25°C_5min_dirty
	Toilet test BPF Lactic acid Sanifresh
Meta SPC 5	
EN 1656	RP_2019-06-019_metaSPC5_L7_EN1656_30°C_1min_dirty

EN 1657 EN 16437	RP_2019-07-005_mSPC5_L7_EN1656_30°C_5min_dirty RP_2019-08-008_ EN1656_30°C_5min_dirty_metaSPC 5 RP_2019-08-023_Emollients+ EN1656_30°C_min_dirty_metaSPC 5-6 RP_2019-03-045_mSPC5_EN1657_30°C_1min_dirty RP_2019-07-032_metaSPC 5_L7_skin test_30°C_1min_dirty RP_2019-07-033_metaSPC 5_L7_skin test_30°C_5min_dirty
Meta SPC 6	
EN 1656 EN 1657 EN 16437	RP_2019-04-004_metaSPC 6_EN1656_30°C_60s_dirty RP_2019-03-055_metaSPC 6_L36_EN1657_30°C_1min_dirty RP_2019-07-034_metaSPC 6_L36_skin test_30°C_1min_dirty
Meta SPC 7	
EN 1276 EN 1650 EN 14476 EN 16615	RP_2019-07-041_metaSPC2_L2_EN1276_1min_clean RP_2019-09-004_metaSPC2_L2_EN1650_20°C_2min_clean Test report R-LVCIR003 EN 16615 Meta7
Meta SPC 8	
EN 1656 EN 1657 EN 16437	RP_2020-02_037_mSPC8_EN1656_30°C_5min_milk RP_2019-01-012_mSPC8_EN1657_30°C_5min_milk RP_2019-01-025_mSPC8_skin test_30°C_5min_milk
Meta SPC 10	
EN 1656 EN 1657 EN 16437	RP_2019-01-013_metaSPC 10_L25_EN1656_30°C_5min_milk RP_2019-01-027_metaSPC 10_L25_EN1657_30°C_5min_milk RP_2019-01-026_metaSPC 10_L25_skin test_30°C_5min_milk
Meta SPC 11	
EN 1656  EN 1657 EN 14349 EN 16438 EN 1276  EN 1650  EN 13697  Field trial	RP_2019-07-008_metaSPC11_L26_EN1656_10°C_30min_clean EN 1656 Meta11 RP_2019-06-020_mSPC11_L26_EN1657_10°C_30min_clean RP_2019-07-011_metaSPC_11_L26_EN14349_10°C_30min_clean_v2 RP_2019-07-027_mSPC 11_L26_EN16438_10°C_30min_clean RP_2019-04-115_mSPC 11_L26_EN1276_7°C_2min_dirty RP_2019-04-116_mSPC 11_L26_EN1276_7°C_30sec_dirty RP_2019-07-004_mSPC 11_L26_EN1276_20°C_2min_clean RP_2019-07-002_mSPC 11_L26_EN1276_20°C_15min_clean RP_2019-04-118_mSPC 11_L26_EN1650_7°C_2min_dirty RP_2019-04-122_metaSPC 11_L26_EN1650_7°C_30sec_dirty RP_2019-04-024_mSPC 11_EN1650_20°C_2min_clean RP_2019-04-023_mSPC 11_EN1650_20°C_15min_clean RP_2019-04-150_metaSPC 11_L26_EN13697_7°C_2min_dirty RP_2019-04-151_metaSPC 11_L26_EN13697_7°C_30sec_dirty RP_2019-05-011_metaSPC 11_L26_EN13697_20°C_2min_clean RP_2019-05-010_metaSPC 11_L26_EN13697_20°C_15min_clean FDLDR2019061711 LA MSPC 11 F L26 - 15% 30 sec FDLDR2019080511 LA MSPC 11 F L26 - 8% 2 min
Meta SPC 12	
EN 1276      EN 1650	RP_2019-04-009_metaSPC12_L29_EN1276_50°C_15min_clean RP_2019-04-010_metaSPC 12_L29_EN1276_50°C_15min_milk RP_2019-04-011_metaSPC 12_L29_EN1276_50°C_30min_clean RP_2019-07-009_metaSPC 12_L29_EN1276_50°C_2min_clean_E.f. RP_2019-07-010_metaSPC 12_L29_EN1276_50°C_30min_dirty_E.f. RP_2019-07-018_metaSPC12_L29_EN1276_50°C_2min_dirty RP_2019-04-025_metaSPC12_L29_EN1650_50°C_15min_clean RP_2019-04-027_metaSPC12_L29_EN1650_50°C_30min_clean RP_2019-05-047_metaSPC12_L29_EN1650_50°C_15min_milk RP_2019-07-020_mSPC12_L29_EN1650_50°C_2min_clean RP_2019-07-022_mSPC12_L29_EN1650_50°C_2min_dirty



EN 13697 DIN SPEC 10534	RP_2019-06-001_metaSPC 12_L29_EN1650_50°C_30min_dirty RP_2019-07-031_mSPC12_L29_EN13697_50°C_2min_clean RP_2019-07-024_mSPC12_L29_EN13697_50°C_2min_dirty RP_2019-04-049_metaSPC 12_L29_EN13697_50°C_30min_dirty Binder CLEAN - metaSPC 12 FIELD TRIAL META 12
Meta SPC 13	
EN 1276  EN 1650  EN 13697	RP_2019-03-008_mSPC13_L31_EN1276_20°C_30min_clean RP_2019-03-009_mSPC13_L31_EN1276_20°C_30min_dirty RP_2019-02-092_mSPC13_L31_EN1650_20°C_30min_clean RP_2019-02-093_mSPC13_L31_EN1650_20°C_30min_dirty RP_2019-03-012_mSPC13_L31_EN13697_18-25°C_30min_clean RP_2019-03-013_mSPC13_L31_EN13697_18-25°C_30min_dirty
Meta SPC 14	
EN 1656 EN 1657 EN 16437	RP_2019-04-001_mSPC14_EN1656_30°C_5min_dirty RP_2019-03-006_mSPC14_EN1657_30°C_5min_dirty RP_2019-07-035_metaSPC 14_L34_skin test_30°C_5min_dirty
Meta SPC 15	
EN 13727 EN 13624 EN 1500	RP_2019-06-005_metaSPC15_L33_EN13727_20°C_1min_clean RP_2019-05-019_metaSPC 15_L33_EN13624_20°C_1min_clean STULV19AA2783-1_AAE32085_v1.000
Human Health	IUCLID File
OECD 439	SKINIRR_2019-09-01-mSPC1, D. Skopinski, 2019, 8.1.1 SKINIRR_2019-10-01-mSPC2, D. Skopinski, 2019, 8.1.1 SKINIRR_2019-09-01-mSPC5, D. Skopinski, 2019, 8.1.1 SKINIRR_2019-09-01-mSPC6, D. Skopinski, 2019, 8.1.1 SKINIRR_2019-06-01-mSPC8, D. Skopinski, 2019, 8.1.1 SKINIRR_2019-09-01-mSPC9, D. Skopinski, 2019, 8.1.1 SKINIRR_2019-06-02-mSPC10, D. Skopinski, 2019, 8.1.1 SKINIRR_2019-09-01-mSPC15, D. Skopinski, 2019, 8.1.1 2020-03-035_mSPC4 and 11_irritation test, I. Verschaeve, 2020, 8.1.1
OECD 431	SKINCORR_2019-05-01-mSPC2, D. Skopinski, 2019, 8.1.1 SKINCORR_2019-05-02-mSPC4, M. Degraeve, 2019, 8.1.1 SKINCORR_2019-05-02-mSPC11, M. Degraeve, 2019, 8.1.1

### 3.2 Output tables from exposure assessment tools



HH Exposure  
calculation\_Lactic Acic



ENV- L-LA BPF v1.xlsx



FOCUS PEARL  
Sevilla.docx



ENV- L-LA BPF v2  
.xlsx



emission\_estimation\_  
pt2\_en L-LA.xlsx

### 3.3 Confidential annex

Not available for public PAR.

### 3.4 Other



FOCUS PEARL  
Sevilla.docx