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SALVECO S.A.S.

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

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

Latvian Environment, Geology and Meteorology Centre (LEGMC) on 4th May 2022 received application for a simplified authorisation of the **SALVESAFE H** 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-PB075365-42).

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 of the Regulation (EU) No 528/2012 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 H* family with **Lactic acid** (CAS No. 50-21-5, EC No. 200-018-0) as active substance at the concentration **1.98% w/w** for **product type 1** (human hygiene) as ready-to-use disinfectant for hands with bactericidal, yeasticidal efficacy and virucidal activity only against enveloped viruses in domestic, institutional, industrial and medical area.

LEGMC assigns an authorisation number EU-0028975-0000 for SALVESAFE H.

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 H0		EU-0028975-0001
SALVESAFE H0_R	Savon mains désinfectant sans parfum Disinfecting hand soap fragrance-free	EU-0028975-0002
SALVESAFE H0_RC		EU-0028975-0003
SALVESAFE H0_F	Savon mains mousse désinfectant sans parfum Disinfecting foam hand soap fragrance-free	EU-0028975-0004
SALVESAFE H1		EU-0028975-0005
SALVESAFE H1_R	Savon mains désinfectant Igloo Disinfecting hand soap Igloo	EU-0028975-0006
SALVESAFE H1_F	Savon mains mousse désinfectant Igloo Disinfecting foam hand soap Igloo	EU-0028975-0007
SALVESAFE H2		EU-0028975-0008
SALVESAFE H2_R	Savon mains désinfectant Golden Disinfecting hand soap Golden	EU-0028975-0009
SALVESAFE H2_F	Savon mains mousse désinfectant Golden Disinfecting foam hand soap Golden	EU-0028975-0010
SALVESAFE H3		EU-0028975-0011
SALVESAFE H3_R		EU-0028975-0012
SALVESAFE H3_F		EU-0028975-0013
SALVESAFE H4		EU-0028975-0014
SALVESAFE H4_R	Savon mains désinfectant Fleurs de printemps Disinfecting hand soap Spring blossom	EU-0028975-0015
SALVESAFE H4_F	Savon mains mousse désinfectant Fleurs de printemps Disinfecting foam hand soap Spring blossom	EU-0028975-0016
SALVESAFE H5		EU-0028975-0017
SALVESAFE H5_R		EU-0028975-0018
SALVESAFE H5_F		EU-0028975-0019
SALVESAFE H6		EU-0028975-0020
SALVESAFE H6_R		EU-0028975-0021
SALVESAFE H6_F		EU-0028975-0022
SALVESAFE H7		EU-0028975-0023
SALVESAFE H7_R		EU-0028975-0024
SALVESAFE H7_F		EU-0028975-0025
SALVESAFE H8		EU-0028975-0026
SALVESAFE H8_R	Savon mains désinfectant Framboise Disinfecting hand soap Raspberry	EU-0028975-0027
SALVESAFE H8_F	Savon mains mousse désinfectant Framboise Disinfecting foam hand soap Raspberry	EU-0028975-0028
SALVESAFE H9		EU-0028975-0029
SALVESAFE H9_R	Savon mains désinfectant Tutti frutti Disinfecting hand soap Tutti frutti	EU-0028975-0030
SALVESAFE H9_F	Savon mains mousse désinfectant Tutti frutti Disinfecting foam hand soap Tutti frutti	EU-0028975-0031
SALVESAFE H10		EU-0028975-0032
SALVESAFE H10_R		EU-0028975-0033
SALVESAFE H10_F		EU-0028975-0034

The authorisation numbers are valid until **5th December 2032**.

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 reports on long term storage stability at ambient temperature should be submitted until 4th May 2024.

Appendix:

Annex I - General information, 1 page;

Annex II - Summary of the product characteristics for the biocidal product family, 13 pages;

Annex III – Composition of the biocidal product family (CONFIDENTIAL), 4 pages.

Head of Information Analysis Department

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GENERAL INFORMATION

The following conditions apply:

1. The authorisation numbers shall be indicated on the labels of the biocidal products.
1. 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 products, labels, instructions of use and safety data sheets.
4. If the authorisation holder wants to continue to make available on the market the biocidal product family beyond the 5th December 2032, a new application for authorisation under the simplified authorisation procedure must be submitted.

Summary of product characteristics for a biocidal product family

FAMILY SALVESAFE H

Product type 1 - Human hygiene (Disinfectants)

Authorisation number: EU-0028975-0000

R4BP asset number: EU-0028975-0000

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	FAMILY SALVESAFE H
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1.2. Product type

Product type(s)	PT01 - Human hygiene (Disinfectants)
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1.3. Authorisation holder

Name and address of the authorisation holder	Name	SALVECO S.A.S.
	Address	Avenue Pierre Mendès-France, Saint Die Des Vosges, 88100, France
Authorisation number	EU-0028975-0000	
R4BP asset number	EU-0028975-0000	
Date of the authorisation	5 th December 2022	
Expiry date of the authorisation	5 th December 2032	

1.4. Manufacturer of the biocidal products

Name of manufacturer	SALVECO S.A.S
Address of manufacturer	Avenue Pierre Mendès-France, Z.I. Hellieule 4, F 88100 SAINT DIE DES VOSGES France
Location of manufacturing sites	Avenue Pierre Mendès-France, Z.I. Hellieule 4, F 88100 SAINT DIE DES VOSGES France

1.5. Manufacturer of the active substance

Active substance	Lactic acid
Name of manufacturer	JUNGBUNZLAUER 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	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	2-Hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	1.98	1.98

2.2. *Type of formulation*

Formulation(s)	AL - Any other liquid
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SECOND INFORMATION LEVEL - META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. *Meta SPC 1 identifier*

Identifier	Disinfectant soap for hands
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1.2. *Suffix to the authorisation number*

Number	1
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1.3. *Product type*

Product type	PT01 - Human hygiene (Disinfectants)
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2. META SPC 1 COMPOSITION

2.1. *Qualitative and quantitative information on the composition of the meta SPC 1*

Common name	Function	CAS number	EC number	Content (%)	
				Min	Max
Lactic acid	Active Substance	50-21-5	200-018-0	1.98	1.98

2.2. *Type of formulation of the meta SPC 1*

Formulation	AL - Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Not applicable
Precautionary statements	Not applicable

4. AUTHORISED USE(S) OF THE META SPC 1

4.1. Use description

Product type	PT01 - Human hygiene (Disinfectants)			
Where relevant, an exact description of the authorised use	-			
Target organisms	Bacteria, yeasts and enveloped viruses			
Field(s) of use	Ready-to-use disinfectant for hands with bactericidal, yeasticidal efficacy and virucidal activity only against enveloped viruses in domestic, institutional, industrial and medical area.			
Application method(s)	Wet hand and wrists with water. Place 3 ml of product in the hollow of the hand. Rub hands and wrists for at least 30 seconds. Rinse thoroughly with clean water.			
Application rate(s) and frequency	Application rate: 3 ml Number and timing of application: apply once, repeat if renewed hand disinfection is needed.			
Category(ies) of users	Industrial, Professional and General public (non-professional)			
Pack sizes and packaging material	Type of packaging	Volume	Material of the packaging	User
	Bottle	0.05 - 2 litres	HDPE LDPE PET PE PP	professional industrial non-professional
	Drum	10 - 210 litres	HDPE	professional industrial
	Jerry can	1 - 60 litres	HDPE LDPE	professional industrial users
	Jerry can	1 - 5 litres	HDPE LDPE	non-professional users
	Pouches	0.05 - 5 litres	LDPE LLDPE	professional industrial non-professional
	Doypack	1 - 2 litres	PE	professional industrial non-professional
	<i>PET – polyethylene terephthalate; PE – Polyethylene; HDPE – High density polyethylene; LDPE - Low density polyethylene; LLDPE - Linear low density polyethylene; PP – Polypropylene</i>			

4.1.1. Use-specific instructions for use

Section 5.1

4.1.2. Use-specific risk mitigation measures

Section 5.2

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

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 1

5.1. Instructions for use

Comply with the instruction for use. Wet hand and wrists with running water. Place 3 ml of product in the hollow of the hand. Rub hands and wrists for at least 30 seconds. Rinse thoroughly with clean water. Apply once, repeat if renewed hand disinfection is needed.

5.2. Risk mitigation measures

Avoid contact with eyes.

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

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

IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

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

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

Dispose of contents/container 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 cold and frost. Keep out of reach of children and non-target animals / pets.

Shelf-life - 24 months at room temperature.

6. OTHER INFORMATION

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7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

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

Trade name(s)	SALVESAFE H0				
Authorisation number	EU-0028975-0001				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H0_R Savon mains désinfectant sans parfum Disinfecting hand soap fragrance-free				
Authorisation number	EU-0028975-0002				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H0_RC				
Authorisation number	EU-0028975-0003				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H0_F Savon mains mousse désinfectant sans parfum Disinfecting foam hand soap fragrance-free				
Authorisation number	EU-0028975-0004				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)

Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98
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7.5. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE H1				
Authorisation number	EU-0028975-0005				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H1_R Savon mains désinfectant Igloo Disinfecting hand soap Igloo				
Authorisation number	EU-0028975-0006				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H1_F Savon mains mousse désinfectant Igloo Disinfecting foam hand soap Igloo				
Authorisation number	EU-0028975-0007				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H2				
Authorisation number	EU-0028975-0008				

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H2_R Savon mains désinfectant Golden Disinfecting hand soap Golden				
Authorisation number	EU-0028975-0009				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H2_F Savon mains mousse désinfectant Golden Disinfecting foam hand soap Golden				
Authorisation number	EU-0028975-0010				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H3				
Authorisation number	EU-0028975-0011				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H3_R				
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Authorisation number	EU-0028975-0012				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H3_F				
Authorisation number	EU-0028975-0013				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H4				
Authorisation number	EU-0028975-0014				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H4_R Savon mains désinfectant Fleurs de printemps Disinfecting hand soap Spring blossom				
Authorisation number	EU-0028975-0015				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H4_F Savon mains mousse désinfectant Fleurs de printemps Disinfecting foam hand soap Spring blossom				
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Authorisation number	EU-0028975-0016				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H5				
Authorisation number	EU-0028975-0017				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H5_R				
Authorisation number	EU-0028975-0018				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H5_F				
Authorisation number	EU-0028975-0019				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H6				
Authorisation number	EU-0028975-0020				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)

Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98
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7.21. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE H6_R				
Authorisation number	EU-0028975-0021				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H6_F				
Authorisation number	EU-0028975-0022				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H7				
Authorisation number	EU-0028975-0023				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H7_R				
Authorisation number	EU-0028975-0024				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H7_F				
Authorisation number	EU-0028975-0025				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H8				
Authorisation number	EU-0028975-0026				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H8_R Savon mains désinfectant Framboise Disinfecting hand soap Raspberry				
Authorisation number	EU-0028975-0027				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H8_F Savon mains mousse désinfectant Framboise Disinfecting foam hand soap Raspberry				
Authorisation number	EU-0028975-0028				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H9				
Authorisation number	EU-0028975-0029				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H9_R Savon mains désinfectant Tutti frutti Disinfecting hand soap Tutti frutti				
Authorisation number	EU-0028975-0030				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H9_F Savon mains mousse désinfectant Tutti frutti Disinfecting foam hand soap Tutti frutti				
Authorisation number	EU-0028975-0031				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1,98

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

Trade name(s)	SALVESAFE H10				
Authorisation number	EU-0028975-0032				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H10_R				
Authorisation number	EU-0028975-0033				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98

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

Trade name(s)	SALVESAFE H10_F				
Authorisation number	EU-0028975-0034				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.98