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

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

(submitted by the evaluating Competent Authority)

[Famille de produits Acide Lactique TP3 - QUARON]

Product type(s) [3]

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

Case Number in R4BP: [BC-MB051287-49]

Evaluating Competent Authority: [FRANCE]

Date: [September 2023]

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DISCLAIMER

This dossier was submitted at the same time than the dossier Famille de produits Acide lactique TP3 – HYDRACHIM (BC-QX051284-07). The data provided by the applicant of each dossier were the same for both applications. As a consequence, only one assessment was performed by the rMS and the two PARs are identical (except administrative information related to each application).

For the sake of consistancy, even though cMSs are not the same for both applications, peer review of both dossiers is launched simultaneously and the results of the evaluation of Famille de produits Acide lactique TP3 – HYDRACHIM will be applied to the dossier Famille de produits Acide Lactique TP3 – QUARON.

1 CONCLUSION

France, as e-CA, received an application for the first authorization of Biocidal product family FAMILLE DE PRODUITS ACIDE LACTIQUE TP3 – QUARON based on 9.8% w/w of L(+) lactic acid. Biocidal product family FAMILLE DE PRODUITS ACIDE LACTIQUE TP3 – QUARON contains 3 Meta SPC which are liquids, thick liquids and film forming thick liquids intended to be use for disinfection for teat of milkable animals by dipping/spraying (manual, semi-automatics, automatics) by professional users.

Conclusion of Physico chemical properties and analytical methods

The physico-chemical properties of the biocidal product family FAMILLE DE PRODUITS ACIDE LACTIQUE TP3 – QUARON have been described and considered acceptable in the conditions of use detailed in the SPC.

For all Meta SPC of the family, the accelerated stability (8 weeks at 40°C) data indicates a shelf life of 2 years at ambient temperature when stored in commercial packaging material (HDPE). The final reports of the long term storage studies should be provided in post authorisation.

Products of Meta SPC 1 and 3 should be protected from frost. After storage, products of Meta SPC 2 should be shaken before use. All products should not be stored above 40°C.

No classification for physical hazards applies for the products of the family.

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

Conclusion of Efficacy

The family product FAMILLE DE PRODUITS ACIDE LACTIQUE TP3 – QUARON has shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C) for the following uses:

- In META-SPC1 - Teat disinfection of milkable animals, with a contact time of 1 minute before milking (after cleaning) and/or 5 minutes after milking, by manual dipping, manual foam dipping, manual spraying, automated and semi-automated spraying, against bacteria, yeasts, enveloped viruses and bacteriophages (only in pre-milking).

- In META-SPC2 - Teat disinfection of milkable animals, with a contact time of 5 minutes after milking, by manual and semi-automated dipping, against bacteria, yeasts and enveloped viruses.

- In META-SPC3 - Teat disinfection of milkable animals, with a contact time of 5 minutes after milking, by manual and semi-automated dipping, against bacteria, yeasts and enveloped viruses

Resistance
No resistance phenomenon has been reported with lactic acid in the scientific literature.

No incidence of resistance to Lactic acid has been recorded until now. (Source: Assessment Report. L (+) Lactic Product types 2, 3 and 4. June 2017. RMS, Germany)

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

Conclusion on the risk for human and animal Health

For the industrial/professional users and for the treated animals, the risk is acceptable for products of meta-SPC 1, 2 and 3 for all the claimed uses considering the qualitative risk assessment for local effects, with the application of risk mitigation measures (RMM) and the wear of personal protective equipment (PPE) as listed in the SPC.

Conclusion on the risk for consumer under indirect exposure via food

Regarding the intended uses on PT 03, residues in food, feed, milk or drinking water might be expected.
Nevertheless, based on the low concentration of L-(+)-lactic acid, the endogenous production and the authorized uses of this active substance as food additive (E 270), significant indirect exposure via intended uses is not expected.

Conclusion on the risk for the environment

No substance of concern has been identified for the environment.

It has been demonstrated that uses of the BPF does not pose a risk to the environmental compartments.

Overall conclusion:

Authorized uses are the following:

Meta SPC	Field of use	Target organisms	Application rate	Users	Conclusions
Meta SPC 1 (Liquid : pre-post milking)	#1: Pre- and/or post-milking teat disinfection: Manual Liquid dipping	Bacteria Yeasts Enveloped viruses Bacteriophages (only for pre-milking)	Ready to use products Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection	Professionals	**Acceptable**
	#2: Pre- and/or post-milking teat disinfection : Manual Liquid dipping with foam				
	#3: Pre- and/or post-milking teat disinfection : Semi auto Liquid dipping				
	#4: Pre- and/or post-milking teat disinfection : Semi auto Liquid dipping with foam				
	#5: Pre- and/or post-milking teat disinfection : Manual Liquid Spraying		Ready to use products Application rate: - cows and buffaloes: 6 to 20ml - sheep: 3 to 10 ml		
	#6: Pre- and/or post-milking teat disinfection : Semi auto Liquid Spraying				
	#7: Pre- and/or post-milking teat disinfection : Automated Liquid Spraying (spray robot)				

	#8: Pre- and/or post-milking teat disinfection : Automated Liquid Spraying (robot milking)		- goats: 5 to 12 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection		
Meta SPC 2 (Thick liquid : post milking)	#9: Post-milking teat disinfection : Manual thick liquid : dipping #10: Post-milking Tteat disinfection : Semi automated thick liquid : dipping	Bacteria Yeasts Enveloped viruses	Ready to use products Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for post-milking disinfection		**Acceptable**
Meta SPC 3 (Thick liquid with film forming : post milking)	#11: Post-milking teat disinfection : Manual thick liquid (film forming) : dipping #12: Post-milking teat disinfection : Semi automated thick liquid (film forming) dipping	Bacteria Yeasts Enveloped viruses			**Acceptable**

2 ASSESSMENT REPORT

PART I - FIRST INFORMATION LEVEL

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier	**Country (if relevant)**
Famille de produits Acide Lactique TP3 - QUARON	France

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	STOCKMEIER FRANCE SAS
	Address	3 rue de la Buhotière 35091 Rennes France
Authorisation number	**FR-2023-0055**	
Date of the authorisation	**20/09/2023**	
Expiry date of the authorisation	**19/09/2033**	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	QUARON SAS
Address of manufacturer	3 rue de la Buhotière – Saint-Jacques de la Lande - BP 89 152, F-35091 Rennes CEDEX 9 France
Location of manufacturing sites	- 3 rue de la Buhotière, F-35136 Saint-Jacques de la Lande France - Rue des Criquiers, F-60220 Formerie France

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

Active substance	L(+) lactic acid
Name of manufacturer	Purac Bioquimica sa
Address of manufacturer	Gran Vial 19-25 08160 MONTMELÓ Spain
Location of manufacturing sites	Gran Vial 19-25 08160 MONTMELÓ Spain

Active substance	L(+) lactic acid
Name of manufacturer	Purac Bioquimica sa

Address of manufacturer	Gran Arkelsedijk 46 4206 AC Gorinchem The Netherlands
Location of manufacturing sites	Arkelsedijk 46 NL-4200 GORINCHEM Netherlands

Active substance	L(+) lactic acid
Name of manufacturer	Jungbunzlauer S.A.
Address of manufacturer	ZI Portuaire - BP 32 F-67390 Marcklosheim France
Location of manufacturing sites	Jungbunzlauer S.A ZI Portuaire - BP 32 F-67390 Marcklosheim France

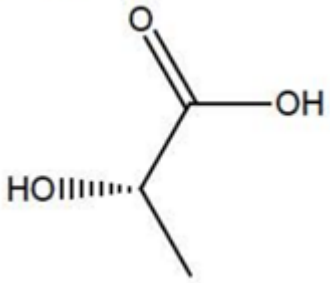
2.1.2 Product family composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

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

2.1.2.2 Candidate(s) for substitution

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

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family[2]

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance*	79-33-4	201-196-2	9.8	9.8
		Technical active substance**			10.26	10.26

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Content in the biocidal product family of the TK containing the active substance					12.25	12.25

*based on the content of active substance in the TK used for the formulation of the biocidal product (80% w/w for lactic acid).
**calculated and based on the minimum purity of active substance: 95.5% w/w for lactic acid.

2.1.2.4 Information on technical equivalence

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

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

2.1.2.5 Information on the substance(s) of concern

For Human Health and environment, no Substance of Concern has been identified in any Meta SPCs.
Please see the confidential annex for further details.

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

The biocidal product contains the active substance "Lactic Acid", which is not considered to have endocrine disrupting properties.
None of the co-formulants contained in the QUARON TP-3 are regulatory identified as endocrine disruptors or have significant ED properties.
However, there are indications that some co-formulants could have ED properties and they should be further assessed in the frame of REACH Regulation.
Please refer to Confidential Annex for further details.

2.1.2.7 Type of formulation

AL: Any other liquid

PART II - SECOND INFORMATION LEVEL - META SPC 1

2.1.3 Meta SPC 1 administrative information

2.1.3.1 Meta SPC identifier

Identification	Ready-to-use LIQUID products

2.1.3.2 Suffix to the authorisation number

2.1.3.3 Product type(s)

Product type(s)	PT 03

2.1.4 Meta SPC 1 composition

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product family of the TK containing the active substance					12.25

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	Eye Dam.1
Hazard statement	H318: Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H318: Causes serious eye damage

Classification	
Precautionary statements	P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P280: Wear eye protection. P310: Immediately call a POISON CENTER/doctor/…
Note	EUH208: Contains carvone and d-limonene. May produce an allergic reaction

2.1.6 Authorised use(s) of the META SPC 1

2.1.6.1 Use description

Table 1. Use # 1 – Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by manual liquid dipping

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medical teat disinfection pre- and/or post-milking
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Bacteriophages (pre-milking only)
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Manual dipping before and/or after milking
Application rate(s) and frequency	Ready-to-use Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection Contact time: 1 minute for pre-milking & 5 minutes for post-milking Ambient temperature
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE): bottles of 1L, jerricans of 5L, 10L, 20L, 22L, drums of 60L, 220L, containers of 1000L

2.1.6.1.1 Use-specific instructions for use

- Fill manually the clean and dry 300 ml dipping cup with the 225ml of the ready to use product.
- Squeeze three to six times the dip cup reservoir to make the liquid product rise into the 2/3 of the dipping cup reservoir.
- Apply by dipping manually on animal's teats on the full length of the teat before or after milking.
- For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.
- For post-milking application, leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).
- Clean the application equipment regularly with water.

2.1.6.1.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles and gloves during loading, application by dipping and cleaning of the equipment.

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

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

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

2.1.6.2 Use description

Table 2. Use # 2 – Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by manual dipping with foam

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medical teat disinfection pre- and/or post-milking
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Bacteriophages (pre-milking only)
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Manual dipping with foam before and/or after milking

Application rate(s) and frequency	Ready-to-use Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection Contact time: 1 minute for pre-milking & 5 minutes for post-milking Ambient temperature
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE): bottles of 1L, jerricans of 5L, 10L, 20L, 22L, drums of 60L, 220L, containers of 1000L

2.1.6.2.1 Use-specific instructions for use

- Press the trigger to fill the dipping cup reservoir with the liquid product.
- Apply by dipping manually on animal's teats on the full length of the teat before or after milking.
- For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.
- For post-milking application, leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).
- Clean the application equipment regularly with water.

2.1.6.2.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles and gloves during loading, application by dipping and cleaning of the equipment.

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

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

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

2.1.6.3 Use description

Table 3. Use # 3 – Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by semi-automated liquid dipping

Product Type	Non-medical teat disinfection
Where relevant, an exact description of the authorised use	Bacteria Yeasts Enveloped viruses Bacteriophages (pre-milking only)
Target organism (including development stage)	Indoor Disinfection of teats of milk producing animals
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Semi-automated liquid dipping before and/or after milking
Application rate(s) and frequency	Ready-to-use Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection Contact time: 1 minute for pre-milking & 5 minutes for post-milking Ambient temperature
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE): bottles of 1L, jerricans of 5L, 10L, 20L, 22L, drums of 60L, 220L, containers of 1000L

2.1.6.3.1 Use-specific instructions for use

- Connect the container to the semi-automated dipping equipment.
- Press the trigger to fill the dipping cup reservoir with the liquid product.
- Apply by dipping manually on animal's teats on the full length of the teat before or after milking.
- For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.
- For post-milking application, leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).
- Clean the application equipment regularly with water.

2.1.6.3.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles and gloves during loading, application by dipping and cleaning of the equipment.

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

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

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

2.1.6.4 Use description

Table 4. Use # 4 – Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by semi-automated dipping with foam

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medical teat disinfection
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Bacteriophages (pre-milking only)
Field of use	Indoor Disinfection of teats of milk producing animals

Application method(s)	Semi-automated dipping with foam before and/or after milking
Application rate(s) and frequency	Ready-to-use Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection Contact time: 1 minute for pre-milking & 5 minutes for post-milking Ambient temperature
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE): bottles of 1L, jerricans of 5L, 10L, 20L, 22L, drums of 60L, 220L, containers of 1000L

2.1.6.4.1 Use-specific instructions for use

- Connect the container to the semi-automated dipping equipment.
- Press the trigger to fill the dipping cup reservoir with the foaming product.
- Apply by dipping manually on animal's teats on the full length of the teat before or after milking.
- For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.
- For post-milking application, leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).
- Clean the application equipment regularly with water.

2.1.6.4.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles and gloves during loading, application by dipping and cleaning of the equipment.

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

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

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

2.1.6.5 Use description

Table 5. Use # 5 – Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by manual spraying

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medical teat disinfection
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Bacteriophages (pre-milking only)
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Manual spraying before and/or after milking
Application rate(s) and frequency	Ready-to-use Application rate: - cows and buffaloes: 6 to 20ml - sheep: 3 to 10 ml - goats: 5 to 12 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection Contact time: 1 minute for pre-milking & 5 minutes for post-milking Ambient temperature
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE): bottles of 1L, jerricans of 5L, 10L, 20L, 22L, drums of 60L, 220L, containers of 1000L

2.1.6.5.1 Use-specific instructions for use

- Fill manually the reservoir tank of the adapted trigger spray in good condition.
- Apply on animal's teats on the full length of the teat before or after milking by pressing the trigger spray.
- For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.
- For post-milking application, leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).
- Clean the application equipment regularly with water.

2.1.6.5.2 Use-specific risk mitigation measures

- The professional user has to wear chemical goggles and gloves during loading, application by spraying and cleaning of the equipment.
- The professional bystander has to wear the same PPE than the professional user.

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

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

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

2.1.6.6 Use description

Table 6. Use # 6 – Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by semi-automated spraying

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medical teat disinfection
Target organism (including development stage)	-Bacteria -Yeasts -Enveloped viruses -Bacteriophages (pre-milking only)
Field of use	Indoor

	Disinfection of teats of milk producing animals
Application method(s)	Semi-automated spraying before and/or after milking
Application rate(s) and frequency	Ready-to-use Application rate: - cows and buffaloes: 6 to 20ml - sheep: 3 to 10 ml - goats: 5 to 12 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection Contact time: 1 minute for pre-milking & 5 minutes for post-milking Ambient temperature
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE): bottles of 1L, jerricans of 5L, 10L, 20L, 22L, drums of 60L, 220L, containers of 1000L

2.1.6.6.1 Use-specific instructions for use

- Connect the container to the semi-automated sprayer equipment.
- Apply on animal's teats on the full length of the teat before or after milking by pressing the trigger spray.
- For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.
- For post-milking application, leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).
- Clean the application equipment regularly with water.

2.1.6.6.2 Use-specific risk mitigation measures

-The professional user has to wear chemical goggles and gloves during loading, application by spraying and cleaning of the equipment.

-The professional bystander has to wear the same PPE than the professional user.

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

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

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

2.1.6.7 Use description

Table 7. Use # 7 – Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by automated spraying via a spray robot

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medical teat disinfection
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Bacteriophages (pre-milking only)
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Automated spraying via a spray robot before and/or after milking
Application rate(s) and frequency	Ready-to-use Application rate: - cows and buffaloes: 6 to 20ml - sheep: 3 to 10 ml - goats: 5 to 12 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection Contact time: 1 minute for pre-milking & 5 minutes for post-milking Ambient temperature
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE): bottles of 1L, jerricans of 5L, 10L, 20L, 22L, drums of 60L, 220L, containers of 1000L

2.1.6.7.1 Use-specific instructions for use

- Connect the container to the spray robot equipment.
- Automatic spraying of the liquid product on animal's teats on the full length of the teat before or after milking.
- For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.
- For post-milking application, leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).
- Clean the application equipment regularly with water.

2.1.6.7.2 Use-specific risk mitigation measures

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

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

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

2.1.6.8 Use description

Table 8. Use # 8 – Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by automated spraying via a robotic milking

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medical teat disinfection
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses Bacteriophages (pre-milking only)
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Automated spraying via a robotic milking device before and/or after milking

Application rate(s) and frequency	Ready-to-use Application rate: - cows and buffaloes: 6 to 20ml - sheep: 3 to 10 ml - goats: 5 to 12 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection Contact time: 1 minute for pre-milking & 5 minutes for post-milking Ambient temperature
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE): bottles of 1L, jerricans of 5L, 10L, 20L, 22L, drums of 60L, 220L, containers of 1000L

2.1.6.8.1 Use-specific instructions for use

- Fill the tank of the automated robotic milking device.
- Automatic spraying of the liquid product on animal's teats on the full length of the teat before or after milking.
- For pre-milking application, clean carefully the teats before application of the product. Set up the robotic milking device to wash the teats one minute after the application then wipe with a single use paper or a towel.
- For post-milking application, leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).
- Clean the application equipment regularly with water.

2.1.6.8.2 Use-specific risk mitigation measures

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

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

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

2.1.7 General directions for use of the meta SPC 1

2.1.7.1 Instructions for use

- Comply with the instructions for use. - Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.). - Inform the registration holder if the treatment is ineffective. - The product must be brought to a temperature above 20°C before use.

2.1.7.2 Risk mitigation measures

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

- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. - IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance. - IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor. - IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: - The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

2.1.7.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. - Dispose of unused product, its packaging and all other waste in accordance with local regulations.

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

- Do no store above 40°C. - Protect from frost.

- Shelf-life : 2 years

2.1.8 Other information

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

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

Trade name(s)	Product 1-1 - Quaron				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	Product 1-2 - Quaron				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	Product 1-3 - Quaron				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	Product 1-4 - Quaron				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	FESTA LACTYPUR ; NET LACT ; LAC DUO ; LACTILAV ; FOAM LACTIQUE ; FOAM LACTIQUE ROBOT ; LACTY F ; INDAL LAC PUR G ; LACTILAV G ; FOAM LACTIQUE G; LAC G DUO ; FOAM LACTIQUE G ; INDAL LAC PUR ; INDAL LAC SPRAY				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8

		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	LACTIM TEA ; LAC MOUSS TEA ; LAC RBTT ; LACTY RT ; INDAL LAC FOAM ; FESTA LACTYSPRAY ; FESTA LACTYFOAM ; PULVE LACT ; LAC MOUSS ; LACTIM ; SPRAY LACTIQUE MOUSSE ; SPRAY LACTIQUE M ; LACTY S ; INDAL ROBLACSPRAY ; FESTA LACTYROBOT ; SPRAY LACT R ; LAC RBT ; LACTIMOUSSE ; SPRAY LACTIQUE ; SPRAY LACTIQUE ROBOT ; LACTY R				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

PART II - SECOND INFORMATION LEVEL - META SPC 2

2.1.10 Meta SPC 2 administrative information

2.1.10.1 Meta SPC identifier

Identification	Ready-to-use THICK LIQUIDS products

2.1.10.2 Suffix to the authorisation number

2.1.10.3 Product type(s)

Product type(s)	TP 03

2.1.11 Meta SPC 2 composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product family of the TK containing the active substance					12.25

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

AL: Any other liquid

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

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008
[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]

Classification	
Hazard category	Eye Dam.1
Hazard statement	H318: Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H318: Causes serious eye damage
Precautionary statements	P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P280: Wear eye protection. P310: Immediately call a POISON CENTER/doctor/…
Note	EUH208: Contains carvone and d-limonene. May produce an allergic reaction.

2.1.13Authorised use(s) of the META SPC 2

2.1.13.1 Use description

Table 9. Use # 1 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping with a thick liquid

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medical teat disinfection
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Manual thick liquid dipping after milking
Application rate(s) and frequency	Ready-to-use Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for post-milking disinfection Contact time: 5 minutes Ambient temperature
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE): bottles of 1L, jerricans of 5L, 10L, 20L, 22L, drums of 60L, 220L, containers of 1000L

2.1.13.1.1 Use-specific instructions for use

- Fill manually the clean and dry 300 ml dipping cup with the 225ml of the ready to use product.
- Squeeze three to six times the dip cup reservoir to make the thick liquid product rise into the 2/3 of the dipping cup reservoir.
- Apply by dipping manually on animal's teats on the full length of the teat after milking.
- For post-milking application, leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes). At the next milking, clean the teats with a a single use paper or a towel.
- Clean the application equipment regularly with water.

2.1.13.1.2 Use-specific risk mitigation measures

-The professional user has to wear chemical goggles and gloves during loading, application by dipping and rinsing of the equipment.

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

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

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

2.1.13.2 Use description

Table 10. Use # 2 – Teat disinfection of milkable animals: Post-milking teat disinfection by semi-automated dipping with a thick liquid

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medical teat disinfection
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Semi-automated thick liquid dipping after milking
Application rate(s) and frequency	Ready-to-use Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for post-milking disinfection Contact time: 5 minutes Ambient temperature

Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE): bottles of 1L, jerricans of 5L, 10L, 20L, 22L, drums of 60L, 220L, containers of 1000L

2.1.13.2.1 Use-specific instructions for use

- Connect the container to the semi-automated dipping equipment.
- Press the trigger to fill the dipping cup reservoir with the thick liquid product.
- Apply by dipping manually on animal's teats on the full length of the teat after milking.
- For post-milking application, leave the product until next milking. Keep the animals standing at least 5 minutes. At the next milking, clean the teats with a a single use paper or a towel.
- Clean the application equipment regularly with water.

2.1.13.2.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles and gloves during loading, application by dipping and cleaning of the equipment.

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

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

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

2.1.14 General directions for use of the meta SPC 2

2.1.14.1 Instructions for use

- Comply with the instructions for use.
- Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.).
- Inform the registration holder if the treatment is ineffective.
- The product must be brought to a temperature above 20°C before use.

2.1.14.2 Risk mitigation measures

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

- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.
- IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor:
- The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

2.1.14.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
- Dispose of unused product, its packaging and all other waste in accordance with local regulations.

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

- Do no store above 40°C.
- After storage, shake before use.
- Shelf-life : 2 years

2.1.15 Other information

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

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

Trade name(s)	Product 2-1 - QUARON				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	Product 2-2 - QUARON				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	Product 2-3 - QUARON				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26

Content in the biocidal product of the TK containing the active substance	12.25

Trade name(s)	Product 2-4 – QUARON				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	Product 2-5 - QUARON				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	Product 2-6 - QUARON				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8

		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	INDAL LAC DIP M ; FESTA M LACTY; LACTI PRO MENTHE ; LACTY DIP MENTHE ; INDAL NATUR A+; FESTA COSME LACTY ; FESTA COSME LACT ; TREMP LACT C ; LAC DIP COS ; LACTICOS ; LACTIQUE SOFT ; LACTIQUE TS ; LACTY TT ; INDAL LAC DIP ; FESTA LACTY ; TREMP LACT E ; LAC DIP E ; LACTIPRO ; LACTIQUE EPAIS ; LACTIQUE ÉTÉ ; LACTY DIP				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	LACTY TTM ; LACTIQUE TSM ; LACTICOS M ; LACTIQUE SOFT M				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

PART II - SECOND INFORMATION LEVEL - META SPC 3

2.1.17 Meta SPC 3 administrative information

2.1.17.1 Meta SPC identifier

Identification	Ready-to-use FILM-FORMING THICK LIQUIDS

2.1.17.2 Suffix to the authorisation number

2.1.17.3 Product type(s)

Product type(s)	TP 03

2.1.18 Meta SPC 3 composition

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product family of the TK containing the active substance					12.25

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

AL: Any other liquid

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

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

Classification	
Hazard category	Eye Dam.1

Classification	
Hazard statement	H318: Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H318: Causes serious eye damage
Precautionary statements	P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor/… P280: Wear eye protection.
Note	EUH208: Contains carvone and d-limonene. May produce an allergic reaction

2.1.20 Authorised use(s) of the META SPC 3

2.1.20.1 Use description

Table 11. Use # 1 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping with a film-forming property thick liquid

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medical teat disinfection
Target organism (including development stage)	Bacteria Yeasts Enveloped viruses
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Manual film-forming property thick liquid dipping after milking
Application rate(s) and frequency	Ready-to-use Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for post-milking disinfection Contact time: 5 minutes Ambient temperature

Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE): bottles of 1L, jerricans of 5L, 10L, 20L, 22L, drums of 60L, 220L, containers of 1000L

2.1.20.1.1 Use-specific instructions for use

- Fill manually the clean and dry 300 ml dipping cup with the 225ml of the ready to use product.
- Squeeze three to six times the dip cup reservoir to make the film-forming thick liquid product rise into the 2/3 of the dipping cup reservoir.
- Apply by dipping manually on animal's teats on the full length of the teat after milking.
- For post-milking application, leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes). At the next milking, clean the teats with a a single use paper or a towel.
- Clean the application equipment regularly with water.

2.1.20.1.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles and gloves during loading, application by dipping and cleaning of the equipment.

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

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

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

2.1.20.2 Use description

Table 12. Use # 2 – Teat disinfection of milkable animals: Post-milking teat disinfection by semi-automated dipping with a film-forming property thick liquid

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medical teat disinfection

Target organism (including development stage)	Bacteria Yeasts Enveloped viruses
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Semi-automated film-forming property thick liquid dipping after milking
Application rate(s) and frequency	Ready-to-use Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for post-milking disinfection Contact time: 5 minutes Ambient temperature
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE): bottles of 1L, jerricans of 5L, 10L, 20L, 22L, drums of 60L, 220L, containers of 1000L

2.1.20.2.1 Use-specific instructions for use

- Connect the container to the semi-automated dipping equipment.
- Press the trigger to fill the dipping cup reservoir with the film-forming thick liquid product.
- Apply by dipping manually on animal's teats on the full length of the teat after milking.
- For post-milking application, leave the product until next milking. Keep the animals standing for five minutes. At the next milking, clean the teats with a a single use paper or a towel.
- Clean the application equipment regularly with water.

2.1.20.2.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles and gloves during loading, application by dipping and cleaning of the equipment.

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

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

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

2.1.21 General directions for use of the meta SPC 3

2.1.21.1 Instructions for use

- Comply with the instructions for use. - Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.). - Inform the registration holder if the treatment is ineffective. - The product must be brought to a temperature above 20°C before use.

2.1.21.2 Risk mitigation measures

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

- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.
- IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor:
- The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

2.1.21.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
- Dispose of unused product, its packaging and all other waste in accordance with local regulations.

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

- Do no store above 40°C.
- Protect from frost.
- Shelf-life : 2 years

2.1.22 Other information

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

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

Trade name(s)	Product 3-1 - QUARON

Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	Product 3-2 - QUARON				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	Product 3-3 - QUARON				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	Product 3-4 - QUARON

Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	Product 3-5 - QUARON				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	Product 3-6 - QUARON				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	INDAL CRYSTAL FILM ; FESTA CAP LACTY ; FESTA CAP LACT ; TREMP LACT FILM ; LAC DIP FILM ; LACTIBAR ; LACTIQUE + ; LACTIQUE H ; LACTY FILM ; LACTY FILM GT ; LACTIBAR GT ;

	TREMP CITLACT FILM ; LAC CIT DIP FILM				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

Trade name(s)	LACTIQUE H BLUE ; LACTIQUE HB				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L(+) lactic acid	2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	9.8
		Technical active substance			10.26
Content in the biocidal product of the TK containing the active substance					12.25

2.1.24 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	1L	HDPE	Wadded screw cap	Professional	Yes
Jerrycan	5L, 10L, 20L and 22L	HDPE	Screw cap	Professional	Yes
			Degassing screw cap		

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
			Tap		
Drums	60L and 220L	HDPE	Bung Degassing bung Screw-threaded bung/plug Tap	Professional	Yes
Intermediate bulk containers	1000L	HDPE	Screw cap Screwed butterfly valve Tap	Professional	Yes

2.1.25 Documentation

2.1.25.1 Data submitted in relation to product application

A list of studies performed on products is provided in the PAR in Annex 3. No new study is provided related to active substance.

Physico-chemical properties: Studies were performed on several products from the Family.
Efficacy data: Studies were performed on several products from the Family.
Toxicology data: Studies were performed on several products from the Family.
Residues data: No specific residue data were submitted in the context of this dossier.
Ecotoxicological data: Studies were performed on several products from the Family.

2.1.25.2 Access to documentation

A letter of access to the data of the CAR of L(+) Lactic Acid (PT3) has been submitted by [redacted] (owners of studies on L(+) Lactic Acid) and allows STOCKMEIER FRANCE SAS to refer to active substance data.

2.2 Assessment of the biocidal product family

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

1.1.1.1 Meta SPC 1 - Ready-to-use LIQUID products

1.1.1.1.1 Use #1

1.1.1.1.1.1 USE DESCRIPTION

Table 1. Use # 1 – Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by manual liquid dipping

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medicinal teat disinfection
Target organism (including development stage)	- Bacteria - Yeasts - Enveloped virus - Bacteriophages
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Manual liquid dipping before and after milking
Application rate(s) and frequency	Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE) containers of 1L, 5L, 10L, 20L, 22L, 60L, 220L and 1000L.

1.1.1.1.1.2 USE-SPECIFIC INSTRUCTIONS FOR USE

Always read the label or leaflet before use and follow all the instructions provided. The product must be used at room temperature. Can be used before and/or after each milking cycle.

Fill manually the clean and dry 300 ml dipping cup with the 225ml of the ready to use product.

Squeeze three to six times the dip cup reservoir to make the liquid product rise into the 2/3 of the dipping cup reservoir.

Apply by dipping manually on animal's teats on the full length of the teat before or after milking.

For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.

For post-milking application, leave the product until next milking. Keep the animals standing at least 5 minutes (efficacy contact time against microorganisms). At the next milking, clean the teats with a single use paper or a towel.

Clean the application equipment regularly with water.

1.1.1.1.1.3 USE-SPECIFIC RISK MITIGATION MEASURES

Wear chemical goggles and gloves during manual dipping cup filling operation.

1.1.1.1.2 Use #2

1.1.1.1.2.1 USE DESCRIPTION

Table 2. Use # 2 – Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by manual dipping with foam

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medicinal teat disinfection
Target organism (including development stage)	- Bacteria - Yeasts - Enveloped virus - Bacteriophages
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Manual dipping with foam before and/or after milking
Application rate(s) and frequency	Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection
Category(ies) of users	Professionals

Pack sizes and packaging material	High-density polyethylene (HDPE) containers of 1L, 5L, 10L, 20L, 22L, 60L, 220L and 1000L.

1.1.1.1.2.2 USE-SPECIFIC INSTRUCTIONS FOR USE

Always read the label or leaflet before use and follow all the instructions provided.

The product must be used at room temperature.

Can be used before and/or after each milking cycle.

Fill manually the clean and dry 300 ml dipping cup with the 225ml of the ready to use product.

Squeeze three to six times the dip cup reservoir to make the foaming product rise into the 2/3 of the dipping cup reservoir.

Apply by dipping manually on animal's teats on the full length of the teat before or after milking.

For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.

For post-milking application, leave the product until next milking. Keep the animals standing at least 5 minutes (efficacy contact time against microorganisms). At the next milking, clean the teats with a single use paper or a towel.

Clean the application equipment regularly with water.

1.1.1.1.2.3 USE-SPECIFIC RISK MITIGATION MEASURES

Wear chemical goggles and gloves during manual dippinp cup filling operation.

1.1.1.1.3 Use #3

1.1.1.1.3.1 USE DESCRIPTION

Table 3. Use # 3 – Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by semi-automated liquid dipping

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medicinal teat disinfection
Target organism (including development stage)	- Bacteria - Yeasts - Enveloped virus - Bacteriophages
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Semi-automated liquid dipping before and/or after milking

Application rate(s) and frequency	Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE) containers of 1L, 5L, 10L, 20L, 22L, 60L, 220L and 1000L.

1.1.1.1.3.2 USE-SPECIFIC INSTRUCTIONS FOR USE

Always read the label or leaflet before use and follow all the instructions provided. The product must be used at room temperature. Can be used before and/or after each milking cycle. Connect the container to the semi-automated dipping equipment. Press the trigger to fill the dipping cup reservoir with the liquid product. Apply by dipping manually on animal's teats on the full length of the teat before or after milking. For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel. For post-milking application, leave the product until next milking. Keep the animals standing at least 5 minutes (efficacy contact time against microorganisms). At the next milking, clean the teats with a single use paper or a towel. Clean the application equipment regularly with water.

1.1.1.1.3.3 USE-SPECIFIC RISK MITIGATION MEASURES

No RMM.

1.1.1.1.4 Use #4

1.1.1.1.4.1 USE DESCRIPTION

Table 4. Use # 4 – Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by semi-automated dipping with foam

Product Type	PT3

Where relevant, an exact description of the authorised use	Non-medicinal teat disinfection
Target organism (including development stage)	- Bacteria - Yeasts - Enveloped virus - Bacteriophages
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Semi-automated dipping with foam before and/or after milking
Application rate(s) and frequency	Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE) containers of 1L, 5L, 10L, 20L, 22L, 60L, 220L and 1000L.

1.1.1.1.4.2 USE-SPECIFIC INSTRUCTIONS FOR USE

Always read the label or leaflet before use and follow all the instructions provided.

The product must be used at room temperature.

Can be used before and/or after each milking cycle.

Connect the container to the semi-automated dipping equipment.

Press the trigger to fill the dipping cup reservoir with the foaming product.

Apply by dipping manually on animal's teats on the full length of the teat before or after milking.

For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.

For post-milking application, leave the product until next milking. Keep the animals standing at least 5 minutes (efficacy contact time against microorganisms). At the next milking, clean the teats with a single use paper or a towel.
Clean the application equipment regularly with water.

1.1.1.1.4.3 USE-SPECIFIC RISK MITIGATION MEASURES

No RMM.

1.1.1.1.5 Use #5

1.1.1.1.5.1 USE DESCRIPTION

Table 5. Use # 5 – Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by manual spraying

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medicinal teat disinfection
Target organism (including development stage)	- Bacteria - Yeasts - Enveloped virus - Bacteriophages
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Manual spraying before and/or after milking
Application rate(s) and frequency	Application rate: - cows and buffaloes: 6 to 20ml - sheep: 3 to 10 ml - goats: 5 to 12 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE) containers of 1L, 5L, 10L, 20L, 22L, 60L, 220L and 1000L.

1.1.1.1.5.2 USE-SPECIFIC INSTRUCTIONS FOR USE

Always read the label or leaflet before use and follow all the instructions provided.

The product must be used at room temperature.

Can be used before and/or after each milking cycle.

Fill manually the reservoir tank of the adapted trigger spray in good condition.

Apply on animal's teats on the full length of the teat before or after milking by pressing the trigger spray.

For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.

For post-milking application, leave the product until next milking. Keep the animals standing at least 5 minutes (efficacy contact time against microorganisms). At the next milking, clean the teats with a single use paper or a towel.

Clean the application equipment regularly with water.

1.1.1.1.5.3 USE-SPECIFIC RISK MITIGATION MEASURES

Wear chemical goggles and gloves during manual filling and spraying application operations.

1.1.1.1.6 Use #6

1.1.1.1.6.1 USE DESCRIPTION

Table 6. Use # 6 – Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by semi-automated spraying

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medicinal teat disinfection
Target organism (including development stage)	- Bacteria - Yeasts - Enveloped virus - Bacteriophages
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Semi-automated spraying before and/or after milking
Application rate(s) and frequency	Application rate: - cows and buffaloes: 6 to 20ml - sheep: 3 to 10 ml - goats: 5 to 12 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE) containers of 1L, 5L, 10L, 20L, 22L, 60L, 220L and 1000L.

1.1.1.1.6.2 USE-SPECIFIC INSTRUCTIONS FOR USE

Always read the label or leaflet before use and follow all the instructions provided. The product must be used at room temperature.

Can be used before and/or after each milking cycle. Connect the container to the semi-automated sprayer equipment. Apply on animal's teats on the full length of the teat before or after milking by pressing the trigger spray. For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel. For post-milking application, leave the product until next milking. Keep the animals standing at least 5 minutes (efficacy contact time against microorganisms). At the next milking, clean the teats with a single use paper or a towel. Clean the application equipment regularly with water.

1.1.1.1.6.3 USE-SPECIFIC RISK MITIGATION MEASURES

Wear chemical goggles and gloves during manual spraying application operation.

1.1.1.1.7 Use #7

1.1.1.1.7.1 USE DESCRIPTION

Table 7. Use # 7 – Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by automated spraying via a spray robot

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medicinal teat disinfection
Target organism (including development stage)	- Bacteria - Yeasts - Enveloped virus - Bacteriophages
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Automated spraying via a spray robot before and/or after milking
Application rate(s) and frequency	Application rate: - cows and buffaloes: 6 to 20ml - sheep: 3 to 10 ml - goats: 5 to 12 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection
Category(ies) of users	Professionals

Pack sizes and packaging material	High-density polyethylene (HDPE) containers of 1L, 5L, 10L, 20L, 22L, 60L, 220L and 1000L.

1.1.1.1.7.2 USE-SPECIFIC INSTRUCTIONS FOR USE

Always read the label or leaflet before use and follow all the instructions provided. The product must be used at room temperature. Can be used before and/or after each milking cycle. Connect the container to the spray robot equipment. Automatic spraying of the liquid product on animal's teats on the full length of the teat before or after milking. For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel. For post-milking application, leave the product until next milking. Keep the animals standing at least 5 minutes (efficacy contact time against microorganisms). At the next milking, clean the teats with a single use paper or a towel. Clean the application equipment regularly with water.

1.1.1.1.7.3 USE-SPECIFIC RISK MITIGATION MEASURES

No RMM.

1.1.1.1.8 Use #8

1.1.1.1.8.1 USE DESCRIPTION

Table 8. Use # 8 – Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by automated spraying via a robotic milking

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medicinal teat disinfection
Target organism (including development stage)	- Bacteria - Yeasts - Enveloped virus - Bacteriophages
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Automated spraying via a robotic milking device before and/or after milking
Application rate(s) and frequency	Application rate: - cows and buffaloes: 6 to 20ml - sheep: 3 to 10 ml

	- goats: 5 to 12 ml Frequency: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE) containers of 1L, 5L, 10L, 20L, 22L, 60L, 220L and 1000L.

1.1.1.1.8.2 USE-SPECIFIC INSTRUCTIONS FOR USE

Always read the label or leaflet before use and follow all the instructions provided. The product must be used at room temperature. Can be used before and/or after each milking cycle. Fill the tank of the automated robotic milking device. Automatic spraying of the liquid product on animal's teats on the full length of the teat before or after milking. For pre-milking application, clean carefully the teats before application of the product. Set up the robotic milking device to wash the teats one minute after the application. For post-milking application, leave the product until next milking. Keep the animals standing at least 5 minutes (efficacy contact time against microorganisms). At the next milking, clean the teats with a single use paper or a towel. Clean the application equipment regularly with water.

1.1.1.1.8.3 USE-SPECIFIC RISK MITIGATION MEASURES

Wear chemical goggles and gloves during manual filling operation.

1.1.1.2 **Meta SPC 2 - Ready-to-use THICK LIQUIDS products**

1.1.1.2.1 Use #9

1.1.1.2.1.1 USE DESCRIPTION

Table 9. Use # 9 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping with a thick liquid

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medicinal teat disinfection

Target organism (including development stage)	- Bacteria - Yeasts - Enveloped virus
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Manual thick liquid dipping after milking
Application rate(s) and frequency	Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for post-milking disinfection
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE) containers of 1L, 5L, 10L, 20L, 22L, 60L, 220L and 1000L.

1.1.1.2.1.2 USE-SPECIFIC INSTRUCTIONS FOR USE

Always read the label or leaflet before use and follow all the instructions provided. The product must be used at room temperature. Can be used after each milking cycle. Fill manually the clean and dry 300 ml dipping cup with the 225ml of the ready to use product. Squeeze three to six times the dip cup reservoir to make the thick liquid product rise into the 2/3 of the dipping cup reservoir. Apply by dipping manually on animal's teats on the full length of the teat after milking. For post-milking application, leave the product until next milking. Keep the animals standing at least 5 minutes (efficacy contact time against microorganisms). At the next milking, clean the teats with a single use paper or a towel. Clean the application equipment regularly with water.

1.1.1.2.1.3 USE-SPECIFIC RISK MITIGATION MEASURES

No RMM.

1.1.1.2.2 Use #10

1.1.1.2.2.1 USE DESCRIPTION

Table 10. Use # 10 – Teat disinfection of milkable animals: Post-milking teat disinfection by semi-automated dipping with a thick liquid

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medicinal teat disinfection
Target organism (including development stage)	- Bacteria - Yeasts - Enveloped virus
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Semi-automated thick liquid dipping after milking
Application rate(s) and frequency	Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for post-milking disinfection
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE) containers of 1L, 5L, 10L, 20L, 22L, 60L, 220L and 1000L.

1.1.1.2.2.2 USE-SPECIFIC INSTRUCTIONS FOR USE

Always read the label or leaflet before use and follow all the instructions provided.

The product must be used at room temperature.

Can be used after each milking cycle.

Connect the container to the semi-automated dipping equipment.

Press the trigger to fill the dipping cup reservoir with the thick liquid product.

Apply by dipping manually on animal's teats on the full length of the teat after milking. For post-milking application, leave the product until next milking. Keep the animals standing at least 5 minutes (efficacy contact time against microorganisms). At the next milking, clean the teats with a single use paper or a towel.
Clean the application equipment regularly with water.

1.1.1.2.2.3 USE-SPECIFIC RISK MITIGATION MEASURES

No RMM.

1.1.1.3 **Meta SPC 3 - Ready-to-use FILM-FORMING THICK LIQUIDS**

1.1.1.3.1 Use #11

1.1.1.3.1.1 USE DESCRIPTION

Table 21. Use # 11 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping with a film-forming property thick liquid

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medicinal teat disinfection
Target organism (including development stage)	- Bacteria - Yeasts - Enveloped virus
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Manual film-forming property thick liquid dipping after milking
Application rate(s) and frequency	Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for post-milking disinfection
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE) containers of 1L, 5L, 10L, 20L, 22L, 60L, 220L and 1000L.

1.1.1.3.1.2 USE-SPECIFIC INSTRUCTIONS FOR USE

Always read the label or leaflet before use and follow all the instructions provided.

The product must be used at room temperature.

Can be used after each milking cycle.

Fill manually the clean and dry 300 ml dipping cup with the 225ml of the ready to use product.

Squeeze three to six times the dip cup reservoir to make the film-forming thick liquid product rise into the 2/3 of the dipping cup reservoir.

Apply by dipping manually on animal's teats on the full length of the teat after milking.

For post-milking application, leave the product until next milking. Keep the animals standing at least five minutes (efficacy contact time against microorganisms). At the next milking, clean the teats with a single use paper or a towel.

Clean the application equipment regularly with water.

1.1.1.3.1.3 USE-SPECIFIC RISK MITIGATION MEASURES

No RMM.

1.1.1.3.2 Use #12

1.1.1.3.2.1 USE DESCRIPTION

Table 32. Use # 12 – Teat disinfection of milkable animals: Post-milking teat disinfection by semi-automated dipping with a film-forming property thick liquid

Product Type	PT3
Where relevant, an exact description of the authorised use	Non-medicinal teat disinfection
Target organism (including development stage)	- Bacteria - Yeasts - Enveloped virus
Field of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Semi-automated film-forming property thick liquid dipping after milking
Application rate(s) and frequency	Application rate: - cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml Frequency: - cows and buffaloes: 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for post-milking disinfection
Category(ies) of users	Professionals
Pack sizes and packaging material	High-density polyethylene (HDPE) containers of 1L, 5L, 10L, 20L, 22L, 60L, 220L and 1000L.

1.1.1.3.2.2 USE-SPECIFIC INSTRUCTIONS FOR USE

Always read the label or leaflet before use and follow all the instructions provided. The product must be used at room temperature. Can be used after each milking cycle. Connect the container to the semi-automated dipping equipment. Press the trigger to fill the dipping cup reservoir with the film-forming thick liquid product. Apply by dipping manually on animal's teats on the full length of the teat after milking.

For post-milking application, leave the product until next milking. Keep the animals standing for five to fifteen minutes (efficacy contact time against microorganisms). At the next milking, clean the teats with a single use paper or a towel. Clean the application equipment regularly with water.

1.1.1.3.2.3 USE-SPECIFIC RISK MITIGATION MEASURES

No RMM.

1.1.2 General directions for use

1.1.2.1 Instructions for use

Please refer to Use-specific instructions for uses given in the Authorized uses 2.1.4 above.

1.1.2.2 Risk mitigation measures

Please refer to Use-specific risk mitigation measures given in the Authorized uses 2.1.4 above.

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

Please refer to the Authorized uses 2.1.4 above.

1.1.2.4 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.

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

Meta SPC 1: - Do no store above 40°C. - Protect from frost. - Shelf-life : 2 years Meta SPC 2: - Do no store above 40°C. - After storage, shake before use. - Shelf-life : 2 years Meta SPC 3: - Do no store above 40°C. - Protect from frost. - Shelf-life : 2 years

1.1.3 Other information

Application codes

2.2.2 Physical, chemical and technical properties

The biocidal products family is composed of 3 Meta SPCs. All products are water-based ready-to-use (AL formulations). The pure concentration of the active substance L(+)lactic acid is 9.8% w/w in every case.
The physico-chemical and technical properties of the Meta SPCs and their stability are covered by representative formulations, which contain the highest possible concentration of perfume for the Meta SPC they cover (dyes have not been taken into account). These representative mixtures are:

- Product 1-x for Meta SPC 1.
- Product 2-x for Meta SPC 2.
- Product 3-x for Meta SPC 3.

The compositions of the 3 products are reported in the BPF overview table.

Moreover, additional viscosity determinations were performed on a second formula for Meta SPCs 2 and 3, because two different thickening agents exist for those Meta SPCs.

Some stability studies are still ongoing. The available results are summarised in the table below.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
Physical state at 20 °C and 101.3 kPa	Sensory observation	Meta SPC 1, Product 1-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 1-X / 2019-10-30	Homogeneous fluid, without phase separation or precipitations	[redacted] 2020, Report 19.537246.0001	Acceptable
		Meta SPC 2, Product 2-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 2-x / 2019-10-21	Homogeneous fluid, without phase separation or precipitations	[redacted] 2020, Report 19.535563.0001	Acceptable
		Meta SPC 3, Product 3-x (9.8% w/w lactic acid), Batch COM 22 /	Homogeneous viscous liquid, without phase separation or precipitations	[redacted] 2020, Report 19.533848.0001	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
		Méta SPC 3-x / 2019-10-09			
Colour at 20 °C and 101.3 kPa	Sensory observation	Meta SPC 1, Product 1-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 1-X / 2019-10-30	Green	[redacted] 2020, Report 19.537246.0001	Acceptable
		Meta SPC 2, Product 2-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 2-x / 2019-10-21	Yellow	[redacted] 2020, Report 19.535563.0001	Acceptable
		Meta SPC 3, Product 3-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 3-x / 2019-10-09	Intense magenta matt colour	[redacted] 2020, Report 19.533848.0001	Acceptable
Odour at 20 °C and 101.3 kPa	Sensory observation	Meta SPC 1, Product 1-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 1-X / 2019-10-30	Mint characteristic odour	[redacted] 2020, Report 19.537246.0001	Acceptable
		Meta SPC 2, Product 2-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 2-x / 2019-10-21	Mint characteristic odour	[redacted] 2020, Report 19.535563.0001	Acceptable
		Meta SPC 3, Product 3-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 3-x / 2019-10-09	Mint characteristic odour	[redacted] 2020, Report 19.533848.0001	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
Acidity / alkalinity	pH: CIPAC MT 75.3 Acidity: CIPAC MT 191	Meta SPC 1, Product 1-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 1-X / 2019-10-30	pH (pure test item): 2.76 Acidity: 5.16% w/w as H_2SO_4	[redacted] 2020, Report 19.537246.0001	Acceptable
		Meta SPC 2, Product 2-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 2-x / 2019-10-21	pH (pure test item): 2.68 Acidity: 5.08% w/w as H_2SO_4	[redacted] 2020, Report 19.535563.0001	Acceptable
		Meta SPC 3, Product 3-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 3-x / 2019-10-09	pH (pure test item): 2.55 Acidity: 5.00% w/w as H_2SO_4	[redacted] 2020, Report 19.533848.0001	Acceptable
Relative density / bulk density	OECD 109	Meta SPC 1, Product 1-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 1-X / 2019-10-30	1.060 g/mL at 20°C	[redacted] 2020, Report 19.537246.0001	Acceptable
		Meta SPC 2, Product 2-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 2-x / 2019-10-21	1.067 g/mL at 20°C	[redacted] 2020, Report 19.535563.0001	Acceptable
		Meta SPC 3, Product 3-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 3-x / 2019-10-09	1.053 g/mL at 20°C	[redacted] 2020, Report 19.533848.0001	Acceptable
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Meta SPC 1, Product 1-x (9.8%	Storage at 40°C for 8 weeks in a 1L commercial packaging (HDPE bottle).		Acceptable

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td>Analytical method for active substance: SOPa-LABCHI-512 validated in 2.2.4</td><td>w.w lactic acid), Batch COM 22 / Méta SPC 1-x / 2020-04-20</td><td>
<table>
<tr><th></th><th>Before storage</th><th>After storage</th></tr>
<tr><td>L-(+)-lactic acid</td><td>9.45% w/w</td><td>9.39% w/w (-0.6%)</td></tr>
<tr><td>Appearance</td><td>Limpid homogeneous dark green fluid liquid of a mint characteristic odour, without phase separation of precipitations</td><td>No change</td></tr>
<tr><td>Packaging</td><td>White HDPE bottle containing about 1L of liquid; no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging</td><td>No change</td></tr>
<tr><td>Weight loss</td><td>/</td><td>-0.09%</td></tr>
<tr><td>pH (pure test item at 25°C)</td><td>2.77</td><td>2.83</td></tr>
<tr><td>Acidity</td><td>5.36% w/w as H_2SO_4</td><td>5.26% w/w as H_2SO_4</td></tr>
</table>
The loss of active substance (0.6%) is lower than the accepted threshold of 10%. Moreover, the physicochemical properties of the formulation were observed to be stable throughout the storage period.
</td><td></td><td>The fictive formula is considered stable after 8 weeks at 40°C.

The products of Meta SPC 1 should not be stored above 40°C.

A shelf-life of 2 years can be granted for products of Meta SPC 1.</td></tr>
<tr><td></td><td></td><td>Meta SPC 2, Product 2-x (9.8%</td><td>Storage at 40°C for 8 weeks in a 1L commercial packaging (HDPE bottle).</td><td>[redacted] 2020, Report</td><td>Acceptable</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td>w/w lactic acid), Batch COM 22 / Méta SPC 2-x / 2019-10-21</td><td>
<table>
<tr><th></th><th>Before storage</th><th>After storage</th></tr>
<tr><td>L-(+)-lactic acid</td><td>9.89% w/w</td><td>9.84% w/w (-0.5%)</td></tr>
<tr><td>Appearance</td><td>Homogeneous yellow limpid fluid of a mint characteristic odour, without phase separation of precipitations</td><td>No change</td></tr>
<tr><td>Packaging</td><td>White HDPE bottle containing about 1L of liquid; no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging</td><td>No sample leaks, discolouration, foulings, spots. A slight bulge of 1mm is detected on the bottom</td></tr>
<tr><td>Weight loss</td><td>/</td><td>-0.18%</td></tr>
<tr><td>pH (pure test item at 25°C)</td><td>2.68</td><td>2.88</td></tr>
<tr><td>Acidity</td><td>5.08% w/w as H_2SO_4</td><td>5.25% w/w as H_2SO_4</td></tr>
</table>
The loss of active substance (0.5%) is lower than the accepted threshold of 10%. Moreover, the physicochemical properties of the formulation were observed to be stable throughout the storage period.
</td><td>19.535563.0001</td><td>The fictive formula is considered stable after 8 weeks at 40°C.

The products of Meta SPC 2 should not be stored above 40°C.

A shelf-life of 2 years can be granted for products of Meta SPC 2.</td></tr>
<tr><td></td><td></td><td>Meta SPC 2, Product 2-x</td><td>Storage at 40°C for 8 weeks.</td><td>[redacted], 2021, Report</td><td>Acceptable</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>Kinematic viscosity before storage:
• At 20°C: 1142.59 mm²/s
• At 40°C: 1118.48 mm²/s

Kinematic viscosity after storage:
• At 20°C: 1139.39 mm²/s
• At 40°C: 1111.11 mm²/s

The above results show that the viscosity remains stable when the product is subjected to an accelerated storage procedure.</td><td>20.516048.0001</td><td></td></tr>
<tr><td></td><td></td><td>Meta SPC 2, Product 2-6</td><td>Additionnal viscosity data were provided as two different thickening agents are present in this Meta SPC.

Storage at 40°C for 8 weeks.

Kinematic viscosity before storage:
• At 20°C: 1691.87 mm²/s
• At 40°C: 1545.02 mm²/s

Kinematic viscosity after storage:
• At 20°C: 1594.75 mm²/s
• At 40°C: 1420.40 mm²/s

The above results show that the viscosity remains stable when the product is subjected to an accelerated storage procedure.</td><td>[redacted] 2021, Report 20.515774.0001</td><td>Acceptable</td></tr>
<tr><td></td><td></td><td>Meta SPC 3, Product 3-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 3-x / 2019-10-09</td><td>Storage at 40°C for 8 weeks in a 1L commercial packaging (HDPE bottle).
<table><tr><td></td><td>Before storage</td><td>After storage</td></tr><tr><td>L-(+)-lactic acid</td><td>9.62% w/w</td><td>9.46% w/w (-1.7%)</td></tr></table></td><td>[redacted] 2020, Report 19.533848.0001</td><td>Acceptable

The fictive formula is considered stable after 8 weeks at 40°C.</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Appearance</td><td>Homogeneous viscous liquid with an intense magenta matt colour of a mint characteristic odour, without phase separation of precipitations</td><td>No change</td></tr>
<tr><td>Packaging</td><td>White matt HDPE bottle; no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging</td><td>No sample leaks, discolouration, foulings, spots. A slight bulge of 1mm is detected on the bottom</td></tr>
<tr><td>Weight loss</td><td>/</td><td>-0.17%</td></tr>
<tr><td>pH (pure test item at 25°C)</td><td>2.55</td><td>2.80</td></tr>
<tr><td>Acidity</td><td>5.00% w/w as H_2SO_4</td><td>4.92% w/w as H_2SO_4</td></tr>
</table>

The loss of active substance (1.7%) is lower than the accepted threshold of 10%. Moreover, the physicochemical properties of the formulation were observed to be stable throughout the storage period.</td><td></td><td>The products of Meta SPC 3 should not be stored above 40°C.

A shelf-life of 2 years can be granted for products of Meta SPC 3.</td></tr>
<tr><td></td><td></td><td>Meta SPC 3, Product 3-x</td><td>Storage for 8 weeks at 40°C.

Kinematic viscosity before storage:
• At 20°C: 1926.35 mm²/s
• At 40°C: 1509.97 mm²/s

Kinematic viscosity after storage:
• At 20°C: 1924.53 mm²/s</td><td>[redacted], 2021, Report 20.516296.0001</td><td>Acceptable</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>• At 40°C: 1446.24 mm²/s

The above results show that the viscosity remains stable when the product is subjected to an accelerated storage procedure.</td><td></td><td></td></tr>
<tr><td></td><td></td><td>Meta SPC 3, Product 3-6</td><td>Additionnal viscosity data were provided as two different thickening agents are present in this Meta SPC.

Storage for 8 weeks at 40°C.

Kinematic viscosity before storage:
• At 20°C: 198.11 mm²/s
• At 40°C: 125.35 mm²/s

Kinematic viscosity after storage:
• At 20°C: 46.86 mm²/s
• At 40°C: 27.22 mm²/s

The viscosity decreased after storage. However, this is not considered to have an adverse effect on the use of the product.</td><td>[redacted] 2021, Report 20.515829.0001</td><td>A decrease of the viscosity is observed after storage.
However, it is not considered to have an adverse effect on the use of the product.</td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>Gifap monograph no.17

Analytical method for active substance: SOPa-LABCHI-512 validated in 2.2.4</td><td>Meta SPC 1, Product 1-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 1-x / 2019-10-30</td><td>Storage at 25°C in a 1L commercial packaging (HDPE bottle).
Only interim results after 12 months are currently available. The total study duration will be 2 years.
<table><tr><td></td><td>Before storage</td><td>After 12 months of storage</td></tr><tr><td>L-(+)-lactic acid</td><td>9.39% w/w</td><td>9.58% w/w (+2%)</td></tr><tr><td>Appearance</td><td>Homogeneous green limpid fluid of a mint characteristic odour, without</td><td>No change</td></tr></table></td><td>[redacted] 2021, Study 19.537246.0003, Interim report</td><td>Intermediate results of the long term stability study are acceptable.

The product is considered stable after 12 months.

A shelf-life of 2 years can be granted for products of Meta</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>phase separation of precipitations</td><td></td></tr>
<tr><td>Packaging</td><td>White bottle containing about 1L of liquid; no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging</td><td>No change</td></tr>
<tr><td>Weight loss</td><td>/</td><td>-0.06%</td></tr>
<tr><td>pH (pure test item at 25°C)</td><td>2.76</td><td>2.76</td></tr>
<tr><td>Acidity</td><td>5.16% w/w as H_2SO_4</td><td>5.31% w/w as H_2SO_4</td></tr>
</table>
The active substance content and appearance of the product and its packaging are stable during a storage of 12 months at ambient temperature.</td><td></td><td>SPC 1 based on the accelerated storage results.

Final results of the long term storage study should be provided in post authorisation.</td></tr>
<tr><td></td><td></td><td>Meta SPC 2, Product 2-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 2-X / 2019-10-21</td><td>Storage at 25°C in a 1L commercial packaging (HDPE bottle).
Only interim results after 12 months are currently available. The total study duration will be 2 years.
<table>
<tr><td></td><td>Before storage</td><td>After 12 months of storage</td></tr>
<tr><td>L-(+)-lactic acid</td><td>9.89% w/w</td><td>9.42% w/w (-4.8%)</td></tr>
<tr><td>Appearance</td><td>Homogeneous yellow limpid fluid of a mint characteristic odour, without</td><td>Viscous yellow fluid of a mint characteristic odour. It presents a</td></tr>
</table></td><td>[redacted] 2021, Study 19.535563.0003, Interim report</td><td>Intermediate results of the long term stability study are acceptable.

The product is considered stable after 12 months.

A shelf-life of 2 years can be granted for products of Meta</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>phase separation of precipitations</td><td>phase separation which stably disappears after a moderate manual mixing</td></tr>
<tr><td>Packaging</td><td>White HDPE bottle containing about 1L of liquid; no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging</td><td>No change</td></tr>
<tr><td>Weight loss</td><td>/</td><td>-0.20%</td></tr>
<tr><td>pH (pure test item at 25°C)</td><td>2.68</td><td>2.90</td></tr>
<tr><td>Acidity</td><td>5.08% w/w as H_2SO_4</td><td>5.36% w/w as H_2SO_4</td></tr>
</table>
The active substance content and appearance of the product and its packaging are stable during a storage of 12 months at ambient temperature.
However, a phase separation is observed after storage. The labels should mention: “after storage, shake before use.”</td><td></td><td>SPC 2 based on the accelerated storage results.

However, after storage, the products should be shaken before use.

Final results of the long term storage study should be provided in post authorisation.</td></tr>
<tr><td></td><td></td><td>Meta SPC 2, Product 2-x</td><td>Data provided in 03/23:
After 6 months storage at 25°C : viscosity 1171 mm²/s
After 12 months storage at 25°C : viscosity 1140 mm²/s</td><td>[redacted] 2023 Study 20.516048.0003</td><td>Viscosity is stable after 2 years.</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>After 18 months storage at 25°C : viscosity 1173 mm²/s
After 24 months storage at 25°C : viscosity 1176 mm²/s</td><td></td><td></td></tr>
<tr><td></td><td></td><td>Meta SPC 2, Product 2-6</td><td>Data provided in 03/23:
After 6 months storage at 25°C : viscosity 1600 mm²/s
After 12 months storage at 25°C : viscosity 1598 mm²/s
After 18 months storage at 25°C : viscosity 1611 mm²/s
After 24 months storage at 25°C : viscosity 1576 mm²/s</td><td>[redacted] 2023 Study 20.515774.0003</td><td>Viscosity is stable after 2 years.</td></tr>
<tr><td></td><td></td><td>Meta SPC 3, Product 3-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 3-x / 2019-10-09</td><td>Storage at 25°C in a 1L commercial packaging (HDPE bottle).
Only interim results after 12 months are currently available. The total study duration will be 2 years.
<table>
<tr><th></th><th>Before storage</th><th>After 12 months of storage</th></tr>
<tr><td>L-(+)-lactic acid</td><td>9.62% w/w</td><td>9.13% w/w (-5%)</td></tr>
<tr><td>Appearance</td><td>Homogeneous viscous liquid with an intense magenta matt colour of a mint characteristic odour, without phase separation of precipitations</td><td>No change</td></tr>
</table></td><td>[redacted], 2021, Study 19.533848.0003, Interim report</td><td>Intermediate results of the long term stability study are acceptable.

The product is considered stable after 12 months.

A shelf-life of 2 years can be granted for products of Meta SPC 3 based on the accelerated storage results.

Final results of the long term storage study should be</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Packaging</td><td>White matt HDPE bottle; no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging</td><td>No change</td></tr>
<tr><td>Weight loss</td><td>/</td><td>-0.17%</td></tr>
<tr><td>pH</td><td>2.55</td><td>2.75</td></tr>
<tr><td>Acidity</td><td>5.00% w/w as H_2SO_4</td><td>4.96% w/w as H_2SO_4</td></tr>
</table>
A decrease of the active substance content is observed after 12 months. The ppearance of the product and its packaging are stable during a storage of 12 months at ambient temperature.</td><td></td><td>provided in post authorisation.</td></tr>
<tr><td></td><td></td><td>Meta SPC 3, Product 3-x</td><td>Data provided in 03/23:
After 6 months storage at 25°C : viscosity 1965 mm²/s
After 12 months storage at 25°C : viscosity 2165 mm²/s
After 18 months storage at 25°C : viscosity 2046 mm²/s
After 24 months storage at 25°C : viscosity 2035 mm²/s</td><td>[redacted] 2023 Study 20.516296.0003</td><td>Viscosity is stable after 2 years.</td></tr>
<tr><td></td><td></td><td>Meta SPC 3, Product 3-6</td><td>Data provided in 03/23:
After 6 months storage at 25°C : viscosity 1965 mm²/s
After 12 months storage at 25°C : viscosity 2165 mm²/s
After 18 months storage at 25°C : viscosity 2046 mm²/s</td><td>[redacted] 2023 Study 20.515829.0001</td><td>Viscosity is stable after 2 years.</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
			After 24 months storage at 25°C : viscosity 2035 mm²/s		
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Meta SPC 1, Product 1-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 1-X / 2019-10-30	Storage at 0°C for one week. The test item at initial time was a homogeneous green limpid fluid of a mint characteristic odour, without phase separation or precipitation. The test item after 7 days at 0°C was a green limpid fluid of a mint characteristic odour, without phase separation, a precipitation of 0.5mL was detected. The precipitate did not dissolve after three inversions of the tube at room temperature. However, the labels mention to protect the products from frost.	[redacted] 2020, Report 19.537246.0001	Products of Meta SPC 1 should be protected from frost.
	Waiver	Meta SPC 3	No test was performed. The labels mention to protect the products from frost.		Products of Meta SPC 3 should be protected from frost.
	CIPAC MT 39.3	Meta SPC 2, Product 2-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 2-x / 2019-10-21	Storage at 0°C for one week. A phase separation of about 0.5-2 cm was observed, without precipipation.	[redacted] 2020, Report 19.535563.0001	After cold storage, products of Meta SPC 2 should be shaken before use.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	No particular effect has been observed in literature concerning effect of light on lactic acid. Besides, the UV-spectrum of L(+) lactic acid shows that no absorbance in the wavelength range of 290-800 nm takes place. Therefore, L(+) lactic acid cannot undergo direct photolysis in sunlight.				Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	The effect of temperatures higher than normal were assessed during the accelerated storage studies. No adverse effect on the products were observed. The effect of humidity is not relevant considering the formulation type of the products (water-based AL formulations).				Acceptable The products of the family should not be stored above 40°C.
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	This parameter will be assessed during the storage study at ambient temperature. Based on the accelerated storage results and on the preliminary ambient storage results, there is no reactivity between the products and their container material.				Acceptable
Wettability	Not relevant considering the formulations type (water-based AL formulations).				Not relevant
Suspensibility, spontaneity and dispersion stability	Not relevant considering the formulations type (water-based AL formulations).				Not relevant
Wet sieve analysis and dry sieve test	Not relevant considering the formulations type (water-based AL formulations).				Not relevant
Emulsifiability, re-emulsifiability and emulsion stability	Not relevant considering the formulations type (water-based AL formulations).				Not relevant
Disintegration time	Not relevant considering the formulations type (water-based AL formulations).				Not relevant
Particle size distribution, content of dust/fines, attrition, friability	Not relevant considering the formulations type (water-based AL formulations).				Not relevant
Persistent foaming	Not relevant considering the formulations type (water-based AL formulations).				Not relevant
Flowability/Pourability/Dustability	Not relevant considering the formulations type (water-based AL formulations).				Not relevant

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
Burning rate — smoke generators	Not relevant considering the formulations type (water-based AL formulations).				Not relevant
Burning completeness — smoke generators	Not relevant considering the formulations type (water-based AL formulations).				Not relevant
Composition of smoke — smoke generators	Not relevant considering the formulations type (water-based AL formulations).				Not relevant
Spraying pattern — aerosols	Not relevant considering the formulations type (water-based AL formulations).				Not relevant
Physical compatibility	No application is foreseen in combination with other products. Therefore, no study of physical or chemical compatibility needs to be performed.				Acceptable
Chemical compatibility					Acceptable
Degree of dissolution and dilution stability	Not relevant considering the formulations type (water-based AL formulations).				Not relevant
Surface tension	OECD 115 (ring method)	Meta SPC 1, Product 1-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 1-X / 2019-10-30	30.89 mN/m for the neat test item at 20°C. The substance is considered as a surface-active.	[redacted] 2020, Report 19.537246.0001	Acceptable
		Meta SPC 2, Product 2-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 2-x / 2019-10-21	35.27 mN/m for the neat test item at 20°C. The substance is considered as a surface-active.	[redacted] 2020, Report 19.535563.0001	Acceptable
		Meta SPC 3, Product 3-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 3-x / 2019-10-09	33.90 mN/m for the neat test item at 20°C. The substance is considered as a surface-active.	[redacted] 2020, Report 19.533848.0001	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
Viscosity	OECD 114 (capillary method)	Meta SPC 1, Product 1-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 1-X / 2019-10-30	Kinematic viscosity: 20°C: 2.391 mm²/s 40°C: 1.430 mm²/s	[redacted] 2020, Report 19.537246.0001	Acceptable
	OECD 114 (rotational viscometer)	Meta SPC 2, Product 2-6 (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 2-6 / 2020-04-27	Kinematic viscosity: 20°C: 1691.87 mm²/s 40°C: 1545.02 mm²/s	[redacted] 2020, Study 20.515774.0001, Interim report	Acceptable
		Meta SPC 2, Product 2-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 2-x / 2020-04-27	Kinematic viscosity: 20°C: 1142.59 mm²/s 40°C: 1118.48 mm²/s	[redacted], 2020, Study 20.516048.0001, Interim report	Acceptable
		Meta SPC 3, Product 3-6 (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 3-6 / 2020-04-27	Kinematic viscosity: 20°C: 198.11 mm²/s 40°C: 125.35 mm²/s	[redacted] 2020, Study 20.515829.0001, Interim report	Acceptable
		Meta SPC 3, Product 3-x (9.8% w/w lactic acid), Batch COM 22 / Méta SPC 3-x / 2020-04-27	Kinematic viscosity: 20°C: 1926.36 mm²/s 40°C: 1509.97 mm²/s	[redacted], 2020, Study 20.516296.0001, Interim report	Acceptable

Conclusion on the physical, chemical and technical properties of the product
The products of the family are AL formulations. The physical, chemical and technical properties of the products of the family were determined and found to be in compliance with the intended uses.

Accelerated storage studies are available to cover all Meta SPCs. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE packaging material (commercial packaging material). The long term storage stability studies (24 months) are on-going. Interim results after 12 months of storage show that the products are stable. The final reports of the long term storage studies should be provided in post authorisation.

The products of the family should not be stored above 40°C.

Low temperature storage results are available for Meta SPC 2 and show that after cold storage, the products should be shaken before use.
Products of Meta SPC 1 and 3 should be protected from frost.

Labelling implications:

- Protect from frost.
  - Applicable to Meta SPCs 1 and 3.
- After storage, shake before use.
  - Applicable to Meta SPC 2.
- Do not store above 40°C.
  - Applicable to all products.
- Shelf-life = two years.
  - Applicable to all products.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
Explosives	Differential Sanning Calorimetry	Meta SPC 3, Product 3-2 (9.8% w/w lactic acid), Batch COM22/ RTU FILM-FORMING PRODUCT 9.8% LACTIC ACID/3-2H/2020-07-07	The behaviour of the tested product was assessed during a heating procedure under nitrogen and at the atmospheric pressure using the Differential Scanning Calorimetry method (DSC). Conditions: Crucibles with crimped lids Isotherm at about 25 °C for 5 min Heating phase from 25 °C to 600 °C at 5 °C/min No exothermic reaction was observed up to 600°C. Hence, according to the Guidance on the Application of the CLP Criteria, it can be concluded that the test item presents no potential for explosive properties. The test item is a representative worst-case of the family, as it contains almost all co-formulants of the family and all co-formulants that could potentially be associated with expected explosive properties. Therefore, explosive properties are not anticipated for the products of the family.	[redacted] 2020, Report 20-907023-003	Acceptable Products in BPF are not considered as explosive.
Flammable gases	Waiver	Not relevant because the products are liquid formulations.			Not relevant
Flammable aerosols	Waiver	Not relevant because the products are liquid formulations not intended to be used as aerosols.			Not relevant
Oxidising gases	Waiver	Not relevant because the products are liquid formulations.			Not relevant
Gases under pressure	Waiver	Not relevant because the products are liquid formulations.			Not relevant

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
Flammable liquids	EC A.9	Meta SPC 3, Product 3-2 (9.8% w/w lactic acid), Batch COM22/ RTU FILM-FORMING PRODUCT 9.8% LACTIC ACID/3-2H/2020-07-07	No flash point up to 130°C (boiling point) was observed. The test item is representative of the rest of the family in terms of its composition. Even though the small differences in composition between the Meta SPCs could potentially lead to some differences in flammability potential, the flash point of the other formulations of the family could not possibly reach values below 60°C since no flash point was observed on the test item. Hence, no product of the family needs to be classified as a flammable liquid.	[redacted] 2020, Report 20-907023-002	Acceptable Products in BPF are not considered as flammable. (see confidential PAR)
Flammable solids	Waiver	Not relevant because the products are liquid formulations.			Not relevant
Self-reactive substances and mixtures	Differential Sanning Calorimetry	Meta SPC 3, Product 3-2 (9.8% w/w lactic acid), Batch COM22/ RTU FILM-FORMING PRODUCT 9.8% LACTIC ACID/3-2H/2020-07-07	The behaviour of the tested product was assessed during a heating procedure under nitrogen and at the atmospheric pressure using the Differential Scanning Calorimetry method (DSC). Conditions: Crucibles with crimped lids Isotherm at about 25 °C for 5 min Heating phase from 25 °C to 600 °C at 5 °C/min No exothermic reaction was observed up to 600°C. Hence, according to the Guidance on the Application of the CLP Criteria, it can be concluded that the test item presents no potential for self-reactive properties. The test item is a representative worst-case of the family, as it contains almost all co-formulants of the family and all co-formulants that could potentially be	[redacted] 2020, Report 20-907023-003	Acceptable Products in BPF are not considered to have self-reactive properties.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
			associated with expected self-reactive properties. Therefore, self-reactive properties are not anticipated for the products of the family.		
Pyrophoric liquids	Waiver	No study is needed because the formulations are known to be stable in air at room temperature for prolonged periods of time. The classification procedure does not need to be applied.			Acceptable Products in BPF are aqueous solutions.
Pyrophoric solids	Waiver	Not relevant because the products are liquid formulations.			Not relevant
Self-heating substances and mixtures	Waiver	The test procedure needs not be applied if the product is completely molten at 160°C. Therefore it is not relevant to consider the products in this hazard class, because the products are liquid formulations (i.e. they are completely molten at ambient temperature).			Acceptable
Substances and mixtures which in contact with water emit flammable gases	Waiver	Not relevant because the products are water-based formulations.			Not relevant
Oxidising liquids	Waiver	No experimental study is available. Consideration of the structure indicates that L-(+)-lactic acid does not have oxidising properties. According to CLP criteria (Annex I §2.14.4), "For organic substances or mixtures, the classification procedure for this class shall not apply if: (a) the substance or mixture does not contain oxygen, fluorine or chlorine; or (b) the substance or mixture contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen. None of the co-formulants contains halogen atoms. All the oxygen atoms present in the formulations components are linked only to carbon or hydrogen. Therefore, the products cannot be oxidising and this classification can be waived without further testing.			Acceptable Products of the BPF are not considered as oxidising liquids.
Oxidising solids	Waiver	Not relevant because the products are liquid formulations.			Not relevant

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td>Organic peroxides</td><td>Waiver</td><td colspan="3">Not relevant because the formulations do not fall under the definition of organic peroxides.</td><td>Not relevant</td></tr>
<tr><td>Corrosive to metals</td><td>UN C.1</td><td>Meta SPC 3, Product 3-2 (9.8% w/w lactic acid), Batch COM22/ RTU FILM-FORMING PRODUCT 9.8% LACTIC ACID/3-2H/2020-07-07</td><td>2 mm thickness aluminium and steel plates (50mm length, 20mm width) were exposed to the test item in defined conditions for 7 days at 55 °C ± 1 °C.
For each material, one specimen was immersed, one was half way immersed and one was placed in the gaseous phase.

The loss of mass for steel plates is summarized below:
<table>
<tr><th></th><th>Loss of mass (g)</th><th>Loss of mass (%)</th></tr>
<tr><td>Immersion</td><td>0.5303</td><td>3.4</td></tr>
<tr><td>Half way immersion</td><td>0.5170</td><td>3.3</td></tr>
<tr><td>Gaseous phase</td><td>0.0009</td><td>0.0</td></tr>
</table>
The loss of mass for aluminium plates is summarized below:
<table>
<tr><th></th><th>Loss of mass (g)</th><th>Loss of mass (%)</th></tr>
<tr><td>Immersion</td><td>0.0256</td><td>0.5</td></tr>
<tr><td>Half way immersion</td><td>0.0164</td><td>0.3</td></tr>
<tr><td>Gaseous phase</td><td>0.0025</td><td>0.0</td></tr>
</table>
The maximum weight loss of the metal plates after 7 days was 3.4%, which is lower than the 13.5% limit.

Moreover, no localised corrosion was observed on plates. Therefore, the test</td><td>[redacted] 2020, Report 20-907023-001</td><td>Acceptable

Products of the BPF are not classified as corrosive to metals.
See confidential PAR</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
			item does not need to be classified as corrosive to metals following United Nations Recommendations on the Transport of Dangerous Goods - Manual of Tests and Criteria and following Regulation EC No. 1272/2008 (CLP). Since the pH of all Meta SPCs are close, and compositions in surfactants or chelating agent are very close between meta SPC, it can be concluded that the test item is representative of the family and that products of the BPF do not needs to be classified as corrosive to metals.		
Auto-ignition temperatures of products (liquids and gases)	EC A.15	Meta SPC 3, Product 3-2 (9.8% w/w lactic acid), Batch COM22/ RTU FILM-FORMING PRODUCT 9.8% LACTIC ACID/3-2H/2020-07-07	The auto-ignition temperature of the test item was 478°C ± 3 °C. The test item is representative of the rest of the family in terms of its composition. Even though the small differences in composition between the Meta SPCs could potentially lead to some differences in flammability potential, the auto-ignition temperature of the other formulations of the family could not possibly reach values significantly below 478°C. Hence, no hazard in terms of auto-ignition is possible for any of the products of the family.	[redacted] 2020, Report 20-907023-002	Acceptable (See confidential PAR)
Relative self-ignition temperature for solids	Waiver	Not relevant because the products are liquid formulations.			Not relevant
Dust explosion hazard	Waiver	Not relevant because the products are liquid formulations.			Not relevant

Conclusion on the physical hazards and respective characteristics of the product

The products of the family are neither flammable nor auto-flammable. They have no explosive and no oxidizing properties. They are not classified as corrosive to metals (H290).

2.2.4 Methods for detection and identification

Active substance L-(+)-lactic acid – Method SOPa-LABCHI-512

The analytical quantification of L-(+) lactic acid is done by HPLC-UV.

An analytical method validation of L-(+) lactic acid in the reference products 2-y and 3-y of the Meta SPC 2 and 3, respectively, is performed by definition of the specificity, the linearity, the accuracy, the precision and the reproducibility of the method.

An additional validation (specificity and recovery) was performed on formulation 1-y, which contains all co-formulants of the family that were not present in the products 2-y and 3-y.

The compositions of the 3 tested products are reported in a specific tab "analytical details" in the BPF overview table.

The three method validations thus allow to cover the whole family.

Overview of the method

L-(+)-Lactic acid is determined by HPLC-UV using external calibration.
Column settings:

Column	AMINEX HPX-87H, 300 mm x 7.8 mm x 9 µm
Column temperature	25°C
Mobile phase	4mM Sulphuric acid solution
Flow	0.6 mL/min
Elution	Isocratic
Injection volume	20 µL
Detector	214 nm ± 4 nm
Run time	20 min
L-(+)-Lactic acid retention time	Peak 1 about 11 min, Peak 2 about 12 min

Sample preparation: see "Analytical method" column below.

Method validation

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
L-(+)-lactic acid (active substance) in Meta SPC 2, Product 2-y (9.8% w/w lactic acid), Batch COM 22 / MétaSPC 2-y / 2019-10-22	HPLC-UV About 200 mg of the test item are accurately weighed into a 50-mL volumetric flask and diluted to volume with milliQ water. The solution was filtered with RC 0.45 µm syringe filters before analysis.	Linearity: 5 analyte levels: 50%, 75%, 100%, 126% and 153% of target concentration (= 9.8% w/w) Accuracy: 3 reconstituted samples, 3 analyte levels: 51%, 102% and 153% of target concentration (= 9.8% w/w) Precision: 5 independent preparations	The response of the method was found to be linear between 201 and 613 mg/L L-(+)-Lactic acid (equivalent to 4.9%-15%). r = 1 y = 1381*x + 0 (the intercept was set to 0 because the confidence interval of the intercept includes 0).	In the Blank solution and in the Placebo solution no interferences were present at retention time of L-(+)-Lactic acid peaks. Two peaks belong to L-(+)-Lactic acid, peak 1 at about 11.04 minutes and peak 2 at about 11.89 minutes. They are both detected in the Reference and in the Test Solutions. The retention times of the analyte peaks in the Reference Solution correspond to those of the analyte in the Test Solution.	98, 98, 99	98.33	0.34 ≤ 1.90 (for samples at target concentration (= 9.8% w/w))	Not required for active substances	[redacted] 2019 Report 19.535398.0001

				UV-vis spectra of L-(+)-Lactic acid peaks in the Reference and Test solutions are equivalent. Chromatograms of blank solution, placebo solution, reference and test solutions were provided.					
L-(+)-lactic acid (active substance) in Meta SPC 3, Product 3-y (9.8% w/w lactic acid), Batch COM 22 / MétaSPC 3-y / 2019-10-08	HPLC-UV About 200 mg of the test item are accurately weighed into a 50-mL volumetric flask and diluted to volume with milliQ water.	Linearity: 5 analyte levels: 50%, 75%, 100%, 126% and 153% of target concentration (= 9.8% w/w) Accuracy: 3 reconstituted samples, 3 analyte levels: 48%, 106% and 152% of target concentration (= 9.8% w/w) Precision: 5 independent preparations	The response of the method was found to be linear between 201 and 613 mg/L L-(+)-Lactic acid (equivalent to 4.9%-15%). r = 1 y = 1380*x + 0 (the intercept was set to 0 because the	In the Blank solution and in the Placebo solution no interferences were present at retention time of L-(+)-Lactic acid peaks. Two peaks belong to L-(+)-Lactic acid, peak 1 at about 11.05 minutes and peak 2 at about 11.90 minutes. They are both detected in the Reference and in the Test Solutions. The retention times of the analyte peaks in the	100, 101, 102	101	0.33 ≤ 1.90 (for samples at target concentration (= 9.8% w/w))	Not required for active substances	[redacted], 2019 Report 19.533783.0001

			confidence interval of the intercept includes 0).	Reference Solution correspond to those of the analyte in the Test Solution. UV-vis spectra of L-(+)-Lactic acid peaks in the Reference and Test solutions are equivalent. Chromatograms of blank solution, placebo solution, reference and test solutions were provided.					
Meta SPC 1, Product 1-y (9.8% w/w lactic acid), Batch COM22/MétaSPC1-y/2020-09-23	HPLC-UV A quantity of 1.15 g of the test item was weighed into a 50-mL volumetric flask and the volume was made up with water for HPLC.	Recovery: 9.8% w/w; 2 preparations (2 measurements per preparation)	Covered by the other test items	To define the specificity of the analytical method, the following solutions were analysed: -solvent blank -formulation blank -reference item -test item No peak appears in the solvent blank and in the formulation blank near the	100.6 - 100.9	100.8	0.21	Not required for active substances	[redacted] 2020, Report 20-907023-004

	The solution was manually stirred then diluted 5 times with water.			peaks of lactic acid. In the reference item and in the test item, the peaks at the retention times at about 11.2 min and 12.0 represent respectively lactic acid I and lactic acid II. No additional peak appears in the reference item and in the test item near the peaks of lactic acid. Chromatograms of blank solution, placebo solution, reference and test solutions were provided. The specificity is therefore defined.					

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

Not required because relevant residues arising from the application of L(+) lactic acid are not expected.

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Not required because relevant residues arising from the application of L(+) lactic acid are not expected.									

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Not required because relevant residues arising from the application of L(+) lactic acid are not expected.									

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

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Not required because relevant residues arising from the application of L(+) lactic acid are not expected.									

Conclusion on the methods for detection and identification of the product
An analytical method was developed and validated for the determination of the active substance L-(+)-lactic acid in the formulations of the family. It was shown to possess sufficient analytical qualities in terms of linearity, precision, accuracy and specificity. The development and validation of an analytical method for the determination of citric acid in the products of the family is ongoing. The analytical method should be provided in post-authorisation. Residue analytical methods for L(+) lactic acid in food of plant and animal origin, in soil, air, drinking and surface water are not required. Since L(+)lactic acid is not classified as toxic or very toxic, analytical methods in body fluids and tissues are not required.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

MG 01: Disinfectants

PT3: Veterinary hygiene

The "Famille de produits Acide lactique TP3" is a PT3 biocidal family for professional users intended to be applied as teats disinfectants before and/or after milking. The family includes several products, and related uses, which were separated in three Meta SPCs:

- Meta SPC 1 includes ready to use liquid products at 9.8 % w/w L(+) lactic acid, used for pre- and post-milking teat disinfection. Teats of animals are treated by manual dipping (liquid/foam) using a teat dip cup, semi-automated dipping (liquid/foam) using a teat dip cup, manual spraying using a trigger spray, semi-automated spraying using an electronic sprayer or automated spraying using an automated sprayer or an robotic milking device, with a contact time of one minute for pre-milking application and five minutes for post-milking application. When the product is used during pre-milking, the teats must be cleaned before application of the product.

- Meta SPC 2 includes ready to use thick liquid products at 9.8 % w/w L(+) lactic acid, used for post-milking teat disinfection. Teats of animals are treated by manual dipping using a teat dip cup or semi-automated dipping using a teat dip cup, with a contact time of five minutes.

- Meta SPC 3 includes ready to use film-forming thick liquid products at 9.8 % w/w L(+) lactic acid, used for post-milking teat disinfection. Teats of animals are treated by manual dipping using a teat dip cup or semi-automated dipping using a teat dip cup, with a contact time of five minutes.

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

The biocidal product family is used to disinfect the teats of the udders of dairy animals, before milking and/or after milking. They are intended to be used against bacteria, yeasts, enveloped virus and bacteriophages (this last target organism is only concerned for the pre-milking application).

The product is used for the purpose of the protection of human and animal health (to prevent spoilage of milk and to prevent the transmission of disease causing microorganisms for animals)

2.2.5.3 Effects on target organisms, including unacceptable suffering

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

2.2.5.4 Mode of action, including time delay

The dissociation degree of Lactic acid in solution depends on pH value. In contact of undissociated form of Lactic acid with biological materials, such as micro-organisms, the Lactic acid is able to pass the cells membrane. At a relatively low pH, the Lactic acid inhibits the pathogens through the penetration of the undissociated form across the membrane, which interferes with the metabolic functions of the pathogen. The decrease in the intracellular pH causes dissipation of the membrane and leads to membrane disruption. Therefore, the mode of action for this product is inhibiting of cells growth and biomass producing and finally cells are destroyed.
Contact times for the different activities claimed are determined in the efficacy tests (see table below).

2.2.5.5 Efficacy data

1- <u>Inactivity of co-formulants (see composition of the family in the confidential PAR)</u>

a) Efficacy tests have been performed in accordance with the technical agreements for biocides (TAB efficacy) to demonstrate the non-activity of one co-formulant (perfume) present in the composition of the family. The co-formulant in question is clarified in the confidential PAR.

Since all products of the family contain this co-formulant at the same concentration, two comparative set of tests were performed on the Meta SPC 1 product 1-2 (representative product of the family) in both conditions before milking (3 g/L BSA, 1min, 30°C) and after milking (10 g/L skimmed milk, 5min, 30°C) according to:

TAB Test 1:
- The product without active substance (replaced by water).

TAB Test 3:
- The product with co-formulant and active substance,
- The product without co-formulant (replaced by water),

Test results are presented in the table below.
According to TAB test 1, the log reduction obtained is less than 3 for pre and post milking.
According to TAB test 3, the log reduction of the product with co-formulant and active substance, and the product without co-formulant is similar and not shows no more than 1.5 log difference, for pre and post milking.

Therefore according to requirements of the TAB, this coformulant is not considered as active in the conditions of use claimed.

b) Another co-formulant (pH regulator) is also an active substance approved according to BPR. Refer to confidential PAR regarding the non-activity justification of this co-formulant.

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Bactericidal	Teat disinfection pre-milking (PT3)	"GFB/COM22 Formule product 1-2 Meta SPC 1" **(without active substance)**	*Escherichia coli* DSM 682 *Staphylococcus aureus* DSM 799 *Streptococcus uberis* DSM 20569	EN 1656 (March 2010) Phase 2 step 1 test (suspension test)	**TAB Test 1** Concentration tested: *E. coli* and *S. aureus*: 0.1%, 50%, 80% (v/v) *S. uberis:* 0.1%, 10%, 20% (v/v) Temperature: 30°C Contact time: 1 min Clean conditions pre-milking (3g/L BSA) Criteria: lower than 3 log reduction	Bactericidal activity is < 3 log for 1 min contact time in clean condition	Test report IRM RE-1354/0720 RI = 1
Bactericidal	Teat disinfection pre-milking (PT3)	"GFB/COM22 Formule product 1-2 Meta SPC 1" **(with active substance and co-formulant)**	*Escherichia coli* DSM 682 *Staphylococcus aureus* DSM 799 *Streptococcus uberis* DSM 20569	EN 1656 (March 2010) Phase 2 step 1 test (suspension test)	**TAB Test 3** Concentration tested: *E. coli* and *S. aureus*: 0.1%, 50%, 80% (v/v) *S. uberis:* 0.1%, 10%, 20% (v/v) Temperature: 30°C Contact time: 1 min	Bactericidal activity demonstrated at 50% (v/v) for 1 min contact time in clean condition	Test report IRM RE-1352/0720 RI = 1

					Clean-conditions pre milking (3g/L BSA) Criteria: at least a 5 log reduction		
Bactericidal	Teat disinfection pre-milking (PT3)	"GFB/COM22 Formule product 1-2 Meta SPC 1" **(without co-formulant)**	*Escherichia coli* DSM 682 *Staphylococcus aureus* DSM 799 *Streptococcus uberis* DSM 20569	EN 1656 (March 2010) Phase 2 step 1 test (suspension test)	**TAB Test 3** Concentration tested: *E. coli* and *S. aureus*: 0.1%, 50%, 80% (v/v) *S. uberis:* 0.1%, 10%, 20% (v/v) Temperature: 30°C Contact time: 1 min Clean conditions pre-milking (3g/L BSA) Criteria: at least a 5 log reduction	Bactericidal activity demonstrated at 50% (v/v) for 1 min contact time in clean condition	Test report IRM RE-1356/0720 RI = 1
Bactericidal	Teat disinfection post-milking (PT3)	"GFB/COM22 Formule product 1-2 Meta SPC 1" **(without active substance)**	*Escherichia coli* DSM 682 *Staphylococcus aureus* DSM 799 *Streptococcus uberis* DSM 20569	EN 1656 (March 2010) Phase 2 step 1 test (suspension test)	**TAB Test 1** Concentration tested: *E. coli* and *S. aureus*: 0.1%, 50%, 80% (v/v) *S. uberis:* 0.1%, 10%, 20% (v/v) Temperature: 30°C Contact time: 5 min Conditions post-milking (1%	Bactericidal activity is < 3 log for 5 min contact time in dirty condition (skimmed milk)	Test report IRM RE-1355/0720 RI = 1

					skimmed milk powder) Criteria: lower than 3 log reduction		
Bactericidal	Teat disinfection post-milking (PT3)	"GFB/COM22 Formule product 1-2 Meta SPC 1" **(with active substance and co-formulant)**	*Escherichia coli* DSM 682 *Staphylococcus aureus* DSM 799 *Streptococcus uberis* DSM 20569	EN 1656 (March 2010) Phase 2 step 1 test (suspension test)	**TAB Test 3** Concentration tested: *E. coli* and *S. aureus*: 0.1%, 50%, 80% (v/v) *S. uberis*: 0.1%, 10%, 20% (v/v) Temperature: 30°C Contact time: 5 min Conditions post-milking (1% skimmed milk powder) Criteria: at least a 5 log reduction	Bactericidal activity demonstrated at 50% (v/v) for 5 min contact time in dirty condition (skimmed milk)	Test report IRM RE-1353/0720 RI = 1
Bactericidal	Teat disinfection post-milking (PT3)	"GFB/COM22 Formule product 1-2 Meta SPC 1" **(without co-formulant)**	*Escherichia coli* DSM 682 *Staphylococcus aureus* DSM 799 *Streptococcus uberis* DSM 20569	EN 1656 (March 2010) Phase 2 step 1 test (suspension test)	**TAB Test 3** Concentration tested: *E. coli* and *S. aureus*: 0.1%, 50%, 80% (v/v) *S. uberis:* 0.1%, 10%, 20% (v/v) Temperature: 30°C Contact time: 5 min Conditions post-milking (1%	Bactericidal activity demonstrated at 50% (v/v) for 5 min contact time in dirty condition (skimmed milk)	Test report IRM RE-1357/0720 RI = 1

					skimmed milk powder) Criteria: at least a 5 log reduction		

2- Efficacy of the product family "Famille de produits Acide lactique TP3"

Laboratory studies were conducted with representative products of Famille de produits Acide lactique TP3" products according to the Guidance on BPR, Volume II Efficacy – Assessment and Evaluation (Parts B+C).

Efficacy studies are provided for assessing the efficacy of the "Famille de produits Acide lactique TP3" products and are summarised Meta SPC by Meta SPC for more readability. These studies are:

- quantitative suspension tests (phase 2, step 1) for bactericidal, yeasticidal, virucidal and phagocidal efficacy,
- quantitative porous surface tests (phase 2, step 2) for bactericidal efficacy according to a drop/dip test protocol of the CEN draft 2016 (no P2S2 test is available for yeasts, virus and bacteriophages at the time of the submission of the dossier).

For META-SPC1, no variation occurs, except minor variations of colorants and perfume, therefore efficacy tests have been performed with the representative product 1-2.
For Meta-SPC2, minor variations for thickening agent and colorants occur. Efficacy tests have been performed with representative products 2-2 and 2-4. Taking into account the variations of the co-formulants presented in the META-SPC 2, it can be assumed that they have no impact on efficacy and the efficacy results of these representative products support the efficacy of the META-SPC 2.
For Meta-SPC3, minor variations for thickening agent and colorants occur. Efficacy tests have been performed with representative product 3-2. Taking into account the variations of the co-formulants presented in the META-SPC 3, it can be assumed that they have no impact on efficacy and the efficacy results of these representative products support the efficacy of the META-SPC 3.

The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

Meta SPC 1 - Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection (Uses 1 to 8)

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**
Meta SPC 1							
Bactericidal	Teat disinfection pre-milking (PT3)	"GFB/COM22 Formule product 1-2 Meta SPC 1"	*E. coli* DSM 682 *Staphylococcus aureus* DSM 799 *Streptococcus uberis* DSM 20569	EN 1656 (March 2010) Phase 2 step 1 test (suspension test)	Concentration tested: *E. coli* and *S. aureus*: 0.1%, 50%, 80% (v/v) *S. uberis:* 0.1%, 10%, 20% (v/v) Temperature: 30°C Contact time: 1 min Clean conditions pre-milking (3g/L BSA) Criteria: at least a 5 log reduction	Bactericidal activity demonstrated at 50% (v/v) for 1 min contact time in clean condition	Test report N°RE-1263/0719 RI = 1
Bactericidal	Teat disinfection pre-milking (PT3)	"Ready-to-use LIQUID products Pre-milking", product 1-2 of Meta SPC 1	*E. coli* ATCC 10536 *S. aureus* ATCC 6538 *S. uberis* ATCC 19436	Synthetic skin according to the CEN draft (2016) – drop/dip protocol Phase 2 step 2 test (surface test)	Concentration tested: 1%, 80%, 100% (v/v) Temperature: 30°C Contact time: 1 min Clean conditions pre-milking (3 g/L BSA) Criteria: at least a 4 log reduction (pre-milking)	Bactericidal activity demonstrated at 80 % v/v for 1 min contact time in clean conditions	Test report LMH No.5516-1 RI = 1
Yeasticidal	Teat disinfection pre-milking (PT3)	"GFB/COM22 Formule product 1-2 Meta SPC 1"	*C. albicans* ATCC 10231	EN 1657 (May 2016) Phase 2 step 1 test (suspension test)	Concentration tested: 0.1%, 50%, 80% (v/v) Temperature: 30°C Contact time: 1 min Clean conditions pre-milking (3 g/L BSA) Criteria: at least a 4 log reduction	Yeasticidal activity demonstrated at 80 % v/v for 1 min contact time in clean condition	Test report N°RE – 1260/0719 RI = 1
Phagicidal	Teat disinfection pre-	"GFB/COM22 Formule	Bacteriophages P001 DSM 4262	EN 13610 (July 2003) Phase 2 step	Concentration tested: 80%, 50%, 0.1% (v/v) Temperature: 30°C	Phagocidal activity demonstrated at 50%	Test report N°RE-1271/0719

	milking (PT3)	product 1-2 Meta SPC 1"	Bacteriophages P008 DSM 10567	1 test (suspension test)	Contact time: 1 min Clean conditions pre milking (3g/L of bovine albumin) Criteria: reduction of viability of at least 10^4	(v/v) for 1 min contact time in clean condition	RI = 1
Virucidal (enveloped virus)	Teat disinfection pre-milking (PT3)	"GFB/COM22 Formule product 1-2 Meta SPC 1"	MVA = Modified Vacciniavirus Ankara ATCC VR-1508	EN14675 (May 2015) Phase 2 step 1 test (suspension test)	Concentration tested: 97%, 80%, 50%, 0.1% (v/v) Temperature: 30°C Contact time: 1 min Clean conditions pre-milking (3g/L of bovine albumin) Criteria: at least a 4 log reduction	Efficacy against Modified Vaccinia virus Ankara ATCC VR-1508 (MVA) demonstrated at 80% (v/v) for 1 min contact time in clean condition	Test report Virhealth R2006LVYDE001 RI = 1
Bactericidal	Teat disinfection post-milking (PT3)	"GFB/COM22 Formule product 1-2 Meta SPC 1"	*E. coli* DSM 682 *S. aureus* DSM 799 *S. uberis* DSM 20569	EN 1656 (March 2010) Phase 2 step 1 test (suspension test)	Concentration tested: *E. coli* and *S. aureus*: 0.1%, 50%, 80% (v/v) *S. uberis:* 0.1%, 10%, 20% (v/v) Temperature: 30°C Contact time: 5 min Conditions post-milking: 10 g/L of reconstituted skimmed milk Criteria: at least a 5 log reduction	Bactericidal activity demonstrated at 50% (v/v) for 5 min contact time in dirty condition (skimmed milk)	Test report N°RE-1262/0719 RI = 1
Bactericidal	Teat disinfection post-milking (PT3)	"GFB/COM22 Formule product 1-2 Meta SPC 1"	*Escherichia coli* DSM 682 *Staphylococcus aureus* DSM 799 *Streptococcus uberis* DSM 20569	Synthetic skin according to the CEN draft (2016) – drop/dip protocol Phase 2 step 2 test (surface test)	Concentration tested: 0.1%, 40%, 60%, 80%, 100% (v/v) Temperature: 30°C Contact time: 5 min Conditions post-milking: 1% skimmed milk powder) Criteria: at least a 4 log reduction	Bactericidal activity demonstrated at 40% (v/v) for 5 min contact time in dirty condition (skimmed milk)	Test report LMH N°5673-1 RI = 1
Yeasticidal	Teat disinfection post-milking (PT3)	"GFB/COM22 Formule product 1-2 Meta SPC 1"	*C. albicans* ATCC 10231	EN 1657 (May 2016) Phase 2 step 1 test	Concentration tested: 0.1%, 50%, 80% (v/v) Temperature: 30°C Contact time: 5min	Yeasticidal activity demonstrated at 50 % v/v for 5 min contact time in dirty condition (skimmed milk)	Test report N°RE – 1259/0719 RI = 1

				(suspension test)	Conditions post-milking (10 g/L reconstituted skimmed milk) Criteria: at least a 4 log reduction		
Virucidal (enveloped virus)	Teat disinfection post-milking (PT3)	"GFB/COM22 Formule product 1-2 Meta SPC 1"	MVA = Modified Vaccinia virus AnkaraATCC VR-1508	EN14675 (May 2015) Phase 2 step 1 test (suspension test)	Concentration tested: 80%, 50%, 0.1% (v/v) Temperature: 30°C Contact time: 5 min Conditions post milking (10 g/l skimmed milk powder) Criteria: at least a 4 log reduction	Efficacy against enveloped virus demonstrated at 80% (v/v) for 5 min contact time in dirty condition (skimmed milk)	Test report Virhealth R2006LVYDE001 RI = 1

Pre-milking disinfection:

- Phase 2, step 1 tests have been performed for bactericidal activity (EN 1656), yeasticidal activity (EN 1657), phagocidal activity (EN 13610) and against enveloped virus (EN 14475), according to the requirements of the norms for teat disinfection for pre-milking: at 30°C with a contact time of 1 min and BSA (3 g/L), showing the efficacy of the product at 50% v/v against bacteria and bacteriophages, and 80% v/v against yeasts and enveloped virus.
- Phase 2, step 2 test has been performed for bactericidal activity, according to the protocol drop/dip of the CEN draft (2016) showing the efficacy of the product at 30°C with a contact time of 1 min and BSA (3 g/L), at 80% v/v.

In absence of phase 2 step 2 test available for yeasticidal, phagocidal and virucidal activities, results from phase 2 step 1 test (EN 1657, EN 13610 & EN 14475) are acceptable for the time being.

Post-milking disinfection:

- Phase 2, step 1 tests have been performed for bactericidal activity (EN 1656), yeasticidal activity (EN 1657) and against enveloped virus (EN 14475), according to the requirements of the norms for teat disinfection for post-milking: at 30°C with a contact time of 5 min and skimmed milk (1%), showing the efficacy of the product at 50% v/v against bacteria and yeasts and 80% v/v against enveloped virus.
- Phase 2, step 2 test has been performed for bactericidal activity, according to the protocol drop/dip of the CEN draft (2016) showing the efficacy of the product at 30°C with a contact time of 5 min and skimmed milk, at 40% v/v.

In absence of phase 2 step 2 test available for yeasticidal and virucidal activities, results from phase 2 step 1 test (EN 1657 & EN 14675) are acceptable for the time being.

Meta SPC 2 - Teat disinfection of milkable animals: Post-milking teat disinfection (Uses 9 and 10):

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**
Meta SPC 2							
Bactericidal	Teat disinfection post-milking (PT3)	GFB/COM22 – Formule product 2-4 Meta SPC 2	*Escherichia coli* DSM 682 *Staphylococcus aureus* DSM 799 *Streptococcus uberis* DSM 20569	EN 1656 (March 2010) Phase 2 step 1 test (suspension test)	Concentration tested: *E. coli* and *S. aureus*: 0.1%, 50%, 80% (v/v) *S. uberis:* 0.1%, 10%, 20% (v/v) Temperature: 30°C Contact time: 5 min Conditions post-milking (10 g/L of reconstituted milk) Criteria: at least a 5 log reduction	Bactericidal activity demonstrated at 50% (v/v) for 5 min contact time in dirty condition (skimmed milk)	Test report N°RE-1268/0719 RI = 1
Bactericidal	Teat disinfection post-milking (PT3)	"1588-E12 Meta SPC 7", product 2-2 Meta SPC2	*Escherichia coli* ATCC 10536 *Staphylococcus aureus* ATCC 6538 *Streptococcus uberis* ATCC 19436	Synthetic skin according to the CEN draft (2016) – drop/dip protocol Phase 2 step 2 test (surface test)	Concentration tested: 50%, 80%, 100% (v/v) Temperature: 30°C Contact time: 5 min Conditions post-milking (1% skimmed milk powder) Criteria: at least a 4 log reduction	Bactericidal activity demonstrated at 50% v/v for 5 min contact time in dirty condition (skimmed milk)	Test report No. 5420-1 RI = 1
Yeasticidal	Teat disinfection post-milking (PT3)	GFB/COM22 – Formule product 2-4 Meta SPC 2	*C.albicans* ATCC 10231	EN 1657 (May 2016) Phase 2 step 1 test (suspension test)	Concentration tested: 0.1%, 50%, 80% (v/v) Temperature: 30°C Contact time: 5 min Conditions post-milking (10 g/L reconstituted skimmed milk) Criteria: at least a 4 log reduction	Yeasticidal activity demonstrated at 50% v/v for 5 min contact time in dirty condition (skimmed milk)	Test report N°RE – 1267/0719 RI = 1
Virucidal (enveloped virus)	Teat disinfection post-milking (PT3)	GFB/COM22 – Formule product 2-4 Meta SPC 2	Virus of Vaccinia, strain Ankara ATCC	EN 14675 (May 2015) Phase 2 step 1 test	Concentration tested: 0.1%, 50%, 80% (v/v) Temperature: 30°C Contact time: 5 min	Efficacy against enveloped virus demonstrated at 50% v/v for 5 min contact	Test report N° RE-1266/0719 RI = 1

			VR-1508 (MVA)	(suspension test)	Conditions post-milking (10 g/L of reconstituted milk) Criteria: at least a 4 log reduction	time in dirty condition (skimmed milk)	

- Phase 2, step 1 tests have been performed for bactericidal activity (EN 1656), yeasticidal activity (EN 1657) and virucidal activity (EN 14475), according to the requirements of the norms for teat disinfection for post-milking: at 30°C with a contact time of 5 min and skimmed milk (1%), showing the efficacy of the product at 50% v/v against bacteria, yeasts and enveloped virus.
- Phase 2, step 2 test has been performed for bactericidal activity, according to the protocol drop/dip of the CEN draft (2016) showing the efficacy of the product at 30°C with a contact time of 5 min and skimmed milk (1%), at 50% v/v.

Meta SPC 3 - Teat disinfection of milkable animals: Post-milking teat disinfection (Uses 11 and 12):

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**
Meta SPC 3							
Bactericidal	Teat disinfection post-milking (PT3)	GFB/COM22 – Formule product 3-2 Meta SPC 3	*Escherichia coli* DSM 682 *Staphylococcus aureus* DSM 799 *Streptococcus uberis* DSM 20569	EN 1656 (March 2010) Phase 2 step 1 test (suspension test)	Concentration tested: *E. coli* and *S. aureus*: 0.1%, 50%, 80% (v/v) *S. uberis:* 0.1%, 10%, 20% (v/v) Temperature: 30°C Contact time: 5 min Conditions post-milking (10g/L reconstituted skimmed milk) Criteria: at least a 5 log reduction	Bactericidal at 50% (v/v) for 5 min contact time in dirty condition (skimmed milk)	Test report N°RE-1270/0719 RI = 1
Bactericidal	Teat disinfection post-milking (PT3)	"1590-E11 Meta SPC 8", product 3-2 Meta SPC3	*Escherichia coli* ATCC 10536 *Staphylococcus aureus* ATCC 6538 *Streptococcus uberis* ATCC 19436	Synthetic skin according to the CEN draft (2016) – drop/dip protocol Phase 2 step 2 test (surface test)	Concentration tested: 50%, 80%, 100% (v/v) Temperature: 30°C Contact time: 5 min Conditions post-milking (1% skimmed milk powder) Criteria: at least a 4 log reduction	Bactericidal activity demonstrated at 50% v/v for 5 min contact time in dirty condition (skimmed milk)	Test report No. 5422-1 RI = 1
Yeasticidal	Teat disinfection post-milking (PT3)	GFB/COM22 – Formule product 3-2 Meta SPC 3	*C.albicans* ATCC 10231	EN 1657 (May 2016) Phase 2 step 1 test (suspension test)	Concentration tested: 0.1%, 50%, 80% (v/v) Temperature: 30°C Contact time: 5 min Conditions post-milking (10 g/L reconstituted skimmed milk) Criteria: at least a 4 log reduction	Yeasticidal activity demonstrated at 50% v/v for 5 min contact time in dirty condition (skimmed milk)	Test report N°RE – 1269/0719 RI = 1

Virucidal (enveloped virus)	Teat disinfection post-milking (PT3)	GFB/COM22 – Formule product 3-2 Meta SPC 3	Virus of Vaccinia, strain Ankara ATCC VR-1508 (MVA)	EN 14675 (May 2015)	Phase 2 step 1 test (suspension test) Concentration tested: 0.1%, 50%, 80% (v/v) Temperature: 30°C Contact time: 5 min Conditions post-milking (10 g/L of reconstituted milk) Criteria: at least a 4 log reduction	Efficacy against enveloped virus demonstrated at 50% v/v for 5 min contact time in dirty condition (skimmed milk)	Test report R2006LVYDE002 RI = 1

- Phase 2, step 1 tests have been performed for bactericidal activity (EN 1656), yeasticidal activity (EN 1657) and virucidal activity (EN 14475), according to the requirements of the norms for teat disinfection for post-milking: at 30°C with a contact time of 5 min and skimmed milk (1%), showing the efficacy of the product at 50% v/v against bacteria, yeasts and enveloped virus.
- Phase 2, step 2 test has been performed for bactericidal activity, according to the protocol drop/dip of the CEN draft (2016) showing the efficacy of the product at 30°C with a contact time of 5 min and skimmed milk (1%), at 50% v/v.

Conclusion on the efficacy of the product
The family product "Famille de produits Acide lactique TP3" has shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C) for the following uses: - In META-SPC1 - Teat disinfection of milkable animals, with a contact time of 1 minute before milking (after cleaning) and/or 5 minutes after milking, by manual dipping, manual foam dipping, manual spraying, automated and semi-automated spraying, against bacteria, yeasts, enveloped viruses and bacteriophages (only in pre-milking). - In META-SPC2 - Teat disinfection of milkable animals, with a contact time of 5 minutes after milking, by manual and semi-automated dipping, against bacteria, yeasts and enveloped viruses. - In META-SPC3 - Teat disinfection of milkable animals, with a contact time of 5 minutes after milking, by manual and semi-automated dipping, against bacteria, yeasts and enveloped viruses.

2.2.5.6 Occurrence of resistance and resistance management

No resistance phenomenon has been reported with lactic acid in the scientific literature.

No incidence of resistance to Lactic acid has been recorded until now. (Source: Assessment Report. L (+) Lactic Product types 2, 3 and 4. June 2017. RMS, Germany)

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

2.2.5.7 Known limitations

None.

2.2.5.8 Evaluation of the label claims

French competent authorities (FR CA) assessed that family product "Famille de produits Acide lactique TP3" with three META SPC has shown a sufficient efficacy in accordance with the requirements of Guidance on BPR, Volume II Efficacy – Assessment and Evaluation (Parts B+C):

- In META-SPC1 - Teat disinfection of milkable animals, with a contact time of 1 minute before milking (after cleaning) and/or 5 minutes after milking, by manual dipping, manual foam dipping, manual spraying, automated and semi-automated spraying, against bacteria, yeasts, enveloped viruses and bacteriophages (only in pre-milking).

- In META-SPC2 - Teat disinfection of milkable animals, with a contact time of 5 minutes after milking, by manual and semi-automated dipping, against bacteria, yeasts and enveloped viruses.

- In META-SPC3 - Teat disinfection of milkable animals, with a contact time of 5 minutes after milking, by manual and semi-automated dipping, against bacteria, yeasts and enveloped viruses.

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

The family product "Famille de produits Acide lactique TP3" is not intended to be used with another biocidal product.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

No acute oral and dermal toxicity study, nor eye irritation studies neither skin sensitisation study have been performed on any product of the biocidal product family.

However, the applicant has provided two *in vitro* toxicological studies carried out with similar products for skin irritation. A comparison between the composition of the tested products and the worst-case formulation of the compared Meta SPC has been performed (Refer to the Confidential annex).

A classification by calculation according to the CLP Regulation n°1272/2008 rules is performed for the endpoints with no submitted studies. The harmonised classification (when available) and classification proposed in the provided MSDS have been used for active substance and co-formulants.

No human data is available.

Skin corrosion and irritation

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**
In vitro assessment of skin irritating potential, OECD N°439, not GLP, reliable	Test item :product 2-2 (meta-SPC 2), 50 mg/cm² of test item, Topical application for 15min, Washing, Observations after 42 hours by a MIT test	Performed with a 3-dimensional reconstituted human epidermis model (EpiSkin Model)	Mean viability : negative control (PBS) : 100% positive control (SDS 5%) : 21% Test item : 99% **Conclusion:** Mean viability of treated tissues > 50%. According to the OECD 439 guideline, no classification required for the product 2-2	No deviation	[redacted] (2019) Report number: IC-CHEM 19.214
In vitro assessment of skin irritating potential, OECD N°439, not GLP, reliable	Test item :product 3-2 (meta-SPC 3), 50 mg/cm² of test item, Topical application for 15min,	Performed with a 3-dimensional reconstituted human epidermis model (EpiSkin Model)	Mean viability : negative control (PBS) : 100% positive control (SDS 5%) : 21% Test item : 100%	No deviation	[redacted] (2019b) Report number: IC-CHEM 19.215

	Washing, Observations after 42 hours by a MIT test		**Conclusion:** Mean viability of treated tissues > 50%. According to the OECD 439 guideline, no classification required for the product 3-2		

In vitro studies on the skin irritation has been provided on representative products pertaining to the meta- SPC 2 and 3. Both studies show that the tested product is not classified for skin irritation.

Based on the read-across approach, no classification for skin irritation is retained for products pertaining to the meta-SPC 1, 2 and 3.

Please refer to confidential annex for further details.

META SPC 1-2-3

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The products of the meta-SPC 1, 2, 3 are considered to be non-classified for skin irritation
Justification for the value/conclusion	Based on the results of the provided studies and on the read-across approach (please see confidential annex), no classification for skin irritation is proposed for products pertaining to the meta-SPC 1, 2, 3.
Classification of the product according to CLP	Not classified.

Aspiration hazard

META SPC 1-2-3

Conclusion used in Risk Assessment – Aspiration hazard	
Value/conclusion	Not classified
Justification for the value/conclusion	Some ingredients are classified for aspiration hazard (H304). However, they are present at a concentration largely inferior to the aspiration hazard threshold of 10%. Therefore, no classification is required.
Classification of the product according to CLP	Not classified

Eye irritation

No in vitro, in vivo or human data on the eye irritation potential of products pertaining to meta-SPC 1, 2 and 3 are available.

META SPC 1-2-3

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The products of meta-SPC 1, 2, 3 are considered to cause serious eye damage.

Justification for the value/conclusion	No study on eye irritation was performed. The classification is determined using the calculation method of CLP Regulation. Considering the content of active substance and co-formulants in the products, a classification Eye Dam.1 H318 (in accordance with Regulation EC/1272/2008) is needed. Calculation details in Confidential annex.
Classification of the product according to CLP	Classification Serious eye damage category 1, H318: Causes serious eye damage is required.

Respiratory tract irritation

META SPC 1-2-3

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory tract irritation. Since the products of the family are neither classified for skin corrosion (only skin irritation) nor for acute toxicity by inhalation, the labelling EUH071 is not required even for the product for which an exposure to aerosols is expected.
Classification of the product according to CLP	Not irritant for respiratory tract.

Skin sensitization

META SPC 1-2-3

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to the skin.
Justification for the value/conclusion	No study on skin sensitisation was performed. Therefore, the classification is determined according to the CLP Regulation. No classification for skin sensitisation is required. However, several ingredients classified as sensitizing (Skin Sens. 1/1B) are present at a concentration greater than the 1/10th of GCL. Therefore, EUH208 labelling for these ingredients is needed. For more details, please see confidential annex.
Classification of the product according to CLP	Not classified. Additional labelling information EUH208 required for all Meta SPCs.

Respiratory sensitization (ADS)

META SPC 1-2-3Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitizing to the respiratory tract
Justification for the value/conclusion	Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory sensitisation.
Classification of the product according to CLP	Not classified.

Acute toxicity

Acute toxicity by oral route

META SPC 1-2-3

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not toxic by oral route
Justification for the selected value	Based on available data on the composition of the products and according to the classification rules laid down in the CLP Regulation, no classification is required for acute toxicity by oral route for any product of the family QUARON.
Classification of the product according to CLP	Not classified.

Acute toxicity by inhalation

META SPC 1-2-3

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not toxic by inhalation route
Justification for the selected value	Based on available data on the composition of the products and according to the classification rules laid down in the CLP Regulation, no classification is required for acute toxicity by inhalation for any product of the family.
Classification of the product according to CLP	Not classified.

Acute toxicity by dermal route
META SPC 1-2-3

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not toxic by dermal route.
Justification for the selected value	Based on available data on the composition of the products and according to the classification rules laid down in the CLP Regulation, no classification is required for acute toxicity by dermal route for any product of the family QUARON.
Classification of the product according to CLP	Not classified

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Lactic Acid
Value(s)	-
Justification for the selected value	Not relevant

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

According to the definitions of a substance of concern set in the «Guidance on the BPR, volume III Human Health- Assessment & Evaluation (Parts B+C)", no substance of concern has been identified. Please refer to Confidential Annex

Available toxicological data relating to a mixture

Not relevant.

Other

[Please include any relevant information and considerations not covered above e.g. food and feeding stuffs studies, effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product and other test(s) related to the exposure to humans. If not relevant, delete the title.]

2.2.6.2 Exposure assessment

Introductory remarks

The Famille de produits Acide Lactique TP3 - QUARON is a PT3 biocidal family intended to be applied as teats disinfectants before and/or after milking by professional users. The biocidal product family is a water-based family composed of 3 meta-SPC claimed for:

- Pre and/or post milking teat disinfection by manual liquid dipping (**Uses #1, 9 and 11**) → PROFESSIONALS
- Pre and/or post milking teat disinfection by manual dipping with foam (**Use #2**) → PROFESSIONALS
- Pre- and/or post-milking teat disinfection by semi-automated liquid dipping (**Uses #3, 10, 12**) → PROFESSIONALS
- Pre- and/or post-milking teat disinfection by semi-automated dipping with a foam (**Use #4**) → PROFESSIONALS
- Pre- and/or post-milking teat disinfection by manual spraying (**Use #5**) → PROFESSIONALS
- Pre- and/or post-milking teat disinfection by semi-automated spraying (**Use #6**) → PROFESSIONALS
- Pre- and/or post-milking teat disinfection by automated spraying via a spray robot or a robotic milking equipment (**Uses #7 and #8**) → PROFESSIONALS

All the uses of the biocidal product family are summarized for each META SPC in the table below.

Table 1: Summary of Uses developed in the exposure assessment

	META SPC 1	**META SPC 2**	**META SPC 3**
Use 1	×		
Use 2	×		
Use 3	×		
Use 4	×		
Use 5	×		
Use 6	×		
Use 7	×		
Use 8	×		
Use 9		×	
Use 10		×	
Use 11			×
Use 12			×

All disinfectants products of the family are RTU (Ready To Use) liquid formulations.

Following the WG TOX I - 2021 that was held on March 2021 and in the frame of the discussion of the CAR of Lactic Acid TP6, it has been agreed not to perform the comparison of endogenous L-(+)-lactic acid with systemic exposure levels at product authorization. Consequently, no calculation regarding the estimation of level of exposure of lactic acid is necessary.

Therefore, based on the classification "H318- Causes serious eye damage" of all the products of the BPF family, only a qualitative local risk assessment has been performed according to the Guidance on the Biocidal Products Regulation - Volume III Human health - Assessment and Evaluation (Parts B + C).

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

Summary table: main paths of human exposure					
Exposure path	**Primary (direct) exposure**		**Secondary (indirect) exposure**		
	Professional users (including industrial users and trained professional users)	**Non-professional users**	**Professional users** (including industrial users and trained professional users)	**Non-professional bystanders/ General public**	**Via food**
Oral	No	n.a.	No	n.a.	Yes
Dermal	Yes	n.a.	No	n.a.	n.a.
Inhalation	Yes	n.a.	Yes	n.a.	n.a.

List of scenarios

Summary table: exposure scenarios		
Scenario and task number	**Description of scenario and tasks**	**Exposed group**
Professional users		
Primary exposure		
Uses 1, 2, 3, 4, 9, 10, 11, 12 : Teat disinfection of milkable animals by manual liquid/foaming dipping- META SPC 1, 2, 3		
[Scenario 1]	**Application by manual dipping using a teat dip cup**	
Task [1.1]	Mixing and Loading	Professionals/ Industrials
Task [1.2]	Manual application of the product by dipping using a teat dip cup	
Task [1.3]	Post application – Cleaning of equipment	
Task [1.4]	Post application – Cleaning of the treated teats by wiping	
Uses # 5, 6, 7, 8 : Teat disinfection of milkable animals by liquid/foaming spraying – META SPC 1		
[Scenario 2]	**Application by spraying**	
Task [2.1]	Mixing and loading	Professionals/ Industrials
Task [2.2]	Application by manual spraying	
Task [2.3]	Application by automated spraying using a spray robot	
Task [2.4]	Post application – Cleaning of the equipment (sprayer)	
Task [2.5]	Post application – Cleaning of the treated teats by wiping	
Secondary exposure		
[Scenario 3]	**Exposure of bystander during spray application**	Professionals bystander

Professional users (including industrial users)

Uses #1, 2, 3, 4, 9, 10, 11, 12 – Teat disinfection of milkable animals by manual dipping- PT3 (META SPC 1, 2, 3)

Primary exposure

As the same tasks are performed with products of the meta-SPC 1, 2, 3 for the Uses 1,2, 3, 4, 9, 10, 11, 12, the same exposure and risk assessment can be performed for these uses considering the liquid formulation (corresponding to meta-SPC1 products) as a worst case.

In the assessment it is thus considered that the application of a biocidal product in the form of a foam is deemed covered by the application of a liquid.

Scenario 1: Disinfection of teats by manual dipping

Task [1.1] – Mixing and loading

Description of Task [1.1]: Mixing and loading
Before use, RTU products of the meta-SPC 1, 2, 3 are filled into the reservoir of a dip cup. The dip cup is then squeezed to make the product rise into 2/3 of the reservoir for the application by dipping. This loading step is done manually if the packaging is less than 20L or semi-automatically (by connecting the container to the dipping equipment) for the biggest packaging up to 1000L. Exposure of the user may occur during the loading phase due to splashes during filling of the product into the reservoir of the cup.

Task [1.2]: Application by manual dipping

Description of Task [1.2]: Application by dipping (liquid/foam)
According to the applicant, before and after milking, the dip cup (containing liquid/foam products) is put over each teat from below making sure that the full length of each teat is immersed into the disinfectant. The teats are then wiped with a single use paper or a towel. Although dipping cups are designed to limit potential exposure of the professional during the application task, it is still assumed that professional exposure can occur because of the release of spills and drops.

Task [1.3]: Post application – Cleaning of the equipment

Description of Task [1.3]: Cleaning of the equipment
It is considered that after application, a small amount of product will remain in the application equipment. During rinsing of the dipping cup, the professional can be exposed to spills of the product. Despite the dilution of the product with water during the rinsing, it

is assumed, as a worst case, that the product is still classified for human health during the rinsing.

Task [1.4] – Post application- Cleaning of the teats by wiping

Description of Task [1.4]: Cleaning of the treated teats
For pre-milking treatment, the products is left for one minute and then wiped with a single use paper or a towel. For post milking equipment, the product is left until next milking and then wiped. No eye contact is expected during this task.

Combined scenarios

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

Risk characterisation for primary exposure for Uses 1, 2, 3, 4, 9, 10, 11, 12 (Meta-SPC 1, 2 and 3)

Outcome of qualitative local risk assessment

RTU products from meta-SPC 1, 2 and 3 are classified as Eye Damage category 1 - H318 (see confidential PAR for more details on the classification). All the products are intended to be applied by professional users.

A qualitative risk assessment is thus performed. Please refer to the tables below.

For the loading task into the dipping cup, the professional is using the product for a low duration per day and with PPE. Consequently, the local risk is deemed acceptable.

For application by manual dipping using a dip cup and rinsing, the professional is using the product few minutes per day and with PPE. Consequently, the risk is deemed acceptable.

Table – Local effects – Qualitative assessment for disinfection of teats by manual dipping using dip teat cups: Products from Meta SPC 1, 2, 3 are classified for eye damaging Cat.1:

Hazard			Exposure							Risk
Hazard category	**Effects in terms of C&L**	**PT**	**Who is exposed**	**Tasks, uses, processes**	**Potential exposure routes**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE**	**Relevant RMM**	**Conclusion on risk**
HIGH	Eye Dam. Cat 1 (H318)	PT3	Professionals	Loading of the RTU product into the dipping cup	Eye	Frequency: once a day, everyday Duration: Mixing & loading = few minutes	Eye exposure through potential splashes or hand to eye transfer during the different tasks	Chemical goggles	<u>Labelling</u> • Labelling according to CLP <u>Trained personnel</u> • Professional workers • instructions for use minimizing exposure for professionals	**Acceptable** (+) Professionals following instructions for use and RMM on the label (+) Professionals using PPE (+) Low exposure duration (few min per day) (-) High frequency (-) High hazard category

				Application by dipping and cleaning		Frequency: 3 times per day, everyday Duration: Application = few minutes				**Acceptable** (+) Professionals following instructions for use and RMM on the label (+) Professionals using PPE (+) Low exposure duration (few min per day) (+) Exposure limited by the design of the dipping cup (-) Frequency (-) High hazard category

Conclusion for Uses 1, 2, 3, 4, 9, 10, 11, 12: Teat disinfection of milkable animals by manual dipping- PT3 (META SPC 1, 2, 3)

For products pertaining to Meta SPC 1, 2 and 3, the risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) as:

For mixing and loading, dipping and cleaning tasks: chemical goggles.

Uses #5, 6, 7, 8- Teat disinfection of milkable animals by liquid/foaming spraying- PT3 (META SPC 1)

Primary exposure

Scenario 2: Disinfection of teats by spraying

Task [2.1] – Mixing and loading

Description of Task [2.1]: Mixing and loading
The products are RTU solutions which can directly be used for disinfection of teats by manual or automated spraying before and/or after milking. For manual spraying, the reservoir of a hand held trigger spray is filled with the RTU from the jerry can. For automated spraying using a spray robot or a robotic milking device, a can containing up to 1000L of product is opened and a suction tube is inserted by the professional. The product is then transferred to the sprayer or robot by a piping system. Direct contact of the professional with some splashes of the product during the filling cannot be excluded.

Task [2.2] – Application by manual spraying

Description of Task [2.2]: Application by manual spraying
Before and/or after milking, the teats are sprayed with the disinfectant using a trigger sprayer or an electronic sprayer making sure that each teat is totally covered with the disinfectant. During the application process by spraying, professionals are exposed to the classified in-use product, mainly due to the deposition of droplets and splashes.

Task [2.3] – Application by automated spraying

Description of Task [2.3]: Application by fully automated spraying
After filling the tank of the automated robotic milking device/spray robot, the liquid product is applied by spraying on animal's teats on the full length of the teat before or after milking. Based on the automatisation of the spraying procedure, no human exposure is expected during the application and post application tasks. This is in line with the HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017).

Task [2.4] – Post application- Cleaning of the equipment

Description of Task [2.4]: Post application- cleaning of the equipment
After the application by manual spraying, the professional user disposes of the product and cleans the equipment (sprayer) with water regularly, according to the instructions of use. Considering that there is still some product left in the sprayer, potential exposure to aerosols is expected during this task.

Task [2.5] – Post application- cleaning of teats by wiping

Description of Task [2.5]: Post application- cleaning of the treated teats
For pre-milking treatment, the product is left for one minute and then wipe with a single use paper or a towel. For post milking equipment, the product is left until next milking and then wiped. No eye contact is expected during this task.

Combined scenarios

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

Risk characterisation for primary exposure for Uses #5, 6, 7 and 8 (Meta-SPC 1)

Outcome of qualitative local risk assessment

RTU products from meta-SPC 1 are classified as Eye Damage category 1 - H318 (see confidential PAR for more details about the classification). All the products are intended to be applied by professional users.

A qualitative risk assessment is therefore performed. Please refer to the tables below.

For the loading task into the spraying equipment, the professional is using the product for a low duration per day and with PPE. Consequently, the risk is deemed acceptable.

For application by trigger spray/electronic sprayer, the professional is using the product more than few minutes per day (10 sec/cow, 82 cows) at high frequency. As diluted products of meta-SPC 1 are not classified for skin corrosion but only severe eye damage, the risk is deemed acceptable with the use of appropriate PPE.

For application by fully automated spraying using a spray robot/robotic milking equipment, no exposure is expected.
The risk is deemed acceptable without any PPE.

Table – Local effects – Qualitative assessment for disinfection of teats by manual spraying: Products from Meta SPC 1 are classified for eye damaging (H318).

Hazard		Exposure								Risk
Hazard category	**Effects in terms of C&L**	**PT**	**Who is exposed**	**Tasks, uses, processes**	**Potential exposure routes**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE**	**Relevant RMM**	**Conclusion on risk**
HIGH	Eye Dam. Cat 1 (H318)	3	Professionals	Loading of the RTU product into the sprayer	Eye	Frequency: once a day, everyday Duration: Mixing & loading = Few minutes	Eye exposure through potential splashes or hand to eye transfer during the loading	Chemical goggles		**Acceptable** (+) Professionals following instructions for use and RMM on the label (+) Professionals using PPE (+) Low exposure duration (few min per day) (-) Frequency

HIGH	Eye Dam. Cat 1 (H318)	3	Professionals	Application and rinsing with a trigger spray/an electronic sprayer	Eye	Frequency: 3 times per day, everyday Exposure duration: More than few minutes	Eye exposure through potential splashes or hand to eye transfer during the application	Chemical goggles	<u>Labelling</u> • Labelling according to CLP <u>Trained personnel</u> • Professional workers • Instructions for use minimizing exposure for professionals	**Acceptable** (+) Professionals following instructions for use and RMM on the label (+) Professionals using PPE (-) High frequency (-) High exposure duration (+) Not classified for skin corrosion

Conclusion: Teat disinfection of milkable animals by spraying- PT3 (META SPC 1)

*Uses 5 & 6

For products pertaining to Meta SPC 1, the risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) as follows:

For loading, manual spraying using a trigger spray/an electronic sprayer and cleaning tasks: chemical goggles.

*Uses 7 & 8

For products pertaining to Meta SPC 1, the risk is acceptable considering the qualitative risk assessment for local effects without PPE.

Secondary exposure

Description of Scenario 3: Exposure of a professional bystander
The professional bystander present during the application of the products by spraying using an electronic sprayer or a trigger spray can be exposed dermally to aerosols generated by the spray equipment. It is considered that bystander will not be exposed greater than the professional performing the task (see primary exposure).

Risk characterisation for secondary exposure for Uses 5 and 6 (Meta-SPC 1)

Dermal exposure to aerosols generated by the spray equipment is possible for the bystander for meta-SPC 1. Taking this into account, the following risk mitigation measure is required for the professional bystander:

The professional bystander has to wear the same PPE as the professional user.

Overall conclusion on the risk assessment for human health from local exposure

Professional/Industrial user

Overall conclusion on the risk assessment for human health from local exposure			
Use number[1]	**Use description[2]**	**Conclusion[3]**	**Set of RMMs[3]**
Uses 1, 2, 3, 4, 9, 10, 11, 12	Teat disinfection of milkable animals by manual dipping- PT 3 Meta-SPC 1, 2 and 3	Acceptable with the following risk mitigation measure	Professional user: During loading, application by dipping and rinsing: chemical goggles
Uses 5 & and 6	Teat disinfection of milkable animals by manual spraying- PT3- META SPC 1	Acceptable with the following risk mitigation measures	Professional user: During loading, application by trigger spray/electronic sprayer and rinsing: chemical goggles Professional bystander: "The professional bystander has to wear the same PPE as the professional user."
Uses 7 & 8	Teat disinfection of milkable animals by automated spraying - PT3 Meta-SPC 1	Acceptable without any risk mitigation measure	Not applicable

Considering that the absence of classification for skin corrosion/irritation is based on an *in vivo* test, a semi-quantitative evaluation should have been performed for Meta-SPCs for which the content in Lactic Acid is exceeding 10%.
The content in Lactic Acid being 10.26% for all three Meta SPCs and the uses being the treatment of teats by dipping or spraying, the wearing of gloves is added as a risk mitigation measure.

Risk for non-professional users

Not applicable

Risk for the general public

Not applicable

Monitoring data

Not submitted

Dietary exposure

Regarding the use on PT03, residues in food or feed might be expected.
For L(+) lactic acid, the following evaluation was provided in the Assessment Report, 2007:
"*L(+) lactic acid is a naturally occurring alpha-hydroxy acid found in plants, animals and humans. Major sources of L(+) lactic acid in the human organism are endogenous production (e.g. via anaerobic catabolism of glycogen and glucose) production by 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.*
L(+) lactic acid has been approved in the EU as a food additive without an ADI or upper limit (quantum satis; Dir. 95/2/EC), as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMEA 2008)."

Moreover, "*Because of the very low systemic toxicity of L(+) lactic acid, derivation of any systemic toxicological reference dose was regarded unnecessary. Considering the intended uses, exposure is estimated to be clearly below endogenous production (>100 g/person/day) and dietary exposure (>1 g/person/day). Therefore, neither and ADI nor an ARfD have been set".*

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s) [2]**
1.	Food	Lactic Acid (E 270) – Food additive	Quantum satis (Regulation (EU) 1129/2011)
2.	Veterinary	Lactic Acid – All food producing species	No MRL required (Regulation (EC) No 37/2010)
3.	Cosmetic	Lactic Acid – Used as buffering humectant or skin conditioning	Up to a maximum level of 2.5% and a pH ≥ 5 (SCCBFP, 2000)
4.	Feed additives	Feed additive for ruminants and pigs	50 000 mg lactic acid/kg complete feed for functional ruminants and pigs (EFSA Journal 2015;13(12):4198)

[1] e.g. plant protection products, veterinary use, food or feed additives

[2] e.g. MRLs. Use footnotes for references.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not relevant

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

Not relevant

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

Not relevant

Combined scenarios

Summary table: combined systemic exposure associated with production, formulation, and disposal				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [n,…][1]				
Scenarios [n,…]				

[1] *Please include the Tier where relevant*

Aggregated exposure

Risk for consumers via residues in food

Regarding PT03 use, considering properties of L(+) lactic acid, no significant exposure via food is expected. Based on the low concentration of L(+) lactic acid, the endogenous production and the authorised used of this active substance as food additive (E 270), significant indirect exposure via food is not expected.

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

[Please, refer to Guidance for Human Health Risk Assessement, Volume III, Part B - to characterise the risk in case of exposure to several active substances or substances of concern within a product]

2.2.7 Risk assessment for animal health

Considering the claimed uses (disinfectants for veterinary hygiene), direct animal exposure of animals to the biocidal products cannot be excluded.
In the absence of guidance for animal risk assessment, the risk assessment for animal health is considered covered by the risk assessment for human health.
Moreover, the products of the family are classified for eye corrosion (H318) and not classified for skin corrosion nor irritation. Taking into account that the head of the animal is far away from the source of emission, no animal eye exposure is expected during the application of the biocidal product for teat disinfection. Consequently, risks for dairy animals can be considered as acceptable for all the claimed uses.

2.2.8 Risk assessment for the environment

The biocidal products of the family "Famille de produits Acide lactique TP3" are PT3 (Veterinary hygiene biocidal products) disinfectants containing lactic acid (9.8 % w/w technical) that are used for teat disinfection before and/or after milking by professionals. The data on the active substance come from the assessment report of L(+) Lactic acid for PT2, 3, 4 (Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, Assessment Report L(+) Lactic acid Product-type 2, 3 and 4, June 2017). The available ecotoxicological information and e-fate data are used for risk assessment for the environment.

Substances of Concern and Metabolites:
No Substance of Concern is identified (see Confidential Annex) and no metabolite is formed that would need to be addressed in a risk evaluation for the environment.

The following risk assessment is therefore carried out for the active substance only.

2.2.8.1 Effects assessment on the environment

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

No new environmental studies have been carried out with the BPF. The classification of the different meta-SPC, summarized in the table below, has been calculated from classifications of the active substance and co-formulants (see the detailed calculation based on the composition in the confidential annex).

	Meta-SPC 1	Meta-SPC 2	Meta-SPC 3
Classification	Not classified	Not classified	Not classified

Further Ecotoxicological studies

No new data is available.

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

No new data is available.

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

Not relevant.

Data waiving	
Information requirement	Not relevant
Justification	The products are not in the form of bait or granules.

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

Not relevant.

Data waiving	
Information requirement	Not relevant
Justification	The products are not in the form of bait or granules.

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

Not relevant.

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

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

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

At WGII2020, it was stated that Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food constituent and also a growth regulator intended to increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L(+) Lactic acid naturally occurs as a fermentation by-product of anaerobic degradation of organic matter. This substance may covalent bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD+ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not be taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations (Tier 1). Modelling of groundwater exposure in case of Lactic acid largely overestimates concentrations and is considered unrealistic.

For all these reasons, it can be stated that Lactic acid does not cause unacceptable risk for groundwater, without need for further calculations.

Leaching behaviour (ADS)

No new data is available.

Testing for distribution and dissipation in soil (ADS)

No new data is available.

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

No new data is available.

Testing for distribution and dissipation in air (ADS)

No new data is available.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not relevant.

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

Not relevant.

PNEC values summary table

L(+) lactic acid

Based on the L(+) lactic acid assessment report (2017), the relevant PNECs for the environmental risk characterisation are reported below.

PNEC		Justification
$PNEC_{STP}$	10 mg/L	An NOEC of 100 mg/L from an activated sludge respiration test no inhibitory effect is reported in the AR (2017). An assessment factor (AF) of 10 was applied to the NOEC to derive the PNEC.
$PNEC_{water}$	3.9 mg/L	The $PNEC_{water}$ presented in the AR (2017) was derived from the EC_{50} of 3900 mg/L for fish and an AF of 1000.
$PNEC_{sediment,EPM}$	4.8 mg/kg wwt	Equilibrium partitioning method.
$PNEC_{soil,EPM}$	1.9 mg/kg wwt	Equilibrium partitioning method.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 3
Assessed scenarios	Disinfection for veterinary hygiene: non-medicinal teat dips: - Emission to the STP via wastewater - Emission to soil via manure/slurry
ESD(s) used	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, 2011 Technical Agreements for Biocides, February 2021
Approach	Average consumption
Distribution in the environment	Calculated based on ECHA Guidance on the BPR Vol IV, Part B; April 2015 Assessment report: L(+) Lactic acid Product-type 02, 03 and 04, June 2017 Technical Agreements for Biocides, February 2021
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation:No Use: Yes Service life: No
Remarks	/

Emission estimation

To determine the amounts of lactic acid that are emitted to wastewater or to manure, as detailed in the ESD documents, the following product-specific or use-specific input data are required:

- the content of active ingredient (lactic acid) in formulation,
- the amount of product prescribed to be used for one treatment (disinfection of the four teats) of one animal,
- the dilution factor (for preparation of the working solution from the formulation),
- the number of teat disinfection events per cow per day.

These data are further developed below for each META-SPC and then summarised in the tables below.

Content of active ingredient (Fbioc)

The products of the family "Famille de produits Acide lactique TP3" all contain 9.8% (w/w) of lactic acid.

Meta-SPC	Max. % of lactic acid (w/w)	Density (g/mL)	Fbioc max (g/L)
1	9.8	1.06	103.88
2	9.8	1.067	104.57
3	9.8	1.053	103.19

Amount of product prescribed to be used for one treatment (V_{prod})
According to the SPC, the maximum amounts of product prescribed for one treatment are:

- For dipping 10 ml/cow/milking
- For spraying 20 ml/cow/milking

Dilution factor (F_{dil})
Products from the family "Famille de produits Acide lactique TP3" are used undiluted, the dilution factor is thus 1.

Number of teat disinfection events per cow per day (Napp-teat)
According to the Technical Agreements for Biocides Environment (February 2021, entry ENV 64), up to 3 milking events per day are expected when using a milking robot, and up to 2 milking events per day are expected otherwise.
Products that are used only once per milking, i.e. pre-milking disinfection products or post-milking disinfection products, are thus applied 2 or 3 times per day. Products that can be used both before and after milking are thus applied 4 or 6 times per day.

Defining a worst-case scenario

Meta SPC	Fbioc max (g/L)	Vprod max (L)	Napp-teat max	Remarks
Meta SPC 1	103.88	0.02 (spraying)	6	Automated spraying via a spray robot before and/or after milking (uses #7 and 8 as worst cases)
Meta SPC 2	104.57	0.01 (dipping)	2	Manual or semi-automated thick liquid dipping after milking only
Meta SPC 3	103.19	0.01 (dipping)	2	

When summing up the information above, it appears that Meta SPC 1 can be considered as a worst-case scenario as it involves the highest daily emissions due to the following:

- The second highest lactic acid content of the family (Fbioc = 103.88 g/L).
- The highest frequency of use of the family (Napp-teat = 6) since:
    - The products are applied both before and after milking (2 disinfections per milking).
    - The products can be applied by automated spraying with a milking robot (3 milking events per day).

- The highest volume to apply per use of the family (Vprod = 0.02 L).

Only the predicted environmental concentrations (PECs) based on the nitrogen emission standards are presented in the current PAR as a worst-case situation.

Input parameters for calculating the local emission				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
		L(+) Lactic acid		
Type of housing/manure storage (for application of the notification)	cat-subcat (i1)	1 – Dairy cows	[-]	S (ESD Appendix 1: Table 7)
Type of biocide	bioctype (i2)	1 - Disinfectant	[-]	S (ESD Appendix 1: Table 7)
Type of application	appway (i3)	Spraying	[-]	S (ESD Appendix 1: Table 7)
Relevant emission stream	stream(i4)	2 - Waste water 3- Slurry	[-]	P (Appendix 1: Table 7)
Content of technical active ingredient in formulation (product)	Fbioc	103.88	g/L	S
Amount of product prescribed to be used for one treatment (dipping of the four teats) of one animal	Vprod	0.02	L	S
Dilution factor (for preparation of the working solution from the formulation (product))	Fdil	1	[-]	S
Fraction of active ingredient released	F slurry/manure or STP	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	6	[-]	D –TAB ENV 64
Number of days of lactation period	Nday-lact	300	[-]	D
Number of disinfectant applications in one year	Napp-bioc	1800	[-]	TAB ENV 64
Interval between two disinfectant applications	Tbioc-int	0.16	[d]	TAB ENV 64
Number of manure applications for grassland	Napp-grass	4	[-]	D

Number of manure applications for arable land	Napp-arab	1	[-]	D
Manure application time interval for grassland	Tgr-int	53	[-]	D/S (ESD-PT3, 2011; Appendix1: Table 12)
Manure application time interval for arable land	Tar-int	212	[-]	D/S (ESD-PT3, 2011; Appendix1: Table 12)
Number of animal in housing for category/subcategory i1=1	Nanimali1	100	[-]	D/S (ESD-PT3, 2011; Appendix1: Table 8)
Number of milk producing animals per day	Nmp_animal	82	[-]	TAB ENV 63
Amount of nitrogen per animal for category/subcategory i1=1	Qnitrogi1	0.3389	[kg.d^{-1}]	D (ESD-PT3, 2011; Appendix1: Table 11)
If nitrogen immission standards are applied:				
Nitrogen immission standard for one year on grassland	QN,grassland	170	[kg.ha^{-1}]	D (ESD-PT3, 2011; Appendix1: Table 13)
Nitrogen immission standard for one year on arable land	QN,arable_land	170	[kg.ha^{-1}]	D (ESD-PT3, 2011; Appendix1: Table 13)
Mixing depth with soil, grassland	DEPTHgrassland	0.05	[m]	D
Mixing depth with soil, arable land	DEPTHarableland	0.2	[m]	D
Density of wet bulk soil	RHOsoilwet	1700	[kg.m^{-3}]	D
Intermediate calculations				
Number of biocide applications during storage period for application on grassland	**Napp-manure$_{gr}$**	318	[-]	O
Number of biocide applications during storage period for application on arable land	**Napp-manure$_{ar}$**	1272	[-]	O
Amount of active ingredient to be used for one application on one animal	**Qai-prescr**	2.08E-03	[kg]	O
Amount of active ingredient in relevant	**Qai manure**	8.52E-02	[kg]	O (TAB ENV 63)

stream i4 after one application for all animals (Manure/Slurry)				
Amount of active ingredient in relevant stream i4 after one application for all animals (STP)	**Qai STP**	4.20E-01	[kg]	O (TAB ENV 63)
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland	**Qai-grass**	2.71E+01	[kg]	O
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to arable land	**Qai-arab**	1.08E+02	[kg]	O
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland	**Qnitrog-grass**	1.80E+03	[kg]	O
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to arable land	**Qnitrog-arab**	7.18E+03	[kg]	O

Resulting local emission to relevant environmental compartments			
Compartment		**Local emission ($Elocal_{compartment}$)**	**Remarks**
		L(+) Lactic acid	
STP		4.20E-01	[$kg.d^{-1}$]
Intermediate PECsoil calculations			
Soil	Grassland	7.54E-01	[$mg.kg^{-1}_{wwt}$] (after one manure application)
		8.92E-01	[$mg.kg^{-1}_{wwt}$] (after four manure applications)

Resulting local emission to relevant environmental compartments			
Compartment		**Local emission ($Elocal_{compartment}$)**	**Remarks**
		L(+) Lactic acid	
	Arable land	7.54E-01	[$mg.kg^{-1}_{wwt}$] (after one manure application)

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
via STP	Yes	Yes	No	No	Yes	No	Yes	Yes	No
Via Slurry/Manure	Yes	Yes	No	No	Yes	No	Yes	Yes	No

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	90.08	$g.mol^{-1}$	
Vapour pressure (at 20°C)	0.4	Pa	
Water solubility (at 12°C)	1.00E+06	mg/l	
Log Octanol/water partition coefficient	-0.74	Log 10	
Organic carbon/water partition coefficient (Koc)	20	l/kg	
Henry's Law Constant (at 20°C)	3.60E-05	Pa/m3/mol	
Biodegradability	Readily biodegradable failing the 10-days window criterion		
DT_{50} for degradation in soil	30	d or hr (at 12ºC)	
ktotal (0.2 m relevant for STP and slurry/manure arable land)	2.61E-02	d^{-1}	Calculated
ktotal (0.05 m relevant for slurry/manure grass land)	3.51E-02	d^{-1}	Calculated

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
Air	2.50E-05	

Water	22.5	Simple treat v4.0
Sludge	0.20	
Degraded in STP	77.3	

Calculated PEC values

PECs for sediments were not calculated for L(+) Lactic acid. PNEC sediment being calculated using equilibrium partitioning, it is covered by PEC/PNEC water.

Summary table on calculated PEC values for L(+)lactic acid				
	PEC_{STP}	**PEC_{water}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[µg/l]
via STP	4.72E-02	4.72E-03	1.07E-03*	**6.94E-01**
via slurry/manure – concentrations after ten years				
grassland	n.r.	1.90E-01	8.92E-01	**1.90E+03**
arable land	n.r.	1.60E-01	7.54E-01	**1.60E+03**

n.r.: not relevant
* twa

Primary and secondary poisoning

Primary poisoning

Primary poisoning via the direct consumption of the products by wild birds and mammals is unlikely. Therefore, primary poisoning is not considered relevant for this evaluation.

Secondary poisoning

As detailed in the exposure assessment section above, active substance L(+) Lactic Acid has a log Kow <3 and BCF < 100. Thus, these values indicate a negligible potential risk for bioconcentration in biota and no accumulation of substances in the food chain is expected. The secondary poisoning assessment is not relevant for this substance.

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: As stated in the L(+) lactic acid assessment report, L(+) lactic acid is not considered to be used as fumigant. The vapour pressure of L(+) lactic acid is 0.4 Pa at 20°C and the Henry constant is 3.6×10^{-5} indicating that direct evaporation and volatility from water are expected to be insignificant. In general, emissions of L(+) lactic acid to the atmosphere are unlikely to occur. Due to an estimated half-life in the atmosphere of 2.71 d corresponding to 3.91 d for the chemical lifetime the potential for long-range transport

of L(+) lactic acid in air is indicated (ref. to Annex D of the Stockholm Convention on Persistent Organic Pollutants (17th May 2004): " ... a chemical that migrates significantly through the air, its half-life in air should be greater than two days ... "). However, according to the Vol IV Part B+C (2017) effects on stratospheric ozone and acidification are not expected because L(+) lactic acid does not contain halogens, nitrogen or sulphur substituents. L(+) lactic acid shows no absorption bands in the so-called atmospheric window (range from 800 to 1200 nm). Therefore, L(+) lactic acid has no global-warming potential.

Sewage treatment plant (STP), Aquatic compartment, Terrestrial compartment and Groundwater

A summary of the calculated PEC/PNEC values for each scenario and all the relevant environmental compartments are indicated in the following table. As explained in section "2.2.2.1 - Effects assessment on the environment", there is no need for further calculation in groundwater risk assessment for active substance L(+) Lactic acid.:

Summary table on calculated PEC/PNEC values			
	PEC/PNEC$_{STP}$	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{soil}$**
Via STP			
L(+) Lactic acid	4.72E-03	1.21E-03	5.65E-04
Via slurry/manure – concentrations after ten years			
L(+) Lactic acid			
Grassland	n.r.	4.86E-02	4.70E-01
Arable land	n.r.	4.06E-02	3.97E-01

n.r.: not relevant

Risks are acceptable regarding all the relevant environmental compartments, except in groundwater, for the active substance L(+) Lactic acid when releases are directed to the STP.

Risks are acceptable for the aquatic and terrestrial compartment for the active substance L(+) Lactic acid via slurry/manure application on both grassland and arable land.
.

Primary and secondary poisoning

Primary poisoning

As the proposed uses of BPs will not result in direct exposures to birds and mammals, the risk for the primary poisoning is considered acceptable.

Secondary poisoning

As detailed in the exposure assessment section above, active substance L(+) Lactic Acid has a log Kow <3 and BCF < 100. Thus, these values indicate a negligible potential risk for

bioconcentration in biota and no accumulation of substances in the food chain is expected. The secondary poisoning assessment is not relevant for this substance.

Mixture toxicity

All BPs contain only one active substance. There are no substances of concern with regard to the environment. An assessment of the mixture toxicity is therefore not necessary.

Aggregated exposure (combined for relevant emmission sources)

As stated in the L(+) lactic acid assessment report, According to the " Decision tree on the need for estimation of aggregated exposure" (BIP6 . 7 Decision Tree Agg Expo) the requirement for aggregated exposure estimations was checked for L(+) lactic acid. L(+) lactic acid is also regulated in other regulatory areas (e.g. cosmetics regulation, food legislation). The amount of L(+) lactic acid that is used annually for biocidal purposes amounts to 5% of the total production and import volume of L(+) lactic acid in the EU in 2012. Thus, the biocidal use of L(+) lactic acid accounts for less than 10% of the total production and import volume in the EU."
The intended uses of the BPF products are widely dispersive and do not represent a specific emission pattern. Consequently, it has been concluded that no aggregated exposure assessment for a.s. L(+) lactic acid has to be performed.

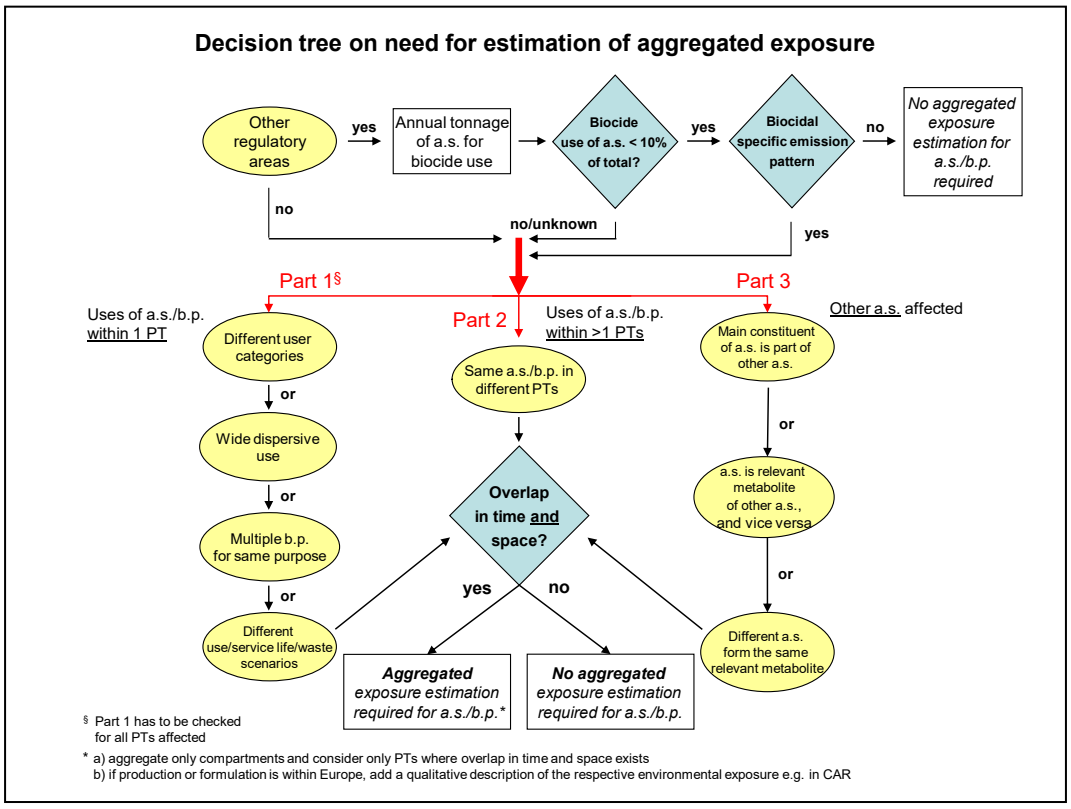


Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product

The biocidal products of the family "Famille de produits Acide lactique TP3" are PT3 (Veterinary hygiene biocidal products) disinfectants containing lactic acid (9.8 % w/w) that are used for teat disinfection before and/or after milking by professionals. No substance of concern has been defined for the environment. The products are emitted to wastewater (milking in a milking parlour) or manure (milking in the stable). For all emission, PEC/PNEC ratio are all < 1.

It can therefore be concluded that the risk for the environment is acceptable for the products of the family "Famille de produits Acide lactique TP3" when they are applied according to their intended uses.

2.2.9 Measures to protect man, animals and the environment

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

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

[Please, refer to Guidance for Human Health Risk Assessement, Volume III, Part B - to characterise the risk in case of exposure to several products]

2.2.11 Comparative assessment

3 ANNEXES[1]

3.1 List of studies for the biocidal product family

Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)
[redacted]	2020	Determination of L-(+)-Lactic acid (CAS 79-33-4) assay and physical, chemical and technical properties in the product "COM 22 / Méta SPC1-x", batch COM 22 / Méta SPC 1-x / 2019-10-30, accelerated stability study at 0 °C for 7 days and at 54 °C for 14 days [redacted] 19.537246.0001 GLP; Unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Analysis of the product "COM 22 / Méta SPC 1-X", Batch COM 22 / Méta SPC 1-X / 2020-04-20: Determination of the active substance L-(+)-Lactic acid (CAS 79-33-4), Chemical, physical and technical properties and accelerated stability study at 40 °C for 8 weeks [redacted] 20.524572.0001 GLP; Unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Determination of the active substance L-(+)-Lactic acid (CAS 79-33-4) and physical, chemical and technical properties, in the product "COM 22 / Méta SPC 1-x", batch COM 22 / Méta SPC 1-x / 2019-10-30 after a long-term storage procedure for 24 months at 25°C (T 6M) [redacted]	Yes	Commission 22 du Groupement des formulateurs de biocides

1 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)
		Interim report – Study N. 19.537246.0003 GLP; Unpublished		
[redacted]	2020	Determination of viscosity in the product "COM 22 / Méta SPC 2-6", batch COM 22 / Méta SPC 2-6 / 2020-04-27 and of density and viscosity after accelerated stability study at 40°C for 8 weeks [redacted] Interim report – Study N. 20.515774.0001 GLP; Unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Determination of L-(+)-Lactic acid (CAS 79-33-4) assay and physical, chemical and technical properties in the product "COM 22 / Méta SPC 2-x", batch COM 22 / Méta SPC 2-x / 2019-10-21, accelerated stability study at 0°C for 7 days and at 40°C for 8 weeks [redacted] 19.535563.0001 GLP; Unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Determination of active substance L-(+)-lactic acid (CAS 79-33-4) and of viscosity in the product “COM 22 / Méta SPC 2-X”, batch COM 22 / Méta SPC 2-x / 2020-04-27 and of density and viscosity after accelerated stability study at 40°C for 8 weeks [redacted] Interim report – Study N. 20.516048.0001 GLP; Unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Determination of the active substance L-(+)-lactic acid (CAS 79-33-4) and physical, chemical and technical properties, in the product "COM 22 / Méta SPC 2-x", batch COM 22 / Méta SPC 2-x / 2019-10-21 after a long-term storage	Yes	Commission 22 du Groupement des formulateurs de biocides

Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)
		procedure for 24 months at 25 °C (T 6M) [redacted] Interim report – Study N. 19.535563.0003 GLP; Unpublished		
[redacted]	2020	Determination of viscosity in the product "COM 22 / Méta SPC 3-6", batch COM 22 / Méta SPC 3-6 / 2020-04-27 and of density and viscosity after accelerated stability study at 40°C for 8 weeks [redacted] Interim report – Study N. 20.515829.0001 GLP; Unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Determination of L-(+)-Lactic acid (CAS 79-33-4) assay and physical, chemical and technical properties in the product "COM 22 / Méta SPC 3-x", batch COM 22 / Méta SPC 3-x / 2019-10-09 and accelerated stability study at 40 °C for 8 weeks [redacted] 19.533848.0001 GLP; Unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Determination of active substance L-(+)-lactic acid (CAS 79-33-4) and of viscosity in the product “COM 22 / Méta SPC 3-X”, batch COM 22 / Méta SPC 3-x / 2020-04-27 and of density and viscosity after accelerated stability study at 40°C for 8 weeks [redacted] Interim report – Study N. 20.516296.0001 GLP; Unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Determination of the active substance L-(+)-Lactic acid (CAS 79-33-4) and physical, chemical and technical properties, in the product "COM 22 / Méta SPC 3-x", batch	Yes	Commission 22 du Groupement des formulateurs de biocides

Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)
		COM 22 / Méta SPC 3-x / 2019-10-09 after a long-term storage procedure for 24 months at 25 °C (T 6M) [redacted] Interim report – Study N. 20.515829.0001 GLP; Unpublished		
[redacted]	2020	Test methods for corrosion to metals on RTU FILM-FORMING PRODUCT 9.8% LACTIC ACID [redacted] 20-907023-001 GLP; Unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Physico-chemical tests on RTU FILM-FORMING PRODUCT 9.8% LACTIC ACID [redacted] 20-907023-002 GLP; Unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Determination of exothermic reactions by DSC method on RTU FILM-FORMING PRODUCT 9.8% LACTIC ACID [redacted] 20-907023-003 GLP; Unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2019	VALIDATION OF AN ANALYTICAL PROCEDURE FOR THE DETERMINATION OF THE ACTIVE SUBSTANCE L-(+)-LACTIC ACID (CAS 79-33-4) IN THE PRODUCT "COM22 / Méta SPC 3-y", BATCH COM22 / Méta SPC 3-y / 2019-10-08 [redacted] Test report 19.533783.0001 GLP; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2019	VALIDATION FOR AN ANALYTICAL PROCEDURE FOR THE DETERMINATION OF THE ACTIVE SUBSTANCE L-(+)-LACTIC ACID (CAS 79-33-4° IN THE PRODUCT "COM 22	Yes	Commission 22 du Groupement des formulateurs de biocides

Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)
		/ Méta SPC 2-y", BATCH COM 22/ Méta SPC 2-y / 2019-10-22 [redacted] Test report 19.535398.0001 GLP; unpublished		
[redacted]	2020	Validation of the analytical method for the determination of lactic acid in COM22/MÉTASPC1-Y [redacted] 20-907023-004 GLP; Unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2019	Efficacy test for bactericidal activity on synthetic skin according to the CEN draft (2016) - drop/dip protocol LMH Test report No.5516-1 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2019	Efficacy test for bactericidal activity on synthetic skins according to the CEN draft (2016) - drop/dip protocol LMH Test report No.5420-1 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2019	Efficacy test for bactericidal activity on synthetic skins according to the CEN draft (2016) - drop/dip protocol LMH Test report No.5422-1 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2019	Quantitative suspension test yeasticidal activity EN1657 IRM Test report N°RE - 1260/0719 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2019	Quantitative suspension test yeasticidal activity EN1657 IRM Test report N°RE - 1259/0719 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides

Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)
[redacted]	2019	Quantitative suspension test yeasticidal activity EN1657 IRM Test report N°RE - 1267/0719 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2019	Quantitative suspension test yeasticidal activity EN1657 IRM Test report N°RE - 1269/0719 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2019	Quantitative suspension test bactericidal activity EN1656 IRM TEST REPORT N°RE-1262/0719 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2019	Quantitative suspension test bactericidal activity EN1656 IRM TEST REPORT N°RE-1263/0719 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2019	Quantitative suspension test virucidal activityNF EN14675 IRM TEST REPORT N°RE-1266/0719 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2019	Quantitative suspension test bactericidal activity EN1656 IRM TEST REPORT N°RE-1268/0719 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2019	Quantitative suspension test bactericidal activity EN1656 IRM TEST REPORT N°RE-1270/0719 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides

Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)
[redacted]	2019	Quantitative suspension test virucidal (bacteriophages) activity EN13610 IRM TEST REPORT N°RE-1271/0719 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2019	Efficacy test for bactericidal activity on synthetics skins according to an adapted protocol of CEN draft (2016) - drop/dip protocol LMH Test report N°5673-1 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Quantitative suspension test virucidal activity NF EN14675 VIRHEALTH TEST REPORT N°R2006LVYDE002 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Quantitative suspension test virucidal activity NF EN14675 VIRHEALTH TEST REPORT N°R2006LVYDE001 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Quantitative suspension test bactericidal activity EN1656 IRM TEST REPORT N°1354-0 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Quantitative suspension test bactericidal activity EN1656 IRM TEST REPORT N°1352-0720 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Quantitative suspension test bactericidal activity EN1656 IRM TEST REPORT N°1356-0720 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides

Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)
[redacted]	2020	Quantitative suspension test bactericidal activity EN1656 IRM TEST REPORT N°1355-0720 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Quantitative suspension test bactericidal activity EN1656 IRM TEST REPORT N°1353-0720 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2020	Quantitative suspension test bactericidal activity EN1656 IRM TEST REPORT N°1357-0720 Not GLP ; unpublished	Yes	Commission 22 du Groupement des formulateurs de biocides
[redacted]	2019a	In vitro assessment of skin irritating potential « Reconstituted human apidermis » model OECD guideline N°439 [redacted] Study IC-CHEM 19.214 Not GLP ; unpublished	Yes	Commission 22 du Groupe de formulateurs de biocides
[redacted]	2019 b	In vitro assessment of skin irritating potential « Reconstituted human apidermis » model OECD guideline N°439 [redacted] Study IC-CHEM 19.215 Not GLP ; unpublished	Yes	Commission 22 du Groupe de formulateurs de biocides
[redacted]	2018	Ready Biodegradability of Lactic acid 80% food grade in a Closed Bottle Test [redacted] 80031161 GLP; Unpublished	Yes	Jungbunzlauer International AG

3.2 Output tables from exposure assessment tools

3.3 New information on the active substance

3.4 Residue behaviour

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

3.6 Confidential annex

See the confidential PAR

3.7 Other