

Riga

28.08.2019 Nr. 4-6/1259

SALVECO S.A.S.

Avenue Pierre Mendès-France Saint Die Des Vosges, 88100 France

On authorisation of the biocidal product family SALVESAFE E under the simplified authorisation procedure

Latvian Environment, Geology and Meteorology Centre (LEGMC) on 18th March 2019 received application for the simplified authorisation of the **SALVESAFE** E family in accordance with Chapter V of the *Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products* (Regulation (EU) 528/2012) submitted by **SALVECO S.A.S.** through Register for Biocidal Products (Case No. BC-DN050009-43).

LEGMC as Latvian competent authority has evaluated the above mentioned application and considers that biocidal product family meets the conditions of the 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.

Therefore, LEGMC grants authorisation for SALVESAFE E family with Lactic acid (CAS No. 50-21-5, EC No. 200-018-0) as active substance at the concentration 2.38% w/w for product type 3 (veterinary hygiene) as non-medical pre-milking and post-milking teat disinfectants.

LEGMC assigns an authorisation number EU-0020512-0000 for SALVESAFE E family.



In accordance with Asset numbers in R4BP3 the authorisation numbers for biocidal products within family are following:

Trade name	Other trade name	Authorisation number
SALVESAFE E1		EU-0020512-0001
SALVESAFE E2		EU-0020512-0002
SALVESAFE E19		EU-0020512-0003
SALVESAFE E7	DEOSAN Triathlon Mole Valley Lactocide	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

The authorisation numbers are valid until 28th August 2029.

A person placing on the market or using the biocidal products included in the biocidal product family shall comply with the conditions for placing on the market or use of the above mentioned biocidal product family set out in Annex I - III.

The biocidal products authorised in accordance with Article 26 of the Regulation (EU) 528/2012 may be made available on the market in all Member States according to conditions laid down in Article 27 of the Regulation (EU) 528/2012.

LEGMC sets the following post-authorisation condition:

 the test report on long term storage stability at ambient temperature should be submitted until 1th February 2021.

Appendix:

Annex I - General information, 1 page;

Annex II - Summary of the product characteristics for the biocidal product family, 20 pages;

Annex III - Composition of the biocidal product family, 4 pages.

Head of Information Analysis Department

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Annex I Latvian Environment, Geology and Meteorology Centre 28.08.2019 letter No. 4-6/1259 pp. 1

GENERAL INFORMATION

The following conditions apply:

- 1. The authorisation numbers shall be indicated on the labels of the biocidal products.
- SALVECO S.A.S. shall inform LEGMC about any changes in accordance with Commission Implementing Regulation (EU) No 354/2013 of 18th April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.
- 2. The biocidal products shall not be placed on the market unless it complies with the requirements and conditions of the authorisation specified in the Summary of Product Characteristics.
- 3. SALVECO S.A.S. is fully responsible of the composition of the biocidal product's, labels, instructions of use and it's safety data sheets.
- 4. In accordance with Article 31 of the Regulation (EU) 528/2012 the authorisation of the biocidal product family shall be re-opened for review before the 28th August 2029.



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Summary of product characteristics for the biocidal product family

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Part I - First information level

1. Administrative information

1.1. Family name

	Name	SALVESAFE E
-		

1.2. Product type

D 1	DOT A VI
Product type	PT 3 – Veterinary hygiene (Disinfectants)
	, , 8

1.3. Authorisation holder

Name and address of the	Name	SALVECO	S.A.S.	
authorisation holder	Address	Avenue Pierre Mendès-France Saint Die Des Vosges, F-88100, France		
Authorisation number	EU-0020512-0000			
Authorisation numbers of the	SALVESAFE E1		EU-0020512-0001	
biocidal products within family	SALVESAFE E2		EU-0020512-0002	
	SALVESAFE E19		EU-0020512-0003	
	SALVESA	AFE E7	EU-0020512-0004	
	SALVESA	AFE E8	EU-0020512-0005	
	SALVESA	AFE E20	EU-0020512-0006	
	SALVESA	AFE E13	EU-0020512-0007	
	SALVESA	AFE E14	EU-0020512-0008	
	SALVESAFE E21		EU-0020512-0009	
R4BP asset reference number	EU-0020512-0000			
Date of the authorisation	28 th August 2019			
Expiry date of the authorisation 28 th		st 2029		

1.4. Manufacturer of the biocidal products

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



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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	

1.5. 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. Product family composition and formulation

2.1. Qualitative and quantitative information on the composition of the family

Common name	Function	CAS number	EC number	Content (%, w/w)	
				Min	Max
Lactic acid	Active substance	50-21-5	200-018-0	2.38	2.38

2.2. Type of formulation

Formulation	Ready-to-use water based liquids



Second information level

1. Meta SPC administrative information

1.1. Meta SPC identifier

Identifier	Meta 1 - Pre-milking teat disinfection
1.2. Suffix to the authorisation i	number
Number	-

2. Meta SPC composition

Product type

2.1. Qualitative and quantitative information on the composition of the meta SPC

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

2.2. Type of formulation of the meta SPC

Formulation	Ready-to-use water based liquids
	reday to use water based riquids

3. Hazard and precautionary statements of the meta SPC

Hazard statements	Not applicable
Precautionary statements	Not applicable
Supplemental hazard information	EUH210: Safety data sheet available on request

4. Authorised use of the meta SPC

4.1. Use 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	Bacteria and yeasts
Field of use	Indoor, outdoor

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PT3- Veterinary hygiene (Disinfectants)



	Pre-milking disinfection of teats of milk producing animals	
Application method	Manual and automated spraying	
Application rate and frequency	The application rate: Apply a maximum of 20 mL product p-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	

4.1.1. 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.

4.1.2 Use-specific risk mitigation measures

Not applicable

4.1.3 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.

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

Section 5.4.

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

Section 5.5.

4.2. Use 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	·

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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	

4.2.1 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.

4.2.2 Use-specific risk mitigation measures

Not applicable

4.2.3 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.

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

Section 5.4.

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

Section 5.5.



4.3. Use 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 anima			
Application methods	Manual and automated dipping			
Application rates and frequency	The application rate: Apply a maximum of 20 mL produc 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			

4.3.1 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.

4.3.2 Use-specific risk mitigation measures

Not applicable

4.3.3 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.

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

Section 5.4.

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

Section 5.5.



5. General directions for use

5.1. Instructions for use

Please see section 4 depend on use

5.2. Risk mitigation measures

Not applicable

5.3. 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.

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

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

5.5. 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.

6. Other information

N/A

7. Third information level: individual products in the meta SPC

Trade names	SALVESAFE E1				
Authorisation number	EU-0020512-0001				
Common name	IUPAC name	Function	CAS number	EC number	Content (%, w/w)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	2.38



Trade names	SALVESAFE E2				
Authorisation number	EU-0020512-0002				
Common name	IUPAC name	Function	CAS number	EC number	Content (%, w/w)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	2.38
Trade names	SALVESAFE E19				
Authorisation number	EU-0020512-0003				
Common name	IUPAC name	Function	CAS number	EC number	Content (%, w/w)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	2.38

8. Meta SPC administrative information

8.1. Meta SPC identifier

Identifier	Meta 2 - Pre-milking and post-milking teat disinfection
8.2. Suffix to the authorisat	ion number
Number	-
8.3. Product type	
Product type	PT3- Veterinary hygiene (Disinfectants)

9. Meta SPC composition

9.1. Qualitative and quantitative information on the composition of the meta SPC

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

9.2. Type of formulation of the meta SPC

Formulation	Ready-to-use water based liquids



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10. Hazard and precautionary statements of the meta SPC

Hazard statements	Not applicable
Precautionary statements	Not applicable
Supplemental hazard information	EUH210: Safety data sheet available on request

11. Authorised use of the meta SPC

11.1. Use 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	Bacteria and yeasts
Field of use	Indoor, outdoor Pre- and post-milking disinfection of teats of milk producing animals
Application method	Manual and automated spraying
Application rate 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

11.1.1. 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.

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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 cows standing or walking at least 5 minutes.



11.1.2. Use-specific risk mitigation measures

Not applicable

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

Section 12.3.

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

Section 12.4.

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

Section 12.5.

11.2. Use 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

11.2.1. 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 cows standing or walking at least 5 minutes.

11.2.2. Use-specific risk mitigation measures

Not applicable

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

Section 12.3.

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

Section 12.4.

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

Section 12.5.

$11.3.\ Use\ 3-Ready-to-use\ non-medical\ pre-milking\ and\ post-milking\ teat\ disinfection-dipping$

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



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

11.3.1. 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 cows standing or walking at least 5 minutes.

11.3.2. Use-specific risk mitigation measures

Not applicable

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

Section 12.3.

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

Section 12.4.

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

Section 12.5.

12. General directions for use

12.1. Instructions for use

Please see section 11. depend on use

12.2. Risk mitigation measures

Not applicable



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12.3. 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.

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

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

12.5. 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.

13. Other information

N/A

14. Third information level: individual products in the meta SPC

Trade names	SALVESAFE E7 DEOSAN Triathlon Mole Valley Lactoci				
Authorisation number	EU-0020512-0004				
Common name	IUPAC name	Function	CAS number	EC number	Content (%, w/w)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	2.38
Trade names	SALVESAFE E8				
Authorisation number	EU-0020512-0005				
Common name	IUPAC name	Function	CAS number	EC number	Content (%, w/w)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	2.38



Trade names	SALVESAFE E20				
Authorisation number	EU-0020512-0006				
Common name	IUPAC name	Function	CAS number	EC number	Content (%, w/w)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	2.38

15. Meta SPC administrative information

15.1. Meta SPC identifier

Identifier	Meta 3 - Post-milking teat disinfection
152. Suffix to the authorisation n	umber
Number	-
15.3. Product type	
Product type	PT3- Veterinary hygiene (Disinfectants)

16. Meta SPC composition

16.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	on name Function CAS number		EC number	Content (%)	
				Min	Max
Lactic acid	Active substance	50-21-5	200-018-0	2.38	2.38

16.2. Type of formulation of the meta SPC

Formulation	Ready-to-use water based liquids

17. Hazard and precautionary statements of the meta SPC

Hazard statements	Not applicable
Precautionary statements	Not applicable
Supplemental hazard information	EUH210: Safety data sheet available on request



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18. Authorised use of the meta SPC

18.1. Use 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	Bacteria and yeasts
Field of use	Indoor, outdoor Post-milking disinfection of teats of milk producing animals
Application method	Manual and automated spraying
Application rate 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

18.1.1. 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 cows standing or walking at least 5 minutes.

18.1.2. Use-specific risk mitigation measures

Not applicable

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

Section 19.3.

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

Section 19.4.

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

Section 19.5.



18.2. Use 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

18.2.1. 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 cows standing or walking at least 5 minutes.

18.2.2. Use-specific risk mitigation measures

Not applicable

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

Section 19.3.

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

Section 19.4.

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

Section 19.5.



18.3. Use 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			

18.3.1. 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 cows standing or walking at least 5 minutes.

18.3.2. Use-specific risk mitigation measures

Not applicable

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

Section 19.3.

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

Section 19.4.

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

Section 19.5.



19. General directions for use

19.1. Instructions for use

Please see section 18. depend on use

19.2. Risk mitigation measures

Not applicable

19.3. 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.

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

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

19.5. 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.

20. Other information

N/A

21. Third information level: individual products in the meta SPC

Trade names	SALVESAFE E13						
Authorisation number	EU-0020512-0007						
Common name	IUPAC name	Function	CAS number	EC number	Content (%, w/w)		
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	2.38		



Trade names	SALVESAFE E14							
Authorisation number	EU-0020512-0008							
Common name	IUPAC name	Function	CAS number	EC number	Content (%, w/w)			
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	2.38			
Trade names	CALVECARE FOI							
Trade fiames	SALVESAFE E21							
Authorisation number	EU-0020512-0009							
Common name	IUPAC name	Function	CAS number	EC number	Content (%, w/w)			
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	2.38			



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