LATVIJAS VIDES, ĢEOLOĢIJAS UN METEOROLOĢIJAS CENTRS

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 SIMPLIFIED AUTHORISATION APPLICATION

(submitted by the evaluating Competent Authority)

Public

Biocidal product family: **SALVESAFE E**

Product types: PT3 (Veterinary hygiene)

Lactic acid is included in the Annex I of Regulation (EU) No. 528/2012

Case Number in R4BP3: BC-DN050009-43

Evaluating Competent Authority: Latvia

Date: 21/February/2022

Content

1 CONCLUSION

The ready-to-use biocidal products within biocidal product family *SALVESAFE E*, formulated by SALVECO S.A.S, with active substance *Lactic acid* (CAS No. 50-21-5, EC No. 200-018-0) at the concentration 2.38% are authorised for product type 3 (disinfectants for veterinary hygiene) as teat disinfectants for post- and pre- milking treatment.

SALVESAFE E is claimed with bactericidal and yeasticidal activity. The biocidal products are intended for professional users.

Following evaluation, Latvian CA considers that *SALVESAFE E* meets the conditions laid down in Article 25 of the Regulation (EU) No 528/2012:

- the active substance *Lactic acid* (CAS No. 50-21-5, EC No. 200-018-0) in the biocidal products appears in Annex I and satisfy the restriction specified in that Annex;
- the biocidal products do not contain any substances of concern;
- the biocidal products do not contain nanomaterials;
- the biocidal products are effective;
- the handling of the biocidal products and those intended use do not require personal protective equipment.

A person placing on the market or using the biocidal products included in *SALVESAFE E* family must comply with the conditions for placing on the market or use of the above mentioned biocidal product family set out in authorisation letter issued by Latvian Competent Authority and Summary of Products Characteristics.

In accordance with Article 17(4) of the Regulation (EU) 528/2012 the authorisation number is valid from 28th August 2019 until 28th August 2029.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier	**Country**
SALVESAFE E	EU

2.1.1.1.1 Trade names of the products within the family

Trade name	**Meta SPC**
SALVESAFE E1	1
SALVESAFE E2	
SALVESAFE E19	
SALVESAFE E7	2
SALVESAFE E8	
SALVESAFE E20	
SALVESAFE E22	
SALVESAFE E13	3
SALVESAFE E14	
SALVESAFE E21	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	SALVECO S.A.S.
	Address	Avenue Pierre Mendès-France SAINT DIE DES VOSGES, F-88100, France
Authorisation number for biocidal product family	EU-0020512-0000	
Authorisation numbers of the biocidal products within family	SALVESAFE E1	EU-0020512-0001
	SALVESAFE E2	EU-0020512-0002
	SALVESAFE E19	EU-0020512-0003
	SALVESAFE E7	EU-0020512-0004
	SALVESAFE E8	EU-0020512-0005
	SALVESAFE E20	EU-0020512-0006
	SALVESAFE E13	EU-0020512-0007
	SALVESAFE E14	EU-0020512-0008
	SALVESAFE E21	EU-0020512-0009
	SALVESAFE E22	EU-0020512-0010
Date of the authorisation	28th August 2019	
Expiry date of the authorisation	28th August 2029	

2.1.1.3 Manufacturer of the products of the family

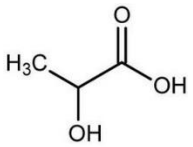
Name of manufacturer 1	**SALVECO S.A.S.**
Address of manufacturer	Avenue Pierre Mendès-France SAINT DIE DES VOSGES, F-88100, FRANCE
Location of manufacturing sites	Avenue Pierre Mendès-France SAINT DIE DES VOSGES, F-88100, FRANCE
Name of manufacturer 2	**MULTIFILL BV BULKONTVANGST**
Address of manufacturer	Constructieweg 25A, 3641, SB Mijdrecht, The Netherlands
Location of manufacturing sites	Constructieweg 25A, 3641, SB Mijdrecht, The Netherlands
Name of manufacturer 3	**Diversey Netherlands Production BV**
Address of manufacturer	Rembrandtlaan 414, 7545, ZW Enschede, The Netherlands
Location of manufacturing sites	Rembrandtlaan 414, 7545, ZW Enschede, The Netherlands
Name of manufacturer 4	**Diversey UK Production Ltd**
Address of manufacturer	Cotes Park Industrial Estate, Somercotes, DE55 4PA, Alfreton, United Kingdom
Location of manufacturing sites	Cotes Park Industrial Estate, Somercotes, DE55 4PA, Alfreton, United Kingdom
Name of manufacturer 5	**Diversey Espana Production S.L.U**
Address of manufacturer	Avenida Conde Duque 5, 7 y 9, Poligono Industrial La Postura, 28343, Valdemoro (Madrid), Spain
Location of manufacturing sites	Avenida Conde Duque 5, 7 y 9, Poligono Industrial La Postura, 28343, Valdemoro (Madrid), Spain
Name of manufacturer 6	**Diversey Italy Production Srl**
Address of manufacturer	Strada Statale 235, 26010, Bagnolo Cremasco (CR), Italy
Location of manufacturing sites	Strada Statale 235, 26010, Bagnolo Cremasco (CR), Italy
Name of manufacturer 7	**Diversey Germany Production oHG**
Address of manufacturer	Morschheimer Strasse 12, 67292, Kirchheimbolanden, Germany
Location of manufacturing sites	Morschheimer Strasse 12, 67292, Kirchheimbolanden, Germany

2.1.1.4 Manufacturer of the active substance

Active substance	Lactic acid
Name of manufacturer	JUNGBUNGZLAUER S.A
Address of manufacturer	Z. I Portuaire BP 32, 67390, Marckolsheim, France
Location of manufacturing sites	Z. I Portuaire BP 32, 67390, Marckolsheim, France

2.1.2 Product family composition and formulation

2.1.2.1 Identity of the active substance

Main constituent	
ISO name	Lactic acid
IUPAC or EC name	2-Hydroxypropanoic acid
EC number	200-018-0
CAS number	50-21-5
Index number in Annex VI of CLP	-
Structural formula	

2.1.2.2 Candidate for substitution

Lactic acid does not meet the conditions laid down in Article 10 of Regulation (EU) No. 528/2012, and therefore is not considered as a candidate for substitution.

Lactic acid is listed in Annex I of the Regulation (EU) No 528/2012 under the Category 1 - Substances authorised as food additives according to Regulation (EC) No 1333/2008.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%) Min-max
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	2.38-2.38%

SALVESAFE E does not contain nanomaterials.

2.1.2.4 Information on technical equivalence

The active substance *Lactic acid* (CAS No. 50-21-5) is not included in the work programme for the systematic examination of all existing active substances contained in biocidal products referred in Regulation (EU) No 528/2012. The assessment of technical equivalence of the active substance listed in Annex I of the Regulation (EU) No 528/2012 is not required.

2.1.2.5 Information on the substance(s) of concern

No substances of concern have been identified in the biocidal product family formulation.

2.1.2.6 Type of formulation

Ready-to-use water based liquids

2.1.3 Hazard and precautionary statements

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

Taking into account the maximal concentration and classification of *Lactic acid* and co-formulants the classification criteria are not fulfilled.

Classification	
Hazard category	Not applicable
Hazard statement	Not applicable
Labelling	
Signal words	Not applicable
Hazard statements	Not applicable
Precautionary statements	Not applicable
Supplemental hazard information	EUH210: Safety data sheet available on request

2.1.4 Authorised uses of the meta SPC

2.1.4.1 Meta SPC 1 - Pre-milking teat disinfection

*Table 1: **Use 1.1** - Ready-to-use non-medical pre-milking teat disinfection - spraying*

Product Type	Product type 3 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organisms (including development stage)	Bacteria and yeasts
Field of use	Indoor, outdoor Pre-milking disinfection of teats of milk producing animals
Application methods	Manual and automated spraying
Application rates and frequency	The application rate: Apply a maximum of 20 mL product per milking event to cover the treated surface. Frequency: maximum 3 pre-milking applications per day
Categories of users	Professional
Pack sizes and packaging material	Bottle (HDPE) - 1 L Jerrycan (HDPE) – 5-60L Drum (HDPE) – 220L IPC (HDPE) – 1000L

1.1.1 Use-specific instructions for use

Before use, bring the product at least 20°C. Fill a manual or automate spraying device with ready to use product from the original packaging and close with spraying head. Apply the product by spray to the full length of each teat. Leave to act at least 1 min. Wipe the product with a single-use paper towel/cloth to avoid any contamination of milk.

1.1.2 Use-specific risk mitigation measures

Not applicable

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

Section 5.3

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

Section 5.4

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

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*Table 2: **Use 1.2** - Ready-to-use non-medical pre-milking teat disinfection - foaming*

Product Type	Product type 3 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organisms (including development stage)	Bacteria and yeasts
Field of use	Indoor, outdoor Pre-milking disinfection of teats of milk producing animals
Application methods	Manual and automated foaming
Application rates and frequency	The application rate: Apply a maximum of 20 mL product per milking event to cover the treated surface. Frequency: maximum 3 pre-milking applications per day
Categories of users	Professional
Pack sizes and packaging material	Bottle (HDPE) - 1 L Jerrycan (HDPE) – 5-60L Drum (HDPE) – 220L IPC (HDPE) – 1000L

1.2.1 Use-specific instructions for use

Before use, bring the product at least 20°C.

Fill the foaming cup with ready to use product from the original packaging. Apply the product to the full length of each teat. Leave to act at least 1 min. Wipe the product with a single-use paper towel/cloth to avoid any contamination of milk.

1.2.2 Use-specific risk mitigation measures

Not applicable

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

Section 5.3

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

Section 5.4

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

Section 5.5

*Table 3: **Use 1.3** - Ready-to-use non-medical pre-milking teat disinfection - dipping*

Product Type	Product type 3 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organisms (including development stage)	Bacteria and yeasts
Field of use	Indoor, outdoor Pre-milking disinfection of teats of milk producing animals
Application methods	Manual and automated dipping
Application rates and frequency	The application rate: Apply a maximum of 20 mL product per milking event to cover the treated surface. Frequency: maximum 3 pre-milking applications per day
Categories of users	Professional
Pack sizes and packaging material	Bottle (HDPE) - 1 L Jerrycan (HDPE) – 5-60L Drum (HDPE) – 220L IPC (HDPE) – 1000L

1.3.1 Use-specific instructions for use

Before use, bring the product at least 20°C. Fill the manual or automated dipping cup with ready to use product from the original packaging. Apply the product to the full length of each teat. Leave to act at least 1 min. Wipe the product with a single-use paper towel/cloth to avoid any contamination of milk.

1.3.2 Use-specific risk mitigation measures

Not applicable

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

Section 5.3

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

Section 5.4

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

Section 5.5

2.1.4.2 Meta SPC 2 - Pre-milking and post-milking teat disinfection

*Table 4: **Use 2.1** - Ready-to-use non-medical pre-milking and post-milking teat disinfection - spraying*

Product Type	Product type 3 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organisms (including development stage)	Bacteria and yeasts
Field of use	Indoor, outdoor Pre- and post-milking disinfection of teats of milk producing animals
Application methods	Manual and automated spraying
Application rates and frequency	The application rate: Apply a maximum of 20 mL product per milking event to cover the treated surface. Frequency: maximum 3 pre-milking and 3 post-milking applications per day
Categories of users	Professional
Pack sizes and packaging material	Bottle (HDPE) - 1 L Jerrycan (HDPE) – 5-60L Drum (HDPE) – 220L IPC (HDPE) – 1000L

2.1.1 Use-specific instructions for use

Before use, bring the product at least 20°C. Fill a manual or automate spraying device with ready to use product from the original packaging and close with spraying head. *Pre-milking* Apply the product by spray to the full length of each teat. Leave to act at least 1 min.

Wipe the product with a single-use paper towel/cloth to avoid any contamination of milk. *Post-milking* The teat should be treated immediately after milking in such a way that the teats are fully covered with the product. Keep the animals standing or walking at least 5 minutes.

2.1.2 Use-specific risk mitigation measures

Not applicable

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

Section 5.3

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

Section 5.4

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

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*Table 5: **Use 2.2** - Ready-to-use non-medical pre-milking and post-milking teat disinfection - foaming*

Product Type	Product type 3 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organisms (including development stage)	Bacteria and yeasts
Field of use	Indoor, outdoor Pre- and post-milking disinfection of teats of milk producing animals
Application methods	Manual and automated foaming
Application rates and frequency	The application rate: Apply a maximum of 20 mL product per milking event to cover the treated surface. Frequency: maximum 3 pre-milking and 3 post-milking applications per day
Categories of users	Professional
Pack sizes and packaging material	Bottle (HDPE) - 1 L Jerrycan (HDPE) – 5-60L Drum (HDPE) – 220L IPC (HDPE) – 1000L

2.2.1 Use-specific instructions for use

Before use, bring the product at least 20°C.

Fill the foaming cup with ready to use product from the original packaging. *Pre-milking* Apply the product to the full length of each teat. Leave to act at least 1 min. Wipe the product with a single-use paper towel/cloth to avoid any contamination of milk. Leave the teats skin dry. *Post-milking* The teat should be treated immediately after milking in such a way that the teats are fully covered with the product. Keep the animals standing or walking at least 5 minutes.

2.2.2 Use-specific risk mitigation measures

Not applicable

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

Section 5.3

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

Section 5.4

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

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*Table 6: **Use 2.3** - Ready-to-use non-medical pre-milking and post-milking teat disinfection - dipping*

Product Type	Product type 3 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organisms (including development stage)	Bacteria and yeasts
Field of use	Indoor, outdoor Pre- and post-milking disinfection of teats of milk producing animals
Application methods	Manual and automated dipping
Application rates and frequency	The application rate: Apply a maximum of 20 mL product per milking event to cover the treated surface. Frequency: maximum 3 pre-milking and 3 post-milking applications per day
Categories of users	Professional
Pack sizes and packaging material	Bottle (HDPE) - 1 L Jerrycan (HDPE) – 5-60L Drum (HDPE) – 220L

	IPC (HDPE) – 1000L

2.3.1 Use-specific instructions for use

Before use, bring the product at least 20°C. Fill the manual or automated dipping cup with ready to use product from the original packaging. *Pre-milking* Apply the product to the full length of each teat. Leave to act at least 1 min. Wipe the product with a single-use paper towel/cloth to avoid any contamination of milk. Leave the teats skin dry. *Post-milking* The teat should be treated immediately after milking in such a way that the teats are fully covered with the product. Keep the animals standing or walking at least 5 minutes.

2.3.2 Use-specific risk mitigation measures

Not applicable

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

Section 5.3

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

Section 5.4

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

Section 5.5

2.1.4.3 Meta SPC 3 - Post-milking teat disinfection

*Table 7: **Use 3.1** - Ready-to-use non-medical post-milking teat disinfection - spraying*

Product Type	Product type 3 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organisms (including development stage)	Bacteria and yeasts
Field of use	Indoor, outdoor Post-milking disinfection of teats of milk producing animals
Application methods	Manual and automated spraying
Application rates and frequency	The application rate: Apply a maximum of 20 mL product per milking event to cover the treated surface. Frequency: maximum 3 post-milking applications per day

Categories of users	Professional
Pack sizes and packaging material	Bottle (HDPE) - 1 L Jerrycan (HDPE) – 5-60L Drum (HDPE) – 220L IPC (HDPE) – 1000L

3.1.1 Use-specific instructions for use

Before use, bring the product at least 20°C. Fill a manual or automate spraying device with ready to use product from the original packaging and close with spraying head. The teat should be treated immediately after milking in such a way that the teats are fully covered with the product. Keep the animals standing or walking at least 5 minutes.

3.1.2 Use-specific risk mitigation measures

Not applicable

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

Section 5.3

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

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

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*Table 8: **Use 3.2** - Ready-to-use non-medical post-milking teat disinfection - foaming*

Product Type	Product type 3 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organisms (including development stage)	Bacteria and yeasts
Field of use	Indoor, outdoor Post-milking disinfection of teats of milk producing animals
Application methods	Manual and automated foaming
Application rates and frequency	The application rate: Apply a maximum of 20 mL product per milking event to cover the treated surface. Frequency: maximum 3 post-milking applications per day
Categories of users	Professional

Pack sizes and packaging material	Bottle (HDPE) - 1 L Jerrycan (HDPE) – 5-60L Drum (HDPE) – 220L IPC (HDPE) – 1000L

3.2.1 Use-specific instructions for use

Before use, bring the product at least 20°C. Fill the foaming cup with ready to use product from the original packaging. The teat should be treated immediately after milking in such a way that the teats are fully covered with the product. Keep the animals standing or walking at least 5 minutes.

3.2.2 Use-specific risk mitigation measures

Not applicable

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

Section 5.3

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

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

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*Table 9: **Use 3.3** - Ready-to-use non-medical post-milking teat disinfection - dipping*

Product Type	Product type 3 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organisms (including development stage)	Bacteria and yeasts
Field of use	Indoor, outdoor Post-milking disinfection of teats of milk producing animals
Application methods	Manual and automated dipping
Application rates and frequency	The application rate: Apply a maximum of 20 mL product per milking event to cover the treated surface. Frequency: maximum 3 post-milking applications per day
Categories of users	Professional
Pack sizes and packaging material	Bottle (HDPE) - 1 L Jerrycan (HDPE) – 5-60L Drum (HDPE) – 220L IPC (HDPE) – 1000L

3.3.1 Use-specific instructions for use

Before use, bring the product at least 20°C. Fill the manual or automated dipping cup with ready to use product from the original packaging. The teat should be treated immediately after milking in such a way that the teats are fully covered with the product. Keep the animals standing or walking at least 5 minutes.

3.3.2 Use-specific risk mitigation measures

Not applicable

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

Section 5.3

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

Section 5.4

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

Section 5.5

2.1.5 General directions for use

Instructions for use

Please see section 2.1.4. depend on use

Risk mitigation measures

Not applicable

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

In case of eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. In case of skin contact: Wash with plenty of water. If swallowed: Rinse mouth. Do not induce vomiting. If symptoms occurs: Get medical advice/attention. If inhaled: Get medical attention if symptoms occur.

Instructions for safe disposal of the product and its packaging

Dispose of contents/container to in accordance with national regulation.

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

Store in original container at room temperature. Protect from direct sun light. Protect from frost. Shelf-life: 2 years.

2.1.6 Packaging of the biocidal products

Type of packaging	Volume of the packaging	Material of the packaging	Type and material of closure	User	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	1L	HDPE	Cap, HDPE	Professional	Yes
Jerrycan	5-60L	HDPE	Cap, HDPE	Professional	Yes
Drum	220L	HDPE	Cap, HDPE	Professional	Yes
IBC	1000L	HDPE	Cap, HDPE	Professional	Yes

2.1.7 Documentation

2.1.7.1 Data submitted in relation to product application

No new data has been submitted as part of this biocidal product family application. Please see Section 3.1 of Confidential Annex for a list of studies and statements used.

2.2 Assessment of the biocidal product family

2.2.1 Intended uses

Product Type	Product type 3 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organisms (including development stage)	Bacteria and yeasts
Field of use	Indoor, outdoor 1. Pre-milking disinfection of teats of milk producing animals 2. Pre-milking and post-milking disinfection of teats of milk producing animals 3. Post-milking disinfection of teats of milk producing animals
Application methods	1. Manual and automated spraying 2. Manual and automated foaming Manual and automated dipping
Application rates and frequency	Apply a maximum of 20 ml product per milking event. Maximum 3 pre-milking and maximum 3 post-milking applications per day
Categories of users	Professional
Pack sizes and packaging material	Bottle (HDPE) - 1 L Jerrycan (HDPE) – 5-60L Drum (HDPE) – 220L IPC (HDPE) – 1000L

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	All members of the family	Liquids	Salveco test reports: No.2019/020-1 No.2019/021-1 No.2019/035-1 No.2022/022
Colour at 20 °C and 101.3 kPa	Visual	SALVESAFE E1 SALVESAFE E7 SALVESAFE E13	Orange	Salveco test reports: No.2019/020-1 No.2019/021-1 No.2019/035-1
		SALVESAFE E2 SALVESAFE E8 SALVESAFE E14	Colourless	
		SALVESAFE E19 SALVESAFE E20 SALVESAFE E21	Blue	
		SALVESAFE E22	Orange	No.2022/022
pH (neat formulation), 20°C	CIPAC MT 75.3	All members of the family	2.15-2.25	Salveco test reports: No.2019/020-1

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
				No.2019/021-1 No.2019/035-1 No.2022/022
Relative density, 20°C	EEC Method A3		1.008-10.013	Salveco test reports: No.2019/020-1 No.2019/021-1 No.2019/035-1 No.2022/022
Viscosity, 20°C	OECD 114	All members of the family	< 50 mPa*s	Salveco test reports: No.2019/020-1 No.2019/021-1 No.2019/035-1 No.2022/022
Surface tension, 20°C	OECD 115	All members of the family	28-30 mN/m Surface active products	Salveco test reports: No.2019/020-1 No.2019/021-1 No.2019/035-1
Storage stability test – **accelerated storage**	Storage for 2 weeks at 54°C (CIPAC MT46.3)	SALVESAFE E1 SALVESAFE E7 SALVESAFE E13	Lactic acid content: initial: 2.34% After: 2.40 % Initial pH: 2.22 end pH: 2.21 Viscosity before and after storage < 50 mPa*s Density before and after storage 1.008 Surface tension before and after storage 29.1 mJ/m^2 and 28.6 mJ/m^2 respectively. Clear, orange liquid after 2 weeks	Salveco test report: No.2019/020-1
		SALVESAFE E2 SALVESAFE E8 SALVESAFE E14	Lactic acid content: initial: 2.36% After: 2.39 % Initial pH: 2.21 end pH: 2.20 Viscosity before and after storage < 50 mPa*s Density before and after storage 1.008 Surface tension before and after storage 28.7 mJ/m2 and 29.0 mJ/m2 respectively. Clear, colourless liquid after 2 weeks	Salveco test report: No.2019/021-1

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		SALVESAFE E19 SALVESAFE E20 SALVESAFE E21	Lactic acid content: initial: 2.37% After: 2.39 % Initial pH: 2.20 end pH: 2.17 Viscosity before and after storage < 50 mPa*s Density before and after storage 1.008 Surface tension before and after storage 28.6 mJ/m2 and 28.7 mJ/m2 respectively. Clear, blue liquid after 2 weeks	Salveco test report: No.2019/035-1
		SALVESAFE E22	Lactic acid content: initial: 2.39% After: 2.37% Initial pH: 2.15 end pH: 2.25 Viscosity before and after storage < 50 mPa*s Density before and after storage 1.013 Clear, orange liquid after 2 weeks Appearance of the tested samples did not change after 2 weeks of storage at 54°C. Furthermore the active substance level of samples did not decrease more than 10%. It can be concluded that the product will most likely comply with a shelf life specification of 2 years	Salveco test report: No.2022/022
Storage stability test – **long term storage at ambient temperature**	Storage at 23°C±4°C during 24 months	Biocidal products with initial concentration of Lactic acid around 2.34-2.38 % are used. The storage stability tests are conducted in HDPE bottles. For the detection and identification of Lactic acid HPLC method is used.	Lactic acid content at the end 2.40-2.42%. Tested concentrations and it's changes are within allowed tolerance limit of the declared nominal content of active substance. The	Salveco Analytical Test Reports: No. 2021/002 No. 2021/003 No. 2021/004

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			changes are less than 10%. No variations in physical state and colour of the products. No significant variations for pH, density and viscosity. No changes in appearance of the packaging.	
Storage stability test – **low temperature stability test for liquids**	-	-	Not required: label mentions "Protect from frost"	-
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	Not required: label mentions "Protect from direct sun light"	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			The effect of temperature on the content of the active substance is reported in the accelerated storage reports (Storage for 2 weeks at 54°C). The biocidal products is a water-based formulations and since the active substance is unlimitedly soluble in water and does not react with water, humidity is not expected.	Salveco test reports: No.2019/020-1 No.2019/021-1 No.2019/035-1
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			HDPE is resistant to active substance. In additional, this point will be covered by long term storage studies	One from the resources https://www.absorbentsonline.com/chemical-resistance-guide-for-high-density-polyethylene.htm
Wettability	-	-	Not applicable (the biocidal products are a ready-to-use liquid products).	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable (the biocidal products are a ready-to-use liquid products).	-
Wet sieve analysis and dry sieve test	-	-	Not applicable (the biocidal products are a ready-to-use liquid products).	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable (the biocidal products are a ready-to-use liquid products).	-
Disintegration time	-	-	Not applicable (the biocidal products are a ready-to-use liquid products).	-
Particle size distribution, content of dust/fines, attrition, friability			All products of the family are ready to use liquids. Although the products are used in spray applications, the products are not sold in or together with spraying equipment. The risk assessment is not requested under the simplified procedure. The MMAD is not relevant to demonstrate efficacy.	Salveco statement, 2019
Persistent foaming	-	-	Not applicable (the biocidal products are a ready-to-use liquid products and do not need to be diluted.	-
Flowability/Pourability/Dustability	-	-	Not applicable (the biocidal product is a ready-to-use liquid product).	-
Burning rate — smoke generators	-	-	Not applicable (the biocidal product is a ready-to-use liquid product).	-
Burning completeness — smoke generators	-	-	Not applicable (the biocidal product is a ready-to-use liquid product).	-
Composition of smoke — smoke generators	-	-	Not applicable (the biocidal product is a ready-to-use liquid product).	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Spraying pattern — aerosols			The products are not an aerosol and are not sold in spray packaging	
Physical compatibility	-	-	Not applicable, products not to be mixed with other products.	-
Chemical compatibility	-	-	Not applicable, products not to be mixed with other products.	-
Degree of dissolution and dilution stability	-	-	Not applicable (the biocidal product is a ready-to-use liquid product).	-

Conclusion on the physical, chemical and technical properties of the product
The data provided by the Applicant was acceptable. All products are ready to use water based liquids. All products are surface active. pH level is between 2.15 and 2.25. Values between these limits will not require any additional considerations. The information on storage stability is considered representative for all products in the family. According to accelerated storage products are stable at ambient temperature during 24 months. Labels contain the conditions: "Protect from frost" and "Protect from direct sun light".

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Results	Reference
Explosives	-	Products do not contain substances with chemicals groups associated with explosive properties and is therefore not considered explosive.	-
Flammable gases	-	Not applicable, products are a liquids	-
Flammable aerosols	-	Not applicable, products are not an aerosols	-
Oxidising gases	-	Not applicable, products are a liquids	-
Gases under pressure	-	Not applicable, not under pressure	-
Flammable liquids	-	Biocidal product family only contains non-flammable components. The flash point of all ingredients > 100°C.	-
Flammable solids	-	Not applicable, products are a liquids	-

Property	Guideline and Method	Results	Reference
Self-reactive substances and mixtures	-	Not applicable due to high water content, as well as products contain no self-reacting substances.	-
Pyrophoric liquids	-	Not applicable due to high water content, as well as products contain no self-reacting substances.	-
Pyrophoric solids	-	Not applicable due to high water, as well as products contain substances that do not ignite spontaneously on coming into contact with air at normal temperatures.	-
Self-heating substances and mixtures	-	Not applicable, no self-heating compounds present.	-
Substances and mixtures which in contact with water emit flammable gases	-	Not applicable, products are a stable aqueous solutions.	-
Oxidising liquids	-	No substances with oxidizing properties in the products.	-
Oxidising solids	-	Not applicable, products are a liquids.	-
Organic peroxides	-	Not applicable, no compounds present with bivalent O-O structure present.	-
Corrosive to metals	UN manual of tests and criteria Part III, 37.4 (test C.1) SALVESAFE E1	Not classified as corrosive to metals. A representative product SALVESAFE E1 was tested on metal corrosion classification. The product shows a negative result for corrosion to metal. After 7 days of testing: Aluminium: max 0.6% Steel: max 4.3% The weight loss is below the threshold of 13.5%. No localized corrosion was observed on all samples except the steel sample which was immersed partially in the liquid. Measurements of the depth	J. Conderaerts. 2019. JC_final_19_084_1_revision

Property	Guideline and Method	Results	Reference
		of localized attack: 72 and 95 µm. The deepest intrusion measures less than 120 µm. The main composition of all products is same and the products have only difference in dyes. Therefore, the data for SALVESAFE E1 is considered to sufficiently support all members in family.	
Auto-ignition temperatures of products (liquids and gases)	-	The products are known to be stable at room temperature and do not ignite spontaneously. The product is not considered to be auto-ignitable.	-
Relative self-ignition temperature for solids	-	Not applicable, products are a liquids	-
Dust explosion hazard	-	Not applicable, products are a liquids	-

Conclusion on the physical hazards and respective characteristics of the product
The biocidal products within *SALVESAFE E* family are water-based ready-to-use liquids, are not flammable and are not expected to have any explosive or oxidising properties. No classification and labelling for physico-chemical hazards is required.

2.2.4 Methods for detection and identification

This is no data requirement for an application in accordance with Article 25 of the Regulation (EU) No 528/2012. However, as the method is also being used for storage stability testing, the method has been validated.

Analytical methods for the analysis of the product as such including the active substance									
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		
SALVESAFE E1	HPLC	2 measurments	0.999	UV spectrum	98.3-102.1	100.2	2.6	< 0.02 g/100g	Salveco test report

(same composition with SALVESAFE E7 and SALVESAFE E13) Lactic acid 2.38% w/w		3.08-4.79g /100g							s: No.2019/174
SALVESAFE E2 (same composition with SALVESAFE E8 and SALVESAFE E14) Lactic acid 2.38% w/w	HPLC	2 measurments 3.08-4.79g /100g	0.999	UV spectrum	98.3-102.1	100.2	2.6	< 0.02 g/100g	Salvec o test report s: No.2019/175
SALVESAFE E19 (same composition with SALVESAFE E20 and SALVESAFE E21) Lactic acid 2.38% w/w	HPLC	2 measurments 3.08-4.79g /100g	0.999	UV spectrum	98.3-102.1	100.2	2.6	< 0.02 g/100g	Salvec o test report s: No.2019/176

Active substance not classified as toxic or very toxic. In additional, Latvian CA takes into account also the following points:

1. *Lactic acid* is a naturally occurring alpha-hydroxy acid. *Lactic acid* is normally found in the blood and interstitial fluid of humans at a level of 10 mg/dl (U.S. EPA, 2008).
2. *Lactic acid* approved for use as a food additive (E270) according Regulation (EU) No. 1333/2008. *Lactic acid* has been approved in the EU as a food additive without an ADI or upper limit (Directive 95/2/EC), as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMA 2008).
3. *Lactic acid* also occurs naturally in the soil. Furthermore, *Lactic acid* is ubiquitous in the environment from natural and man-made sources making it impossible to determine the exact source.

2.2.5 Efficacy against target organisms

SALVESAFE E is developed based on *Lactic acid* as an active substance which provides efficacy of the biocidal products.

The applied standards for suspension tests (phase 2, step 1) are appropriate to support claims for evaluation of bactericidal and yeasticidal activity for *SALVESAFE E*. Since no phase 2, step 2 test is available for PT3 Teat disinfection, a modified EN 16437 was used. Modifications of EN 16437 that were made allow the use of a standardized synthetic skin

(Vitroskin) to stimulate the use on teat skin. The test organisms as well as temperature, contact time and soiling have been adapted according to EN 1656 and EN 1657 for teat disinfection. Applicant used the drop/dip method (skin is dipped in teat disinfectant).

The following Standards were used:

- EN 1656 - Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area. Test method and requirements (phase 2, step 1);
- EN 1657 - Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area. Test method and requirements (phase 2, step 1);
- Modified EN 16437 – Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on porous surfaces without mechanical action. Test method and requirements (phase 2, step 2).

The efficacy studies on bactericidal and yeasticidal activity had been performed for biocidal product *SALVESAFE E1* with 2.38% w/w *Lactic acid* concentration. The tested product has a same composition as all products in family. The difference is only in dye's content. Dyes are not considered as a substance of concern regarding efficacy and are excluded from testing by function.

Efficacy has been successfully demonstrated for intended uses. Full details of the test conditions, test results and necessary statements are provided.

Additional data: In 2021 the applicant notified member SALVESAFE E22 in family. Later, in 2022 the applicant applied on MIC with a request to increase content of emollient within family and in composition of SALVESAFE E22. With aim to support that this change does not impact efficacy, the Applicant submitted two additional studies according to EN 1656 and EN 1657. Two target organisms were selected as representatives for bridging studies.

2.2.5.1 Function and field of use

The biocidal products within *SALVESAFE E* family are ready-to-use liquid solutions for the disinfection of teats of milkable animals (cows, buffaloes, goats, sheep) that claim bactericidal and yeasticidal activity. The products are suitable for pre-milking and post-milking treatments by spraying, foaming and dipping applications by professional users.

Phase 2 Step 1 and Step 2 efficacy testing for pre-milking and post-milking applications have been done under high soiling conditions. Therefore, products can be applied without any pre-cleaning of the teats.

2.2.5.2 Effects on target organisms, including unacceptable suffering

Phase 2, step 1 tests (EN 1656:2009/AC:2010 and EN 1657:2016) have been carried out to prove bactericidal and yeasticidal efficacy of the product under test conditions defined for pre-milking and post-milking teat disinfection.

- To demonstrate the **bactericidal activity** in a quantitative suspension test according to the EN 1656:2009/AC:2010 three reference strains were tested: Staphylococcus aureus ATCC 6538 (or DSM 799), Streptococcus uberis ATCC 19436 and Escherichia coli ATCC 10536.

For *pre-milking* teat disinfection, the activity against bacteria has been evaluated for the product at a 1 minute contact time with product test concentrations of 80%, 50% and 1%

under dirty conditions (10 g/l BSA + 10 g/l yeast extract) and temperature 30°C. The results showed that the product demonstrates > 5.00 log reduction for all tested bacterial species at 50% and 80% product test concentrations.

For *post-milking* teat disinfection, the activity against bacteria has been evaluated for the product at a 30-seconds contact time with product test concentrations of 80%, 70% and 10% under relevant soiling (10 g/l skimmed milk) and temperature 30°C. The results showed that the product demonstrates > 5.00 log reduction for all tested bacterial species at 80% product test concentrations.

Therefore, the biocidal product with 2.38% w/w concentration of *Lactic acid* can be claimed for a disinfectant with a bactericidal activity under the defined test conditions and exposure of 1 minute (pre-milking teat disinfection) and 30 seconds (post-milking teat disinfection).

Additional data to support that increase of emollient content has no negative impact for bactericidal efficacy:

- For *pre-milking* teat disinfection, the activity against bacteria has been evaluated for the product at 1 minute contact time with product test concentration of 80% under dirty conditions (10 g/l BSA + 10 g/l yeast extract) and temperature 30°C. The results showed that the product demonstrates > 5.00 log reduction.
- For *post-milking* teat disinfection, the activity against bacteria has been evaluated for the product at 5 minutes contact time with product test concentration of 80% under relevant soiling (10 g/l skimmed milk) and temperature 30°C. The results showed that the product demonstrates > 5.00 log reduction.

- To demonstrate the **yeasticidal activity** in a quantitative suspension test according to the EN 1657:2016 yeast Candida albicans ATCC 10231 was tested.

For *pre-milking* teat disinfection, the activity against the yeast has been evaluated for the product at a 1 minute contact time and product test concentrations of 80%, 50% and 1% under dirty conditions (10 g/l BSA + 10 g/l yeast extract) and temperature 30°C. The results showed that the liquid demonstrates > 4.00 log reduction for at 50% and 80% product test concentrations.

For *post-milking* teat disinfection, the activity against yeast has been evaluated for the product at a 30 seconds contact time with product test concentrations of 80%, 70% and 10 % under relevant soiling (10 g/l skimmed milk) and temperature 30°C. The results showed that the liquid demonstrates > 4.00 log reduction at 80% product test concentrations.

Therefore, the biocidal product with 2.38% w/w concentration of *Lactic acid* can be claimed for a disinfectant with a yeasticidal activity under the defined test conditions and exposure of 1 minute (pre-milking teat disinfection) and 30 seconds (post-milking teat disinfection).

Additional data to support that increase of emollient content has no negative impact for yeasticidal efficacy:

- For *pre-milking* teat disinfection, the activity against yeast has been evaluated for the product at 1 minute contact time with product test concentration of 80% under dirty conditions (10 g/l BSA + 10 g/l yeast extract) and temperature 30°C. The results showed that the product demonstrates > 4.00 log reduction.
- For *post-milking* teat disinfection, the activity against yeast has been evaluated for the product at 5 minutes contact time with product test concentration of 80% under relevant soiling (10 g/l skimmed milk) and temperature 30°C. The results showed that the product demonstrates > 4.00 log reduction.

Practical conditions

Due to the absence of a **phase 2, step 2** test for bactericidal and yeasticidal efficacy in prophylactic teat treatment under practical conditions, the proposal has been made to use a modified EN 16437 standard - Chemical disinfectants and antiseptics. Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on porous surfaces without mechanical action.

The main modifications were:

- use of artificial skin – Vitro-skin® as porous surface;

- use of microorganisms specific for teat disinfections – Escherichia coli ATCC 10536, Staphylococcus aureus ATCC 6538, Streptococcus uberis ATCC 19436 and Candida albicans ATCC 10231;

- change of test temperature from 10°C to 30°C;

- dirty soiling for pre-milking – 10 g/L BSA + 10 g/L yeast extract; specific soiling for post-milking – 10 g/L skimmed milk;

- selected test protocol to demonstrate the application in both pre and post milking applications: "drop-dip" (immersion of the carrier for 1 or 5 min in test product, then removal and subsequent processing.

For pre-milking application 100% product concentration demonstrated acceptable bactericidal and yeasticidal efficacy (> 4 log reduction for all tested bacterial species and > 3 log reduction for yeast C. albicans) within 1 min contact time under dirty conditions and 30°C.

For post-milking application 100% product concentration demonstrated acceptable bactericidal and yeasticidal efficacy (> 4 log reduction for all tested bacterial species and > 3 log reduction for yeast C. albicans) within 5 min contact time under specific soiling (1% skimmed milk) and 30°C.

Therefore, the biocidal product with 2.38 % w/w concentration of *Lactic acid* is a disinfectant with a bactericidal and yeasticidal activity under the practical conditions according to claimed intended use.

2.2.5.3 Mode of action, including time delay

In solution, *Lactic acid* exists in a pH-dependent equilibrium between the undissociated and dissociated form. Only in its undissociated state, the acid is able to pass the cell membrane. At a relatively low pH, the uncharged acid enters the cell. Inside the cell, the Lactic acid dissociates due to the higher pH. The molecules remain inside the cell, because the resulting ions cannot pass the membrane. The pH inside the cell is lowered and metabolic reactions are inhibited. Further effects are also reported. Decrease of the membrane permeability for amino acids, organic acids, phosphates resulting in uncoupling of both substrate transport and oxidative phosphorylation from the electron transport system. Furthermore, an inhibition of the glycolysis by the lactate ion is observed.

The results of the efficacy tests conclusively demonstrate that the biocidal product with the concentration of 2.38% w/w *Lactic acid* after a 1 minute contact time for PT3 pre-milking application and 5 minutes contact time for PT3 post-milking application reached sufficient efficacy to reduce the target organisms (bacteria and yeast) below the required threshold.

2.2.5.4 Efficacy data

Experimental data on the efficacy of the tested biocidal products against target organisms for supporting of the family

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Bactericide	Teat disinfection, pre-milking	SalveSafe Teat (2.38% w/w a.s.)	*Staphylococcus aureus* ATCC 6538 *Streptococcus uberis* ATCC 19436 *Escherichia coli* ATCC 10536	EN prEN 1656/2017; Quantitative suspension test (phase 2, step 1) Validated by eCA according to: EN 1656:2009/AC:2010; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 80%, 50%, 1% - Diluent: water for injections - Test method: dilution-neutralization - Contact time: 1 minute - Soiling: 10 g/L BSA + 10 g/L yeast extract (dirty conditions) - Test temperature: 30°C	Tested product demonstrated bactericidal activity at tested concentrations of 50% and 80% under defined conditions (pass R > 5 log)	Confidential PAR
Bactericide	Teat disinfection, post-milking	SalveSafe Teat (2.38% w/w a.s.)	*Staphylococcus aureus* DSM 799 *Streptococcus uberis* ATCC 19436 *Escherichia coli* ATCC 10536	EN 1656:2010 Validated by eCA according to: EN 1656:2009/AC:2010; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 80%, 70%, 10% - Diluent: distilled water - Test method: dilution-neutralization - Contact time: 30 seconds - Soiling: 10 g/L skimmed milk - Test temperature: 30°C	Tested product demonstrated bactericidal activity at 80 % product concentration under defined conditions (pass R > 5 log)	Confidential PAR
Yeasticide	Teat disinfection, pre-milking	SalveSafe Teat (2.38% w/w a.s.)	*Candida albicans* ATCC 10231	EN 1657:2016; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 80%, 50%, 1% - Diluent: water for injections - Test method: dilution-neutralization - Contact time: 1 minute - Soiling: 10 g/L BSA + 10 g/L yeast extract (dirty conditions) - Test temperature: 30°C	Tested product demonstrated yeasticidal activity at tested concentrations of 50% and 80% under defined conditions (pass R > 4 log)	Confidential PAR

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Yeasticide	Teat disinfection, post-milking	SalveSafe Teat (2.38% w/w a.s.)	*Candida albicans* ATCC 10231	prEN 1657:2015 Validated by eCA according to: EN 1657:2016; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 80%, 70%, 10% - Diluent: distilled water - Test method: dilution-neutralization - Contact time: 30 seconds - Soiling: 10 g/L skimmed milk - Test temperature: 30°C	Tested product demonstrated yeasticidal activity at 80% product concentration under defined conditions (pass R > 4 log)	Confidential PAR
Bactericide and Yeasticide	Teat disinfection, pre-milking	SalveSafe Teat (2.38% w/w a.s.)	*Staphylococcus aureus* DSM 799 *Streptococcus uberis* CIP 103219T *Escherichia coli* DSM 682 *Candida albicans* CIP 48.72	Modified EN 16437:2014 Quantitative porous surface test without mechanical action (phase 2, step 2)	- Tested product concentrations: 100%, 80%, 1% - Test protocol: drop-dip - Diluent: hard water - Carriers: VitroSkin® - Test method: dilution-neutralization - Contact time: 1 minute - Soiling: 10 g/L BSA + 10 g/L yeast extract (dirty conditions) - Test temperature: 30°C	Tested product demonstrated bactericidal activity (R > 4 log) at 100% product concentration under defined conditions (dirty, 30°C, 1 min contact time) Tested product demonstrated yeasticidal activity (R > 3 log) at 100% product concentration under defined conditions (dirty, 30°C, 1 min contact time)	Confidential PAR
Bactericide and Yeasticide	Teat disinfection, post-milking	SalveSafe Teat (2.38% w/w a.s.)	*Staphylococcus aureus* ATCC 6538 *Streptococcus uberis* ATCC 19436 *Escherichia coli* ATCC 10536 *Candida albicans* ATCC 10231	Modified EN 16437:2014 Quantitative porous surface test without mechanical action (phase 2, step 2)	- Tested product concentrations: 100%, 80%, 10% - Test protocol: drop-dip - Diluent: water for injections - Carriers: VitroSkin® - Test method: dilution-neutralization - Contact time: 5 minutes - Soiling: 10 g/L skim milk - Test temperature: 30°C	Tested product demonstrated bactericidal activity (R > 4 log) at 100% product concentration under defined conditions (1% skim milk soiling, 30°C, 5 min contact time) Tested product demonstrated yeasticidal activity (R > 3 log) at 100% product concentration under defined conditions (1% skim milk soiling, 30°C, 5 min contact time)	Confidential PAR

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Bactericide and yeasticide	Teat disinfection, pre-milking and post-milking	SalveSafe Teat (2.38% w/w a.s.)	*Staphylococcus aureus ATCC 6538* *Candida albicans ATCC 10231*	EN 1656/2019; EN 1657/2016; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 80% - Diluent: none - Test method: dilution-neutralization - Contact time: 1 minute (pre-milking) and 5 minutes (post-milking) - Soiling: 10 g/L BSA + 10 g/L yeast extract (pre-milking) and 10 g/L skim milk (post-milking) - Test temperature: 30°C	Tested product demonstrated bactericidal and yeasticidal activity at 80% under defined conditions (pass R > 5 log)	Confidential PAR

Conclusion on the efficacy of the product

SALVESAFE E family meets the bactericidal and yeasticidal activity for pre-milking and post-milking teat disinfection.

Phase 2 Step 1 and Step 2 efficacy testing for pre-milking and post-milking applications have been done under high soiling conditions. Therefore, products can be applied without any pre-cleaning of the teats.

Phase 2 Step 1 and Step 2 shows, that the biocidal product with 2.38% w/w concentration of *Lactic acid* can be claimed for a disinfectant with a bactericidal and yeasticidal activity for 1 minute for pre-milking teat disinfection and 5 minutes for post-milking teat disinfection.

LV CA concludes that the tested product covers all members within SALVESAFE E family. Dyes are not considered as a substance of concern regarding efficacy and are excluded from testing by function. Additional data shows that increase of emollient content doesn't impact product efficacy.

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

2.2.5.5 Occurrence of resistance and resistance management

The efficacy of the biocidal product family has provided due the content of the active substance – *Lactic acid*. The resistance of target organisms to the biocidal product family actually could mean resistance to the *Lactic acid*. The possibility of the development of the resistance to *Lactic acid* was not evaluated. However, Latvian CA revising the scientific literature (Theron MM., 2010) concludes that no clear scientific evidence exists that target organisms have developed resistance against the organics acid, such as *Lactic acid*.

2.2.5.6 Known limitations

No limitations and no undesirable or unintended side-effects have been observed during these studies.

2.2.5.7 Evaluation of the label claims

SALVESAFE E family is intended to be used as pre-milking and post-milking teat disinfectants.

The evaluation of efficacy demonstrates that the biocidal products within family meet agreed criteria for reduction of bacteria and yeast population in the presence of organic soiling.

The Latvian CA considers that the following label claim can be used on product label for professional users:

- Ready-to-use teat disinfectant for pre-milking treatment: bactericidal and yeasticidal activity at 1 minute contact time.

- Ready-to-use teat disinfectant for post-milking treatment: bactericidal and yeasticidal activity at 5 minutes contact time.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

No classification is proposed for human health, as the criteria for classification under Regulation (EC) 1272/2008 are not met.

Skin corrosion and irritation

Summary table of animal studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 404 of April 24, 2002 for Testing of Chemicals. Acute Dermal Irritation/Corrosion.	Confidential PAR	Test item applied as it is, 0.5 ml for 4 hours	<u>Erythema</u> Animal 1: **0.7** Animal 2: **1.0** Animal 3: **0.3** <u>Oedema</u> Animal 1: **0** Animal 2: **0** Animal 3: **0** Fully reversible after 72 h No histopathological changes observed	-	Confidential PAR

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not corrosive or irritating to skin.
Justification for the value/conclusion	According to the CLP criteria and additivity approach, classification is met with respect to local effects on the skin (irritation) for the individual products of the BPF and thus the BPF itself. The conclusion is made based on RAC opinion for L(+)-Lactic acid, content of individual components, generic cut-off values specified in CLP Annex I, Table 1.1 and generic concentration limits (GCL) specified in CLP Annex I, Table 3.2.3. The sum of the concentrations/GCL of individual components exceeds a concentration limit 1%. Upon Latvian CA request to support non-classification of the BPF, the Applicant provided study according to the OECD Test Guidance No. 404. The tested formulation contains 3.52% Lactic acid and surfactants at total concentration above the limit within family. Therefore, the tested formulation can be considered as representative worst case and based on point 1.1.3.5 of CLP Latvian CA is in opinion that tested formulation covers all biocidal products within BPF.

	According to Table 3.2.2 of the CLP, the substances and mixtures shall be classified as Skin Irrit. 2 if mean score of ≥ 2.3 and ≤ 4.0 for erythema/eschar or for oedema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal is observed. According to the study, the range of average score for erythema from 0.3 to 1.0 and no signs of oedema. All effects were fully reversible after 72 h. Therefore, the tested product doesn't meet classification criteria. *Additional data* In order to support the good skin tolerance of the products, the Applicant took the initiative to perform the following test under dermatological control: - Study of acute skin compatibility of a test item after single application: 48-hour semi occlusive patch-test. The test item induced no reaction of irritation and has a very good skin compatibility after single application of the investigational product, under semi-occlusive patch on a panel of 11 subjects with sensitive skin on body.
Classification of the product according to CLP	Not relevant

Eye irritation

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD guidelines 405 (GLP)	Confidential PAR	0.1 mL of biocidal product. Ocular examinations were performed 24, 48 and 72 hours following treatment	The ocular reactions observed have been slight to moderate and totally reversible. Test results presented in Confidential PAR	Systemic analgesia and topical ocular anesthetic applied during test	Confidential PAR

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not causing severe damage or eye irritation
Justification for the value/conclusion	For all products the exact composition is known. The detailed BPF composition and classification of individual components is referred in Confidential PAR. According to the CLP criteria and additivity approach, classification is met with respect to local effects on the eyes for the individual products of the BPF and thus the BPF itself. The conclusion is made based on content of individual components, generic cut-off values specified in CLP Annex I, Table 1.1 and generic concentration limits (GCL) specified in CLP Annex I, Table 3.2.3. The sum of the concentrations/GCL of individual components exceeds a concentration limit 1%.

	However, Applicant provided the eyes irritation study according OECD No. 405 for "dummy" formulation with the concentration of co-formulant's and *Lactic acid* above notified limit for family. Based on a results, SALVESAFE E family does not meet the criteria for classification for eye irritation
Classification of the product according to CLP and DSD	No classification required.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	The products do not meet the classification criteria for skin or eye irritation and it can be predicted that it will not have the capacity to cause respiratory tract irritation.
Justification for the conclusion	For all products the exact composition is known. The detailed BPF composition and classification of individual components is referred in Confidential PAR. There are currently no standard tests and no OECD TG available for respiratory irritation and there is no testing requirement for respiratory irritation under the Biocides Regulation. For active substance and each co-formulants valid data are available through Safety Data Sheets. As well, eCA is taken into account information from ECHA C&L inventory base (by majority of self-classifications) and REACH dossier. For one substance a self-classifications indicate on STOT SE 3, H335. However, based on content and Section 3.8 of CLP no classification criteria are fulfilled
Classification of the product according to CLP and DSD	No classification required.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to skin.
Justification for the value/conclusion	Studies on skin sensitisation properties are not required. According to Annex III of the Regulation (EU) 528/2012 "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For all products the exact composition is known. The detailed BPF composition and classification of individual components is referred in Confidential PAR. As well, eCA is taken into account information from ECHA C&L inventory base (by majority of self-classifications) and REACH dossier. Based on information family does not contain substances classified as Skin Sens. 1, H317.
Classification of the product according to CLP and DSD	No classification required.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitisers
Justification for the value/conclusion	Studies on respiratory sensitisation properties are not required. According to Annex III of the Regulation (EU) 528/2012 "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For all products the exact composition is known. For active substance and each co-formulants valid data are available through Safety Data Sheets. As well, eCA is taken into account information from ECHA C&L inventory base (by majority of self-classifications) and REACH dossier. Based on information family does not contain substances classified as Resp. Sens. 1, H334.
Classification of the product according to CLP and DSD	No classification required.

Acute toxicity

No studies are provided for *SALVESAFE E* family.

Safety data sheets have been submitted for active substance and each co-formulant. *SALVESAFE E* family does not contain a component classified for acute toxicity. Therefore, *SALVESAFE E* family does not classified for acute toxicity according to the rules laid down in CLP regulation and synergistic effects between any of the components are not expected.

Assessment for endocrine disrupting properties

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides.

The *SALVESAFE E* family contains Lactic acid as the active substance and seven co-formulants. The products within family were not tested for potential endocrine disruption properties.

For Lactic acid no ED assessment is required because active substance is included in Annex I of the BPR.

A screening phase (in a Confidential PAR) for all co-formulants was performed by the Applicant. None of the co-formulants are subject to a decision regarding endocrine disrupting properties.

2.2.6.2 Exposure assessment

Lactic acid is listed in Annex I of the Regulation (EU) No 528/2012. There are no substances of concern present. Therefore the detailed exposure assessment is not relevant under the simplified authorisation procedure according to Regulation (EU) 528/2012. Latvian CA accepts that the personal protective equipment are not required for the use of the *SALVESAFE E* based on non-classification of family.

2.2.6.3 Risk characterisation for human health

Taking into account the information on wide use of *Lactic acid* in food and cosmetic areas, no presence of substance of concerns, as well as, results on non-classification of family, Latvian CA considers that authorisation of *SALVESAFE E* is acceptable from a human health perspective.

2.2.7 Risk assessment for the environment

2.2.7.1 Effects assessment on the environment

Safety data sheets have been submitted for active substance and each co-formulant. *SALVESAFE E* family does not contain a component classified for environmental hazards.

No studies are provided for *SALVESAFE E* family.

Based on the data provided by the Applicant, there is no concern regarding the ED properties of the co-formulants used in the *SALVESAFE E* family.

2.2.7.2 Exposure assessment

Lactic acid is listed in Annex I of the Regulation (EU) No 528/2012. There are no substances of concern present. Therefore the detailed exposure assessment is not relevant under the simplified authorisation procedure according to Regulation (EU) 528/2012.

2.2.7.3. Risk characterisation for the environment

Taking into account the information on wide use of Lactic acid in food and cosmetic areas, no presence of substance of concerns, as well as, results on no classification of family, Latvian CA considers that authorisation of *SALVESAFE E* family is acceptable from an environmental perspective.

2.2.8 Measures to protect man, animals and the environment

For the protection of man, animals and the environment label must contain the following indications in addition to the elements already listed in Article 69 of Regulation (EU) 528/2012:

1. **The instruction for use must contain the following indications on application:**

The product must be storage at room temperature before the use.

Spraying
Fill a manual or automate spraying device with ready to use product from the original packaging and close with spraying head.
Pre-milking: Apply the product by spray to the full length of each teat. Leave to act at least 1 min. Wipe the product with a single-use paper towel/cloth to avoid any contamination of milk.
Post-milking: The teat should be treated immediately after milking in such a way that the teats are fully covered with the product. Keep the animals standing or walking at least 5 minutes.

Foaming
Fill the foaming cup with ready to use product from the original packaging.
Pre-milking: Apply the product to the full length of each teat. Leave to act at least 1 min. Wipe the product with a single-use paper towel/cloth to avoid any contamination of milk. Leave the teats skin dry.
Post-milking: The teat should be treated immediately after milking in such a way that the teats are fully covered with the product. Keep the animals standing or walking at least 5 minutes.

Dipping
Fill the manual or automated dipping cup with ready to use product from the original packaging.
Pre-milking: Apply the product to the full length of each teat. Leave to act at least 1 min. Wipe the product with a single-use paper towel/cloth to avoid any contamination of milk. Leave the teats skin dry.
Post-milking: The teat should be treated immediately after milking in such a way that the teats are fully covered with the product. Keep the animals standing or walking at least 5 minutes.

2. **Label claim:**

Ready-to-use teat disinfectant for pre-milking treatment: bactericidal and yeasticidal activity at 1 minute contact time.

Ready-to-use teat disinfectant for post-milking treatment: bactericidal and yeasticidal activity at 5 minutes contact time.

3. **Information on first aid instruction:**

In case of eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
In case of skin contact: Wash with plenty of water.
If swallowed: Rinse mouth. Do not induce vomiting. If skin symptoms occurs: Get medical advice/attention.

If inhaled: Get medical attention if symptoms occur.

4. Waste management measures:

Dispose of contents/container to in accordance with national regulation.

5. Storage conditions and stability:

Store in original container at room temperature. Protect from direct sun light. Protect from frost.
Shelf-life: 2 years.

3 References

1. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives
2. U.S. EPA April 25, 2008. USEPA Memorandum from Roger Gardner to A. Bryceland., entitled "Registration Review: Lactic Acid Preliminary Human Health Document".
3. EMA, 2008. Status of MRL Procedures MRL assessments in the context of Council Regulation (EEC) No 2377/90