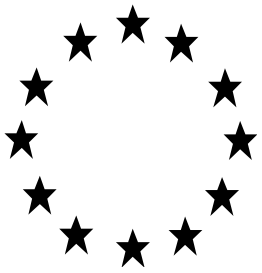
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the evaluating Competent Authority)



Lactic acid Family - Quatchem

Product type 3

L(+)-lactic acid as included in the Union list of approved active substances

Case Number in R4BP: BC-WC050857-29

Evaluating Competent Authority: Latvia

Date: 18 January 2023

Table of Contents

1 CONCLUSION

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product family.

General

The biocidal product family Lactic acid Family - Quatchem comprises of three meta SPCs based on the active substance L(+)-lactic acid for the use as non-medical teat disinfectants in veterinary hygiene (PT3). The three meta SPCs includes four ready-to-use liquid products. The products are intended to be applied in the post-milking phase by manual dipping using a dip cup or hand-held sprayer. The products are for professional use only.

The biocidal product family does not contain any non-active substances which are considered as substances of concern.

The biocidal product family should be considered not to have endocrine-disrupting properties.

Following intended uses in 3 meta SPC have been assessed:

Meta SPC / Use No	Use
Meta SPC 1 / Use #1.1.	Post milking teat disinfection – manual dipping
Meta SPC 1 / Use #1.2.	Post milking teat disinfection - spraying
Meta SPC 2 / Use #2.1.	Post milking teat disinfection – manual dipping
Meta SPC 3 / Use #3.1.	Post milking teat disinfection – manual dipping
Meta SPC 3 / Use #3.2.	Post milking teat disinfection - spraying

Physico-chemical properties

Lactic acid Family – Quatchem contain 4 water-based, liquid ready-to-use products allocated to 3 meta SPCs. All products were tested for relevant endpoints considering formulation type or respective non-submission justifications have been provided.

The products in meta SPC 1 are yellow or red liquids with citrus odour or are odourless. The relative density is 1.03 g/cm^3. The products in commercial packaging are stable for 18 weeks at 30±2°C, for 7 days at 0±2°C and for 24 months at 25±2°C. No changes in the appearance of product or packaging occur. The surface tension of the products is 35.0 to 35.4 mN/m at 20.0±0.5°C and it's considered as surface-active. The viscosity of the products at 20°C: 1.88 mm/s^2 and at 40°C: 1.18 mm/s^2.

The product in meta SPC 2 is yellow liquid with citrus odour. The relative density is 1.05 g/cm^3. The product in commercial packaging is stable for 18 weeks at 30±2°C, for 7 days at 0±2°C and for 24 months at 25±2°C. No changes in the appearance of product or packaging occur. The surface tension of the product is 41.7 to 42.4 mN/m at 20.0±0.5°C and it's considered as surface-active. The viscosity of the product at 20°C: 3.1 × 10^3 mm/s^2 and at 40°C: 2.1 × 10^3 mm/s^2.

The product in meta SPC 3 is green liquid with peppermint odour. The relative density is 1.03 g/cm^3. The product in commercial packaging is stable for 18 weeks at 30±2°C, for 7 days at 0±2°C and for 24 months at 25±2°C. No changes in the appearance of product or

packaging occur. The surface tension of the product is 35.0 to 35.4 mN/m at 20.0±0.5°C and it's considered as surface-active. The viscosity of the product at 20°C: 1.88 mm/s^2 and at 40°C: 1.18 mm/s^2.

Label requirements:

- Store in original container tightly closed.
- Store between 0 °C and + 30 °C.

Shelf life: 24 months.

Biocidal product family is not classified with regard to physical hazards according to the Regulation (EU) No 1272/2008.

A HPLC-DAD method of analysis is available to monitor the concentration of the active substance in the product. No other methods, for relevant impurities or substances of concern, are necessary.

Efficacy

The efficacy data provided demonstrates that the products of meta SPC 1 and 3 are effective against bacteria and yeast with a contact time of 5 minutes.

The efficacy data provided for meta SPC 2 demonstrates that the products are effective against yeasts, however efficacy against bacteria is not demonstrated since required log reduction was not achieved.

Efficacy against bacteria and yeasts has been tested in phase 2 step 1 and phase 2 step 2 tests according to the international guidelines EN 1656, EN 1657, prEN 17422 and EN 16438.

To ensure the efficacy of the product, the following instruction for use is defined in the SPC:

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

Human health

The biocidal product family does not contain any non-active substances which are considered as substances of concern.

The biocidal product family is not considered to have endocrine disrupting properties.

The biocidal product family is classified as follows according to the harmonized classification of the active substance and submitted *In Vitro* studies:

- H315 – Causes skin irritation;
- H318 – Causes serious eye damage;
- For meta SPC 3 only – EUH208: Contains peppermint oil. May produce an allergic reaction.

Professional user risk assessment

The products are intended to be applied in the post-milking phase by manual dipping using a dip cup or hand-held sprayer. The products are for professional use only. Relevant animals to be treated comprise dairy cows, camels, goats and sheep.

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.

Acceptable risks are foreseen for professional using products of the biocidal product family.

The following RMMs are set for biocidal product family Lactic acid Family – Quatchem:

- The use of eye protection during handling of the product is mandatory;
- Avoid hand to eye transfer;
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information);
- Professional users have to ensure that professional bystanders are not present in the treatment area during disinfection process by spraying. If it is necessary for professional bystanders to be present, professional users have to ensure that those wear the same type of PPE as themselves.

General public risk assessment

The biocidal product family is not intended for use by the general public.

Environment

L(+)-lactic acid is a naturally occurring substance found in plants and animals and is found to be readily biodegradable. According to the CLP criteria the product is not classified for environmental hazards.

Acceptable levels of risk have been demonstrated for the proposed use of the biocidal product to the environmental compartments STP, surface water, sediment, and soil. The estimated concentration in groundwater exceeds the quality standard for plant protection products and biocidal products according to Directive 2006/118/EC for drinking water (0.1 µg/L). However, this exceedance is not relevant due to the natural abundance in humans, animals, and microorganisms.

a) Presentation of the biocidal product/biocidal product family including classification and labelling

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

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

b) Description of uses proposed to be authorised

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

c) Comparative assessment

The active substance L(+)-lactic acid contained in the biocidal product family does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered (a) candidate(s) for substitution. Therefore, a comparative assessment of the biocidal product family in accordance with Article 23 of the BPR is not required.

d) Overall conclusion of the evaluation of the uses proposed to be authorised

An overview of the uses to be authorised is present below:

Meta SPC	Use	User	Target organisms	Use conditions	Risk mitigation measures	Conclusion
1	Use # 1.1 – Post milking teat disinfection – manual dipping	professional	Bacteria yeasts	ready-to-use products (RTU, 2% free L(+) lactic acid at target pH=3-4) 5 minutes contact time	The use of eye protection during handling of the product is mandatory. Avoid hand to eye transfer. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).	Acceptable with respective RMM
	Use # 1.2 – Post milking teat disinfection - spraying	professional	Bacteria yeasts	ready-to-use products (RTU, 2% free L(+) lactic acid at target pH=3-4) 5 minutes contact time	The use of eye protection during handling of the product is mandatory. Avoid hand to eye transfer. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). Professional users have to ensure that professional bystanders are not present in the treatment area during disinfection process by	Acceptable with respective RMM

					spraying. If it is necessary for professional bystanders to be present, professional users have to ensure that those wear the same type of PPE as themselves.	
2	Use # 2.1 – Post milking teat disinfection – manual dipping	professional	Bacteria yeasts	ready-to-use products (RTU, 3.2% free L(+) lactic acid at target pH=3-4)	The use of eye protection during handling of the product is mandatory. Avoid hand to eye transfer. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).	Not acceptable: efficacy not demonstrated for bacteria
3	Use # 3.1 – Post milking teat disinfection – manual dipping	professional	Bacteria yeasts	ready-to-use products (RTU, 2% free L(+) lactic acid at target pH=3-4) 5 minutes contact time	The use of eye protection during handling of the product is mandatory. Avoid hand to eye transfer. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).	Acceptable with respective RMM
	Use # 3.2 – Post milking teat	professional	Bacteria yeasts	ready-to-use products (RTU, 2%	The use of eye protection during handling	Acceptable with respective RMM

	disinfection - spraying			free L(+) lactic acid at target pH=3-4) 5 minutes contact time	of the product is mandatory. Avoid hand to eye transfer. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). Professional users have to ensure that professional bystanders are not present in the treatment area during disinfection process by spraying. If it is necessary for professional bystanders to be present, professional users have to ensure that those wear the same type of PPE as themselves.	

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended use(s) of the biocidal product/biocidal product family have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance(s) in the biocidal product/biocidal product family are met.

The physico-chemical properties of the biocidal product/biocidal product family are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised use(s), according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product family is sufficiently effective;

2. the biocidal product family has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. the biocidal product family has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product family has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
   - the fate and distribution of the biocidal product in the environment,
   - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
   - the impact of the biocidal product on non-target organisms,
   - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the use(s) described in the SPC, may be authorised.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	**Country (if relevant)**
Lactic acid Family - Quatchem	All EEA countries (Union authorisation)

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Arrow Regulatory (Ireland) Ltd on behalf of Quatchem
	Address	The Black Church, St. Mary's Place, Dublin 7, D07 P4AX Ireland
Pre-submission phase started on	11/02/2019	
Pre-submission phase concluded on	13/03/2019	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Quat-Chem Ltd. A Neogen Company
Address of manufacturer	1-4 Sandfield Industrial Park, Dodgson Street, Rochdale, Lancashire, United Kingdom, OL16 5SJ
Location of manufacturing sites	1-4 Sandfield Industrial Park, Dodgson Street, Rochdale, Lancashire, United Kingdom, OL16 5SJ

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

Active substance	L(+)-lactic acid
Name of manufacturer	Purac Biochem bv
Address of manufacturer	Arkelsedijk 46 4206 AC, Gorinchem The Netherlands
Location of manufacturing sites	Arkelsedijk 46 4206 AC, Gorinchem The Netherlands

Active substance	L(+)-lactic acid
Name of manufacturer	Jungbunzlauer S.A.
Address of manufacturer	Z.I. et Portuaire, B.P. 32 FR-67390, Marckolsheim

	France
Location of manufacturing sites	Z.I. et Portuaire, B.P. 32 FR-67390, Marckolsheim France

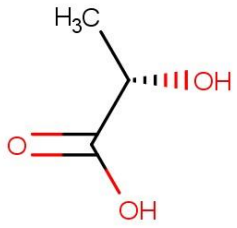
2.1.2 Product family composition and formulation

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)	
ISO name	L(+)-lactic acid
IUPAC or EC name	(S)-2-Hydroxypropanoic acid
EC number	201-196-2
CAS number	79-33-4
Index number in Annex VI of CLP	607-743-00-5
Minimum purity / content	≥ 95.5% w/w (dry weight)
Structural formula	

2.1.2.2 Candidate(s) for substitution

L(+)-lactic acid is not a Candidate for Substitution as it does not meet the criteria stated in Article 10 of Regulation (EU) 528/2012. A comparative assessment is therefore not required under Article 23 of Regulation (EU) No 528/2012

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

Not applicable

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
L(+)-lactic acid	(S)-2-Hydroxypropanoic acid	Active substance	79-33-4	201-196-2	4.0 (tech.)	4.0 (tech.)
					3.82 (pure)	3.82 (pure)
Other co-formulants	-	Non-active substance	-	-	Please see Conf. Annex	

2.1.2.5 Information on technical equivalence

Technical Equivalence is not required for L(+)-lactic acid obtained from Purac Biochem bv, this substance was assessed for the Reference Specification. L(+)-lactic acid obtained from Jungbunzlauer S.A. comply with Technical Equivalence requirements (Decision number: TAP-D-1403137-31-00/F; Asset number: EU-0020049-0000).

2.1.2.6 Information on the substance(s) of concern

The biocidal product family does not contain any substance of concern.
The biocidal product is not considered to have endocrine disrupting properties. For more information, please see Confidential Annex 3.6 for further details.

2.1.2.7 Type of formulation

AL – Any other liquid

PART II - SECOND INFORMATION LEVEL - META SPC 1

2.1.3 Meta SPC 1 administrative information

2.1.3.1 Meta SPC identifier

Identification	META SPC 1

2.1.3.2 Suffix to the authorisation number

Number	1-1

2.1.3.3 Product type(s)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)

2.1.4 Meta SPC 1 composition

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
L(+)-lactic acid	(S)-2-Hydroxypropanoic acid	Active substance	79-33-4	201-196-2	4.0 (tech.)	4.0 (tech.)
					3.82 (pure)	3.82 (pure)

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

AL – Any other liquid

2.1.5 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1

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

Classification	
Hazard category	Skin Irrit. 2 Eye Dam. 1
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage
Labelling	
Hazard Pictogram	 GHS05: Corrosion
Signal words	Danger
Hazard statements	H315: Causes skin irritation H318: Causes serious eye damage
Precautionary statements	P280: Wear protective gloves/eye protection. P264: Wash hands thoroughly after handling. P305 + P351 + P338 + P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor. P302 + P352: IF ON SKIN: Wash with plenty of water. P332 + P313: If skin irritation occurs: Get medical advice/attention. P321: Specific treatment (see first aid instruction on this label). P362 + P364: Take off contaminated clothing and wash it before reuse. P501: Dispose of contents/container in accordance with national regulations.
Note	Article 69 (1) of the Regulation (EU) No 528/2012 establishes that the authorisation holder shall ensure that biocidal products are classified and labelled in accordance with the Regulation (EC) No 1272/2008.

2.1.6 Authorised use(s) of the META SPC 1

2.1.6.1 Use description

Table 1. Use # 1.1 – Post milking teat disinfection – manual dipping

Product Type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	**-**
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor

	Teat disinfection post-milking by manual dipping using a dip cup.
Application method(s)	Manual dipping using a dip cup
Dilution (%)	Ready-to-use (RTU) product
Application rate(s) and frequency	Application rate: 2 % free L(+)-lactic acid, at target pH=3-4. Contact time for dipping at 30°C in dirty conditions: – 5 minutes for bacteria and yeasts. Application frequency: up to twice per day
Category(ies) of users	Professional
Pack sizes and packaging material	1000 litres high density polyethylene (HDPE) container with HDPE closure; 200 litres plastic drum with HDPE closure; 25 litres HDPE keg with DIN 61 HDPE screw cap; 5 litres HDPE keg with DIN 51 HDPE screw cap.

2.1.6.1.1 Use-specific instructions for use

See general directions for use of meta SPC 1. Product to be applied post-milking by use of a dipping cup. Pre-clean teat with dry wipe, pour the product into the reservoir of the dip cup. When using a dip cup, the cup is applied to each teat in turn and the operator squeezes the product from the reservoir into the cup. The cup has a non-return value so any residual product cannot go back into the reservoir.

2.1.6.1.2 Use-specific risk mitigation measures

See general directions for use of meta SPC 1.

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

See general directions for use of meta SPC 1.

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

See general directions for use of meta SPC 1.

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

See general directions for use of meta SPC 1.

2.1.6.2 Use description

Table 2. Use # 1.2 – Post milking teat disinfection - spraying

Product Type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	**-**

Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor Teat disinfection post-milking by using hand-held sprayer
Application method(s)	Manual spraying using hand-held sprayer
Dilution (%)	RTU product
Application rate(s) and frequency	Application rate: 2 % free L(+)-lactic acid, at target pH=3-4. Contact time for spraying at 30°C in dirty conditions: – 5 minutes for bacteria and yeasts. Application frequency: up to twice per day
Category(ies) of users	Professional
Pack sizes and packaging material	1000 litres HDPE container with HDPE closure; 200 litres plastic drum with HDPE closure; 25 litres HDPE keg with DIN 61 HDPE screw cap; 5 litres HDPE keg with DIN 51 HDPE screw cap.

2.1.6.2.1 Use-specific instructions for use

See general directions for use of meta SPC 1. Product to be applied post-milking by use of a hand-held sprayer. Pre-clean teat with dry wipe, pour the product into the reservoir of the sprayer. The operator will spray each animal once after milking.

2.1.6.2.2 Use-specific risk mitigation measures

See general directions for use of meta SPC 1. Professional users have to ensure that professional bystanders are not present in the treatment area during disinfection process by spraying. If it is necessary for professional bystanders to be present, professional users have to ensure that those wear the same type of PPE as themselves.

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

See general directions for use of meta SPC 1.

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

See general directions for use of meta SPC 1.

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

See general directions for use of meta SPC 1.

2.1.7 General directions for use of the meta SPC 1

2.1.7.1 Instructions for use

See use-specific instruction for use of meta SPC 1. Always read the label or leaflet before use and follow all the instructions. The product must be brought to room temperature before use. The amount of product applied per teat is dependent upon the animal being treated. For large mammals (cows, camels) – up to 10ml per teat, and for small mammals (sheep, goats) – up to 5ml per teat. Make sure that the teats are fully covered with disinfectant. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

2.1.7.2 Risk mitigation measures

The use of eye protection during handling of the product is mandatory. Avoid hand to eye transfer. Wear protective chemical resistant gloves during product handling phase (nitrile gloves – EN 374 or EN 455).

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

IF ON SKIN: Immediately wash with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor. IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. 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 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.

2.1.7.4 Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Keep out of reach of children. Store in original container tightly closed. Store between 0 °C and + 30 °C. Shelf life: 24 months

2.1.8 Other information

-

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

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

Trade name(s)	Synodex Lactopost Lactopost Y Lactopost Plus Lactopost Extra Synodex Y Synodex Extra Synodex Plus Udder X Teat Care Lacto Gold Lacto Extra Lactogold Lacto Spray				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+)-lactic acid	(S)-2-Hydroxypropanoic acid	Active substance	79-33-4	201-196-2	4.0 (tech.)
					3.82 (pure)

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

Trade name(s)	Laxsan Hexsan Lactopost R Laxsan R Hexfoam Deosan LA1 Hexsan Extra Hexsan Plus Laxsan Plus Laxsan Extra Hexsan R LA1 Condition Pink
Authorisation number	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L(+)-lactic acid	(S)-2-Hydroxypropanoic acid	Active substance	79-33-4	201-196-2	4.0 (tech.)
					3.82 (pure)

PART II - SECOND INFORMATION LEVEL - META SPC 2

Meta SPC 2 is not proposed for authorisation. Therefore, it does not appear on the Assessment Report section. Please refer to the PAR.

PART II - SECOND INFORMATION LEVEL - META SPC 3

2.1.11 Meta SPC 3 administrative information

2.1.11.1 Meta SPC identifier

Identification	META SPC 3

2.1.11.2 Suffix to the authorisation number

Number	1-3

2.1.11.3 Product type(s)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)

2.1.12 Meta SPC 3 composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L(+)-lactic acid	(S)-2-Hydroxypropanoic acid	Active substance	79-33-4	201-196-2	4.0 (tech.)	4.0 (tech.)
					3.82 (pure)	3.82 (pure)

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

AL – Any other liquid

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

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

Classification	
Hazard category	Skin Irrit. 2 Eye Dam. 1
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage
Labelling	
Hazard Pictogram	
	GHS05: Corrosion
Signal words	Danger
Hazard statements	H315: Causes skin irritation H318: Causes serious eye damage
Precautionary statements	P280: Wear protective gloves/eye protection. P264: Wash hands thoroughly after handling. P305 + P351 + P338 + P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor. P302 + P352: IF ON SKIN: Wash with plenty of water. P332 + P313: If skin irritation occurs: Get medical advice/attention. P321: Specific treatment (see first aid instruction on this label). P362 + P364: Take off contaminated clothing and wash it before reuse. P501: Dispose of contents/container in accordance with national regulations.
Note	EUH208: Contains peppermint oil. May produce an allergic reaction.
	Article 69 (1) of the Regulation (EU) No 528/2012 establishes that the authorisation holder shall ensure that biocidal products are classified and labelled in accordance with the Regulation (EC) No 1272/2008.

2.1.14 Authorised use(s) of the META SPC 3

2.1.14.1 Use description

Table 3. Use # 3.1 – Post milking teat disinfection – manual dipping

Product Type	PT03 – Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor Teat disinfection post-milking by manual dipping using a dip cup
Application method(s)	Manual dipping using a dip cup
Dilution (%)	RTU product
Application rate(s) and frequency	Application rate: 2 % free L(+)-lactic acid, at target pH=3-4. Contact time for dipping at 30°C in dirty conditions: – 5 minutes for bacteria and yeasts. Application frequency: up to twice per day
Category(ies) of users	Professional
Pack sizes and packaging material	1000 litres HDPE container with HDPE closure; 200 litres plastic drum with HDPE closure; 25 litres HDPE keg with DIN 61 HDPE screw cap; 5 litres HDPE keg with DIN 51 HDPE screw cap.

2.1.14.1.1 Use-specific instructions for use

See general directions for use of meta SPC 3. Product to be applied post-milking by use of a dipping cup. Pre-clean teat with dry wipe, pour the product into the reservoir of the dip cup. When using a dip cup, the cup is applied to each teat in turn and the operator squeezes the product from the reservoir into the cup. The cup has a non-return value so any residual product cannot go back into the reservoir.

2.1.14.1.2 Use-specific risk mitigation measures

See general directions for use of meta SPC 3.

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

See general directions for use of meta SPC 3.

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

See general directions for use of meta SPC 3.

2.1.14.1.5 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 of meta SPC 3.

2.1.14.2 Use description

Table 4. Use # 3.2 – Post milking teat disinfection - spraying

Product Type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	**-**
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor Teat disinfection post-milking by using hand-held sprayer
Application method(s)	Manual spraying using hand-held sprayer
Dilution (%)	RTU product
Application rate(s) and frequency	Application rate: 2 % free L(+)-lactic acid, at target pH=3-4. Contact time for spraying at 30°C in dirty conditions: – 5 minutes for bacteria and yeasts. Application frequency: up to twice per day
Category(ies) of users	Professional
Pack sizes and packaging material	1000 litres HDPE container with HDPE closure; 200 litres plastic drum with HDPE closure; 25 litres HDPE keg with DIN 61 HDPE screw cap; 5 litres HDPE keg with DIN 51 HDPE screw cap.

2.1.14.2.1 Use-specific instructions for use

See general directions for use of meta SPC 3. Product to be applied post-milking by use of a hand-held sprayer. Pre-clean teat with dry wipe, pour the product into the reservoir of the sprayer. The operator will spray each animal once after milking.

2.1.14.2.2 Use-specific risk mitigation measures

See general directions for use of meta SPC 3. Professional users have to ensure that professional bystanders are not present in the treatment area during disinfection process by spraying. If it is necessary for professional bystanders to be present, professional users have to ensure that those wear the same type of PPE as themselves.

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

See general directions for use of meta SPC 3.

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

See general directions for use of meta SPC 3.

2.1.14.2.5 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 of meta SPC 3.

2.1.15 General directions for use of the meta SPC 3

2.1.15.1 Instructions for use

See use-specific instruction for use of meta SPC 3. Always read the label or leaflet before use and follow all the instructions. The product must be brought to room temperature before use. The amount of product applied per teat is dependent upon the animal being treated. For large mammals (cows, camels) – up to 10ml per teat, and for small mammals (sheep, goats) – up to 5ml per teat. Make sure that the teats are fully covered with disinfectant. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

2.1.15.2 Risk mitigation measures

The use of eye protection during handling of the product is mandatory. Avoid hand to eye transfer. Wear protective chemical resistant gloves during product handling phase (nitrile gloves – EN 374 or EN 455).

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

IF ON SKIN: Immediately wash with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor. IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. 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 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.

2.1.15.4 Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Keep out of reach of children. Store in original container tightly closed. Store between 0 °C and + 30 °C. Shelf life: 24 months

2.1.16 Other information

-

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

2.1.17 Trade name(s), authorisation number and specific composition of each individual pro

Trade name(s)	Synoshield Lactopost G Synoshield P Lactopost P Synoshield G Lactoshield Lactoshield Plus Lactoshield Extra Synoshield Extra Synoshield Plus Lactopost Protect Udder Shield Teat Care Mint Lacto Plus Lacto Care Green Lactosal Lacto Care P Previoshield				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+)-lactic acid	(S)-2-Hydroxypropanoic acid	Active substance	79-33-4	201-196-2	4.0 (tech.) 3.82 (pure)

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)
IBC	1000 L	HD-PE (HDPE UV stabilised PE)	HDPE	Professional	Yes
Drum	200 L	Plastic / Polymer UN Approved Container	HDPE	Professional	Yes

Keg	25 L	HDPE (High Density Polyethylene)	Screw cap DIN 61; HDPE	Professional	Yes
Keg	5 L	HDPE (High Density Polyethylene)	Screw cap DIN 51; HDPE	Professional	Yes

2.1.19 Documentation

2.1.19.1 Data submitted in relation to product application

All data submitted in support of the Lactic Acid Family – Quatchem are added in the reference list contained in Annex 3.1.

2.1.19.2 Access to documentation

The Applicant is the data holder of the product data and has a letter of access (LoA) to the active substance's dossier.

A letter of access is available to the original dossier of the active substance from Purac Biochem bv, which is an approved substance supplier for PT3 according to Article 95 of Regulation (EU) No 528/2012.

2.1.19.3 Similar conditions of use

The biocidal product family Lactic acid Family – Quatchem is deemed to be eligible for Union authorisation. ECHA has concluded that based on the information provided by the applicant, the application could meet the basic requirements of Article 42(1) of the Regulation (EU) No 528/2012.

2.2 Assessment of the biocidal product family

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

Table 1. Use # 1 – Post milking test disinfection – manual dipping

Product Type	3
Where relevant, an exact description of the authorised use	Post-milking teat disinfection
Target organism (including development stage)	Bacteria Yeasts
Field of use	Disinfection of teats of milk-producing animals (Farms) Dirty, Indoor
Application method(s)	Apply to pre-cleaned teats The product is applied manually using a dip cup. The product is poured into the reservoir of the dip cup. When using a dip cup, the cup is applied to each teat in turn and the operator squeezes the product from the reservoir into the cup. The cup has a non-return value so any residual product cannot go back into the reservoir. The animals must be prevented from sitting down for 5 minutes after application.
Application rate(s) and frequency	The amount of product applied per teat is dependent upon the animal being treated: Large mammals (cows, camels): 10 mL per teat Small mammals (sheep, goats): 5 mL per teat Two to three times a day for up to 12 hours.
Category(ies) of users	Professional
Pack sizes and packaging material	Please see the relevant section.

Table 2. Use # 2 – Post milking test disinfection – spraying

Product Type	3
Where relevant, an exact description of the authorised use	Post-milking teat disinfection
Target organism (including development stage)	Bacteria Yeasts
Field of use	Disinfection of teats of milk-producing animals (Farms) Dirty, Indoor
Application method(s)	Apply to pre-cleaned teats The product is applied by spraying (hand held spray). The product is poured into the reservoir of the sprayer. The operator will spray each animal once after milking.

	The animals must be prevented from sitting down for 5 minutes after application.
Application rate(s) and frequency	The amount of product applied per teat is dependent upon the animal being treated: Large mammals (cows, camels): 10 mL per teat Small mammals (sheep, goats): 5 mL per teat Two to three times a day for up to 12 hours.
Category(ies) of users	Professional
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual assessment	Meta SPC 1: Synodex Batch number: [redacted]	Liquid	[redacted] ([redacted]) Ref No.: [redacted]
		Meta SPC 2: Synofilm Batch number: [redacted]	Liquid	[redacted] ([redacted]) Ref No.: [redacted]
		Meta SPC 3: Synoshield Batch number: [redacted]	Liquid	[redacted] ([redacted]) Ref No.: [redacted]
Colour at 20 °C and 101.3 kPa	Visual assessment	Meta SPC 1 a: Synodex Batch number: [redacted] and [redacted]	Yellow	[redacted] ([redacted]) Ref No.: [redacted] [redacted] ([redacted])
		Meta SPC 1 b: Laxsan Batch number: [redacted]	Red	[redacted] ([redacted])
		Meta SPC 2: Synofilm Batch number: [redacted]	Yellow	[redacted] ([redacted]) Ref No.: [redacted]
		Meta SPC 3: Synoshield Batch number: [redacted]	Green	[redacted] ([redacted]) Ref No.: [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Odour at 20 °C and 101.3 kPa	Organoleptic analysis	Meta SPC 1 a: Synodex Batch number: [redacted]	Citrus	[redacted] ([redacted])
		Meta SPC 1 b: Laxsan Batch number: [redacted]	Odourless	[redacted] ([redacted])
		Meta SPC 2: Synofilm Batch number: [redacted]	Citrus	[redacted] ([redacted])
		Meta SPC 3: Synoshield Batch number: [redacted]	Peppermint	[redacted] ([redacted])
Acidity / alkalinity	CIPAC MT 191 CIPAC MT 75.3	Synodex: Meta SPC 1 a: Synodex Batch number: [redacted]	<u>As eq. H_2SO_4:</u> Initial: 1.278% w/w 18 weeks at 30 ± 2 °C: 1.393% w/w <u>pH (neat):</u> Initial: 3.53 18 weeks at 30 ± 2 °C: 3.66 <u>pH (1% aq. dispersion):</u> Initial: 3.35 18 weeks at 30 ± 2 °C: 3.57	[redacted] ([redacted]) Ref No.: [redacted]
		Meta SPC 2: Synofilm Batch number: [redacted]	<u>As eq. H_2SO_4:</u> Initial: 2.00% w/w 18 weeks at 30 ± 2 °C: 2.14% w/w	[redacted] ([redacted]) Ref No.: [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			pH (neat): Initial: 3.71 18 weeks at 30 ± 2 °C: 3.67 pH (1% aq. dispersion): Initial: 3.60 18 weeks at 30 ± 2 °C: 3.67	
		Meta SPC 3: Synoshield Batch number: [redacted]	As eq. H_2SO_4: Initial: 1.38% w/w 18 weeks at 30 ± 2 °C: 1.47% w/w pH (neat): Initial: 3.51 18 weeks at 30 ± 2 °C: 3.52 pH (1% aq. dispersion): Initial: 3.50 18 weeks at 30 ± 2 °C: 3.53	[redacted] ([redacted]) Ref No.: [redacted]
Relative density / bulk density	EU Method A3 OECD 109	Meta SPC 1 Synodex and Laxsan Batch number: - *(Product used for read-across: Synoshield; Batch number: [redacted])*	Read-across to the studies on products in meta SPC 3 is applicable. [redacted] Therefore, the relative density of products in both meta SPCs is likely to be very similar. Testing on products in meta SPC 1 is therefore not scientifically justified. Mean density at 20.0 ± 0.5 °C: 1.03 $\times 10^3$ kg/m^3; Relative density at 20.0 ± 0.5 °C: 1.03	[redacted] ([redacted]) Ref No.: [redacted]
		Meta SPC 2: Synofilm	Mean density at 20.0 ± 0.5 °C: 1.05 $\times 10^3$ kg/m^3;	[redacted] ([redacted])

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Batch number: [redacted]	Relative density at 20.0 ± 0.5 °C: 1.05	Ref No.: [redacted]
		Meta SPC 3: Synoshield Batch number: [redacted]	Mean density at 20.0 ± 0.5 °C: 1.03 $\times 10^3$ kg/m^3; Relative density at 20.0 ± 0.5 °C: 1.03	[redacted] ([redacted]) Ref No.: [redacted]
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Meta SPC 1 a: Synodex Batch number: [redacted]	Active substance content: L(+)-lactic acid Initial: 3.90 % w/w (RSD = 0.413%) 18 weeks at 30 ± 2 °C: 3.99 % w/w (RSD = 0.334%) Weight decrease: < 0.194% after 18 weeks at 30 ± 2 °C – no significant change There was no significant change in the appearance of the test item or its container during storage at 30 ± 2 °C for 18 weeks. L(+)-lactic acid content increased by 2.2% after 18 weeks of storage at 30°C. **eCA remarks:** It can be concluded that the product will most likely comply with shelf life of 2 years.	[redacted] ([redacted]) Ref No.: [redacted]
		Meta SPC 2: Synofilm Batch number: [redacted]	Active substance content: L(+)-lactic acid Initial: 6.39 % w/w (RSD = 5.92 × 10^{-2} %)	[redacted] ([redacted]) Ref No.: [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			18 weeks at 30 ± 2 °C: 6.47 % w/w (RSD = 0.250%) Weight decrease: < 0.188% after 18 weeks at 30 ± 2 °C – no significant change There was no significant change in the appearance of the test item or its container during storage at 30 ± 2 °C for 18 weeks. L(+)-lactic acid content increased by 1.24% after 18 weeks at 30°C. **eCA remarks:** It can be concluded that the product will most likely comply with shelf life of 2 years.	
		Meta SPC 3: Synoshield Batch number: [redacted]	Active substance content: L(+)-lactic acid Initial: 3.96 % w/w (RSD = 0.258 %) 18 weeks at 30 ± 2 °C: 3.94 % w/w (RSD = 1.37 %) Weight decrease: < 0.188% after 18 weeks at 30 ± 2 °C – no significant change There was no significant change in the appearance of the test item or its container during storage at 30 ± 2 °C for 18 weeks.	[redacted] ([redacted]) Ref No.: [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			L(+)-lactic acid content decreased by 0.5% after 18 weeks at 30°C. **eCA remarks:** It can be concluded that the product will most likely comply with shelf life of 2 years.	
Storage stability test – **long term storage at ambient temperature**		Meta SPC 1 Synodex and Laxsan Batch number: - *(Product used for read-across: Synoshield; Batch number: [redacted])*	An ambient storage study on products in meta SPC 3 has been performed. [redacted]. Furthermore, the products are stored in identical containers. For these reasons, it is expected that the stability of products in both meta-SPC 1 and 3 would be similar and hence, read across to meta SPC 3 is justified. **Final storage time for meta SPC 1: 24 months**	[redacted] ([redacted]) Ref No.: [redacted]
		Meta SPC 2: Synofilm Batch number: [redacted]	The active substances content, appearance, pH and acidity/alkalinity were all determined prior to placing the samples on storage and after 3, 6, 12, 18 and 24 months. Active substance content: L(+)-lactic acid Initial: 6.39 % w/w (RSD = 5.92 × 10^{-2} %) 3 months: 6.40 % w/w (RSD = 0.119%) 6 months: 6.21 % w/w (RSD = 2.49%)	[redacted] ([redacted]) Ref No.: [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			12 months: 6.42% w/w (RSD = 0.307%) 18 months: 6.47% w/w (RSD = 6.97 × 10^{-2} %) 24 months: 6.51% w/w (RSD = 0.384 %) L(+)-lactic acid content increased by 1.88% after 24 months at 25±2°C. pH and acidity/alkalinity: As eq. H_2SO_4 Initial: 2.00% w/w 3 months: 2.11% w/w 6 months: 2.12% w/w 12 months: 2.17% w/w 18 months: 2.17% w/w 24 months: 2.16% w/w pH (neat) Initial: 3.71 3 months: 3.66 6 months: 3.65 12 months:3.66 18 months:3.63 24 months:3.67 pH (1% aq. dispersion) Initial: 3.60 3 months: 3.55 6 months: 3.45 12 months: 3.40	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			18 months: 3.69 24 months: 3.46 <u>Appearance and packaging for both batches:</u> Initial: Yellow, translucent liquid with bubbles dispersed throughout and with no sedimentation or precipitation. 5 L, white opaque, plastic (PE-HD) container with a moulded handle on top. There is one yellow, opaque, plastic (PE) screw-on lid secured to the container with yellow, opaque, plastic tamper-proof seal. There are two manufacturer's labels on the container. No signs of corrosion, degradation or seepage through the walls or seal of the container. 3 months: no change 6 months: no change 12 months: no change 18 months: no change 24 months: no change **Final storage time for meta SPC 2: 24 months**	
		Meta SPC 3: Synoshield Batch number: [redacted]	The active substances content, appearance, pH and acidity/alkalinity were all determined prior to placing the samples on storage and after 3, 6, 12, 18 and 24 months. Active substance content: <u>L(+)-lactic acid</u> Initial: 3.96 % w/w (RSD = 0.258%) 3 months: 3.89 % w/w (RSD = 0.646%) 6 months: 3.63 % w/w	[redacted] ([redacted]) Ref No.: [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			(RSD = 1.99%) 12 months: 3.99% w/w (RSD = 0.648%) 18 months: 4.04% w/w (RSD = 6.24 x 10^{-2}%) 24 months: 4.00% w/w (RSD = 0.397%) L(+)-lactic acid content increased by 1.01% after 24 months at 25±2°C. pH and acidity/alkalinity: As eq. H_2SO_4 Initial: 1.38% w/w 3 months: 1.44% w/w 6 months: 1.47% w/w 12 months: 1.50% w/w 18 months: 1.51% w/w 24 months: 1.49% w/w pH (neat) Initial: 3.51 3 months: 3.56 6 months: 3.47 12 months: 3.48 18 months: 3.45 24 months: 3.50 pH (1% aq. dispersion) Initial: 3.50 3 months: 3.26 6 months: 3.39	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			12 months: 3.30 18 months: 3.66 24 months: 3.40 <u>Appearance and packaging for both batches:</u> Initial: Green, translucent liquid with no sedimentation or precipitation. 5 L, white opaque, plastic (PE-HD) container with a moulded handle on top. There is one yellow, opaque, plastic (PE) screw-on lid secured to the container with yellow, opaque, plastic tamper-proof seal. There are two manufacturer's labels on the container. No signs of corrosion, degradation or seepage through the walls or seal of the container. 3 months: no change 6 months: no change 12 months: no change 18 months: no change 24 months: no change **Final storage time for meta SPC 3: 24 months**	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Meta SPC 1: Synodex Batch number: [redacted]	Physically stable to storage for 7 days at 0 ± 2 °C Visual assessment: Initial – pale yellow, transparent liquid with no signs of precipitation, or separated material. 7 days - pale yellow, transparent liquid with no signs of precipitation, or separated material.	[redacted] ([redacted]) Ref No.: [redacted]
		Meta SPC 2: Synofilm Batch number: [redacted]	Physically stable to storage for 7 days at 0 ± 2 °C Visual assessment: Initial – yellow transparent liquid with bubbles through out	[redacted] ([redacted]) Ref No.: [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			7 days - yellow transparent liquid with bubbles through out No signs of precipitate, sedimentation or separated material.	
		Meta SPC 3: Synoshield Batch number: [redacted]	Physically stable to storage for 7 days at 0 ± 2 °C Visual assessment: Initial – Green transparent liquid 7 days - Green transparent liquid No signs of precipitate, sedimentation or separated material.	[redacted] ([redacted]) Ref No.: [redacted]
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	waiver	All meta SPCs	The products are stored in opaque PE-HD packaging designed to prevent UV/light deterioration of the products. Product should only be stored in its original packaging.	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	Meta SPC 1: Synodex Batch number: [redacted]	During the accelerated storage stability test, there was 2.2% increase in the L(+)-lactic acid content of the product during storage at 30 ± 2 °C for 18 weeks. Product should be stored in temperatures below 30°C.	[redacted] ([redacted]) Ref No.: [redacted]
		Meta SPC 2: Synofilm Batch number: [redacted]	During accelerated storage stability test, there was a 1.24% increase in the L(+)-lactic acid content in the product at 30 ± 2 °C after 18 weeks. Product should be stored in temperatures below 30°C.	[redacted] ([redacted]) Ref No.: [redacted]
		Meta SPC 3: Synoshield Batch number: [redacted]	During accelerated storage stability test, there was a 0.5% decrease in the L(+)-lactic acid content in the product at 30 ± 2 °C after 18 weeks.	[redacted] ([redacted]) Ref No.: [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Product should be stored in temperatures below 30°C.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	Meta SPC 1 Synodex and Laxsan Batch number: - *(Product used for read-across: Synoshield; Batch number: [redacted])*	Read-across to the studies on products in meta SPC 3 is applicable. [redacted]. Therefore, the reactivity towards container material of products in both meta SPCs is likely to be very similar. Testing on products in meta SPC 1 is therefore not scientifically justified.	-
		Meta SPC 2: Synofilm Batch number: [redacted]	There was no significant change in the appearance of the test item or its container during storage at 25 ± 2 °C for 24 months.	[redacted] ([redacted]) Ref No.: [redacted]
		Meta SPC 3: Synoshield Batch number: [redacted]	There was no significant change in the appearance of the test item or its container during storage at 25 ± 2 °C for 24 months.	[redacted] ([redacted]) Ref No.: [redacted]
Wettability	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Suspensibility, spontaneity and dispersion stability	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Wet sieve analysis and dry sieve test	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Emulsifiability, re-emulsifiability	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
and emulsion stability				
Disintegration time	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Particle size distribution, content of dust/fines, attrition, friability	waiver	Meta SPC 1: Synodex and Meta SPC 3: Synoshield	According to Technical Agreements for Biocides (TAB) – APCP, vers. 2.0. February 2020, entry 4.2.2. MMAD is not required, since BPF fulfils all mentioned criteria: 1. The product may be used in spray applications, but the product is not sold with a trigger sprayer or together with other spraying equipment; 2. For human health exposure and risk assessment, the Assessment Report for L(+)-lactic acid (AR, June 2017) has been considered. In addition to AR, June 2017, eCA has followed the 1st Coordination Webex on UA-APPs on BPs with L(+)-lactic acid meeting discussions and Human health WG decisions from 2020 and 2021. Considering Human health WG-I-2021 (discussion point 6.1.) discussion and conclusions of the CAR of L(+)-lactic acid for product type 6, it has been agreed not to perform the comparison of endogenous L-(+)-lactic acid with systemic exposure levels at product authorization. Considering this, MMAD is not relevant for human health. 3. The MMAD is not relevant for efficacy assessment.	-
		Meta SPC 2: Synofilm	Particle size distribution is not applicable, the product is not intended for spraying application.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Persistent foaming	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Flowability/Pourability/Dustability	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Burning rate — smoke generators	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Burning completeness — smoke generators	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Composition of smoke — smoke generators	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Spraying pattern — aerosols	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Physical compatibility	waiver	All meta SPCs	The product is not intended to be used in conjunction with any other substances, mixtures, biocidal products or non-biocidal products.	-
Chemical compatibility	waiver	All meta SPCs	The product is not intended to be used in conjunction with any other substances, mixtures, biocidal products or non-biocidal products.	-
Degree of dissolution and dilution stability	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Surface tension	EU Method A5 OECD 115 – Ring method	Meta SPC 1 Synodex and Laxsan Batch number: -	[redacted]. The products contain surface active ingredients. Testing on products in meta SPC 3 indicate that the products	[redacted] ([redacted]) Ref No.: [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		(Product used for read-across: Synoshield; Batch number: [redacted])	are surface active and this is a desired property of this type of formulation for the proposed use. Testing on products in meta SPC 1 is therefore not scientifically justified. 35.0 to 35.4 mN/m at 20.0 ± 0.5 °C The test item is surface active.	
		Meta SPC 2: Synofilm Batch number: [redacted]	41.7 to 42.4 mN/m at 20.0 ± 0.5 °C The test item is surface active.	[redacted] ([redacted]) Ref No.: [redacted]
		Meta SPC 3: Synoshield Batch number: [redacted]	35.0 to 35.4 mN/m at 20.0 ± 0.5 °C The test item is surface active.	[redacted] ([redacted]) Ref No.: [redacted]
Viscosity	OECD 114 – Capillary viscometer method	Meta SPC 1 Synodex and Laxsan Batch number: - *(Product used for read-across: Synoshield; Batch number: [redacted])*	[redacted]. The products contain co-formulants that are added to make the liquids viscous so they remain on the teat. Testing on products in meta SPC 3 indicate that the products are viscous and this is a desired property of this type of formulation for the proposed use. Testing on products in meta SPC 1 is therefore not scientifically justified. 1.88 mm^2/s at 20.0 ± 0.5 °C 1.18 mm^2/s at 40.0 ± 0.5 °C Newtonian liquid	[redacted] ([redacted]) Ref No.: [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Meta SPC 2: Synofilm Batch number: [redacted]	3.1 × 10^3 mm^2/s at 20.0 ± 0.5 °C 2.1 × 10^3 mm^2/s at 40.0 ± 0.5 °C Newtonian liquid	[redacted] ([redacted]) Ref No.: [redacted]
		Meta SPC 3: Synoshield Batch number: [redacted]	1.88 mm^2/s at 20.0 ± 0.5 °C 1.18 mm^2/s at 40.0 ± 0.5 °C Newtonian liquid	[redacted] ([redacted]) Ref No.: [redacted]

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

Lactic acid Family – Quatchem contain 4 water-based, liquid ready-to-use products allocated to 3 meta SPCs. All products were tested for relevant endpoints considering formulation type or respective non-submission justifications have been provided.

The products in meta SPC 1 are yellow or red liquids with citrus odour or are odourless. The relative density is 1.03 g/cm^3. The products in commercial packaging are stable for 18 weeks at 30±2°C, for 7 days at 0±2°C and for 24 months at 25±2°C. No changes in the appearance of product or packaging occur. The surface tension of the products is 35.0 to 35.4 mN/m at 20.0±0.5°C and it's considered as surface-active. The viscosity of the products at 20°C: 1.88 mm/s^2 and at 40°C: 1.18 mm/s^2.

The product in meta SPC 2 is yellow liquid with citrus odour. The relative density is 1.05 g/cm^3. The product in commercial packaging is stable for 18 weeks at 30±2°C, for 7 days at 0±2°C and for 24 months at 25±2°C. No changes in the appearance of product or packaging occur. The surface tension of the product is 41.7 to 42.4 mN/m at 20.0±0.5°C and it's considered as surface-active. The viscosity of the product at 20°C: 3.1 × 10^3 mm/s^2 and at 40°C: 2.1 × 10^3 mm/s^2.

The product in meta SPC 3 is green liquid with peppermint odour. The relative density is 1.03 g/cm^3. The product in commercial packaging is stable for 18 weeks at 30±2°C, for 7 days at 0±2°C and for 24 months at 25±2°C. No changes in the appearance of product or packaging occur. The surface tension of the product is 35.0 to 35.4 mN/m at 20.0±0.5°C and it's considered as surface-active. The viscosity of the product at 20°C: 1.88 mm/s^2 and at 40°C: 1.18 mm/s^2.

Label requirements:

- Store in original container tightly closed.

- Store between 0 °C and + 30 °C.

Shelf life: 24 months.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	EU Method A14	All meta SPCs	The explosives endpoint is waived based on structural considerations. For more details, please see the extended waiver in the Conf. Annex.	-
Flammable gases	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Flammable aerosols	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Oxidising gases	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Gases under pressure	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Flammable liquids	EU Method A9	Meta SPC 1 Synodex and Laxsan Batch number: - *(Product used for read-across: Synoshield; Batch number: [redacted])*	Read-across to Synoshield (meta SPC 3): [redacted]. Changes to dye and perfume are deemed to have no impact on the physico-chemical properties of the product. Not flammable; there is no flash point up to the boiling temperature of ~103 °C was observed.	[redacted] ([redacted]) Ref No.: [redacted]
		Meta SPC 2: Synofilm Batch number: [redacted]	Not flammable; there is no flash point up to the boiling temperature of ~106 °C was observed.	[redacted] ([redacted]) Ref No.: [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Meta SPC 3: Synoshield Batch number: [redacted]	Not flammable; there is no flash point up to the boiling temperature of ~103 °C was observed.	[redacted] ([redacted]) Ref No.: [redacted]
Flammable solids	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Self-reactive substances and mixtures	waiver	All meta SPCs	The self-reactive substances and mixtures endpoint is waived based on structural considerations. For more details, please see the extended waiver in the Conf. Annex.	-
Pyrophoric liquids	waiver	Meta SPC 1: Synodex and Meta SPC 3: Synoshield	None of the components in the formulation are pyrophoric. The products are classified as not flammable or not combustible and do not have flash points below 446°C.	-
		Meta SPC 2: Synofilm	None of the components in the formulation are pyrophoric. The products are classified as not flammable or not combustible and do not have flash points below 438°C.	-
Pyrophoric solids	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Self-heating substances and mixtures	waiver	All meta SPCs	According to CLP criteria, the surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore, liquids are not classified as self-heating. Furthermore, product contains > 85% water and none of the components is classified as self-heating. Not expected that the product would be a self-heating mixture.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Substances and mixtures which in contact with water emit flammable gases	waiver	All meta SPCs	The products contain >85% water. According to Regulation (EC) No 1272/2008 Annex I Section 2.12.4.1. the classification procedure for this class need not be applied if: (a) the chemical structure of the substance or mixture does not contain metals or metalloids; or (b) experience in production or handling shows that the substance or mixture does not react with water, e.g., the substance is manufactured with water or washed with water; or (c) the substance or mixture is known to be soluble in water to form a stable mixture. The products fulfil all 3 requirements; therefore, no further testing is necessary.	-
Oxidising liquids	EU Method A21	All meta SPC	The oxidising liquids endpoint is waived based on structural considerations. For more details, please see the extended waiver in the Conf. Annex.	-
Oxidising solids	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-
Organic peroxides	waiver	All meta SPCs	None of the products contain components which are classified as organic peroxides. Due to the properties of the individual components, the high-water content and known experience, none of the products are expected to cause a fire or explosion.	
Corrosive to metals	UN Test C.1	Meta SPC 1: Synodex Batch number: [redacted]	The tested metal plates showed the following mass loss over a period of 7 days at 55 ± 1 °C. In the case of uniform corrosion, a minimum mass loss of 13.5 % is equivalent to the CLP criterion of 6.25 mm/year and the test result is considered positive. In the case	[redacted] ([redacted]) Ref No.: [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			of localized corrosion, the test result is considered positive if the deepest intrusion exceeds 0.12 mm. <u>Aluminium (Mass loss %):</u> Headspace: 2.70 × 10^{-2} Partially Immersed: 1.06 Fully Immersed: 3.50 <u>Steel (Mass loss %):</u> Headspace: 1.65 Partially Immersed: 4.24 Fully Immersed: 5.41 Based on the test results it can be concluded that the product is not corrosive to both aluminium and steel metals. ***eCA remark:*** The localised corrosion was assessed as part of the "Classification of corrosion to Metals" study. During evaluation, the Applicant clarified that since there was no evidence that any localised corrosion had occurred in the study so the corrosion was concluded as uniform.	
		Meta SPC 2: Synofilm Batch number: [redacted]	The tested metal plates showed the following mass loss over a period of 7 days at 55 ± 1 °C. In the case of uniform corrosion, a minimum mass loss of 13.5 % is equivalent to the CLP criterion of 6.25 mm/year and the test result is considered positive. In the case of localized corrosion, the test result is considered positive if the deepest intrusion exceeds 0.12 mm. <u>Aluminium (Mass loss %):</u> Headspace: 3.75 × 10^{-2}	[redacted] ([redacted]) Ref No.: [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Partially Immersed: 0.145 Fully Immersed: 0.272 <u>Steel (Mass loss %):</u> Headspace: 1.34 Partially Immersed: 1.79 Fully Immersed: 3.18 Based on the test results it can be concluded that the product is not corrosive to both aluminium and steel metals. ***eCA remark:*** The localised corrosion was assessed as part of the "Classification of corrosion to Metals" study. During evaluation, the Applicant clarified that since there was no evidence that any localised corrosion had occurred in the study so the corrosion was concluded as uniform.	
		Meta SPC 3: Synoshield Batch number: [redacted]	The tested metal plates showed the following mass loss over a period of 7 days at 55 ± 1 °C. In the case of uniform corrosion, a minimum mass loss of 13.5 % is equivalent to the CLP criterion of 6.25 mm/year and the test result is considered positive. In the case of localized corrosion, the test result is considered positive if the deepest intrusion exceeds 0.12 mm. <u>Aluminium (Mass loss %):</u> Headspace: 3.77×10^{-2} Partially Immersed: 0.859 Fully Immersed: 1.55 <u>Steel (Mass loss %):</u> Headspace: 0.607	[redacted] ([redacted]) Ref No.: [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Partially Immersed: 3.09 Fully Immersed: 2.86 Based on the test results it can be concluded that the product is not corrosive to both aluminium and steel metals. ***eCA remark:*** The localised corrosion was assessed as part of the "Classification of corrosion to Metals" study. During evaluation, the Applicant clarified that since there was no evidence that any localised corrosion had occurred in the study so the corrosion was concluded as uniform.	
Auto-ignition temperatures of products (liquids and gases)	EU Method A15	Meta SPC 1 Synodex and Laxsan Batch number: - *(Product used for read-across: Synoshield; Batch number: [redacted])*	Read-across to Synoshield (meta SPC 3): [redacted] Auto-ignition temperature: 446 °C	[redacted] ([redacted]) Ref No.: [redacted]
		Meta SPC 2: Synofilm Batch number: [redacted]	438 °C	[redacted] ([redacted]) Ref No.: [redacted]
		Meta SPC 3: Synoshield Batch number: [redacted]	446 °C	[redacted] ([redacted]) Ref No.: [redacted]
Relative self-ignition	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
temperature for solids				
Dust explosion hazard	waiver	All meta SPCs	Not applicable to the ready-to-use liquid formulation.	-

Conclusion on the physical hazards and respective characteristics of the product
Biocidal product family is not classified with regard to physical hazards according to the Regulation (EU) No 1272/2008.

2.2.4 Methods for detection and identification

Determination of L(+)-lactic acid is performed by high-performance liquid chromatography (HPLC) equipped with a diode array detector.

The blank, standard and sample solutions were analyzed by high performance liquid chromatography (HPLC) using the following conditions:

HPLC: Agilent Technologies 1200, incorporating autosampler and workstation,

Column: Grace, Prevail Organic Acid, 3µm Rocket (53 x 7 mm id)

Column temperature.: 30°C

Mobile phase A: 0.025M potassium dihydrogen phosphate adjusted to approximately pH 2.5 using phosphoric acid

Flow rate: 1.0 mL/min

Injection vol: 20 µL

UV detector wavelength: 210 nm

Retention time: approximately 2.7 minutes.

	Meta SPC 2: **Synofilm**	*Meta SPC 3:* **Synoshield**
Linearity:	Aliquots (A = 1.2543 g and B = 1.2535 g) of L(+)-lactic acid reference item were weighed into 250 mL volumetric flasks, 50 mL of 1 M sodium hydroxide and the standards were then sonicated for 20 minutes. After sonication, the solutions were allowed to cool and then diluted to nearly the top of the volumetric flask with purified water before 1.75 mL of sulfuric	Aliquots (A = 1.2543 g and B = 1.2535 g) of L(+)-lactic acid reference item were weighed into 250 mL volumetric flasks, 50 mL of 1 M sodium hydroxide and the standards were then sonicated for 20 minutes. After sonication, the solutions were allowed to cool and then diluted to nearly the top of the volumetric flask with purified water before 1.75 mL of sulfuric acid solution was added

	acid solution was added to ensure the pH was between pH 1 and 3. Finally each standard solution was diluted to volume (250 mL) with purified water. Standard stock solution A was then diluted with purified water to cover the nominal concentration range of 250 to 1.25 x 103 mg/L. Also, Standard stock solution B was then diluted with purified water at a nominal concentration of 500 mg/L.	to ensure the pH was between pH 1 and 3. Finally each standard solution was diluted to volume (250 mL) with purified water. Standard stock solution A was then diluted with purified water to cover the nominal concentration range of 250 to 1.25E+03 mg/L. Also, Standard stock solution B was then diluted with purified water at a nominal concentration of 500 mg/L.
Precision (Repeatability):	*Samples:* Aliquots of test item were weighed into 250 mL volumetric flasks, 50 mL of 1 M sodium hydroxide was added, and the samples were then sonicated for 20 minutes. After sonication, the solutions were allowed to cool and then diluted to nearly the top of the volumetric flask with purified water before 1.75 mL of sulfuric acid solution was added to ensure the pH was between pH 1 and 3. Finally each sample was diluted to volume with purified water, mixed and analyzed. *Standard Solutions:* The standard stock solutions from the linearity were diluted with purified water to give a nominal concentration of 500 mg/L. *Blank:* The non-analyte interference blank was used. *Precision (Replicate Injections):* In a further assessment of repeatability, ten replicate injections of a standard solution at the working level (approximately 500 mg/L) were carried out.	*Samples:* Aliquots of test item were weighed into 250 mL volumetric flasks, 50 mL of 1 M sodium hydroxide was added, and the samples were then sonicated for 20 minutes. After sonication, the solutions were allowed to cool and then diluted to nearly the top of the volumetric flask with purified water before 1.75 mL of sulfuric acid solution was added to ensure the pH was between pH 1 and 3. Finally each sample was diluted to volume with purified water, mixed and analyzed. *Standard Solutions:* The standard stock solutions from the linearity were diluted with purified water to give a nominal concentration of 500 mg/L. *Blank:* The non-analyte interference blank was used. *Precision (Replicate Injections):* In a further assessment of repeatability, ten replicate injections of a standard solution at the working level (approximately 500 mg/L) were carried out.
Accuracy:	*Samples:* Aliquots of test item were weighed into 250 mL volumetric flasks and fortified with an aliquot of L(+)-lactic acid reference item (see following table), 50 mL of 1M sodium hydroxide was added, and the samples were then sonicated for 20 minutes. After sonication, the solutions were allowed to cool and then diluted to nearly the top of the volumetric flask with purified water before 1.75 mL of sulfuric acid solution was added to ensure the pH was between pH 1 and 3. Finally each sample was diluted to volume with purified water, mixed and analyzed. *Standard Solutions:* Level 1 - The standard stock solutions from the linearity were diluted with purified water to give a nominal concentration of 700 mg/L. Level 2 - The standard stock solutions from the linearity were diluted with purified water to give a	*Samples:* Aliquots of test item were weighed into 250 mL volumetric flasks and fortified with an aliquot of L(+)-lactic acid reference item, 50 mL of 1M sodium hydroxide was added, and the samples were then sonicated for 20 minutes. After sonication, the solutions were diluted to nearly the top of the volumetric flask with purified water before 1.75 mL of sulfuric acid solution was added to ensure the pH was between pH 1 and 3. Finally each sample was diluted to volume (250 mL) with purified water, mixed and analyzed. *Standard Solutions:* Level 1 - The standard stock solutions from the linearity were diluted with purified water to give a nominal concentration of 700 mg/L. Level 2 - The standard stock solutions from the linearity were diluted with purified water to give a nominal

	nominal concentration of 800 mg/L. Level 3 - The standard stock solutions from the linearity were diluted with purified water to give a nominal concentration of 900 mg/L. *Blank:* The non-analyte interference blank was used.	concentration of 800 mg/L. Level 3 - The standard stock solutions from the linearity were diluted with purified water to give a nominal concentration of 900 mg/L. *Blank:* The non-analyte interference blank was used.
Non-Analyte Interference:	50 mL of 1 M sodium hydroxide was diluted to nearly the top of a 250 mL volumetric flask with purified water before 1.75 mL of sulfuric acid solution was added to ensure the pH was between pH 1 and 3. Finally the sample was diluted to volume with purified water, mixed and analyzed.	50 mL of 1 M sodium hydroxide was diluted to nearly the top of the volumetric flask with purified water before 1.75 mL of sulfuric acid solution was added to ensure the pH was between pH 1 and 3 (measured pH value was approximately pH 2.0). Finally, the sample was diluted to volume (250 mL) with purified water, mixed and analyzed.
Specificity:	The non-analyte interference blank, a precision sample, a standard solution at the working level (approximately 500 mg/L) and the standard blank were analyzed by HPLC-DAD* to obtain and compare their spectra. Identification L(+)-lactic acid was identified by diode array detection (DAD) using the analytical conditions detailed above with the following amendments: Detector: Agilent Technologies G1315B DAD Spectrum: 200 nm to 400 nm Threshold: 1.00 mAU	The non-analyte interference blank, a precision sample, a standard solution at the working level (approximately 500 mg/L) and the standard blank were analyzed by HPLC-DAD to obtain and compare their spectra. Identification L(+)-lactic acid was identified by diode array detection (DAD) using the analytical conditions detailed above with the following amendments: Detector: Agilent Technologies G1315B DAD Spectrum: 200 nm to 400 nm Threshold: 1.00 mAU

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

Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Meta SPC 2: **Synofilm** Batch number: [redacted]	HPLC	Precision: 10 replicates at 500 mg/L RSD: 0.19% RSD_r: 2.03%	$y=1.51 \cdot 10^4 x - 4.55 \cdot 10^3$ R = 1.000 N=6	No evidence of interference Confirmed by diode array and	103 - 104	Level 1 – 104 Level 2 – 103	1.34	Not applicable to mixtures	[redacted] ([redacted]) Ref No.: [redacted]

			Range 251 to 1250 mg/L (Range covers 80-120% of the active substance content in the product)	external standard.		Level 3 - 103			
Meta SPC 3: **Synoshield** Batch number: [redacted]	HPLC	Precision: 10 replicates at 500 mg/L RSD: 0.17% RSD_r: 2.18%	$y=1.51 \cdot 10^4$ $x- 9.08 \cdot 10^3$ R = 1.000 N=6 Range 251 to 1250 mg/L (Range covers 80-120% of the active substance content in the product)	No evidence of interference Confirmed by diode array and external standard.	98.8 - 102	Level 1 – 99.0 Level 2 – 102 Level 3 – 98.8	1.52	Not applicable to mixtures	[redacted] ([redacted]) Ref No.: [redacted]

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

L(+)-lactic acid	This endpoint is not applicable, justification is provided in the L(+)-lactic acid CAR (Germany 2017): the residues in environmental compartments arising from the application of L(+)-lactic acid are not expected.	-

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
L(+)-lactic acid	This endpoint is not applicable, justification is provided in the L(+)-lactic acid CAR (Germany 2017): the residues in soil arising from the application of L(+)-lactic acid are not expected. Therefore, residue analytical methods of L(+)-lactic acid in soil are not required.								-

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
L(+)-lactic acid	This endpoint is not applicable, justification is provided in the L(+)-lactic acid CAR (Germany 2017): the residues in air arising from the application of L(+)-lactic acid are not expected. Therefore, residue analytical methods of L(+)-lactic acid in air are not required.								-

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

L(+)-lactic acid	This endpoint is not applicable, justification is provided in the L(+)-lactic acid CAR (Germany 2017): the residues in water arising from the application of L(+)-lactic acid are not expected. Therefore, residue analytical methods of L(+)-lactic acid in water are not required.	-

Analytical methods for animal and human body fluids and tissues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
L(+)-lactic acid	Not relevant, as the active substance L(+)-lactic acid is not classified as toxic or very toxic.								-

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
L(+)-lactic acid	This endpoint is not applicable, justification is provided in the L(+)-lactic acid CAR (Germany 2017): indirect exposure via residues in milk are not expected. Teat disinfection occurs after milking, and it is assumed that possible residues on teats have been completely broken down at the next milking event. Therefore, residue analytical methods of L(+)-lactic acid in food and feed stuff are not required.								-

Conclusion on the methods for detection and identification of the product
The validation of the analytical methods for the quantitative determination of the active substance have been performed using an actual product. The L(+)-lactic acid content is determined by validated HPLC method with UV detection as indicated in CAR. The method of analysis of active substance L(+)-lactic acid was validated according to the SANCO/ 3030/99 rev. 4 dated 11/07/2000. Analytical methods for monitoring, the determination of residues in soil, air, water and food and feeding stuffs are not required according to the CAR for L(+)-lactic acid.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The biocidal product family comprises of three meta SPCs based on the active substance L(+)-lactic acid for the use as non-medical teat disinfectants in veterinary hygiene (PT3). The three meta SPCs includes four ready-to-use liquid products. The products are intended to be used post-milking. They can be applied manually using dip cup or hand-held sprayer. The products are for professional use only and are bactericidal and yeasticidal.

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

The products are post-milking teat disinfectants intended to control bacteria and yeast on the teats of lactating animals.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The products are based on the active substance, L(+)-lactic acid. The active substance exerts a non-selective mode of action. L(+)-lactic acid has basic activity at the cell wall, disruption of membrane potentials and general membrane permeability of the cytoplasmic membrane.

2.2.5.4 Mode of action, including time delay

According to assessment report for L(+)-lactic acid, 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. No resistance to L(+)-lactic acid has been observed. Furthermore, development of resistance is considered unlikely due to the non-specific mode of action.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
PT3 biocidal product, bactericidal	Teat disinfection (post-milking)	Synodex L(+)-lactic acid conc.: 2 % free L(+)-lactic acid (equilibrium conc.) corresponding to 4 % L(+)-lactic acid	*Streptococcus uberis* DSM 20569, *Staphylococcus aureus* DSM 799, *Escherichia coli* ATCC 10536	prEN 17422 (Based on a modification of EN 16437) Quantitative porous surface test without mechanical action (Phase 2, step 2)	- Tested product concentrations: 10%, 50%, 100% - Diluent: distilled water - Carriers: VitroSkin® - Test method: dilution-neutralization - Interfering substance: 10 g/L skimmed milk - Contact time: 30 minutes - Temperature 30°C	Bactericidal >4 log reduction: *S. uberis, E.coli* >3.8 log reduction: 3.82 log reduction *S. aureus* Product concentration: 100%. Contact time: 30 minutes Interfering Substance: 10/L Skimmed milk Temperature 30°C	[redacted] ([redacted]) [redacted]
PT3 biocidal product, bactericidal	Teat disinfection (post-milking)	Synodex L(+)-lactic acid conc.: 2 % free L(+)-lactic acid (equilibrium conc.) corresponding	*Staphylococcus aureus* NCTC 10788, *Escherichia coli* NCIMB 8879	prEN 17422:2020 Quantitative porous surface test without mechanical action (Phase 2, step 2)	- Tested product concentrations: 25%, 50%, 100% - Diluent: hard water - Carriers: VitroSkin® - Test method: dilution-neutralization - Interfering substance: 10 g/L skimmed milk	PASS Bactericidal >4 log reduction for *E. coli* and *S. aureus* Product concentration: 100%.	[redacted] ([redacted]) [redacted]

Experimental data on the efficacy of the biocidal product against target organism(s)							
		to 4 % L(+)-lactic acid			- Contact time: 5 minutes - Temperature 30°C	Contact time: 5 minutes Interfering Substance: 10/L Skimmed milk Temperature 30°C	
PT3 biocidal product, bactericidal	Teat disinfection (post-milking)	Synodex <u>L(+)-lactic acid conc.:</u> 2 % free L(+)-lactic acid (equilibrium conc.) corresponding to 4 % L(+)-lactic acid	*Streptococcus uberis* DSM 20569	EN 17422:2022 Quantitative porous surface test without mechanical action (Phase 2, step 2)	- Tested product concentrations: 25%, 50%, 100% - Diluent: hard water - Carriers: VitroSkin® - Test method: dilution-neutralization - Interfering substance: 10 g/L skimmed milk - Contact time: 5 minutes - Temperature 30°C	PASS Bactericidal >4 log reduction: *S. uberis* Product concentration: 100%. Contact time: 5 minutes Interfering Substance: 10/L Skimmed milk Temperature 30°C	[redacted] ([redacted]) [redacted]
PT3 biocidal product, bactericidal	Teat disinfection (post-milking)	Synofilm <u>L(+)-lactic acid conc.:</u> 3.2 % free L(+)-lactic acid (equilibrium conc.) corresponding to 6.4 % L(+)-lactic acid	*Streptococcus uberis* NCTC 3858, *Staphylococcus aureus* ATCC 6538, *Escherichia coli ATCC 10536*	EN 1656:2009 Quantitative suspension test (Phase 2, step 1)	- Test concentrations: 120% (1.5x times concentrated product), 80% (RTU), 16% (5 x dilution of RTU), - Interfering substance: 10 g/L skimmed milk powder - Test method: dilution/neutralisation - Diluent: soft water	The product when applied at RTU (80%) and 1.5x (120%) concentration for **5 minutes** contact time under relevant soiling and 30°C demonstrated acceptable efficacy (R > 5 log reduction) against	[redacted] ([redacted]) [redacted]

Experimental data on the efficacy of the biocidal product against target organism(s)							
		Three formulations supplied: *RTU (6.4% L(+)-lactic acid)* *1.5xRTU (9.6% L(+)-lactic acid)* *5 x dilution of RTU (1.28%) L(+)-lactic Acid*			- Contact time: 5 minutes - Temperature 30°C	all tested bacterial species	
PT3 biocidal product, yeasticidal	Teat disinfection (post-milking)	Synofilm <u>L(+)-lactic acid conc.:</u> 3.2 % free L(+)-lactic acid (equilibrium conc.) corresponding to 6.4 % L(+)-lactic acid *Three formulations supplied:* *RTU (6.4% L(+)-lactic acid)* *1.5xRTU (9.6% L(+)-lactic acid)* *5 x dilution of RTU (1.28%) L(+)-lactic acid*	*Candida albicans* ATCC 10231	EN 1657:2016	- Quantitative suspension test (Phase 2, step 1) - Test concentrations: 120% (1.5x times concentrated product), 80% (RTU), 16% (5 x dilution of RTU) - Interfering substance: 10 g/L skimmed milk powder - Test method: dilution/neutralisation - Diluent: soft water - Contact time: 5 minutes - Temperature 30°C	The product when applied at RTU (80%) and 1.5x (120%) concentration for **5 minutes** contact time under relevant soiling and 30°C demonstrated acceptable efficacy (R > 4 log reduction) against yeast *C. albicans.*	[redacted] ([redacted]) [redacted]

Experimental data on the efficacy of the biocidal product against target organism(s)							
PT3 biocidal product, bactericidal	Teat disinfection (post-milking)	Synofilm L(+)-lactic acid conc.: 3.2 % free L(+)-lactic acid (equilibrium conc.) corresponding to 6.4 % L(+)-lactic acid	*Streptococcus uberis* DSM 20569, *Staphylococcus aureus* DSM 799, *Escherichia coli* ATCC 10536	prEN 17422 (Based on a modification of EN 16437) Quantitative porous surface test without mechanical action (Phase 2, step 2)	- Quantitative surface test (Phase 2, step 2) - Tested product concentrations: 10%. 50%, 100% - Diluent: distilled water - Carriers: VitroSkin® - Test method: dilution-neutralization - Interfering substance: 10 g/L skimmed milk - Contact time: 15, 30 minutes - Temperature 30°C	PASS Bactericidal >4 log reduction, all organisms Product concentration: 100%. Contact time: 15 and 30 minutes Interfering Substance: 10/L Skimmed milk Temperature 30°C	[redacted] ([redacted]) [redacted]
PT3 biocidal product, bactericidal	Teat disinfection (post-milking)	Synofilm: L(+)-lactic acid conc.: 3.2 % free L(+)-lactic acid (equilibrium conc.) corresponding to 6.4 % L(+)-lactic acid L(+)-lactic acid (6.4%)	*Escherichia coli* NCIMB 8879 *Staphylococcus aureus* NCTC 10788	prEN 17422:2020 Quantitative porous surface test without mechanical action (Phase 2, step 2)	- Tested product concentrations: 25%, 50%, 100% - Diluent: distilled water - Carriers: VitroSkin® - Test method: dilution-neutralization - Interfering substance: 10 g/L skimmed milk - Contact time: 5 minutes - Temperature 30°C	Bactericidal >4 log reduction for *E. coli* 3.24 log reduction for *S. aureus* Product concentration: 100%. Contact time: 5 minutes Interfering Substance: 10/L Skimmed milk Temperature 30°C	[redacted] ([redacted]) [redacted]

Experimental data on the efficacy of the biocidal product against target organism(s)							
PT3 biocidal product, bactericidal	Teat disinfection (post-milking)	Synofilm: <u>L(+)-lactic acid conc.:</u> 3.2 % free L(+)-lactic acid (equilibrium conc.) corresponding to 6.4 % L(+)-lactic acid L(+)-lactic acid (6.4%)	*Streptococcus uberis* DSM 20569	EN 17422:2022 Quantitative porous surface test without mechanical action (Phase 2, step 2)	- Tested product concentrations: 25%, 50%, 100% - Diluent: hard water - Carriers: VitroSkin® - Test method: dilution-neutralization - Interfering substance: 10 g/L skimmed milk - Contact time: 5 minutes - Temperature 30°C	PASS Bactericidal >4 log reduction: *S. uberis* Product concentration: 100%. Contact time: 5 minutes Interfering Substance: 10/L Skimmed milk Temperature 30°C	[redacted] ([redacted]) [redacted]
PT3 biocidal product, yeasticidal	Teat disinfection (post-milking)	Synofilm <u>L(+)-lactic acid conc.:</u> 3.2 % free L(+)-lactic acid (equilibrium conc.) corresponding to 6.4 % L(+)-lactic acid	*Candida albicans ATCC 10231,*	EN 16438:2014 (modified)	- Quantitative surface test (Phase 2, step 2) - Test concentrations: 100% ready to Use. - Carriers: stainless steel discs - Test method: dilution-neutralization - Interfering substance: 10 g/L skimmed milk - Contact time: 5 minutes - Temperature 30°C	PASS Yeasticidal >3 log reduction Product concentration: 100%. Contact time: 5 minutes Interfering Substance: 10/L Skimmed milk Temperature 30°C	[redacted] ([redacted]) [redacted]
PT3 biocidal product, bactericidal	Teat disinfection (post-milking)	Synoshield: <u>L(+)-lactic acid conc.:</u> 2 % free L(+)-lactic acid	*Streptococcus uberis* NCTC 3858, *Staphylococcus aureus* ATCC 6538,	EN 1656:2009	- Quantitative suspension test (Phase 2, step 1) - Test concentrations: 120% (1.5x times concentrated product),	The product when applied at RTU (80%) and 1.5x (120%) concentration for **5 minutes** contact	[redacted] ([redacted]) [redacted]

Experimental data on the efficacy of the biocidal product against target organism(s)							
		(equilibrium conc.) corresponding to 4 % L(+)-lactic acid *Three formulations supplied:* *RTU (4% L(+)-lactic acid)* *1.5xRTU (6% L(+)-lactic acid)* *5 x dilution of RTU (0.8%) L(+)-lactic acid*	*Escherichia coli ATCC 10536*		80% (RTU), 16% (5 x dilution of RTU) - Interfering substance: 10 g/L skimmed milk powder - Test method: dilution/neutralisation - Diluent: - soft water - Contact time: 5 minutes - Temperature 30°C	time under relevant soiling and 30°C demonstrated acceptable efficacy (R > 5 log reduction) against all tested bacterial species	
PT3 biocidal product, yeasticidal	Teat disinfection (post-milking)	Synoshield: <u>L(+)-lactic acid conc.:</u> 2 % free L(+)-lactic acid (equilibrium conc.) corresponding to 4 % L(+)-lactic acid *Three formulations supplied:* *RTU (4% L(+)-lactic acid)* *1.5xRTU (6% L(+)-lactic acid)*	*Candida albicans* ATCC 10231	EN 1657:2016	- Quantitative suspension test (Phase 2, step 1) - Test concentrations: 120% (1.5x times concentrated product), 80% (RTU), 16% (5 x dilution of RTU) - Interfering substance: 10 g/L skimmed milk powder - Test method: dilution/neutralisation - Diluent: soft water - Contact time: 5 minutes - Temperature 30°C	The product when applied at RTU (80%) and 1.5x (120%) concentration for **5 minutes** contact time under relevant soiling and 30°C demonstrated acceptable efficacy (R > 4 log reduction) against yeast *C. albicans.*	[redacted] ([redacted]) [redacted]

Experimental data on the efficacy of the biocidal product against target organism(s)							
		5 x dilution of RTU (0.8%) L(+)-lactic Acid					
PT3 biocidal product, bactericidal	Teat disinfection (post-milking)	Synoshield: <u>L(+)-lactic acid conc.:</u> 2 % free L(+)-lactic acid (equilibrium conc.) corresponding to 4 % L(+)-lactic acid	*Streptococcus uberis* DSM 20569, *Staphylococcus aureus* DSM 799, *Escherichia coli* ATCC 10536	prEN 17422 (Based on a modification of EN 16437) Quantitative porous surface test without mechanical action (Phase 2, step 2)	- Quantitative surface test (Phase 2, step 2) - Tested product concentrations: 10%. 50%, 100% - Diluent: distilled water - Carriers: VitroSkin® - Test method: dilution-neutralization - Interfering substance: 10 g/L skimmed milk - Contact time: 30 minutes - Temperature 30°C	PASS Bactericidal>4 log reduction Product concentration: 50% and 100%. Contact time: 30 minutes Interfering Substance: 10/L Skimmed milk Temperature 30°C	[redacted] ([redacted]) [redacted]
PT3 biocidal product, bactericidal	Teat disinfection (post-milking)	Synoshield: <u>L(+)-lactic acid conc.:</u> 2 % free L(+)-lactic acid (equilibrium conc.) corresponding to 4 % L(+)-lactic acid	*Escherichia coli* NCIMB 8879 *Staphylococcus aureus* NCTC 10788	prEN 17422:2020 Quantitative porous surface test without mechanical action (Phase 2, step 2)	- Tested product concentrations: 25%, 50%, 100% - Diluent: hard water - Carriers: VitroSkin® - Test method: dilution-neutralization - Interfering substance: 10 g/L skimmed milk - Contact time: 5 minutes - Temperature 30°C	PASS Bactericidal >4 log reduction for *E. coli* and *S. aureus* Product concentration: 100%. Contact time: 5 minutes Interfering Substance: 10/L Skimmed milk	[redacted] ([redacted]) [redacted]

Experimental data on the efficacy of the biocidal product against target organism(s)							
						Temperature 30°C	
PT3 biocidal product, bactericidal	Teat disinfection (post-milking)	Synoshield: <u>L(+)-lactic acid conc.:</u> 2 % free L(+)-lactic acid (equilibrium conc.) corresponding to 4 % L(+)-lactic acid	*Streptococcus uberis* DSM 20569	EN 17422:2022 Quantitative porous surface test without mechanical action (Phase 2, step 2)	- Tested product concentrations: 25%, 50%, 100% - Diluent: hard water - Carriers: VitroSkin® - Test method: dilution-neutralization - Interfering substance: 10 g/L skimmed milk - Contact time: 5 minutes - Temperature 30°C	PASS Bactericidal >4 log reduction: *S. uberis* Product concentration: 100%. Contact time: 5 minutes Interfering Substance: 10/L Skimmed milk Temperature 30°C	[redacted] ([redacted]) [redacted]
PT3 biocidal product, yeasticidal	Teat disinfection (post-milking)	Synoshield: <u>L(+)-lactic acid conc.:</u> 2 % free L(+)-lactic acid (equilibrium conc.) corresponding to 4 % L(+)-lactic acid	*Candida albicans* ATCC 10231,	EN 16438:2014 (modified)	- Quantitative surface test (Phase 2, step 2) - Test concentrations: 100% ready to Use. - Carriers: stainless steel discs - Test method: dilution-neutralization - Interfering substance: 10 g/L skimmed milk - Contact time: 5 minutes - Temperature 30°C	PASS Yeasticidal >3 log reduction Product concentration: 100%. Contact time: 5 minutes Interfering Substance: 10/L Skimmed milk Temperature 30°C	[redacted] ([redacted]) [redacted]
Additional tests (not related to claim)							
PT3 biocidal product, bactericidal	Teat disinfection (post-milking)	Synofilm <u>L(+)-lactic acid conc.:</u>	*Staphylococcus aureus* ATCC 6538,	EN 16437:2014 Quantitative porous surface test	- Quantitative surface test (Phase 2, step 2) - Concentrations: 10%. 50%, 100%	Bactericidal >4 log reduction for 3 organisms	[redacted] ([redacted]) [redacted]

Experimental data on the efficacy of the biocidal product against target organism(s)							
		3.2 % free L(+)-lactic acid (equilibrium conc.) corresponding to 6.4 % L(+)-lactic acid	*Enterococcus hirae* ATCC 10541, *Pseudomonas aeruginosa* ATCC 15442, *Proteus vulgaris* ATCC 13315	without mechanical action (Phase 2, step 2)	- Interfering substance: skimmed milk 10 g/L - Contact time: 5 minutes, 15 minutes - Temperature 30°C	3.82 log reduction S. aureus Product Concentration: 100% Contact time: 15 minutes Interfering Substance: 10/L Skimmed milk Temperature 30°C	
PT3 biocidal product, bactericidal	Teat disinfection (post-milking)	Synodex <u>L(+)-lactic acid conc.:</u> 2 % free L(+)-lactic acid (equilibrium conc.) corresponding to 4 % L(+)-lactic acid	*Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541, *Pseudomonas aeruginosa* ATCC 15442, *Proteus vulgaris* ATCC 13315	EN 16437:2014 Quantitative porous surface test without mechanical action (Phase 2, step 2)	- Concentrations: 10%. 50%, 100% - Interfering substance: skimmed milk 10 g/L - Contact time: 5 minutes, 15 minutes - Temperature 30°C	Bactericidal >4 log reduction for 2 organisms (*Pseudomonas aeruginosa, Proteus vulgaris)* Product Concentration: 100% Contact time: 15 minutes Interfering Substance: 10/L Skimmed milk Temperature 30°C	[redacted] ([redacted]) [redacted]

Conclusion on the efficacy of the product

Meta SPC 1: Synodex is the representative product

The representative biocidal product for meta SPC 1, Synodex, is broadly similar to the representative product for meta SPC 3, Synoshield. From the Confidential Annex Section 3.6.1, it can be seen that [redacted].
The co-formulants used to formulate a member product of meta SPC 3, with the exception of the active substance, L(+)-lactic acid, are unlikely to have any additional positive effect on the outcome of the product's efficacy. Likewise, the co-formulants used to formulate a member product of meta SPC 1 are unlikely to have any adverse effect on the efficacy of the product.

Given the above, it is proposed that the efficacy data to support the representative product for meta SPC 3, Synoshield, is read across to support the representative product for meta SPC 1, Synodex.

Phase 2 Step 1 tests to support efficacy against both bacteria and yeasts were submitted in support of Synoshield (6.7-A1, 6.7-A2). Both studies included the active substance, L(+)-lactic acid, at the 4.0% concentration as also found in Synodex. A Phase 2 Step 2 test (a modified EN 16437 test for use with teat dip products) was also submitted in support of Synoshield (6.7-A3). The product, Synoshield was shown to be effective (>4 log reduction) in this test at a concentration of both 100% and 50% of the product as supplied, which is equal to or below the concentration found in Synodex.

An EN 16347 test, modified for use with teat dip products was also submitted specifically in support of Synodex. It was noted that the product achieved a greater than 4 log reduction for 2 of the three organisms but the marginally lower figure of 3.82 was recorded for one organism (*S.aureus*). This study was not conducted to a published EN Standard as, at the time of testing, no teat dip Veterinary Phase 2 Step 2 test had been published. In fact, at the time of writing, the relevant EN Standard is still only available in a draft form as prEN 17422. Consequently, it was the Applicant's opinion at the time, and still their opinion, that a 3.82 log reduction, in a methodology that has yet to be fully validated, was, when taken with the read across from 6.7-A3, sufficient evidence of efficacy.

Therefore, Synodex is considered bactericidal at a product concentration of 100% and an application contact time of 30 minutes.

At the EFF WG-III-2022, it was agreed that 30 minutes for bacterial claim is not acceptable. Following the discussions at the EFF WG-III-2022 (discussion point 7.3.), to support the bacterial claim, the Applicant provided new efficacy studies performed according to EN17422:2022.

According to the new efficacy studies, the representative biocidal product for Meta SPC 1, Synodex demonstrates >5.13 log reduction for *E. coli;* 4.69 log reduction for *S. aureus* and >5.01 log for *S. uberis* (5 min contact time, RTU product).

Therefore, Synodex is considered bactericidal at a product concentration of 100% and an application contact time of 5 minutes.

Synodex is also considered yeasticidal at a product concentration of 100% and an application contact time of 5 minutes.

Meta SPC 2: Synofilm is the representative product.

Synofilm: (L(+)-lactic acid (6.4%)) was found to be bactericidal (6.7-B1) in relevant efficacy tests – including Phase 2 Step 2 Porous Surface Tests modified to reflect a skin surface application (6.7-B3; 6.7-B4) at a product concentration of 100% and an application contact time of 15 minutes. This study was carried out under teat dip conditions interfering substance of 10g/L skimmed milk powder and a temperature of 30°C.

At the EFF WG-III-2022, it was agreed that 15 minutes for bacterial claim is not acceptable. Following the discussions at the EFF WG-III-2022 (discussion point 7.3.), to support the bacterial claim, the Applicant provided new efficacy studies performed according to EN17422:2022.

According to the new efficacy studies, the representative biocidal product for meta SPC 2, Synofilm demonstrates > 5.01 log reduction for *S. uberis;* > 5.20 log reduction for *E. coli* and 3.24 log reduction for *S. aureus* after 5 min contact time with RTU product. During ad hoc follow-up meeting (10 October 2022), the members of the EFF WG agreed that since required log reduction for *S. aureus* is not achieved, efficacy of meta SPC 2 is not demonstrated and therefore, cannot be authorised.

Synofilm was also shown to be yeasticidal (6.7-B2) in relevant efficacy tests – including a Phase 2 Step 2 Porous Surface test (6.7-B5) at a product concentration of 100% and an application contact time of 5 minutes. This study was carried out under teat dip conditions interfering substance of 10g/L skimmed milk powder and a temperature of 30°C.

Meta SPC 3: Synoshield is the representative product

Synoshield: (L(+)-lactic acid (4%)) was found to be bactericidal (6.7-A1) in relevant efficacy tests – including a Phase 2 Step 2 Porous Surface modified to reflect a skin surface application (6.7-A3) at a product concentration of 50% and an application contact time of 30 minutes. This study was carried out under teat dip conditions interfering substance of 10g/L skimmed milk powder and a temperature of 30°C.

At the EFF WG-III-2022, it was agreed that 30 minutes for bacterial claim is not acceptable. Following the discussions at the EFF WG-III-2022 (discussion point 7.3.), to support the bacterial claim, the Applicant provided new efficacy studies performed according to EN17422:2022.

According to the new efficacy studies, the representative biocidal product for meta SPC 3, Synoshield demonstrates > 4.82 log reduction for *E. coli*, 4.08 log reduction for *S. aureus* and > 5.01 log reduction for *S. uberis* after 5 min contact time with RTU product.

Therefore, Synoshield is considered bactericidal at a product concentration of 100% and an application contact time of 5 minutes.

Synoshield was also shown to be yeasticidal (6.7-A2) in relevant efficacy tests – including a Phase 2 Step 2 Porous Surface test (6.7-A4) at a product concentration of 100% and an application contact time of 5 minutes. This study was carried out under teat dip conditions interfering substance of 10g/L skimmed milk powder and a temperature of 30°C.

2.2.5.6 Occurrence of resistance and resistance management

The Assessment Report for the active substance indicates that due to the non-specific mode of action no acquired resistance occurs. In addition, the risk of development of cross resistance or co-resistance is in general low. Considering the non-specific mode of activity, the risk of organisms developing resistance mechanisms is minimal.

2.2.5.7 Known limitations

None

2.2.5.8 Evaluation of the label claims

The in-use concentration range given for the products is consistent with the known effects of individual active substances and the efficacy data provided supports the label claims of bactericidal and yeasticidal when used as a post-milking teat dip.

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

The products are not intended for use with other biocidal products.

2.2.6 Risk assessment for human health

For the human health hazard assessment, new information (*in vitro* skin corrosion and irritation studies) is provided on the biocidal products within biocidal product family. For the other endpoints, the following approach for the C&L of biocidal products was taken: If there is a harmonised C&L for an active substance or a co-formulant, this classification will be used to derive the classification of the mixture. If there is no harmonised C&L available for a certain active substance or co-formulant, the most appropriate information on the classification will be used.

[redacted]

[redacted]

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

For the human health hazard assessment, following e-consultation *"e-consultation on lactic acid products classified for skin hazard and used for teat disinfection"* and discussions in Human health WG-III-2020 (Discussion point 7.2.) the applicant has submitted *in vitro* skin corrosion and irritation studies. The studies were performed according to following guidelines:

- Test Guideline No. 431 In Vitro Skin Corrosion: Reconstructed Human Epidermis (RhE) Test Method;
- Test Guideline No. 439 In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method.

In vitro corrosivity study was conducted on Synofilm (meta SPC 2) and *in vitro* irritation studies were conducted on Synodex (meta SPC 1), Synofilm (meta SPC 2) and Synoshield (meta SPC 3).

In addition to OECD guidance studies, a number of field trials performed in working farms in the UK, were performed to assess whether there was any evidence for adverse effects on the teats of lactating cows, after milking, that had been treated with products from this biocidal product family.

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 No. 431, *In Vitro* Skin Corrosion: Reconstructed Human Epidermis (RhE) Test Method Reliability: 1	Meta SPC 2: Synofilm Active substance content: 6.4 % Dose: 50 µL Batch number: [redacted]	Undiluted product Duration of treatment: 3 and 60 min. Three replicates	Skin corrosive potential of tests chemicals is predicted by the mean tissue viability of tissues exposed to a test chemical. The percentage tissue viability obtained was following: After 3 min. = 96.872% After 60 min. = 96.495%	Product of meta SPC 2 was classified as non-corrosive to human skin	[redacted] ([redacted]) Ref No. [redacted]
OECD guideline No. 439, *In Vitro* Skin Irritation: Reconstructed Human Epidermis Test Method Reliability: 1	Meta SPC 1: Synodex Active substance content: 2.16 % (free L(+)-lactic acid)* Dose: 30 µL Batch number: [redacted]	Undiluted product Duration of treatment: 60 min. Post treatment: 42 hours Three replicates	Skin irritant potential of tests chemicals is predicted by the mean tissue viability of tissues exposed to a test chemical. The percentage tissue viability obtained was following: After 60 min. = 4.898%	Product of meta SPC 1 was classified as irritant to human skin	[redacted] ([redacted]) Ref No. [redacted]

OECD guideline No. 439, *In Vitro* Skin Irritation: Reconstructed Human Epidermis Test Method Reliability: 1	Meta SPC 2: Synofilm Active substance content: 6.4 % Dose: 30 µL Batch number: [redacted]	Undiluted product Duration of treatment: 60 min. Post treatment: 42 hours Three replicates	Skin irritant potential of tests chemicals is predicted by the mean tissue viability of tissues exposed to a test chemical. The percentage tissue viability obtained was following: After 60 min. = 5.393%	Product of meta SPC 2 was classified as irritant to human skin	[redacted] ([redacted]) Ref No. [redacted]
OECD guideline No. 439, *In Vitro* Skin Irritation: Reconstructed Human Epidermis Test Method Reliability: 1	Meta SPC 3: Synoshield Active substance content: 2.20 % (free L(+)-lactic acid)* Dose: 30 µL Batch number: [redacted]	Undiluted product Duration of treatment: 60 min. Post treatment: 42 hours Three replicates	Skin irritant potential of tests chemicals is predicted by the mean tissue viability of tissues exposed to a test chemical. The percentage tissue viability obtained was following: After 60 min. = 5.863%	Product of meta SPC 3 was classified as irritant to human skin	[redacted] ([redacted]) Ref No. [redacted]

* The lactic acid level presented by the testing laboratory is based on an internal Quat-Chem analytical test method. This method is a titration method and only detects the level of free acid and not the total lactic acid (which is lactic acid and lactate that is formed in the formulation). The lactic acid content as given in the composition table is based on the amount of lactic acid added at the start of manufacture. As part of the process, lactic acid will exist as free lactic acid and lactate (due to the buffering in the formulation). The method of analysis used to determine the lactic acid concentration in the certificates of analysis therefore measures free lactic acid only. This is why there is often a difference between the lactic acid content in the actual composition of the product and the content quoted in the certificates of analysis (which are subsequently cited by the laboratories in the testing study reports). A statement on free lactic acid determination as opposed to total lactic acid measurement has been provided.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Biocidal product family Lactic acid Family – Quatchem is classified as Skin Irrit. 2; H315.
Justification for the value/conclusion	The active substance L(+)-lactic acid is classified as Skin corr. 1C; H314 with GCL ≥ 5% according to Table 3.2.3. of CLP. Biocidal product family Lactic acid Family – Quatchem contain L(+)-lactic acid in the range of 4 – 6.4 %. Other components of the products classified for skin corrosion and skin irritation are present below the generic cut-off value 1 % and can thus be disregarded according to Regulation No 1272/2008

	Annex I, Table 1.1. *In Vitro* study for skin corrosion (OECD guideline No. 431) for product Synofilm (active substance content: 6.4 %) and *In Vitro* for skin irritation (OECD guideline No. 439) for products Synodex (free L(+)-lactic acid content: 2.16 %), Synofilm (active substance content: 6.4 %) and Synoshield (free L(+)-lactic acid content: 2.20 %). *In Vitro* study for skin corrosion for product Synofilm indicated non-corrosion to skin, but *In Vitro* studies on skin irritation for products Synodex, Synofilm and Synoshield indicated irritation to skin, therefore all products within biocidal product family are classified as irritating to human skin.
Classification of the product according to CLP and DSD	H315 – Causes skin irritation

Eye irritation

No in vitro, in vivo or human data are available. Under CLP, in the absence of data, preparations may be classified for eye irritation/serious eye damage by calculation in accordance with section 3.3.3.3 of the CLP. It is assumed that the relevant ingredients of a mixture causing eye irritation or serious eye damage are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a presumption (e.g., in the case of corrosive ingredients) that an ingredient present at a concentration of less than 1% can still be relevant for classifying the mixture for eye irritation/eye damage. The principle of additivity is applied. It is therefore considered that additional animal studies are not required in order to avoid unnecessary suffering of animals.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Biocidal product family Lactic acid Family – Quatchem is classified as Eye Dam. 1; H318.
Justification for the value/conclusion	The active substance L(+)-lactic acid is classified as Eye Dam. 1; H318 and GCL C ≥ 3 % according to Table 3.3.3 of CLP is assigned. In addition, L(+)-lactic acid is also classified as Skin Corr. 1C; H314. The biocidal product family contain L(+)-lactic acid in the range of 4 – 6.4 %. As the sum of ingredients classified as Eye Dam. Cat. 1 and Skin Corr. Cat. 1A, 1B or 1C is more than 3 %, according to the table 3.3.3 of the CLP, the biocidal product family is classified as Eye Dam. Cat. 1, H318.
Classification of the product according to CLP and DSD	H318 – Causes serious eye damage

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Biocidal product family Lactic acid Family – Quatchem is not classified.
Justification for the conclusion	There are no components of the products that are classified for respiratory tract irritation. No classification for respiratory tract irritation is justified.
Classification of the product according to CLP and DSD	Not classified

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Products of meta SPC 1 and 2 are not classified.
Justification for the value/conclusion	Products of meta SPC 1 and meta SPC 2 contain [redacted] in the range of [redacted].

	According to the supplier SDS, [redacted] is classified as Skin Sens. 1, H317. A GCL of 1 % and an elicitation limit of 0.1 % applies according to table 3.4.5 and 3.4.6 of CLP. The Guidance on the Application of the CLP Criteria, vers. 5.0, July 2017, p. 77 has been followed to determine the classification based on mixtures in mixtures. The [redacted] itself contains five components classified as skin sensitizers, two of which trigger skin sensitisation classification of the [redacted] mixture as the concentration is > GCL of 1%. The other three ingredients do not trigger skin sensitisation in [redacted]. Also, according to Guidance on the Application of the CLP Criteria, vers. 5.0, July 2017, p. 351 the additivity concept is not applicable for respiratory or skin sensitisation, i.e. if one single classified substance is present in the mixture above the generic or specific concentration limit, the mixture must be classified for that hazard. If the mixture contains two substances each below the generic or specific concentration limits, the mixture will not be classified. In meta SPC 1 and meta SPC 2 the maximum concentration of a single ingredient will be < 0.1 % in the mixture. Products do not warrant classification with respect to skin sensitisation and do not require a labelling phrase for elicitation with respect to sensitised individuals.
Classification of the product according to CLP and DSD	Not classified

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Products of meta SPC 3 are not classified.
Justification for the value/conclusion	Products of meta SPC 3 contain perfume Peppermint oil in the range of [redacted] %. According to the supplier SDS, Peppermint oil is classified as Skin Sens. 1, H317. A GCL of 1 % and an elicitation limit of 0.1 % applies according to table 3.4.5 and 3.4.6 of CLP. Products do not warrant classification with respect to skin sensitisation but do require a labelling phrase for elicitation with respect to sensitised individuals. EUH208: Contains (name of sensitising ingredient). May produce allergic reaction.
Classification of the product according to CLP and DSD	Labelling requirement: EUH208: Contains peppermint oil. May produce an allergic reaction.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Biocidal product family Lactic acid Family – Quatchem is not classified.
Justification for the value/conclusion	There are no components of the products that are classified for respiratory sensitisation or require a labelling phrase for elicitation with respect to sensitised individuals. No classification for respiratory sensitisation is justified.

Classification of the product according to CLP and DSD	Not classified

Acute toxicity

Acute toxicity by oral route

No animal or human data are available. Under CLP, in the absence of data, preparations may be classified for acute oral toxicity by calculation of acute toxicity estimate (ATE) of relevant ingredients. The category of toxicity of mixture is derived according to Table 3.1.1 of CLP. In accordance with section 3.1.3.3 of the CLP, it is assumed that the relevant ingredients of a mixture are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a reason to suspect that an ingredient present at a concentration of less than 1 % can still be relevant for classifying the mixture for acute toxicity.

According to CLP, the following formula for estimation of ATE for mixture is used:

$$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$$

where C i = concentration of ingredient i (%),

i = the individual ingredient from 1 to n,

n = the number of ingredients,

ATE i = Acute Toxicity Estimate of ingredient i.

ATEmix = Acute Toxicity Estimate of mixture.

It is therefore considered that additional animal studies are not required in order to avoid unnecessary suffering of animals.

Value used in the Risk Assessment – Acute oral toxicity	
Value	Biocidal product family Lactic acid Family – Quatchem is not classified.
Justification for the selected value	Biocidal product family contains one component that is classified for acute oral toxicity but are present below the generic cut-off value of 1 % and can thus be disregarded according to Regulation No 1272/2008 Annex I, table 1.1. Products do not warrant classification with respect to acute oral toxicity.
Classification of the product according to CLP and DSD	Not classified

Acute toxicity by inhalation

No animal or human data are available. Under CLP, in the absence of data, preparations may be classified for acute inhalation toxicity by calculation of acute toxicity estimate (ATE) of relevant ingredients. The category of toxicity of mixture is derived according to Table 3.1.1 of CLP. In accordance with section 3.1.3.3 of the CLP, it is assumed that the relevant ingredients of a mixture are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless

there is a reason to suspect that an ingredient present at a concentration of less than 1 % can still be relevant for classifying the mixture for acute toxicity.

According to CLP, the following formula for estimation of ATE for mixture is used:

$$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$$

where C_i = concentration of ingredient i (%)

i = the individual ingredient from 1 to n

n = the number of ingredients

ATE_i = Acute Toxicity Estimate of ingredient i

ATE_{mix} = Acute Toxicity Estimate of mixture

It is therefore considered that additional animal studies are not required in order to avoid unnecessary suffering of animals.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Biocidal product family Lactic acid Family – Quatchem is not classified.
Justification for the selected value	There are no components of the products that are classified for acute toxicity via the inhalation route and consequently no classification for acute inhalation toxicity is required.
Classification of the product according to CLP and DSD	Not classified

Acute toxicity by dermal route

No animal or human data are available. Under CLP, in the absence of data, preparations may be classified for acute dermal toxicity by calculation of acute toxicity estimate (ATE) of relevant ingredients. The category of toxicity of mixture is derived according to Table 3.1.1 of CLP. In accordance with section 3.1.3.3 of the CLP, it is assumed that the relevant ingredients of a mixture are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a reason to suspect that an ingredient present at a concentration of less than 1 % can still be relevant for classifying the mixture for acute toxicity.

According to CLP, the following formula for estimation of ATE for mixture is used:

$$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$$

where C_i = concentration of ingredient i (%)

i = the individual ingredient from 1 to n

n = the number of ingredients

ATE_i = Acute Toxicity Estimate of ingredient i

ATE_{mix} = Acute Toxicity Estimate of mixture

It is therefore considered that additional animal studies are not required in order to avoid unnecessary suffering of animals.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Biocidal product family Lactic acid Family – Quatchem is not classified.
Justification for the selected value	There are no components of the products that are classified for acute toxicity via the dermal route and consequently no classification for acute dermal toxicity is required.
Classification of the product according to CLP and DSD	Not classified

Information on dermal absorption

Value used in the Risk Assessment – Dermal absorption	
Substance	L(+)-lactic acid
Value(s)	Not relevant
Justification for the selected value(s)	Following the 1st Coordination Webex on UA-APPs on BPs with L(+)-lactic acid and Human health WG-I-2021 (discussion point 6.1.) meeting discussions it has been agreed not to perform the comparison of endogenous L-(+)-lactic acid with systemic exposure levels at product authorization. Therefore, any calculation regarding the estimation of level of exposure of L(+)-lactic acid does not need to be performed and dermal absorption value is not relevant. Therefore, for L(+)-lactic acid a semi-quantitative local risk assessment using the dermal NOAEC of 10% is performed when the meta SPC is not classified in order to prevent some irritating effects triggered by repeated exposure. When the meta SPC are classified for dermal effects (H315, H314), only a qualitative local risk assessment has been performed.

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 indicated in the annex A.

The biocidal product family Lactic Acid Family – Quatchem contains no substances of concern.

Available toxicological data relating to a mixture

Not relevant

Other

Endocrine disruption

For the assessment of endocrine-disrupting properties of co-formulants, please refer to the Section 3.6.3. of the Confidential annex to the PAR. Overall, none of the co-formulants are anticipated to have ED potential.

2.2.6.2 Exposure assessment

The biocidal product family Lactic acid Family - Quatchem comprises of three meta SPCs based on the active substance L(+)-lactic acid for the use as non-medical teat disinfectants in veterinary hygiene (PT3). The three meta SPCs includes four ready-to-use liquid products. The products are intended to be applied in the post-milking phase by manual dipping using a dip cup or hand-held sprayer. The products are for professional use only. Relevant animals to be treated comprise dairy cows, camels, goats and sheep.

Following the 1st Coordination Webex on UA-APPs on BPs with L(+)-lactic acid (28/01/2020) meeting 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.

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 Human health WG-I-2021 (discussion point 6.1), a semi-quantitative local risk assessment using the dermal NOAEC of 10% is performed when the meta SPC is not classified in order to prevent some irritating effects triggered by repeated exposure. When the meta SPC are classified for dermal effects (H315, H314), only a qualitative local risk assessment has been performed

Secondary exposure is not considered relevant due to the toxicological profile of the active substance.

Lactic acid Family - Quatchem is classified for skin proprieties: Skin Irrit. 2, H315, therefore, a qualitative local risk assessment is performed for this BPF.

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

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	**M/L phase**		
1.1	M/L phase: Manual mixing and loading of RTU product (dipping cup or hand-held sprayer)	The RTU product is filled undiluted into the reservoir of a dip cup or hand-held sprayer. Re-filling of a dip cup or of trigger sprayer is done analogously and covered by this scenario.	Professional
2.	**Application phase**		
2.1	Application phase: Manual spraying using a hand-held sprayer and a fixed reservoir	After milking, teats are sprayed with the hand-held sprayer making sure that each teat is covered with the disinfectant.	Professional
2.2	Application phase: Manual dipping using a dipping cup	After milking, the dipping cup is put over each teat from below making sure that the full length of each teat is immersed into the disinfectant.	Professional
3.	**Post-application phase**		
3.1	Post-application phase: Cleaning of teats and removal of dried residues post-milking	Cleaning of teats by wiping with a dry wipe before milking is only relevant if the cows have received a post-milking treatment. The disinfectant is expected to have completely dried up and either fallen off or rubbed off during the time span between treatment and cleaning. Any exposure to remains of the disinfectant on the teats is considered to be negligible.	Professional
3.2	Post application phase: Disposal of excess product	Only a small amount of product will remain in the application equipment, which will be further diluted by the wash-water.	Professional

3.3	Post application phase: Cleaning and maintenance of spraying/dipping equipment including tanks/reservoirs	After application, the reservoir is emptied, and the entire dipping or spraying equipment is cleaned with water. Only a small amount of product will remain in the application equipment, which will be further diluted by the wash-water.	Professional
4.	**Secondary exposure of professional bystanders**		
4.1	Secondary inhalation exposure of professional bystanders during manual teat disinfection (dip cup, hand held sprayer)	Inhalation exposure of professional bystanders towards the RTU product during manual teat disinfection using a dipping cup or hand-held sprayer is expected to be at maximum in the same range as for the person performing the task (i.e. during the application phase).	professional
5.	**Secondary exposure of general public**		
Not relevant.			

Industrial exposure

Not relevant.

Professional exposure

Scenario 1.1 - M/L phase: Manual mixing and loading of RTU product (dipping cup or hand-held sprayer)

Lactic acid Family - Quatchem is classified for skin irritation, therefore, a qualitative local risk assessment is performed.

Scenario 2.1: Application phase: Manual spraying using a hand-held sprayer and a fixed reservoir

Lactic acid Family - Quatchem is classified for skin irritation, therefore, a qualitative local risk assessment is performed.

Scenario 2.2: Application phase: Manual dipping using a dipping cup

Lactic acid Family - Quatchem is classified for skin irritation, therefore, a qualitative local risk assessment is performed.

Scenario 3.1: Post-application phase: Cleaning of teats and removal of dried residues post-milking

Lactic acid Family - Quatchem is classified for skin irritation, therefore, a qualitative local risk assessment is performed.

Scenario 3.2: Post application phase: Disposal of excess product

Lactic acid Family - Quatchem is classified for skin irritation, therefore, a qualitative local risk assessment is performed.

Scenario 3.3: Post application phase: Cleaning and maintenance of spraying/dipping equipment including tanks/reservoirs

Lactic acid Family - Quatchem is classified for skin irritation, therefore, a qualitative local risk assessment is performed.

Scenario 4.1 - Secondary inhalation exposure of professional bystanders during manual teat disinfection (dip cup, hand held sprayer)

Lactic acid Family - Quatchem is classified for skin irritation, therefore, a qualitative local risk assessment is performed.

Combined scenarios

Not considered based on the above mentioned.

Non-professional exposure

Not relevant.

Exposure of the general public

Not relevant.

Monitoring data

Not available.

Dietary exposure

L(+)-lactic acid is a naturally occurring alpha-hydroxy acid found in 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, AR, March 2017).

According to the assessment report for L(+)-lactic acid for PT3, no livestock exposure assessment has been performed and the following has been concluded regarding dietary risk assessment:

– Residues in food from the intended PT3 use are expected to be low compared to naturally occurring levels in food. Therefore, the intended use does not significantly contribute to consumer exposure to L(+)-lactic acid.

Information of non-biocidal use of the active substance

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).

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

Not relevant.

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

Not relevant.

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

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
AEL short-term	Not allocated – not necessary				
AEL medium-term	Not allocated – not necessary				
AEL long-term	Not allocated – not necessary				
ARfD	Not allocated – not necessary				
ADI	Not allocated – not necessary				
NOAEC dermal-acute, medium term, long term	concentration of 10% derived from the result of irritation/corrosion studies in rabbits*	10%	n.r.	n.r.	10%

*Derived from rabbit irritation/corrosion studies: 88% and 50 % L(+)-lactic acid were corrosive in rabbits (88 % were irritant in human patch tests); 10 % were non-irritant in rabbits and guinea pigs (range-finding Buehler test). As the rabbit is the most sensitive species it seems to be reasonable to assume that this concentration would be without effect on human skin.

Maximum residue limits or equivalent

Not relevant. No MRL set under regulations for veterinary medicinal products (EMA, 1996) and plant production products (inclusion in Annex IV of Regulation 396/2005).

Specific reference value for groundwater

No specific reference value for groundwater was established. Therefore, the European standard value of 0.1 µg/L for the maximum admissible concentration of pesticides in drinking water (Council Directive 98/83/EC) applies.

Risk for industrial users

Not applicable

Risk for professional users

Systemic effects

Because of very low systemic toxicity of L(+)-lactic acid the assessment is not necessary.

Local effects

The products of biocidal product family Lactic acid Family - Quatchem are classified as Skin Irrit. 2, H315 (Causes skin irritation) and Eye Dam. 1, H318 (Causes serious eye damage). As such, a user must wear suitable protective gloves and eye protection when handling the products.

As the products warrants classification with respect to local effects on skin and eyes, according to Guidance on the Biocidal Product Regulation, Volume III Human Health – Assessment and Evaluation (Parts B+C), version 4.0, December 2017 a qualitative local risk assessment is triggered.

PT 3 Primary Exposure / Professional use

Hazard		**Exposure**					**Risk**
Hazard category	*Effects in terms of C&L*	*Tasks, uses, processes*	*Potential exposure route*	*Frequency and duration of potential exposure*	*Potential degree of exposure*	*Relevant RMM & PPE*	*Conclusion*
HIGH	H318 H315	1. M/L phase; 2. Application phase; 3. Post-application phase; 4. Secondary exposure of professional bystanders	Skin, Eyes (splashes, hand to eye transfer)	More than few minutes but equal to or less than few hours per day	4 – 6.4 % L(+)-lactic acid	**Product characteristics:** - Labelling according to CLP - Clear use description - Technical data sheets provided along with product **Technical and organisational RMMs:** - Training for staff on good practice - Good standard of ventilation - Regular cleaning of equipment and work area - Minimisation of splashes and spills - Minimise number of staff exposed - Good standard of personal hygiene **PPE:** - Substance/task appropriate gloves - Chemical goggles	The risk is **acceptable**: + used for short duration; + low vapour exposure; + low amount used per event; + professionals using appropriate PPE; + proper instructions for use; + labelling according to CLP.

Conclusion

Acceptable risks are foreseen for professional using products of all meta SPCs and all scenarios.

The following RMMs are set for biocidal product family Lactic acid Family – Quatchem:

- The use of eye protection during handling of the product is mandatory;
- Avoid hand to eye transfer;
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

Risk for non-professional users

Not applicable

Risk for the general public

Not applicable

Risk for consumers via residues in food

Please see section ***"Dietary exposure"***.

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

Not relevant.
The biocidal product family Lactic acid Family – Quatchem contain only L(+)-lactic acid as the active substance.
The biocidal product family Lactic acid Family – Quatchem contain no substances of concern.

2.2.7 Risk assessment for animal health

The products of Lactic acid Family – Quatchem are intended to be used as post-milking disinfectants. For all products, *In Vitro* corrosion/irritation tests according to OECD guideline are available. When products are classified for dermal effects (H315, H314), only a qualitative local risk assessment has been performed.

A number of trials, on working farms in the UK, were undertaken to assess whether there was any evidence for adverse effects on the teats of lactating cows, after milking, that had been treated with either Synodex or Synofilm (i.e. used as recommended). The teats of the cows were examined pre- and post-milking. The methodology was that advocated by the Agriculture and Horticulture Development Board (AHDB) in the UK, which is a is a levy-funded, not-for-profit organisation working on behalf of Britain's dairy farmers. Details of the methodology can be found at https://dairy.ahdb.org.uk/.

- Application of the test material and dose level:

The test material was applied using teat dipping cup application as part of the standard milking process using the label application rates. Application rates of approximately 5ml per animal were used in teat dipping cups. Following application of the test material, animals were kept standing until the product had fully dried to ensure the highest level of protection. No further cleaning or product removal took place until the next milking timepoint.

- Observation method and duration:

The inspection of the cow's teat/udder was carried out approximately 3 minutes after application of the product as some redness is present for a short period following removal of the milking cluster. Scoring for general condition was performed using the generally accepted system that scores teat end condition on a scale of 0 to 4, with teats in the best condition scoring 0. Skin grading was performed using a scale from 0 to 3, with skin in the best condition scoring 0. Teat scoring was performed using visual observation by the same individual over the whole herd and every time it was done so that results are consistent. A good light source was provided to allow good observation. Any teat irregularities or lesions such as hyperkeratosis, cyanosis and oedema were noted.

- Scoring for irritation or corrosion:

0 – No redness, inflammation or lesions;
1 – Slight redness, inflammation or lesions (slight redness; faint, little different to normal colouring, maximum area 10% of the teat, reversible (disappears) within 30 minutes of application);
2 – Mild redness, inflammation or lesions (mild redness: distinct difference in colouration, visible from 1m distance, maximum area 50% of teat, reversible by next milking);
3 – Severe redness, inflammation or lesions (sever redness: highly coloured, visible from 2m distance, over 50% of teat, not reversible).
Scoring for redness is comparable to erythema and eschar laid out in the OECD 404 test method. The scoring employed is in line with the scoring required in the OECD test but without the score 4. Severe erythema (beef redness) to eschar formation preventing grading of erythema. Use of the product would be discontinued before this level of effect were observed.

- Scoring for teat condition:

There have been various attempts to devise a scoring system for dairy cow teats which can be used to ascertain the damage done by poor milking practices or badly set-up and maintained milking equipment which can indicate the likelihood of a cow being predisposed

to mastitis due to teat end condition. The generally accepted system scores teat end condition on a scale of 0 to 4, with teats in the best condition scoring 0:
0 - Defines a "perfect" teat end. The teat sphincter may be visible (a thickened ring around the teat orifice), the ring itself will be smooth;
1 - The teat orifice is slightly more open, appears rougher and has lost its circular appearance;
2 - Some small roughness appears in the form of keratin fronds, protruding up to 2mm from the raised teat orifice;
3 - A very rough orifice, with keratin protruding all around the teat sphincter;
4 - A rough keratin protrusion of up to 4mm, with the sphincter giving the impression of having been turned inside out.
Scoring is done using a good light source and any teat irregularities or lesions such as hyperkeratosis, cyanosis and oedema noted.
Only teats scoring 3 and 4 are likely to be subjected to an increased likelihood of mastitis, due to the increased potential of infection caused by the damage to the teat end.
All working farms that participated in the trials were monitored by a veterinary surgeon.

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
Field data No standard guideline, but data recorded and assessed in line with acceptable methods Reliability: -	Cows Cow breed: mixed 250 females	Farm: [redacted] Meta SPC 1: Synodex Active substance content: 4.0 % Dosing: as per label conditions (twice per day) Duration of field trial: 12 weeks	Teat score: 2 No sign of teat damage and no visible signs of irritation or soreness and no negative reactions	-	[redacted] ([redacted]) Ref No. [redacted]
Field data No standard guideline, but data recorded and assessed in line with	Cows Cow breed: mixed 220 females	Farm: [redacted] Meta SPC 1: Synodex Active substance	Teat score: 2 No sign of teat damage and no visible signs of irritation or soreness and no negative reactions	-	[redacted] ([redacted]) Ref No. [redacted]

acceptable methods Reliability: -		content: 4.0 % Dosing: as per label conditions (twice per day) Duration of field trial: 12 weeks			
Field data No standard guideline, but data recorded and assessed in line with acceptable methods Reliability: -	Cows Cow breed: Holstein Friesian 200 females	Farm: [redacted] Meta SPC 1: Synodex Active substance content: 4.0 % Dosing: as per label conditions (twice per day) Duration of field trial: 12 weeks Duration of extended field trial: 10 months	Teat score: 2 – 2.5 No sign of teat damage and no visible signs of irritation or soreness and no negative reactions		[redacted] ([redacted]) Ref No. [redacted]
Field data No standard guideline, but data recorded and assessed in line with acceptable methods Reliability: -	Cows Cow breed: Jersey / Holstein 145 females	Farm: [redacted] Meta SPC 2: Synofilm Active substance content: 6.4 % Dosing: as per label conditions (twice per day) Duration of field trial: 8 weeks	Teat score: 1 – 1.5 No sign of teat damage and no visible signs of irritation or soreness and no negative reactions	-	[redacted] ([redacted]) Ref No. [redacted]
Field data No standard guideline, but data recorded and assessed in line with acceptable methods	Cows Cow breed: Jersey / Holstein 200 females	Farm: [redacted] Meta SPC 2: Synofilm Active substance content: 6.4 % Dosing: as per label conditions	Teat score: 1 – 1.5 No sign of teat damage and no visible signs of irritation or soreness and no negative reactions	-	[redacted] ([redacted]) Ref No. [redacted]

Reliability: -		(twice per day) Duration of field trial: 4 weeks			
Field data No standard guideline, but data recorded and assessed in line with acceptable methods Reliability: -	Cows Cow breed: mixed 65 females	Farm: [redacted] Meta SPC 2: Synofilm Active substance content: 6.4 % Dosing: as per label conditions (twice per day) Duration of field trial: 4 weeks	Teat score: 1 – 1.5 No sign of teat damage and no visible signs of irritation or soreness and no negative reactions	-	[redacted] ([redacted]) Ref No. [redacted]

Field data from repeated use on cows show no evidence of irritation or damage to the skin of the udder.

Qualitative assessment

Summary table: estimated local exposure for animals							
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**
High	Skin Irrit. 2, H315 Eye Dam. 1, H318	Animal	Application of the product (dipping, spraying)	Skin Eye (low risk	Few minutes per day	RMM: application done by professional users.	Acceptable

Conclusion: no unacceptable risk for animal health is foreseen.

2.2.8 Risk assessment for the environment

The biocidal product family comprises of three meta SPCs based on the active substance L(+)-lactic acid for the use as non-medical teat disinfectants in veterinary hygiene (PT3). The three meta SPCs includes four ready-to-use liquid products. The products are intended to be used post-milking. They can be applied manually using dip cup or hand-held sprayer. The products are for professional use only.

2.2.8.1 Effects assessment on the environment

Information on classification:

There are valid data available on each of the components and synergistic effects between them are not expected. None of the components of the biocidal product meet neither criteria for being a persistent organic pollutant (POP) under Regulation (EC) No 850/2004, nor the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006.
L(+)-lactic acid is not classified with regards to aquatic toxicity. The biocidal product family contains one co-formulant that is classified as Aquatic Chronic 3, H412 (Harmful to aquatic life with long lasting effects) and one co-formulant that is classified as Aquatic Chronic 1, H410 (Very toxic to aquatic life with long lasting effects) that are above the generic cut-off values that are indicated in Annex I, table 1.1. of the Regulation No 1272/2008.
Other co-formulants that are classified with regards to aquatic toxicity are present below the generic cut-off value of 1 % and can thus be disregarded according to Regulation No 1272/2008 Annex I, table 1.1. Based on Regulation (EC) No 1272/2008 (CLP) section 4.1.3.5.5.4 and Table 4.1.2 the mixture does not require classification for Chronic Aquatic Toxicity.
Therefore, no substances of concern for the environment have been identified and there are no indications of risk due to specific properties of the biocidal products. Consequently environmental risk assessment have been performed based on data that were agreed during the approval of the active substances L(+)-lactic acid.
New studies according to OECD TG 301D and *in silico* on ready biodegradability of L(+)-lactic acid have been conducted and taken into account in the sections below.

Primary and secondary poisoning and bioaccumulation potential:

Primary poisoning is not relevant because the products are designed to be used indoors only, with limited quantities of active substance and limited frequency of use. As the products are not intended to be placed indiscriminately or broadcast in the environment and as the products will not be applied together with food attractants or in the form of granular baits; primary poisoning is unlikely.

The estimated log K_{ow} of L(+)-lactic acid is –0.74 indicating a low potential for bioconcentration in biota. Therefore, it is justified that accumulation of L(+)-lactic acid in the food chain is not expected, and the risk of secondary poisoning in aquatic and terrestrial predators is negligible.
In the following sections the environmental risk assessment is presented, in which all uses have been assessed in line with the available guidance documents and models, which are:

- Assessment Report for L(+)-lactic acid in product types 02, 03 and 04, eCA DE, March 2017 (referred to in the following as AR, March 2017);

- Guidance on the Biocidal Products Regulation, Volume IV Environment, Part A: Information Requirements, version 1.2, May 2018;
- Guidance on the Biocidal Products Regulation, Volume IV Environment – Assessment and Evaluation (Parts B+C), version 2.0, October 2017 (referred to in the following as Vol. IV, Part B+C);
- Technical guidance document on risk assessment, Part II, 2003 (TGD)
- Emission Scenario Document for PT3: Emission scenarios for veterinary hygiene biocidal products (JRC Scientific and Technical Reports, 2011);
- Technical Agreements for Biocides Environment, version 2.1, December 2019 (TAB, ENV);
- Environment Working Group II-2020 decision, point 7.4 Harmonised assessment of groundwater concentrations for lactic acid in product authorisations.

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 products within the biocidal product family. A summary of the PNEC values agreed in the Assessment Report for L(+)-lactic acid is presented in the following table.

PNEC	PNEC (from AR, March 2017)	Justification
STP	10 mg/L	Based on the respiration inhibition of activated sludge according to the OECD guideline 209 with applied assessment factor of 10.
Fresh water	3.9 mg/L	Based on experimental study on the inhibition on algal growth by applying an assessment factor of 1000.
Sediment	4.8 mg/kg$_{ww}$	Equilibrium partitioning method (EPM) according to the TGD on Risk assessment.
Soil	1.9 mg/kg$_{ww}$	
Groundwater	0.1 µg/L = 0.0001 mg/L	According to Directive 98/83/EC
Atmosphere	The vapour pressure of L(+)-lactic acid is 0.4 Pa at 20°C and the Henry constant is 3.6 x 10^{-5} indicating that direct evaporation and volatility from water are expected to be insignificant. In general, emissions of L(+)-lactic acid to the atmosphere are unlikely to occur.	
Bioaccumulation	Bioconcentration factors estimated with log Kow = -0.74 are found to be low BCF $_{fish}$ = 0.048 L/kg and BCF $_{earthworms}$ = 6.78 L/kg indicating a low potential for bioaccumulation.	

Further Ecotoxicological studies

Data waiving	
Information requirement	-
Justification	All information on the ecotoxicology of the products can be extrapolated from the information on the active substances and co-formulants. Ecotoxicity data for the active substances are summarised in the Competent Authority Report. No additional testing with the product is, therefore, considered necessary.

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

No data are available

Data waiving	
Information requirement	-
Justification	This is not a core data requirement. The products are intended for use indoors there will be no direct exposure of the environment.

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

No data are available

Data waiving	
Information requirement	-
Justification	The products are not in the form of a bait or granules and therefore this endpoint does not apply.

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

No data are available.

Data waiving	
Information requirement	-
Justification	The products are not in the form of a bait or granules and therefore this endpoint does not apply.

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

No data are available.

Data waiving	
Information requirement	-
Justification	The products are intended for use indoors therefore there will be no direct exposure of the environment.

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

The products are intended for use as non-medical teat disinfectants in veterinary hygiene for dairy cows and other milkable animals. All products within the biocidal product family are intended for indoor use only for the use as non-medical teat disinfectants in veterinary hygiene (PT3). The products are applied to the teats post-milking by dipping using a dip

cup or spraying using hand-held sprayer. According to the ESD for PT3, exposure to the environment is predominantly secondary, via liquid manure to soil or to surface water via the municipal sewer. According to the ESD for PT3 no exposure of the air compartment is foreseen and considering properties of the active substance it is scientifically justifiable that the exposure of the air compartment is assumed as negligible.

When applied post-milking, the products will only partly remain on the animal teats between two milking events. The part which simply falls off or is lost due to contact with the surfaces will finally end up in the liquid manure. The part remaining on the teats will be removed before the next milking by wiping with a dry cloth or a single paper towel. If disposable tissues are used, the product will end up in the waste bin.

Residues are also released to the environment during cleaning of the equipment such as dipping cup or hand-held sprayer. Considering that most farms are not connected to the municipal sewer, waste water is often released to the manure depot instead. If present, residues may be released to individual sewage treatment plants as well when equipment is for instance rinsed above sinks. In all other cases release to the municipal sewer and subsequently to a sewage treatment plant (STP) is most likely.

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

According to the AR, March 2017, L(+)-lactic acid degradation after 20 days was 60 and 67% at concentrations of 2 and 4 mg/l, respectively. However, the level of degradation within 10 days cannot be assessed. Therefore L(+)-lactic acid were classified as readily biodegradable but failing 10-days window criterion. However additional information obtained via a literature search shows that the current assessment of the biodegradation behaviour of the of L(+)-lactic acid in soil (default degradation half-live of 90-days) is overly conservative. Therefore for the product authorisation, a new study on the ready biodegradability with appropriate test design in order to address the 10-day window of L(+)-lactic acid was submitted by the applicant. The new study done according to OECD TG 301D was considered to be valid, all criteria for acceptability of the test were met. The biodegradation of L(+)-lactic acid did exceed 60% within a 10-day window.

Summary table on further studies on fate and behaviour in the environment						
Method, Guideline, GLP status, Reliability	Compartment	pH	Temp [°C]	Initial TS concentration, C_0[mg/l]	Biodegradation [%]	Reference
Ready Biodegradability of Lactic acid 80% food grade in a Closed Bottle Test, OECD TG 301D, GLP Reliability: 1	Aerobic activated sludge	7.2	22 ± 1 darkness	Test item: L(+)-lactic acid 80% food grade with purity 79.6% Test item was tested in duplicate at concentration of 5.06 mg/L corresponding to an oxygen demand of 4.32 mg O2/L based on ThOD of 0.853 mg oxygen per mg test item.	Biodegradation of test item reached in the mean 50% after 3 days of incubation and continuously increased to 71% after 14 days and 80% after 28 days. The percentage biodegradation did exceed 60% within the 10-day window. Test item therefore can be considered as ready biodegradable.	[redacted] ([redacted]) Ref No.: [redacted]
In silico prediction of Ready Biodegradability for L-(+)-lactic acid, EPISuite BIOWIN v4.10 module and VEGA Reliability: 2	Based on results using EPISuite BIOWIN v4.10 module and VEGA L(+)-lactic acid was predicted as readily biodegradable. The half-life for L(+)-lactic acid for bulk soil based on results from standardised biodegradation test results was calculated as 30 days.					[redacted] ([redacted]) Ref No.: [redacted]

Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment	
Value/conclusion	The biodegradation of L(+)-lactic acid did exceed 60% within 10-day window.
Justification for the value/conclusion	For the biocidal product family authorisation, a new study on ready biodegradability according to OECD 301D was submitted in order to address the 10-day window of L(+)-lactic acid.

Leaching behaviour (ADS)

Data waiving	
Information requirement	-
Justification	A leaching test is not required for this type of product.

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	-
Justification	No additional test on distribution and dissipation in the soil is needed on the basis of intended uses and available data on the L(+)-lactic acid. Therefore, distribution and dissipation in soil is expected to be the same as for the active substance. A new ready biodegradability study demonstrating that L(+)-lactic acid passes the 10-day window. This allows the use of a default DT50 of 30 days in soil for use in risk assessment.

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

Data waiving	
Information requirement	-
Justification	No additional test on distribution and dissipation in water and sediment is needed on the basis of intended uses and available data on the L(+)-lactic acid. Therefore, distribution and dissipation in water and sediment is expected to be the same as for the active substances. A new ready biodegradability study demonstrating that L(+)-lactic acid is ready biodegradable and passes the 10-day window. This allows the use of a default DT50 of 15 days in water and sediment for use in risk assessment.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	-
Justification	No further data are required.

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)

Data waiving	
Information requirement	-
Justification	The biocidal product will not be sprayed outside. Not relevant.

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

Data waiving	
Information requirement	-

Justification	The biocidal product will not be sprayed outside. Not relevant.

2.2.8.2 Exposure assessment

The biocidal product family consists of four formulations, which contain a maximum of 6.4% w/w L(+)-lactic acid. All formulations are ready-to-use products for use in PT3 (veterinary hygiene) as non-medicinal teat disinfectants; they are water-based products which are applied manually using dip cup or hand-held sprayer, post to milking. Products are applied for teat disinfection of milk producing animals (cows, camels, sheep, goats).

The exposure assessment considers the PT3 use as a non-medicinal teat dip disinfectant based on the average consumption approach, considering the maximum in use concentration of L(+)-lactic acid (6.4% w/w). Emission calculations were performed according to the PT3 ESD (2011) and taking into account amendments outlined in the TAB (v2.1, 2019).

Assessed PT	PT3
Assessed scenarios	One representative worst-case scenario was chosen using formulation with highest active substance concentration: Scenario PT3: Veterinary hygiene: non-medicinal teat dips
ESD(s) used	JRC 2011, Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products. ECHA 2019, Technical Agreements for Biocides Environment (ENV), version 2.1, December 2019.
Approach	average consumption
Distribution in the environment	Calculated based on BPR Guidance, Volume IV Environment, Assessment & Evaluation (Parts B + C)
Groundwater simulation	During the Environmental WG-II-2020 it was concluded that a quantitative assessment of L(+)-lactic acid in groundwater is not necessary. Arguments to support a qualitative assessment without further calculations are provided in the section 2.2.8.3.
Confidential Annexes	No
Life cycle steps assessed	Production: No, not required for this PT Formulation: No, not required for this PT Use: Yes Service life: No, covered by use step
Remarks	None

Emission estimation

Scenario PT3 – Veterinary hygiene: non-medicinal teat disinfection

The emission calculations considered the maximum active substance concentration in the products (6.4% w/w) for all products in the Meta group. According to the intended uses, the products can be applied manually using dip cup or hand-held sprayer.

According to the intended uses, biocidal products are used for teat disinfection of milk producing animals – cows, camels, sheep and goats. According to the ENV TAB (v2.1, ENV 61), cows are considered worst-case with reference to teat disinfection, as their herds are larger than those of buffaloes, sheep, and goats. In addition, cows have a higher number

of teats compared to other dairy species like sheep and goats, resulting in a lower consumption per treatment. In conclusion, the default values provided for cows are realistic case to cover also buffaloes, sheep and goats.

The products are applied at a maximum application rate of 10 ml product per teat, or 40 ml per cow (4 teats treated per animal). The maximum number of milking events per day is two.

According to the PT3 ESD (2011), a milking herd consists of 100 animals which lactate for 300 days per year. In the TAB (v2.1, ENV 63) it is agreed that the number of milk producing animals per day ($N_{mp\text{-}animal}$) contributing to emissions to slurry/manure is 82.

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks[1]**
Type of housing/manure storage (for application of the notification)	cat-subcat (i1)	'Dairy cows' i1 = 1	[-]	D (Appendix 1: Table 7, JRC 2011)
Type of biocide	bioctype (i2)	'Disinfectant' i2 = 1	[-]	D (Appendix 1: Table 7, JRC 2011)
Type of application	appway (i3)	'Spraying' i3 = 1 'Dipping' i3 = 2	[-]	D (Appendix 1: Table 7, JRC 2011)
Relevant emission stream	stream (i4)	'Manure' (i4 = 1); 'Waste water (wwater)' (i4 = 2) 'Slurry' (i4 = 3);	[-]	P (Appendix 1: Table 7, JRC 2011)
Content of active ingredient in formulation (product)	Fbioc	67.2*	g/l	S
Amount of product prescribed to be used for one treatment (dipping of the four teats) of one animal	$Vprod_{i1,i2,i3}$	0.04	l	S Products applied at rate of 10 ml per teat.
Dilution factor (for preparation of the working solution from the formulation (product))	F_{dil}	1	[-]	S The dilution factor is 1 as the formulation is ready-to-use solution.
Fraction of active ingredient released	$(F_{stp} = F_{ww})$ / F_{stp}	0.5	[-]	D

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks[1]**
	$F_{slurry/manure}$	0.5	[-]	D
	F_{air}	0	[-]	D
	F_{teat}	0.5	[-]	D
Number of teat dipping events for one animal and one day (dipping of the four teats of one animal = one disinfectant application)	Napp-teat	2	[-]	D
Number of days of lactation period (corresponds to number of emission days)	Nday-lact (= Temission)	300	[-]	D
Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period)	Napp-bioc	600	[-]	D (TAB v2.0, ENV 64: Napp-bioc = Napp-teat x Nday-lact)
Interval between two disinfectant applications (dipping events)	Tbioc-int	0.5	d	D (TAB v2.0, ENV 64: Tbioc-int = 1/Napp-teat)
Number of manure applications for grassland	Nlapp-grass	4	[-]	D
Number of manure applications for arable land	Nlapp-arab	1	[-]	D
Manure storage time interval for grassland	Tgr-int	53**	d	D (Appendix 1: Table 12, JRC 2011)
Manure storage time interval for arable land	Tar-int	212***	d	D (Appendix 1: Table 12, JRC 2011)
Number of animals in housing for category/subcategory i1 =1	$Nanimal_{i1}$	100	[-]	D (Appendix 1: Table 8, JRC 2011)
Number of milk producing animals per day	Nmp_animal	82	[-]	D (TAB v2.0, ENV 63)
Amount of phosphate per animal for category/subcategory i1 =1	$Qphosph_{i1}$	0.10466	kg/ animal/d	D (Appendix 1: Table 11, JRC 2011)

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks[1]**
Amount of nitrogen per animal for category/subcategory i1 =1	$Qnitrog_{i1}$	0.33890	kg/ animal/d	D (Appendix 1: Table 11, JRC 2011)
Applying nitrogen emission standards:				
Nitrogen emission standard for one year on grassland	$Q_{N,grassland}$	170	kg/ha	D (Appendix 1: Table 13, JRC 2011)
Nitrogen emission standard for one year on arable land	$Q_{N,arable\_land}$	170	kg/ha	D (Appendix 1: Table 13, JRC 2011)
Mixing depth with soil, grassland	$DEPTH_{grassland}$	0.05	m	D
Mixing depth with soil, arable land	$DEPTH_{arable\_land}$	0.20	m	D
Density of wet bulk soil	$RHOsoil_{wet}$	1700	kg/m^3	D

[1] S: data set; D: default; O: output; P: pick list

* Calculated based on a product density of 1.05 g/ml and a L(+)-lactic acid concentration of 6.4% w/w.

** As Tbioc-int < Tgr/ar-int, the 'Number of biocide applications during the storage period for application on grassland' (Napp-manuregr) is 106 (calculated from Napp-manuregr = Tgr-int/Tbioc-int).

*** As Tbioc-int < Tgr/ar-int, the 'Number of biocide applications during storage the period for application on arable land' (Napp-manurear) is 422 (calculated from Napp-manurear = Tar-int/Tbioc-int).

Calculations for Scenario PT3 – *Veterinary hygiene: non-medicinal teat disinfection*

Output	**Symbol**	**Value**	**Unit**	**Remarks[1]**
Soil exposure For stream *i4* = 1 and 3				
Concentration of the biocide (active ingredient) in soil (mg.kg-1) in the case of an imission standard for nitrogen and land application on grassland	$PIECgrs\text{-}N_{i1,i2,i3,i4}$	0.397	mg/kg_{wwt}	O
Concentration of the biocide (active ingredient) in soil (mg.kg-1) in the case of an imission standard for nitrogen and land application on arable land	$PIECars\text{-}N_{i1,i2,i3,i4}$	0.397	mg/kg_{wwt}	O
STP				
Local emission to a standard STP or an on-site waste water treatment plant	$Qai\text{-}stp_{i1,i2,i3,i4} = Elocal_{waste\ water}$	0.221	Kg/d	O

Further information and considerations on scenario PT3 - *Veterinary hygiene: non-medicinal teat disinfection*

The scenario in the ESD for PT3 results in an emission estimation, the calculation of the "$Elocal_{compartment}$" to the STP and the calculation for initial PEC (PIEC) values in the soil – grassland and arable land from the emission to manure/slurry.
The calculation sheets are provided in Annex 3.2.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water *	Seawater sediment *	STP	Air	Soil	Ground-water	Other
PT3 – teat disinfection: STP	(+)	(+)	-	-	+	-	(+)	(+)	-
PT3 – teat disinfection: manure/slurry	(+)	(+)	-	-	-	-	+	(+)	-
+ directly exposed / (+) indirectly exposed / - not exposed * Based on the intended use it can be concluded that the risk to the marine environment is considered to be negligible.									

In the case of release via the STP the distribution in the environment and resulting PEC values were calculated following Guidance on the Biocidal Products Regulation, Volume IV Environment – Assessment and Evaluation (Parts B+C), vers. 2.0, October 2017. The following table summarises active substance L(+)-lactic acid specific input parameters utilised in the following exposure assessment. All substance specific input parameters were obtained from the AR, March 2017 unless stated otherwise.

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	90.08	g/mol	AR, June 2017
Melting point	53.0	°C	AR, June 2017
Boiling point	204.2	°C	AR, June 2017
Vapour pressure	0.4	Pa (at 20 °C)	AR, June 2017
Water solubility	Completely miscible, 1E+05 mg/L at 20°C used for RA purposes	mg/l	AR, June 2017
Log Octanol/water partition coefficient	-0.74	Log 10 (at 20 °C)	AR, June 2017
Organic carbon/water partition coefficient (Koc)	20	l/kg	AR, June 2017
Henry's Law Constant	3.6×10^{-5}	Pa/m3/mol (at 20 °C)	AR, June 2017

Biodegradability	readily biodegradable		[redacted] ([redacted]) Ref No.: [redacted]
Rate constant for STP	1	h^{-1}	table 4, page 62, Guidance on BPR: Vol IV Environment Parts B+C ver. 2.0 October 2017
DT_{50} for biodegradation in surface water	No data		
DT_{50} for hydrolysis in surface water	No hydrolysis		AR, June 2017
DT_{50} for photolysis in surface water	Not applicable		AR, June 2017
DT_{50} for degradation in soil	30	days	table 6, page 67, Guidance on BPR: Vol IV Environment Parts B+C ver. 2.0 October 2017
DT_{50} for degradation in air	2.71	days	AR, June 2017
BCF fish	0.048	L/kg wwt	AR, June 2017
BCF earthworm	6.78	L/kg wwt	AR, June 2017

For L(+)-lactic acid, the distribution in the sewage treatment plants (STP) is calculated using Simple treat 4.0 version which is integrated in EUSES 2.2.0 version according to the TAB-ENV (Version 2, 2018) ENV #9. These results are present below:

Calculated fate and distribution in the STP – L(+)-lactic acid		
Compartment	Percentage [%]	Remarks
Air	1.09E-5	Calculated with EUSES 2.2.0 Simple Treat 4.0
Water	8.002	
Sludge	0.258	
Degraded in STP	91.73	

Calculated PEC values

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC seawater**	**PEC seased**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	mg/l	mg/l	mg/kg_{wwt}	mg/l	mg/kg_{wwt}	mg/kg_{wwt}	mg/l	mg/m^3
Via STP	0.009	0.0009	0.0011	-	-	7.4E-4	2.1E-6	-
Via manure/slurry – Concentrations after <u>one year,</u> nitrogen standard. Leaching from the top soil layer between two applications is considered.								
grassland	-	0.062	0.075	-	-	0.29	0.62	-

Arable land	-	0.058	0.071	-	-	0.27	0.58	-
Via manure/slurry – Concentrations after ten years, nitrogen standard. Leaching from the top soil layer between two applications is considered.								
grassland	-	0.062	0.075	-	-	0.29	0.62	-
Arable land	-	0.058	0.071	-	-	0.28	0.58	-

Primary and secondary poisoning

Primary poisoning

Primary poisoning is not relevant because the products are designed to be used indoors only, with limited quantities of active substance and limited frequency of use. As the products are not intended to be placed indiscriminately or broadcast in the environment and as the products will not be applied together with food attractant or in the form of granular baits; primary poisoning is unlikely.

Secondary poisoning

The estimated log K_{ow} of L(+)-lactic acid is –0.74 indicating a low potential for bioconcentration in biota. Therefore, it is justified that accumulation of L(+)-lactic acid in the food chain is not expected, and the risk of secondary poisoning in aquatic and terrestrial predators is negligible.

Summary table on Log K_{ow} and BCF values			
	Log K_{ow}	**BCF $_{fish}$**	**BCF $_{earthworm}$**
L(+)-Lactic acid	-0.74	0.048 L/kg	6.78 L/kg

2.2.8.3 Risk characterisation

In the risk assessment, when the PEC/PNEC values are calculated to be above 1, comparison with the natural background levels in the concerned compartment is made.

Atmosphere

Conclusion:

The vapour pressure of L(+)-lactic acid is 0.4 Pa at 20°C and the Henry constant is 3.6 x 10^{-5} indicating that direct evaporation and volatility from water are expected to be insignificant. In general, emissions of L(+)-lactic acid to the atmosphere are unlikely to occur.

Sewage treatment plant (STP)

L(+)-lactic acid: $PNEC_{STP}$ = 10 mg/L

Summary table on calculated PEC/PNEC values

	PEC/PNEC$_{STP}$
PT3 – teat disinfection: STP	0.0009

Conclusion: The PEC$_{STP}$/PNEC$_{STP}$ ratio is < 1, therefore, the use of L(+)-lactic acid for teat disinfection does not pose an unacceptable risk to microorganisms in the STP.

Aquatic compartment

L(+)-lactic acid: PNEC$_{freshwater}$ = 3.9 mg/L
L(+)-lactic acid: PNEC$_{sediment}$ = 4.8 mg/L

Summary table on calculated PEC/PNEC values				
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC seawater**	**PEC/PNEC$_{s}$ eased**
PT3 – teat disinfection: STP	0.00023	0.00022	-	-
PT3 – teat disinfection: manure/slurry - grassland	0.016	0.019	-	-
PT3 – teat disinfection: manure/slurry – arable land	0.015	0.018	-	-

Conclusion: The PEC$_{water}$/PNEC$_{water}$ and PEC$_{sed}$/PNEC$_{sed}$ ratios are < 1. It indicated that the risk to the aquatic compartment and sediment can be considered to be acceptable. Considering the intended use, it was concluded that risk to marine environment is considered to be negligible.

During Environmental WG-I-2022 (discussion point 7.8.), it was concluded that a quantitative assessment of L(+)-lactic acid in surface water (via STP and via manure) is not necessary such as for groundwater. The same argumentation as used for groundwater can be used for surface water (via STP and via manure).

The following justification was proposed and confirmed by the Working Group: *Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food constituent and also a growth regulator intended to increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L(+) lactic acid naturally occurs as a fermentation by-product of anaerobic degradation of organic matter. This substance may covalent bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD+ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations (tier*

1). Modelling of groundwater exposure in case of lactic acid largely overestimates concentrations and is considered unrealistic. For all these reasons, it can be stated that lactic acid does not cause unacceptable risk for groundwater and no further calculations are needed.

Terrestrial compartment

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
PT3 – teat disinfection: STP	5.1E-7
PT3 – teat disinfection: manure/slurry - grassland	0.15
PT3 – teat disinfection: manure/slurry – arable land	0.14

Conclusion: The PEC$_{soil}$/PNEC$_{soil}$ ratio for soil remains well below the trigger value of 1, indicating no risk for the soil.

During Environmental WG-III-2021 (discussion point 7.2.), it was concluded that a quantitative assessment of L(+)-lactic acid in soil is not necessary such as for groundwater. The same argumentation as used for groundwater can be used for soil.

The following justification was proposed and confirmed by the Working Group: *Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food constituent and also a growth regulator intended to increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L(+) lactic acid naturally occurs as a fermentation by-product of anaerobic degradation of organic matter. This substance may covalent bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD+ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations (tier 1). Modelling of groundwater exposure in case of lactic acid largely overestimates concentrations and is considered unrealistic. For all these reasons, it can be stated that lactic acid does not cause unacceptable risk for groundwater and no further calculations are needed.*

Groundwater

The predicted concentration of the active substance L(+)-lactic acid in groundwater exceeds the quality standard for plant protection products and biocidal products according to Directive 2006/118/EC for drinking water (0.1 µg/L).

The assessment of groundwater concentrations for L-(+)-lactic acid was discussed at Environmental Working Group. According to the Environmental WG-II-2020, discussion point 7.4 "Harmonised assessment of groundwater concentrations for lactic acid": *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 groundwater is not necessary; only arguments to support a qualitative assessment without further calculations should be provided*.

The following justification was proposed and confirmed by the Working Group: *Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food constituent and also a growth regulator intended to increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L(+) lactic acid naturally occurs as a fermentation by-product of anaerobic degradation of organic matter. This substance may covalent bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD+ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations (tier 1). Modelling of groundwater exposure in case of lactic acid largely overestimates concentrations and is considered unrealistic. For all these reasons, it can be stated that lactic acid does not cause unacceptable risk for groundwater and no further calculations are needed.*

Primary and secondary poisoning

Primary poisoning

Primary poisoning is not relevant because the products are designed to be used indoors only, with limited quantities of active substance and limited frequency of use. As the products are not intended to be placed indiscriminately or broadcast in the environment and as the products will not be applied together with food attractant or in the form of granular baits; primary poisoning is unlikely.

Secondary poisoning

The estimated log K_{ow} of L(+)-lactic acid is –0.74 indicating a low potential for bioconcentration in biota. Therefore, it is justified that accumulation of L(+)-lactic acid in the food chain is not expected, and the risk of secondary poisoning in aquatic and terrestrial predators is negligible.

Summary table on Log K_{ow} and BCF values			
	Log K_{ow}	**BCF $_{fish}$**	**BCF $_{earthworm}$**
L(+)-lactic acid	-0.74	0.048 L/kg	6.78 L/kg

Mixture toxicity

An assessment regarding the mixture toxicity has been performed according to the Guidance on BPR: Vol IV Environment Parts B+C, Version 2.0 October 2017.

Screening step

Screening Step 1: Identification of the concerned environmental compartments

Concerned environmental compartments (likely to be at risk): STP (direct), freshwater (indirect), freshwater sediment (indirect), soil (direct) and groundwater (indirect).

Screening Step 2: Identification of relevant substances

Refer to the Confidential Annex for full details of the products.

The active substance in the products is L(+)-lactic acid.

The formulations do not contain substances that are classified as hazardous to the environment, or meet the criteria to be classified as hazardous to the environment, according to Regulation (EC) No 1272/2008, and that are present in the biocidal products at a concentration leading to the product to be regarded as hazardous to the environment.

The formulations do not contain substances that meet the criteria for being persistent organic pollutants (POP) under Regulation (EC) No 850/2004, or which meet the criteria for being persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006.

The formulations do not contain substances that represent 'other grounds for concern' to the environment such as – active substances from other PTs, substances with synergistic effects or bioavailability.

As no substances of concern for the environment have been identified according to Article 3(f) of the BPR, only the active substance L(+)-lactic acid is relevant for consideration in the risk assessment for the environment.

Screening Step 3: Screen on synergistic interactions

According to the tables 57 and 58 of Appendix 11 of the Guidance on the Biocidal Products Regulation Volume IV Environment – Assessment and Evaluation (Parts B+C) Vers. 2.0, October 2017, synergisms between active substance and other co-formulants is not expected. Additionally, synergistic interactions between the product constituents are not indicated in the literature.

Screening step	
Y	Significant exposure of environmental compartments? (Y/N)
N	Number of relevant substances >1? (Y/N)
N	Indication for synergistic effects for the product or its constituents in the literature? (Y/N)

Conclusion: There are no substances of concern for the environment within the formulations and synergistic interactions between the constituents is not anticipated. Therefore, the risk to the environment from the use of the Lactic acid Family - Quatchem

formulations is addressed by the risk assessment for the active substance presented above. No further consideration of mixture toxicity is necessary.

Aggregated exposure (combined for relevant emission sources)

Conclusion: The discussion regarding the necessity of the aggregated exposure for L(+)-lactic acid was already included in the AR, March 2017. L(+)-lactic acid is approved for use in biocidal products in PT 1, 2, 3, 4, and notified for PT6. Although the active substance is used in several PTs where use and emissions could overlap in time and space, it was concluded that no aggregated exposure is necessary due to the fact the L(+)-lactic acid is also regulated in other regulatory areas under the cosmetic and food regulations. In addition, the amount of L(+)-lactic acid that is used annually for biocidal purposes amounts to 5 % of the total production and import volume of L(+)-lactic acid in the EU in 2012. Thus, the biocidal use of L(+)-lactic acid accounts for less than 10 % of the total production and import volume in the EU. The intended uses are widely dispersive and do not represent a specific emission pattern. Consequently, it has been concluded that no aggregated exposure assessment for active substance L(+)-lactic acid has to be performed.

Overall conclusion on the risk assessment for the environment of the product
The biocidal product family comprises of three meta SPCs based on the active substance L(+)-lactic acid for the use as non-medical teat disinfectants in veterinary hygiene (PT3). The three meta SPCs includes four ready-to-use liquid products. The products are intended to be used post-milking. They can be applied manually using dip cup or hand-held sprayer. The products are for professional use only. The biocidal product family contains L(+)-lactic acid in range 4.0 – 6.4 % w/w (as pure). A new ready biodegradation study has been carried out to show that L(+)-lactic acid passes the 10-day window, so a DT50 of 30 days in soil can be applied for risk assessment. The resulting PEC/PNEC ratios confirm that no unacceptable risk is identified. Acceptable levels of risk have been demonstrated for the proposed use of the biocidal product to the environmental compartments STP, surface water, sediment, and soil. The estimated concentration in groundwater exceeds the quality standard for plant protection products and biocidal products according to Directive 2006/118/EC for drinking water (0.1 µg/L). However, this exceedance is not relevant due to the natural abundance in humans, animals, and microorganisms.

2.2.9 Measures to protect man, animals and the environment

Please see Summary of Products Characteristics (SPC) of the Biocidal product Family.

2.2.10 Assessment of a combination of biocidal products

The biocidal product is not intended to be used in combination with other biocidal products.

2.2.11 Comparative assessment

Not relevant. L(+)-lactic acid is not candidate for substitution. As a result, a comparative assessment is not required.

3 Annexes

3.1 List of studies for the biocidal product family

Author(s)	Year	Title	Report no.	Legal entity Owner	Report date	GLP	Data Protection Claimed (Yes/No)
[redacted]	2020	Report Synodex: Determination of Low Temperature Stability	[redacted]	QuatChem	23 March 2020	yes	yes
[redacted]	2019	Report Synofilm: Determination of Accelerated Storage Stability	[redacted]	QuatChem	08 March 2019	yes	Yes
[redacted]	2019	Report Synoshield: Determination of Accelerated Storage Stability	[redacted]	QuatChem	24 May 2019	yes	yes
[redacted]	2020	Determination of colour and odour characteristics of the lactic acid formulations in meta-SPC 1	[redacted]	QuatChem	14 August 2020	no	yes
[redacted]	2020	Determination of colour characteristics of the lactic acid formulations in meta-SPC 1	[redacted]	QuatChem	14 August 2020	no	yes
[redacted]	2020	Determination of colour and odour characteristics of the lactic acid formulations in meta-SPC 2	[redacted]	QuatChem	14 August 2020	no s	yes
[redacted]	2020	Determination of colour and odour characteristics of the lactic acid formulations in meta-SPC 3	[redacted]	QuatChem	14 August 2020	no	yes
[redacted]	2020	Report Synodex: Determination of Accelerated Storage Stability	[redacted]	QuatChem	13 August 2020	yes	yes
[redacted]	2018	Report Synoshield: Determination of Physico-Chemical Properties	[redacted]	QuatChem	13 November 2018	yes	yes
[redacted]	2019	Report Synofilm: Determination of Physico-Chemical Properties	[redacted]	QuatChem	11 January 2019	yes	Yes
[redacted]	2020	Report Synoshield: Determination of	[redacted]	QuatChem	15 December	yes	Yes

Author(s)	Year	Title	Report no.	Legal entity Owner	Report date	GLP	Data Protection Claimed (Yes/No)
		Long-Term Storage Stability			2020		
[redacted]	2021	Report Synofilm: Determination of Long-Term Storage Stability	[redacted]	QuatChem	01 April 2021	yes	yes
[redacted]	2020	Report Synodex: classification of Corrosion to Metals	[redacted]	QuatChem	05 February 2020	yes	yes
[redacted]	2020	Report Synofilm: classification of Corrosion to Metals	[redacted]	QuatChem	04 March 2020	yes	yes
[redacted]	2020	Report Synoshield: classification of Corrosion to Metals	[redacted]	QuatChem	04 March 2020	yes	yes
[redacted]	2019	Report Synofilm: Analytical Method Validation	[redacted]	QuatChem	12 March 2019	yes	Yes
[redacted]	2019	Report Synoshield: Analytical Method Validation	[redacted]	QuatChem	21 March 2019	yes	Yes
[redacted]	2020	Test Report: Modified EN 16437 2014 Chemical disinfectants and antiseptics – Quantitative surface test for evaluation of bactericidal activity of chemical and antiseptics used in the veterinary area on porous surfaces without mechanical action – Test method and requirements (Phase 2, step 2)	[redacted]	Quat-Chem Limited	28 January 2020	Yes	Yes
[redacted]	2018	Test Report BSEN 1656:2009, Bactericidal activity	[redacted]	Quat-Chem Limited	28 July 2018	Yes	Yes
[redacted]	2018	Test Report BSEN 1657:2016, Yeasticidal activity	[redacted]	Quat-Chem Limited	28 July 2018	Yes	Yes
[redacted]	2020	Test Report: Modified EN 16437 2014 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of	[redacted]	Quat-Chem Limited	28 January 2020	Yes	Yes

Author(s)	Year	Title	Report no.	Legal entity Owner	Report date	GLP	Data Protection Claimed (Yes/No)
		chemical disinfectants and antiseptics used in the veterinary area on porous surfaces without mechanical action – Test method and requirements (phase 2, step 2)					
[redacted]	2019	Laboratory Report	[redacted]	Quatchem	24 January 2019	Yes	Yes
[redacted]	2018	Test Report BSEN 1656:2009, Bactericidal activity	[redacted]	Quat-Chem Limited	28 July 2018	Yes	Yes
[redacted]	2018	Test Report BSEN 1657:2016, Yeasticidal activity	[redacted]	Quat-Chem Limited	28 July 2018	Yes	Yes
[redacted]	2020	Test Report: Modified EN 16437 2014 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on porous surfaces without mechanical action – Test method and requirements (phase 2, step 2)	[redacted]	Quat-Chem Limited	28 January 2020	Yes	Yes
[redacted]	2019	Laboratory Report	[redacted]	Quatchem	24 January 2019	Yes	Yes
[redacted]	2019	Test Report: Modified EN 16437 2014 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on porous surfaces without mechanical action – Test method and requirements (phase 2, step 2)	[redacted]	Arrow Regulatory	11 October 2019	Yes	Yes
[redacted]	2019	Test Report: Modified EN 16437 2014 Chemical disinfectants and antiseptics –	[redacted]	Arrow Regulatory	11 October 2019	Yes	Yes

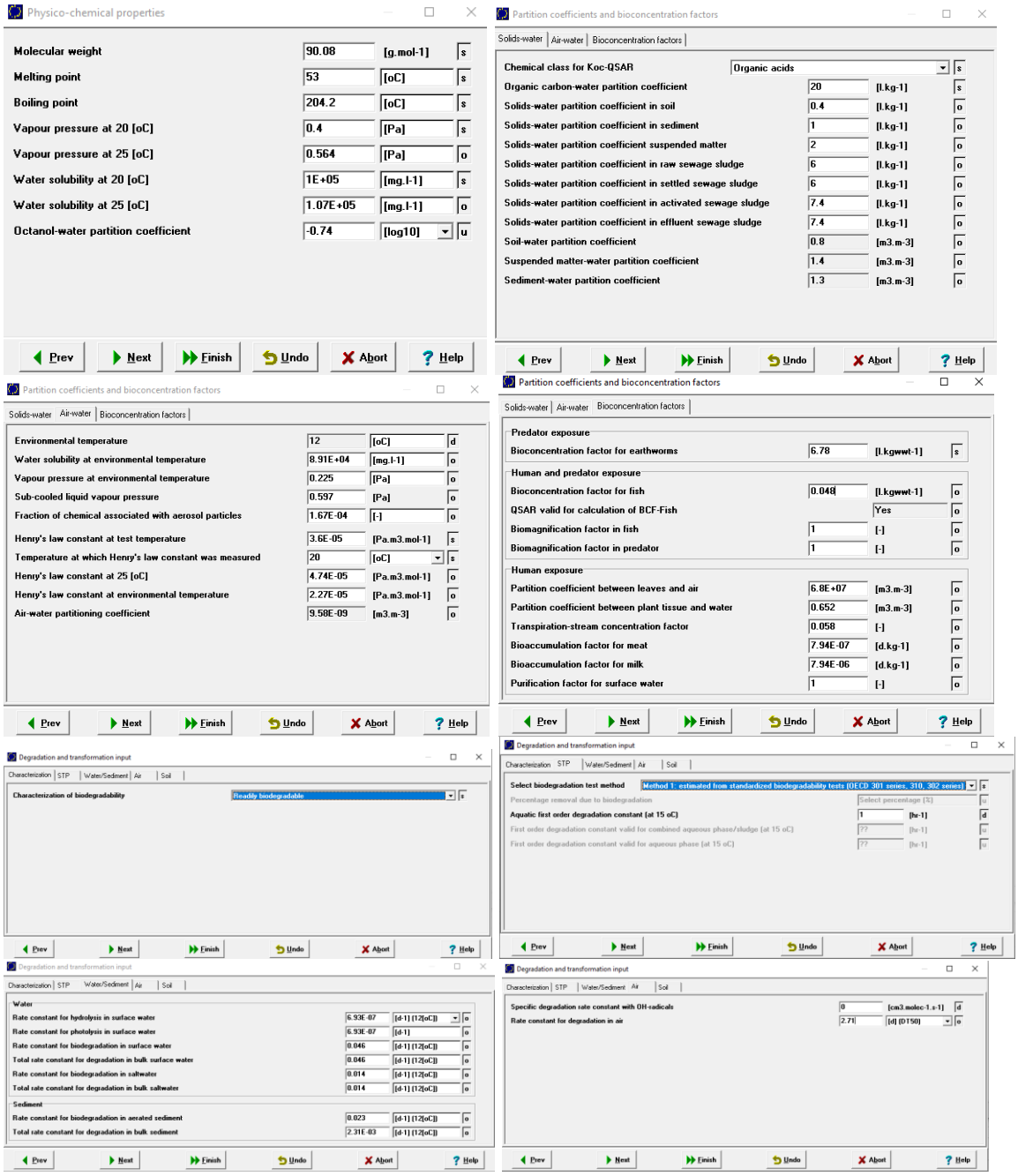
Author(s)	Year	Title	Report no.	Legal entity Owner	Report date	GLP	Data Protection Claimed (Yes/No)
		Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on porous surfaces without mechanical action – Test method and requirements (phase 2, step 2)					
[redacted]	2022	EN 17422:2022 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of teat disinfectants used in the veterinary are – Test method and requirements (phase 2, step 2) 22F/028 Synofilm	[redacted]	Quat-Chem Ltd	12 September 2022	Yes	Yes
[redacted]	2022	EN 17422:2022 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of teat disinfectants used in the veterinary are – Test method and requirements (phase 2, step 2) 22G/047 Synodex	[redacted]	Quat-Chem Ltd	12 September 2022	Yes	Yes
[redacted]	2022	EN 17422:2022 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of teat disinfectants used in the veterinary are – Test method and requirements (phase 2, step 2) 22G/095 Synoshield	[redacted]	Quat-Chem Ltd	12 September 2022	Yes	Yes
[redacted]	2022	prEN 17422:2022 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of teat disinfectants used in the veterinary are – Test method and requirements (phase 2, step 2)	[redacted]	Quat-Chem Ltd	5 August 2022	Yes	Yes

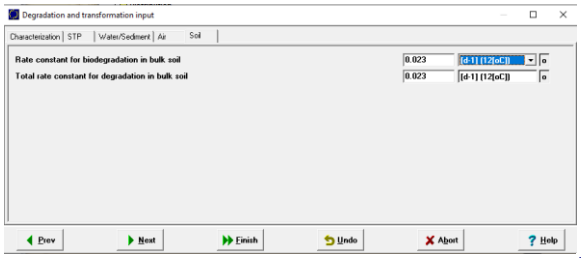
Author(s)	Year	Title	Report no.	Legal entity Owner	Report date	GLP	Data Protection Claimed (Yes/No)
		22G/047 Synoshield					
[redacted]	2022	prEN 17422:2022 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of teat disinfectants used in the veterinary are – Test method and requirements (phase 2, step 2) 22F/028 Synoshield	[redacted]	Quat-Chem Ltd	22 July 2022	Yes	Yes
[redacted]	2022	prEN 17422:2022 Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of teat disinfectants used in the veterinary are – Test method and requirements (phase 2, step 2) 22G/095 Synoshield	[redacted]	Quat-Chem Ltd	19 August 2022	Yes	Yes
[redacted]	2020	*In Vitro* Assessment of the Skin Corrosion Potential of Synofilm according to OECD Test Guideline 431 (reconstructed human epidermis (RHE) Test Method)	[redacted]	Quatchem	4 February 2020	Yes	Yes
[redacted]	2020	*In Vitro* Assessment of the Skin Irritation Potential of 1 test item according to OECD Test Guidline 439 (Reconstructed Human Epidermis Test Method)	[redacted]	Quatchem Limited	4 February 2020	Yes	Yes
[redacted]	2020	*In Vitro* Assessment of the Skin Irritation Potential of 1 test item according to OECD Test Guidline 439 (Reconstructed Human Epidermis Test Method)	[redacted]	Quatchem Limited	4 February 2020	Yes	Yes
[redacted]	2020	*In Vitro* Assessment of the Skin Irritation Potential of 1 test item according to OECD Test Guidline 439	[redacted]	Quatchem Limited	4 February 2020	Yes	Yes

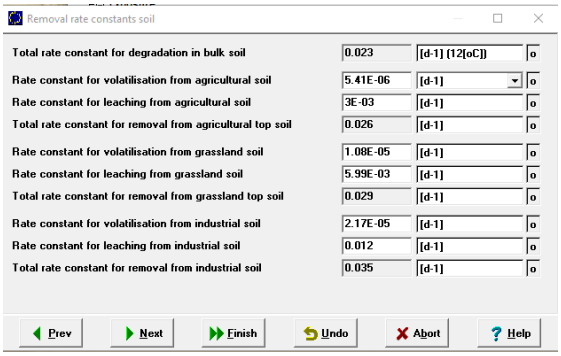
Author(s)	Year	Title	Report no.	Legal entity Owner	Report date	GLP	Data Protection Claimed (Yes/No)
		(Reconstructed Human Epidermis Test Method)					
[redacted]	2019	On-site product trial feedback, Farm: [redacted]	[redacted]	Quatchem Limited	10 January 2019	-	Yes
[redacted]	2019	On-site product trial feedback, Farm: [redacted]	[redacted]	Quatchem Limited	10 January 2019	-	Yes
[redacted]	2019	On-site product trial feedback, Farm: [redacted]	[redacted]	Quatchem Limited	10 January 2019	-	Yes
[redacted]	2019	On-site product trial feedback, Farm: [redacted]	[redacted]	Quatchem Limited	3 May 2019	-	Yes
[redacted]	2020	Field Trial for *In Vivo* Skin irritation of Synofilm in milking cows [redacted]	[redacted]	Quatchem Limited	11 November 2019	-	Yes
[redacted]	2019	On-site product trial feedback, Farm: [redacted]	[redacted]	Quatchem Limited	3 May 2019	-	Yes
[redacted]	2018	Ready Biodegradability of Lactic acid 80% food grade in a Closed Bottle Test	[redacted]	Jungbunzlauer International AG	22 November 2018	Yes	Yes
[redacted]	2018	*In silico* prediction of Ready Biodegradability for L-(+)-lactic acid	[redacted]	Jungbunzlauer S.A.	6 December 2018	Yes	Yes

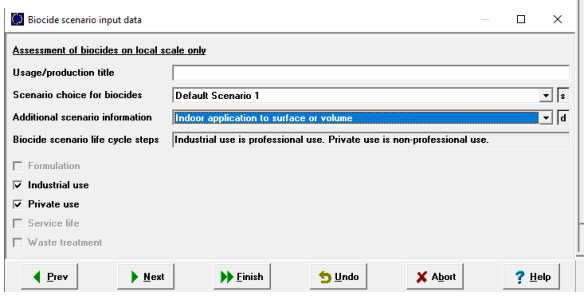
3.2 Output tables from exposure assessment tools

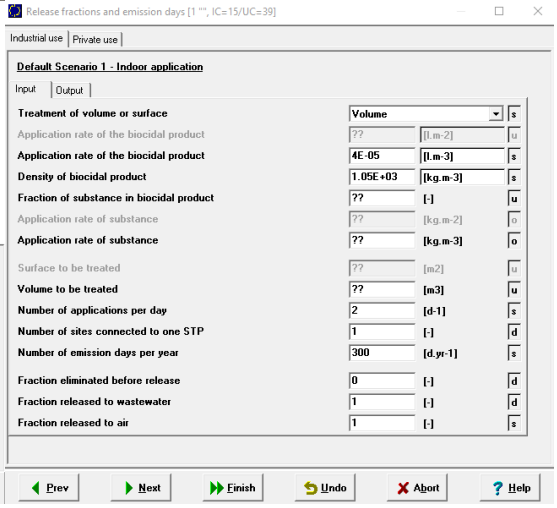
Input - output parameters / EUSES 2.2.0 / Average consumption based approach / Calculated fate and distribution in the STP

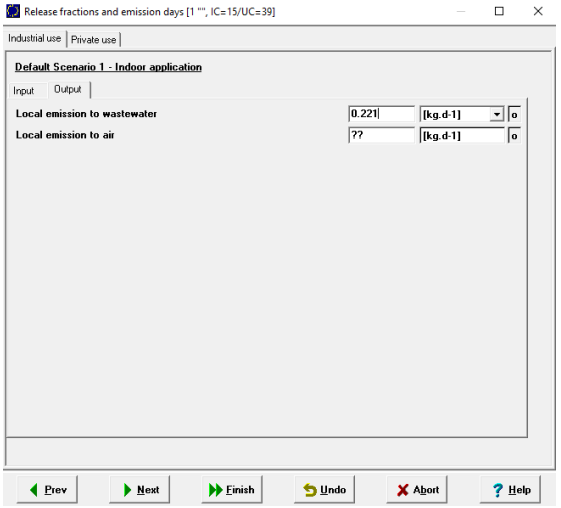


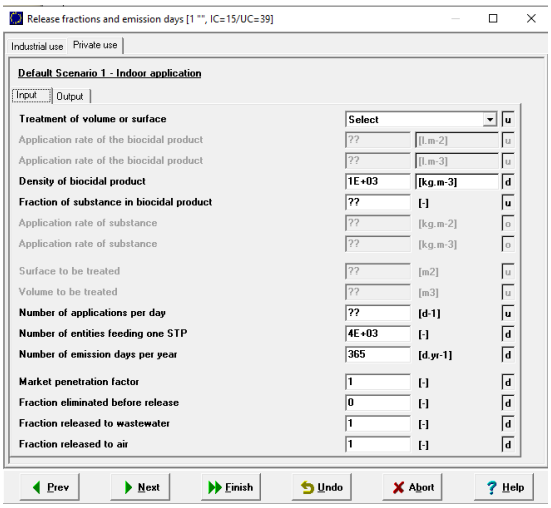

Degradation and transformation input
Characterization | STP | Water/Sediment | Air | Soil
Rate constant for biodegradation in bulk soil
0.023
[d-1] (12[oC])
Total rate constant for degradation in bulk soil
0.023
[d-1] (12[oC])
Prev
Next
Finish
Undo
Abort
Help

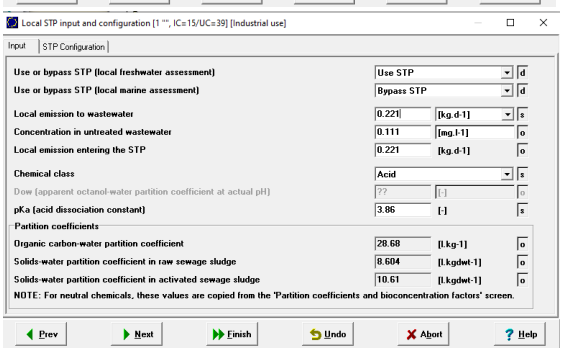

Removal rate constants soil
Total rate constant for degradation in bulk soil 0.023 [d-1] (12[oC])
Rate constant for volatilisation from agricultural soil 5.41E-06 [d-1]
Rate constant for leaching from agricultural soil 3E-03 [d-1]
Total rate constant for removal from agricultural top soil 0.026 [d-1]
Rate constant for volatilisation from grassland soil 1.08E-05 [d-1]
Rate constant for leaching from grassland soil 5.99E-03 [d-1]
Total rate constant for removal from grassland top soil 0.029 [d-1]
Rate constant for volatilisation from industrial soil 2.17E-05 [d-1]
Rate constant for leaching from industrial soil 0.012 [d-1]
Total rate constant for removal from industrial soil 0.035 [d-1]
Prev
Next
Finish
Undo
Abort
Help

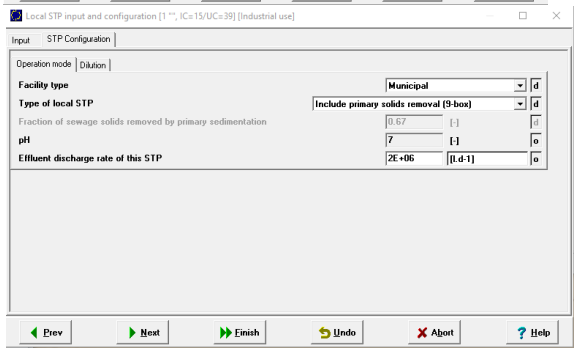

Biocide scenario input data
Assessment of biocides on local scale only
Usage/production title
Scenario choice for biocides Default Scenario 1
Additional scenario information Indoor application to surface or volume
Biocide scenario life cycle steps Industrial use is professional use. Private use is non-professional use.
Formulation
Industrial use
Private use
Service life
Waste treatment
Prev
Next
Finish
Undo
Abort
Help

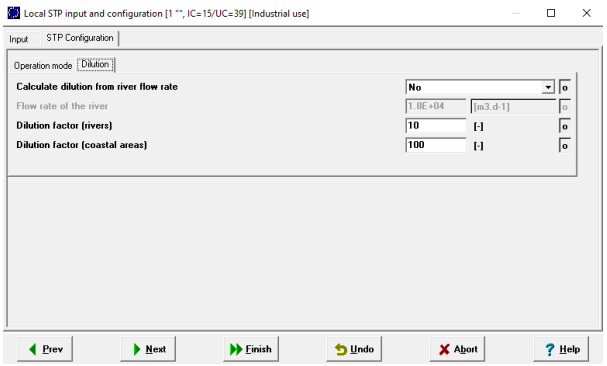

Release fractions and emission days [1 "", IC=15/UC=39]
Industrial use | Private use
Default Scenario 1 - Indoor application
Input | Output
Treatment of volume or surface Volume
Application rate of the biocidal product ?? [l.m-2]
Application rate of the biocidal product 4E-05 [l.m-3]
Density of biocidal product 1.05E+03 [kg.m-3]
Fraction of substance in biocidal product ?? [-]
Application rate of substance ?? [kg.m-2]
Application rate of substance ?? [kg.m-3]
Surface to be treated ?? [m2]
Volume to be treated ?? [m3]
Number of applications per day 2 [d-1]
Number of sites connected to one STP 1 [-]
Number of emission days per year 300 [d.yr-1]
Fraction eliminated before release 0 [-]
Fraction released to wastewater 1 [-]
Fraction released to air 1 [-]
Prev
Next
Finish
Undo
Abort
Help

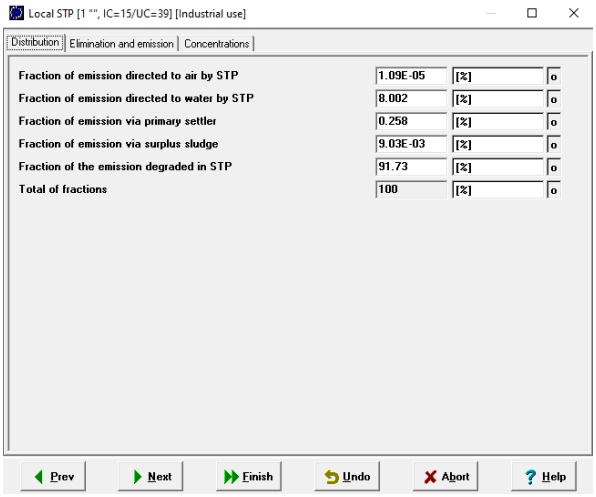

Release fractions and emission days [1 "", IC=15/UC=39]
Industrial use | Private use
Default Scenario 1 - Indoor application
Input | Output
Local emission to wastewater 0.221 [kg.d-1]
Local emission to air ?? [kg.d-1]
Prev
Next
Finish
Undo
Abort
Help


Release fractions and emission days [1 "", IC=15/UC=39]
Industrial use | Private use
Default Scenario 1 - Indoor application
Input | Output
Treatment of volume or surface Select
Application rate of the biocidal product ?? [l.m-2]
Application rate of the biocidal product ?? [l.m-3]
Density of biocidal product 1E+03 [kg.m-3]
Fraction of substance in biocidal product ?? [-]
Application rate of substance ?? [kg.m-2]
Application rate of substance ?? [kg.m-3]
Surface to be treated ?? [m2]
Volume to be treated ?? [m3]
Number of applications per day ?? [d-1]
Number of entities feeding one STP 4E+03 [-]
Number of emission days per year 365 [d.yr-1]
Market penetration factor 1 [-]
Fraction eliminated before release 0 [-]
Fraction released to wastewater 1 [-]
Fraction released to air 1 [-]
Prev
Next
Finish
Undo
Abort
Help


Local STP input and configuration [1 "", IC=15/UC=39] [Industrial use]
Input | STP Configuration
Use or bypass STP (local freshwater assessment) Use STP
Use or bypass STP (local marine assessment) Bypass STP
Local emission to wastewater 0.221 [kg.d-1]
Concentration in untreated wastewater 0.111 [mg.l-1]
Local emission entering the STP 0.221 [kg.d-1]
Chemical class Acid
Dow (apparent octanol-water partition coefficient at actual pH) ?? [-]
pKa (acid dissociation constant) 3.86 [-]
Partition coefficients
Organic carbon-water partition coefficient 28.68 [l.kg-1]
Solids-water partition coefficient in raw sewage sludge 8.604 [l.kgdwt-1]
Solids-water partition coefficient in activated sewage sludge 10.61 [l.kgdwt-1]
NOTE: For neutral chemicals, these values are copied from the 'Partition coefficients and bioconcentration factors' screen.
Prev
Next
Finish
Undo
Abort
Help


Local STP input and configuration [1 "", IC=15/UC=39] [Industrial use]
Input | STP Configuration
Operation mode | Dilution
Facility type Municipal
Type of local STP Include primary solids removal (9-box)
Fraction of sewage solids removed by primary sedimentation 0.67 [-]
pH 7 [-]
Effluent discharge rate of this STP 2E+06 [l.d-1]
Prev
Next
Finish
Undo
Abort
Help





ENV_PT03_TeatDip_
LacticAcid_MAy_202

3.3 New information on the active substance

Not applicable

3.4 Residue behaviour

Not applicable

3.5 Confidential annex

The Confidential annex is included in the dossier as a separate file.