



Rīga

28.10.2019 Nr. 4-6/1556

SALVECO S.A.S.

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

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

Latvian Environment, Geology and Meteorology Centre (LEGMC) on 10th July 2019 received application for the simplified authorisation of the **SALVESAFE G** 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-HR052694-18).

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 G 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 2** (disinfectants and algaecides not intended for direct application to humans or animals) and **product type 4** (food and feed area) as **non-porous hard surface's disinfectants**.

LEGMC assigns an authorisation number EU-0021241-0000 for SALVESAFE G 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 G0		EU-0021241-0001
SALVESAFE G1	HYGIOS Désinfectant Multi-usages	EU-0021241-0002
SALVESAFE G2	OSANIS - Nettoyant Désinfectant multi-surfaces OSANIS - Nettoyant Désinfectant Détartrant Sanitaires OSANIS - Nettoyant désinfectant Vitres & Ecrans OSANIS - Nettoyant dégraissant & désinfectant Cuisine	EU-0021241-0003
SALVESAFE G3		EU-0021241-0004
SALVESAFE G5		EU-0021241-0005
SALVESAFE G6	HYGIOS - Désinfectant Sols et Surfaces	EU-0021241-0006
SALVESAFE G7	OSANIS - Nettoyant désinfectant Sols et Surfaces	EU-0021241-0007
SALVESAFE G8		EU-0021241-0008
SALVESAFE G10	On laisse pas bébé dans un coin! - Désinfectant tout usage	EU-0021241-0009
SALVESAFE G11		EU-0021241-0010
SALVESAFE G12		EU-0021241-0011
SALVESAFE G13		EU-0021241-0012
SALVESAFE G14		EU-0021241-0013
SALVESAFE G11 T		EU-0021241-0014
SALVESAFE G12 T	HYGIOS Désinfectant Gel WC	EU-0021241-0015
SALVESAFE G13 T		EU-0021241-0016
SALVESAFE G14 T		EU-0021241-0017

The authorisation numbers are valid until 28th October 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 July 2021.

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, 2 pages.

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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 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 October 2029.

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Summary of product characteristics for the biocidal product family

Part I - First information level

1. Administrative information

1.1. Family name

Name	SALVESAFE G
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1.2. Product type

Product type	Product type 2 - Disinfectants and algaecides not intended for direct application to humans or animals Product type 4 - Food and feed area
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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, F-88100, France	
Authorisation number	EU-0021241-0000		
Authorisation numbers of the biocidal products within family	SALVESAFE G0	EU-0021241-0001	
	SALVESAFE G1	EU-0021241-0002	
	SALVESAFE G2	EU-0021241-0003	
	SALVESAFE G3	EU-0021241-0004	
	SALVESAFE G5	EU-0021241-0005	
	SALVESAFE G6	EU-0021241-0006	
	SALVESAFE G7	EU-0021241-0007	
	SALVESAFE G8	EU-0021241-0008	
	SALVESAFE G10	EU-0021241-0009	
	SALVESAFE G11	EU-0021241-0010	
	SALVESAFE G12	EU-0021241-0011	
	SALVESAFE G13	EU-0021241-0012	
	SALVESAFE G14	EU-0021241-0013	
	SALVESAFE G11_T	EU-0021241-0014	
	SALVESAFE G12_T	EU-0021241-0015	
SALVESAFE G13_T	EU-0021241-0016		
SALVESAFE G14_T	EU-0021241-0017		
<i>R4BP asset reference number</i>	EU-0021241-0000		
Date of the authorisation	28 th October 2019		
Expiry date of the authorisation	28 th October 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

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
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Second information level

1. Meta SPC administrative information

1.1. Meta SPC identifier

Identifier	Meta 1 - Liquid disinfectants for non-porous hard surfaces
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1.2. Suffix to the authorisation number

Number	-
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1.3. Product type

Product type	Product type 2 –Disinfectants and algacides not intended for direct application to humans or animals Product type 4 - Food and feed area
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2. Meta SPC composition

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
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3. Hazard and precautionary statements of the meta SPC

Hazard statements	Not applicable
Precautionary statements	Not applicable
Supplemental hazard information	Not applicable

4. Authorised use of the meta SPC

4.1. Use 1 - Disinfectants for all washable hard surfaces – spraying or foaming

Product Type	Product type 2 –Disinfectants and algaeicides not intended for direct application to humans or animals Product type 4 - Food and feed area		
Where relevant, an exact description of the authorised use	Ready to use multi-purpose disinfectants with bactericidal and yeasticidal efficacy for non-porous hard surfaces in contact and without contact with food and feed in domestic, institutional and industrial area		
Target organisms	Bacteria and yeasts		
Field of use	Indoor Outdoor		
Application method	Spraying or foaming		
Application rate and frequency	The application rate: 20 mL/m ² Apply once. Repeat the application if necessary.		
Categories of users	Industrial, professional and non-professional		
Pack sizes and packaging material	Type of packaging	Volume	Material of the packaging
	Bottle with spray/foam trigger	0.15-1 L	HDPE, LDPE, PET, PE, PP

4.1.1. Use-specific instructions for use

Trigger spray - Apply the product by spraying (apply approx. 17 sprays/1m²) and make sure to wet uniformly the surface by mopping or wiping. Allow to take effect for at least 15 minutes. Rub and brush after the disinfection to remove dirt when necessary. Wipe or rinse to remove the excess of liquid.

Foaming - Apply the product by foaming and make sure to wet uniformly the surface by mopping or wiping. Allow to take effect for at least 15 minutes. Rub and brush after the disinfection to remove dirt when necessary. Wipe or rinse to remove the excess of liquid.

In food and feed area – after disinfection rinse thoroughly with clean water.

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.

4.2. Use 2 - Disinfectants for all washable hard surfaces – pouring and mopping for product distribution

Product Type	Product type 2 –Disinfectants and algaecides not intended for direct application to humans or animals Product type 4 - Food and feed area
Where relevant, an exact description of the authorised use	Ready to use multi-purpose disinfectants with bactericidal and yeasticidal efficacy for non-porous hard surfaces in contact and without contact with food and feed in domestic, institutional and industrial area
Target organisms (including development stage)	Bacteria and yeasts
Field of use	Indoor Outdoor
Application methods	Pouring and mopping/wiping afterwards

Application rates and frequency	20 mL/m ² Apply once. Repeat the application if necessary.		
Categories of users	Industrial, professional and non-professional		
Pack sizes and packaging material	Type of packaging	Volume	Material of the packaging
	Bottle	0.1-2 L	HDPE, LDPE, PET, PE, PP
	Can / Tin	0.1-1 L	HDPE, LDPE, PET, PE, PP
	Jerry can	1-80 L	HDPE, LDPE
	Drum	10-220 L	HDPE

4.2.1 Use-specific instructions for use

Pour product onto the surface to be disinfected. Uniform distribution of the biocidal product should be ensured by mopping or wiping. Ensure that surface is completely wet. Allow to take effect for at least 15 minutes. Rub and brush after the disinfection to remove dirt when necessary. Wipe or rinse to remove the excess of liquid.

In food and feed area – after disinfection rinse thoroughly with clean water.

4.2.2 Use-specific risk mitigation measures

Section 5.2

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.

5. General directions for use

5.1. Instructions for use

Please see section on Use-specific instructions for use

5.2. Risk mitigation measures

For non-professional users: If medical advice is needed, have product container or label at hand. Keep out of reach of children.

For industrial and professional users: Safety data sheet available on request.

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

Not intended for medical area (PT2), milk and meat industry (PT4)

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

Trade names	SALVESAFE G0				
Authorisation number	EU-0021241-0001				
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 G1				
Authorisation number	EU-0021241-0002				
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 G2				
Authorisation number	EU-0021241-0003				
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

Trade names	SALVESAFE G3				
Authorisation number	EU-0021241-0004				
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 G5				
Authorisation number	EU-0021241-0005				
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 G6				
Authorisation number	EU-0021241-0006				
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

Trade names	SALVESAFE G7				
Authorisation number	EU-0021241-0007				
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 G8				
Authorisation number	EU-0021241-0008				
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	SALVESAFE G10				
Authorisation number	EU-0021241-0009				
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

Trade names	SALVESAFE G11				
Authorisation number	EU-0021241-0010				
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 G12				
Authorisation number	EU-0021241-0011				
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 G13				
Authorisation number	EU-0021241-0012				
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 G14				
Authorisation number	EU-0021241-0013				
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 - Liquid disinfectants for toilet bowl
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8.2. Suffix to the authorisation number

Number	-
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8.3. Product type

Product type	Product type 2 - Disinfectants and algacides not intended for direct application to humans or animals
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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	Not applicable

11. Authorised use of the meta SPC

11.1. Use 1 - Toilet bowl disinfection

Product Type	Product type 2 –Disinfectants and algacides not intended for direct application to humans or animals		
Where relevant, an exact description of the authorised use	Ready to use disinfectants with bactericidal and yeasticidal efficacy for surfaces on the inside of toilet's bowl in domestic and institutional area.		
Target organisms	Bacteria and yeasts		
Field of use	Indoor		
Application method	Pouring and flushing		
Application rate and frequency	The application rate: 80 mL Apply once. Repeat the application if necessary.		
Categories of users	Professional and non-professional		
Pack sizes and packaging material	Type of packaging	Volume	Material of the packaging
	Bottle	0.5 - 2 L	HDPE, LDPE

11.1.1. Use-specific instructions for use

Place a nozzle directly under the toilet rim. Apply via pouring around the inside of the toilet bowl surfaces allowing enough liquid to cover the bowl completely. Leave for 15 minutes then scrub and flush.

11.1.2. Use-specific risk mitigation measures

Section 12.2

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.

12. General directions for use

12.1. Instructions for use

Please see section on Use-specific instructions for use

12.2. Risk mitigation measures

For non-professional users: If medical advice is needed, have product container or label at hand. Keep out of reach of children.

For professional users: Safety data sheet available on request.

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 G11_T				
Authorisation number	EU-0021241-0014				
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 G12_T				
Authorisation number	EU-0021241-0015				
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 G13_T				
Authorisation number	EU-0021241-0016				
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 G14_T				
Authorisation number	EU-0021241-0017				
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