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 G**

Product types: **PT2** (Disinfectants and algaecides not intended for direct application to humans or animals) and **PT4** (Food and feed area)

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

Case Number in R4BP3: BC-HR052694-18

Evaluating Competent Authority: Latvia

Date: 27/September/2022
Initial: 29/October/2019

Contents

1 CONCLUSION

The ready-to-use biocidal products within biocidal product family *SALVESAFE G*, 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 2 (disinfectants and algaecides not intended for direct application to humans or animals) and product type 4 (disinfectants for food and feed area) as non-porous hard surface's disinfectants.

SALVESAFE G is claimed as:

- Ready to use multi-purpose disinfectants with bactericidal and yeasticidal efficacy, and virucidal efficacy only against enveloped viruses for non-porous hard surfaces in contact and without contact with food and feed in domestic, institutional and industrial area[1]. The biocidal products are intended for industrial, professional and non-professional users.
- Ready to use disinfectants with bactericidal and yeasticidal efficacy and virucidal efficacy only against enveloped viruses for surfaces on the inside of toilet's bowl in domestic and institutional area. The biocidal products are intended for professional and non-professional users.

Following evaluation, Latvian CA considers that *SALVESAFE G* 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 G* 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 October 2019 until 28th October 2029.

[1] Products are not intended for use in medical area or for milk and meat industry.

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 G	EU

2.1.1.1.1 Trade names of the products within the family

Trade name	**Other trade name**	**meta-SPC**
SALVESAFE G0		1
SALVESAFE G1	HYGIOS Désinfectant Multi-usages	
SALVESAFE G2	OSANIS - Nettoyant Désinfectant multi-surfaces OSANIS - Nettoyant Désinfectant Détartrant Sanitaires OSANIS - Nettoyant désinfectant Vitres & Ecrans OSANIS - Nettoyant dégraissant & désinfectant Cuisine OSANIS - Detergente, disinfettante multisuperficie OSANIS - Detergente, disinfettante Anticalcare Sanitario OSANIS - Ontsmettend reinigingsmiddel voor alle oppervlakken OSANIS - Sanitairreiniger met ontsmettende en ontkalkende werking OSANIS - Allzweck Desinfektionsreiniger OSANIS - Sanitär-Desinfektionsreiniger/Entkalker OSANIS – Detergente desinfectante multisuperficies; OSANIS – Detergente Desinfectante sanitarios OSANIS – Multi Surface Disinfectant Cleaner OSANIS – Bathroom Disinfectant and Descaler	
SALVESAFE G3	SANILAK Nettoyant Désinfectant multi-surfaces	
SALVESAFE G5		
SALVESAFE G6	HYGIOS - Désinfectant Sols et Surfaces	
SALVESAFE G7	OSANIS - Nettoyant désinfectant Sols et Surfaces OSANIS - Desinfektionsreiniger Böden und Oberflächen OSANIS - Ontsmettend reinigingsmiddel voor vloeren en oppervlakken OSANIS - Detergente, disinfettante per Pavimenti e Superfici OSANIS – Detergente desinfectante suelos y superficies OSANIS – Floors and Surfaces Disinfectant and Cleaner	
SALVESAFE G8		
SALVESAFE G10	On laisse pas bébé dans un coin! - Désinfectant tout usage	
SALVESAFE G11		
SALVESAFE G12		
SALVESAFE G13		
SALVESAFE G14	GERM TROL	
SALVESAFE G15	Le désinfectant salle de bain bubble b	

	Le désinfectant biberons et tétines bubble b Le désinfectant multi-surfaces bubble b	
SALVESAFE G16		
SALVESAFE G17		
SALVESAFE G18		
SALVESAFE G19		
SALVESAFE G20		
SALVESAFE G21		
SALVESAFE G22	Le désinfectant sols bubble b	
SALVESAFE G23		
SALVESAFE G24		
SALVESAFE G25		
SALVESAFE G26		
SALVESAFE G27		
SALVESAFE G28		
SALVESAFE G29		
SALVESAFE G30		
SALVESAFE G31		
SALVESAFE G32		
SALVESAFE G33		
SALVESAFE G34		
SALVESAFE G35		
SALVESAFE G11_T		2
SALVESAFE G12_T	HYGIOS Désinfectant Gel WC	
SALVESAFE G13_T		
SALVESAFE G14_T	OSANIS – Gel WC disinfectant OSANIS – Antibacterial WC Gel Jacques Briochin Gel WC Extra Désinfectant Starwax Gel WC Nettoyant Désinfectant Starwax Soluvert Gel WC Nettoyant Désinfectant ORO PRO Gel WC Nettoyant Désinfectant Starwax Gel WC Désinfectant Starwax Soluvert Gel WC Désinfectant ORO PRO Gel WC Désinfectant	
SALVESAFE G29_T		
SALVESAFE G30_T		
SALVESAFE G31_T		
SALVESAFE G32_T		
SALVESAFE G33_T		
SALVESAFE G34_T		
SALVESAFE G35_T		
SALVESAFE G36_T		
SALVESAFE G37_T		

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-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
	SALVESAFE G15	EU-0021241-0018
	SALVESAFE G16	EU-0021241-0019
	SALVESAFE G17	EU-0021241-0020
	SALVESAFE G18	EU-0021241-0021
	SALVESAFE G19	EU-0021241-0022
	SALVESAFE G20	EU-0021241-0023
	SALVESAFE G21	EU-0021241-0024
	SALVESAFE G22	EU-0021241-0025
	SALVESAFE G23	EU-0021241-0026
	SALVESAFE G24	EU-0021241-0027
	SALVESAFE G25	EU-0021241-0028
	SALVESAFE G26	EU-0021241-0029
	SALVESAFE G27	EU-0021241-0030
	SALVESAFE G28	EU-0021241-0031
	SALVESAFE G29	EU-0021241-0032
	SALVESAFE G30	EU-0021241-0033
	SALVESAFE G31	EU-0021241-0034

	SALVESAFE G32	EU-0021241-0035
	SALVESAFE G33	EU-0021241-0036
	SALVESAFE G34	EU-0021241-0037
	SALVESAFE G35	EU-0021241-0038
	SALVESAFE G29_T	EU-0021241-0039
	SALVESAFE G30_T	EU-0021241-0040
	SALVESAFE G31_T	EU-0021241-0041
	SALVESAFE G32_T	EU-0021241-0042
	SALVESAFE G33_T	EU-0021241-0043
	SALVESAFE G34_T	EU-0021241-0044
	SALVESAFE G35_T	EU-0021241-0045
	SALVESAFE G36_T	EU-0021241-0046
	SALVESAFE G37_T	EU-0021241-0047
Date of the authorisation	28th October 2019	
Expiry date of the authorisation	28th October 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	**A2H SARL**
Address of manufacturer	243 Route Esch 1471, LUXEMBOURG, Luxembourg
Location of manufacturing sites	243 Route Esch 1471, LUXEMBOURG, Luxembourg
Name of manufacturer 3	**GESTRA S.A.S**
Address of manufacturer	Allée Robert Schumann, 88110, RAON-L'ETAPE, France
Location of manufacturing sites	Allée Robert Schumann, 88110, RAON-L'ETAPE, France
Name of manufacturer 4	**Harris SAS**
Address of manufacturer	Lieu dit Cardry, 22800, Saint Brandan, France
Location of manufacturing sites	Lieu dit Cardry, 22800, Saint Brandan, France
Name of manufacturer 5	**Brunel Chimie Dérivé SAS**
Address of manufacturer	ZI Rue de Mont Templemars - Zone industrielle A de Seclin, 59139, Noyelles Les Seclin, France
Location of manufacturing sites	ZI Rue de Mont Templemars - Zone industrielle A de Seclin, 59139, Noyelles Les Seclin, France
Name of manufacturer 6	**Oro**

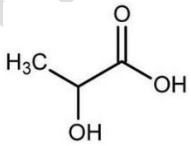
Address of manufacturer	CV-35 (Valencia Ademuz), km 13.1 Izq, 46184, San Antonio Debenagéber – Valencia, Spain
Location of manufacturing sites	CV-35 (Valencia Ademuz), km 13.1 Izq, 46184, San Antonio Debenagéber – Valencia, Spain
Name of manufacturer 7	**Sinto SA**
Address of manufacturer	Avenue des Templiers, 13400, Aubagne, France
Location of manufacturing sites	Avenue des Templiers, 13400, Aubagne, France

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%

The composition of the biocidal product family *SALVESAFE G* and composition of each biocidal product is described in the Section 3.2 of the Confidential Annex. *SALVESAFE G* 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	Not applicable

2.1.4 Authorised uses of the meta SPC

Meta SPC 1: Liquid disinfectants for non-porous hard surfaces

2.1.4.1 *Use 1 – Disinfectants for all washable hard surfaces – spraying or foaming*

Product Type	Product type 2 –Disinfectants and algaecides not intended for direct application to humans or animals Product type 4 - Food and feed area

<table>
<tr><td>Where relevant, an exact description of the authorised use</td><td>Ready to use multi-purpose disinfectants with bactericidal, yeasticidal efficacy and virucidal efficacy only against enveloped viruses for non-porous hard surfaces in contact and without contact with food and feed in domestic, institutional and industrial area</td></tr>
<tr><td>Target organisms (including development stage)</td><td>Bacteria, yeasts and enveloped viruses</td></tr>
<tr><td>Field of use</td><td>Indoor
Outdoor</td></tr>
<tr><td>Application methods</td><td>Spraying or foaming</td></tr>
<tr><td>Application rates and frequency</td><td>The application rate: 20 mL/m^2
Apply once. Repeat the application if necessary.</td></tr>
<tr><td>Categories of users</td><td>Industrial, professional and non-professional</td></tr>
<tr><td>Pack sizes and packaging material</td><td>
<table>
<tr><th>Type of packaging</th><th>Volume</th><th>Material of the packaging</th><th>User</th></tr>
<tr><td>Bottle with spray/foam trigger</td><td>0.15-1 L</td><td>HDPE, LDPE, PET, PE, PP</td><td>Industrial
Professional
Non-professional</td></tr>
<tr><td>Doypack</td><td>1 L</td><td>PE</td><td>Industrial
Professional
Non-professional</td></tr>
</table>
</td></tr>
</table>

2.1.4.2 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.

2.1.4.3 Use-specific risk mitigation measures

Section 2.1.5

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

Section 2.1.5

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

Section 2.1.5

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

Section 2.1.5

2.1.4.7 *Use 2 - Disinfectants for all washable hard surfaces – pouring and mopping for product distribution*

<table>
<tr><td>Product Type</td><td>Product type 2 –Disinfectants and algaecides not intended for direct application to humans or animals
Product type 4 - Food and feed area</td></tr>
<tr><td>Where relevant, an exact description of the authorised use</td><td>Ready to use multi-purpose disinfectants with bactericidal, yeasticidal efficacy and virucidal efficacy only against enveloped viruses for non-porous hard surfaces in contact and without contact with food and feed in domestic, institutional and industrial area</td></tr>
<tr><td>Target organisms (including development stage)</td><td>Bacteria, yeasts and enveloped viruses</td></tr>
<tr><td>Field of use</td><td>Indoor
Outdoor</td></tr>
<tr><td>Application methods</td><td>Pouring and mopping afterwards</td></tr>
<tr><td>Application rates and frequency</td><td>20 mL/m^2
Apply once. Repeat the application if necessary.</td></tr>
<tr><td>Categories of users</td><td>Industrial, professional and non-professional</td></tr>
<tr><td>Pack sizes and packaging material</td><td>
<table>
<tr><th>Type of packaging</th><th>Volume</th><th>Material of the packaging</th><th>User</th></tr>
<tr><td>Bottle</td><td>0.1-2 L</td><td>HDPE, LDPE, PET, PE, PP</td><td>Industrial
Professional
Non-professional</td></tr>
<tr><td>Can / Tin</td><td>0.1-1 L</td><td>HDPE, LDPE, PET, PE, PP</td><td>Industrial
Professional
Non-professional</td></tr>
<tr><td>Jerry can</td><td>1-80 L</td><td>HDPE, LDPE</td><td>Industrial
Professional</td></tr>
<tr><td>Drum</td><td>10-220 L</td><td>HDPE</td><td>Industrial
Professional</td></tr>
<tr><td>Doypack</td><td>1 L</td><td>PE</td><td>Industrial
Professional
Non-professional</td></tr>
<tr><td>IBC</td><td>1000 L</td><td>HDPE</td><td>Industrial
Professional</td></tr>
</table>
</td></tr>
</table>

2.1.4.8 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.

2.1.4.9 Use-specific risk mitigation measures

Section 2.1.5

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

Section 2.1.5

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

Section 2.1.5

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

Section 2.1.5

Meta SPC 2: Liquid disinfectants for toilet bowl

2.1.4.13 Use 3 – Toilet bowl disinfection

<table>
<tr><td>Product Type</td><td colspan="4">Product type 2 –Disinfectants and algaecides not intended for direct application to humans or animals</td></tr>
<tr><td>Where relevant, an exact description of the authorised use</td><td colspan="4">Ready to use disinfectants with bactericidal, yeasticidal efficacy and virucidal efficacy only against enveloped viruses for surfaces on the inside of toilet’s bowl in domestic and institutional area.</td></tr>
<tr><td>Target organisms (including development stage)</td><td colspan="4">Bacteria, yeasts and enveloped viruses</td></tr>
<tr><td>Field of use</td><td colspan="4">Indoor</td></tr>
<tr><td>Application methods</td><td colspan="4">Pouring and flushing</td></tr>
<tr><td>Application rates and frequency</td><td colspan="4">The application rate: 80 mL
Apply once. Repeat the application if necessary.</td></tr>
<tr><td>Categories of users</td><td colspan="4">Professional and non-professional</td></tr>
<tr><td>Pack sizes and packaging material</td><td colspan="4"><table><tr><th>Type of packaging</th><th>Volume</th><th>Material of the packaging</th><th>User</th></tr><tr><td>Bottle</td><td>0.5 - 2 L</td><td>HDPE, LDPE, PET</td><td>Professional
Non-professional</td></tr></table></td></tr>
</table>

2.1.4.14 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.

2.1.4.15 Use-specific risk mitigation measures

Section 2.1.5

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

Section 2.1.5

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

Section 2.1.5

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

Section 2.1.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

Please see section 2.1.4. depend on use

2.1.5.2 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.

2.1.5.3 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.

2.1.5.4 Instructions for safe disposal of the product and its packaging

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

2.1.5.5 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.

2.1.6 Other information

Meta-SPC 1: Not intended for medical area (PT2), milk and meat industry (PT4)

2.1.7 Packaging of the biocidal products

Type of packaging	Volume of the packaging	Material of the packaging	Type and material of closure	User	Use	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	0.10 – 2 L	HDPE, LDPE, PET, PE, PP	Cap, HDPE/PE	Industrial Professional Non-professional	Use 2	Yes
Bottle (for toilet bowl disinfection)	0.50 – 2 L	HDPE, LDPE, PET	Cap, HDPE/PE	Professional Non-professional	Use 3	Yes
Can / Tin	0.10 – 1 L	HDPE, LDPE, PET, PE, PP	Cap, HDPE/PE	Industrial Professional Non-professional	Use 2	Yes
Jerry can	1 - 80 L	HDPE, LDPE	Cap, HDPE/PE	Industrial Professional	Use 2	Yes
Drum	10 – 220 L	HDPE	Cap, HDPE/PE	Industrial Professional	Use 2	Yes
Bottle with spray/foam trigger	0.15 – 1 L	HDPE, LDPE, PET, PE, PP	Spray/foam trigger	Industrial Professional Non-professional	Use 1	Yes
Doypack	1 L	PE	Cap, PE	Industrial Professional Non-professional	Use 1 Use 2	Yes
IBC	1000 L	HDPE	Cap, HDPE	Industrial Professional	Use 2	Yes

2.1.8 Documentation

2.1.8.1 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

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

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, yeasticidal efficacy and virucidal efficacy only against enveloped viruses 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, yeasts and enveloped viruses
Field of use	Indoor Outdoor
Application methods	Spraying or foaming
Application rates 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	Section 2.1.7

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, yeasticidal efficacy and virucidal efficacy only against enveloped viruses 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, yeasts and enveloped viruses
Field of use	Indoor Outdoor
Application methods	Pouring and mopping 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	Section 2.1.7

Use 3 – Toilet bowl disinfection

Product Type	Product type 2 –Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Ready to use disinfectants with bactericidal, yeasticidal efficacy and virucidal efficacy only against enveloped viruses for surfaces on the inside of toilet's bowl in domestic and institutional area
Target organisms (including development stage)	Bacteria, yeasts and enveloped viruses
Field of use	Indoor
Application methods	Pouring and flushing
Application rates 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	Section 2.1.7

2.2.2 Physical, chemical and technical properties

This is no data requirement for an application in accordance with Article 25 of the Regulation (EU) No 528/2012. However, the main properties are addressed by the applicant.

SALVESAFE G is a family of water-based ready for use formulations based on active substance *Lactic acid*.

In the table below the data with regard to the physical and chemical properties of the products is included. The main composition of all products is one and the products have only difference in perfumes. Therefore, the data package is considered to sufficiently support the proposed family structure.

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	Conf.PAR
Colour at at 20 °C and 101.3 kPa	Visual	SALVESAFE G0	Colorless	Conf.PAR
		SALVESAFE G1	Colorless	
		SALVESAFE G2	Colorless	
		SALVESAFE G3	Colorless	
		SALVESAFE G5	Light yellow	
		SALVESAFE G6	Light yellow	
		SALVESAFE G7	Light yellow	
		SALVESAFE G8	Light yellow	
		SALVESAFE G10	Colorless	
		SALVESAFE G11	White	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		SALVESAFE G12	White	
		SALVESAFE G13	White	
		SALVESAFE G14	White	
		SALVESAFE G11_T	White	
		SALVESAFE G12_T	White	
		SALVESAFE G13_T	White	
		SALVESAFE G14_T	White	
		SALVESAFE G15	Colourless	
		SALVESAFE G16	Colourless	
		SALVESAFE G17	Colourless	
		SALVESAFE G18	Colourless	
		SALVESAFE G19	Colourless	
		SALVESAFE G20	Colourless	
		SALVESAFE G21	Colourless	
		SALVESAFE G22	Colourless	
		SALVESAFE G23	Colourless	
		SALVESAFE G24	Colourless	
		SALVESAFE G25	Colourless	
		SALVESAFE G26	Colourless	
		SALVESAFE G27	Colourless	
		SALVESAFE G28	Colourless	
		SALVESAFE G29 / G29_T	White	
		SALVESAFE G30 / G30_T	White	
		SALVESAFE G31 / G31_T	White	
		SALVESAFE G32 / G32_T	White	
		SALVESAFE G33 / G3_T	White	
		SALVESAFE G34 / G34_T	White	
		SALVESAFE G35 / G35_T	White	
		SALVESAFE G36_T	Blue	
		SALVESAFE G37_T	Red	
pH (neat formulation), 20°C	CIPAC MT 75.3	All members of the family	In range 2.18-2.41	Conf.PAR
Relative density, 20°C	EEC Method A3	All members of the family	In range 1.004-1.008	Conf.PAR
		SALVESAFE G0		
		SALVESAFE G1		
		SALVESAFE G2		
		SALVESAFE G3		
		SALVESAFE G5		
		SALVESAFE G6		
		SALVESAFE G7		
Viscosity, 20°C	OECD 114	SALVESAFE G8	< 50 mPa·s at 20°C	Conf.PAR
		SALVESAFE G10		
		SALVESAFE G15		
		SALVESAFE G16		
		SALVESAFE G17		
		SALVESAFE G18		
		SALVESAFE G19		
		SALVESAFE G20		

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		SALVESAFE G21		
		SALVESAFE G22		
		SALVESAFE G23		
		SALVESAFE G24		
		SALVESAFE G25		
		SALVESAFE G26		
		SALVESAFE G27		
		SALVESAFE G28		
		SALVESAFE G11	In range 236 - 287 mPa·s at 20°C	
		SALVESAFE G12		
		SALVESAFE G13		
		SALVESAFE G14		
		SALVESAFE G11_T		
		SALVESAFE G12_T		
		SALVESAFE G13_T		
		SALVESAFE G14_T		
		SALVESAFE G29		
		SALVESAFE G30		
		SALVESAFE G31		
		SALVESAFE G32		
		SALVESAFE G33		
		SALVESAFE G34		
		SALVESAFE G35		
		SALVESAFE G29_T		
		SALVESAFE G30_T		
		SALVESAFE G31_T		
		SALVESAFE G32_T		
		SALVESAFE G33_T		
		SALVESAFE G34_T		
		SALVESAFE G35_T		
		SALVESAFE G36_T		
		SALVESAFE G37_T		
Surface tension, 20°C	OECD 115	All members of the family	In a range of 29.7-32.2 mN/m Surface active products	Conf.PAR
Storage stability test – **accelerated storage**	Storage for 2 weeks at 54°C (CIPAC MT46.3)	All members of the family	**Lactic acid content**: initial: 2.31-2.43% After: 2.34-2.43% **pH** initial: 2.18-2.41 end: 2.18-2.44	Conf.PAR

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			Clear liquids 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.	
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 2.30 % are used. The storage stability tests are conducted in PET and HDPE bottles. For the detection and identification of Lactic acid HPLC method is used.	Lactic acid content at the end around 2.40%. Tested concentrations and it's changes are within allowed tolerance limit of the declared nominal content of active substance. The 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. Circular spray pattern is kept. No blockage or leak of the nozzle. No significant variation in amount of spray delivered. The data for members notified in 2022 will be available in 2024. However, considering the same composition with already authorized products	Conf.PAR

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			the read-across is applicable.	
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.	-
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.calpaclab.com/chemical-compatibility-charts/
Wettability	-	-	Not applicable (the biocidal products are a ready-to-use liquid products).	-
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	-	-	Not applicable (the biocidal products	-

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
and emulsion stability			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	CIPAC method MT187	Salvesafe G	All products of the family are ready to use liquids. 12 members of family are sold in spraying equipment. The composition of the mentioned products is identical except only content of perfume. Therefore, a tested product Salvesafe G represents all of them. Salveco Trigger spray produces a spray with a mean droplet size of about Dv(50)=119.85 µm, Dv(90)=432.54 µm and Dv(10)=55.17 µm. 7.56% of droplets with size < 50.0 µm.	Conf.PAR
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	FEA method 644 E	Salvesafe G	Only 5 members of family are sold in spraying and foaming equipment. The composition of the mentioned products is identical except only content of perfume. Therefore, a tested product Salvesafe G represents all of them. The spray pattern was measured at a distance of 30 cm. The spray pattern of the trigger devices covers a surface area Δ = 0.0603 m^2. Average spray diameter is 27.7 cm. Average discharge rate is 1.22 g (1.23 ml). No clogging or leaking of the valves was observed during 7 repetition. The foam pattern of the foam devices covers a surface area Δ = 0.0095 m^2. Average foam diameter is 10.06 cm. Average discharge rate is 1.26 g (1.27 ml). No clogging or leaking of the valves was observed during 7 repetition.	Conf.PAR
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 2.18 and 2.41. During the storage an appearance of the tested samples did not change. Maximal active substance concentration increase is 3.4%. According to long storage stability tests products are stable at ambient temperature during 24 months. Labels should 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 products are water based products (min water content is 94.91%). The flashpoints for the different components present in the biocidal products are above 60°C. The content of perfume's ingredients classified as Flam. Liq.3 in final product is negligible.	-
Flammable solids	-	Not applicable, products are a liquids	-
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	-	Not applicable, products are a stable aqueous solutions.	-

Property	Guideline and Method	Results	Reference
flammable gases			
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) Salve Safe G Max (worst case product with maximal content of active substance and co-formulants, without day)	Not classified as corrosive to metals. A representative product was tested on metal corrosion classification. The product shows a negative result for corrosion to metal. After 7 days of testing: Aluminium: max 0.60% Steel: max 3.2% 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. Measurement of the depth of localized attack: 70 µm. The deepest intrusion measures less than 120 µm. The data for is considered to sufficiently support all members in family.	Conf.PAR
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
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 G0 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	Salveco test report
SALVESAFE G8 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	Salveco test report
SALVESAFE G13 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	Salveco test report
SALVESAFE G36_T 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	Salveco test reports: No.2022/208

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 G is developed based on *Lactic acid* as an active substance which provides efficacy of the biocidal product.

The efficacy studies on bactericidal, yeasticidal activity and virucidal activity against enveloped viruses have been performed for biocidal product with 2.38 % *Lactic acid* concentration.

The composition of tested products is included in Section 3.3 of Confidential Annex.

The applied Standards for suspension (phase 2, step 1) and quantitative non-porous surface (phase 2, step 2) tests are appropriate to support the claim for the evaluation of biocidal activity for *Salvesafe G*.

The following Standards were used:

- EN 1276:2009 - Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1);
- EN 1650:2008+A1:2013 - Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1);
- EN 13697:2015 – Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements without mechanical action (phase 2, step 2);
- EN 14476:2013+A2:2019 - Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1);
- EN 16777:2018 - Chemical disinfectants and antiseptics – Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2, step 2).

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

2.2.5.1 Function and field of use

The biocidal products within SALVESAFE G are ready-to-use liquid solutions for the disinfection of non-porous hard surfaces that may or may not be associated with food and feed in domestic, institutional and industrial area. Products are not intended for use in medical area or for milk and meat industry. Family is claimed with bactericidal, yeasticidal activity and virucidal activity against enveloped viruses. The products are used by spraying, foaming, pouring or pouring and mopping for product distribution onto surface.

2.2.5.2 Effects on target organisms, including unacceptable suffering

The results of the efficacy studies are summarized in Section 3.3 of Confidential Annex, as well as, in below following Table.

Bactericidal and yeasticidal efficacy (initial application 2019)

To demonstrate the **bactericidal activity** in a quantitative suspension test according to the EN 1276:2009, four reference strains were tested: *Staphylococcus aureus* ATCC 6538*, Enterococcus hirae* ATCC 10541, *Pseudomonas aeruginosa* ATCC 15442 and *Escherichia coli* ATCC 10536.

The activity against bacteria was evaluated with the Disinfectant (SALVESAFE G0) liquid at 15-minutes contact time with product test concentrations of 97%, 80%, 50% and 1% under dirty conditions (0.3% bovine albumin) and test temperature 20°C. The results showed that the product demonstrates > 5.00 log reduction for all tested bacterial species at 80% product test concentration.

The activity against *Pseudomonas aeruginosa*[2] DSM 939 (ATCC 15442) was evaluated with the Gel WC Disinfectant at 15 minutes contact time with the product test concentration of

[2] The worst case organism (bacteria) for the Gel WC Disinfectant in quantitative suspension test (P2S1) was determined based on the results obtained in quantitative non-porous surface test (P2S2, EN13697, Test

80% under dirty conditions (0.3% bovine albumin) and test temperature 20°C. The results showed that the product demonstrates > 5.00 log reduction for *Pseudomonas aeruginosa* DSM 939 at 80% product test concentration. Therefore, a maximal content of co-formulants don't negatively effect on product bactericidal efficacy.

The biocidal product family with 2.38% concentration of Lactic acid can be claimed for a disinfectant with a bactericidal activity under the defined test conditions and exposure of 15 minutes according to the claimed Standard.

To demonstrate the **yeasticidal activity** in a quantitative suspension test according to the EN 1650:2008+A1:2013, yeast *Candida albicans* ATCC 10231 was tested.

The activity against the yeast was evaluated with the Disinfectant (SALVESAFE G0) liquid at a 15-minutes contact time and product test concentrations of 80%, 50% and 1% under dirty conditions (0.3% bovine albumin) and temperature 20°C. The results showed that the product demonstrates > 4.00 log reduction for the yeast at 80% product test concentrations.

The activity against yeast was evaluated with the Gel WC Disinfectant at 15 minutes contact time with the product test concentration of 80% under dirty conditions (0.3% albumin) and test temperature 20°C. The results showed that the product demonstrates > 4.00 log reduction for the yeast at 80% product test concentration. Therefore, a maximal content of co-formulants don't negatively effect on product yeasticidal efficacy.

The biocidal product with 2.38% concentration of Lactic acid can be claimed for a disinfectant with a yeasticidal activity under the defined test conditions and exposure of 15 minutes according to the claimed Standard.

Practical conditions

To demonstrate the **bactericidal activity** in practical conditions quantitative non-porous surface test according to the EN 13697:2015 was performed. Four reference strains were tested: *Staphylococcus aureus* CIP 4.83*, Enterococcus hirae* DSM 3320, *Pseudomonas aeruginosa* DSM 939 and *Escherichia coli* DSM 682.

The activity against bacteria was evaluated with the Disinfectant (SALVESAFE G0) liquid at 15-minutes contact time with product test concentrations of 100%, 80%, and 1% under dirty conditions (0.3% bovine albumin) and test temperature 20°C. The results showed that the product demonstrates > 4.00 log reduction for all tested bacterial species at 100% product test concentration.

The activity against bacteria was evaluated with the Gel WC Disinfectant at 15 minutes contact time with the product test concentrations of 100%, 80% and 1% under dirty conditions (0.3% bovine albumin) and test temperature 20°C. The results showed that the product demonstrates > 4.00 log reduction for all tested bacterial species at 100% product test concentration.

Therefore, the biocidal product family with 2.38% concentration of Lactic acid can be claimed for a disinfectant with a bactericidal activity under the defined test conditions and exposure of 15 minutes according to the claimed Standard.

To demonstrate the **yeasticidal activity** in practical conditions quantitative non-porous surface test according to the EN 13697:2015 was performed. Yeast *Candida albicans* CIP 48.72 was used as the test organism.

Report 172D25-2019). From these results, the limiting organism was estimated to be Pseudomonas aeruginosa (R=4.20), while for other organisms the R-values were above 4.20.

The activity against the yeast was evaluated with the Disinfectant (SALVESAFE G0) liquid at a 15-minutes contact time and product test concentrations of 100%, 80% and 1% under dirty conditions (0.3% albumin) and temperature 20°C. The results showed that the product demonstrates > 3.00 log reduction for the yeast at 80% product test concentrations.

The activity against yeast was evaluated with the Gel WC Disinfectant at 15 minutes contact time with the product test concentration of 100%, 80% and 1% under dirty conditions (0.3% albumin) and test temperature 20°C. The results showed that the product demonstrates > 3.00 log reduction for the yeast at 100% product test concentration.

The biocidal product with 2.38% concentration of Lactic acid can be claimed for a disinfectant with a yeasticidal activity under the defined test conditions and exposure of 15 minutes according to the claimed Standard.

Virucidal activity against enveloped viruses (application on major changes 2022)

To demonstrate the **virucidal activity against enveloped viruses** a quantitative suspension test according to the **EN 14476:2013+A2:2019** is conducted.

Surface disinfection: The activity against enveloped viruses was evaluated with the Multi-Surface disinfectant cleaner (SALVESAFE G0) at 5-minutes contact time, at concentrations of 0.01-97% under dirty conditions (3 g/L BSA + 3.0 ml/l erythrocytes). The tested product demonstrates > 4.0 log reduction for *Modified vacciniavirus Ankara (MVA)* at 10-97% concentration.

The biocidal product family with 2.38% concentration of Lactic acid can be claimed for a disinfectant with a virucidal activity against enveloped viruses under the defined test conditions and exposure of 5 minutes according to the claimed Standard.

Toilet bowl disinfectant: The activity against enveloped viruses was evaluated with the Toilet Disinfectant at 15-minutes contact time, at concentrations of 97% under dirty conditions (3 g/L BSA + 3.0 ml/l erythrocytes). The tested product demonstrates > 4.0 log reduction for *Modified vacciniavirus Ankara (MVA)* at 97% concentration.

The biocidal product family with 2.38% concentration of Lactic acid can be claimed for a disinfectant with a virucidal activity against enveloped viruses under the defined test conditions and exposure of 15 minutes according to the claimed Standard.

To demonstrate the **virucidal activity against enveloped viruses** a quantitative non-porous surface test according to the **EN 16777:2018** is conducted.

Surface disinfection: The activity against enveloped viruses was evaluated with the Multi-Surface disinfectant cleaner (SALVESAFE G0) at 15-minutes contact time, at concentrations of 1-100% under dirty conditions (3 g/L BSA + 3.0 ml/l erythrocytes). The tested product demonstrates > 4.0 log reduction for *Modified vacciniavirus Ankara (MVA)* at 50-100% concentration.

The biocidal product family with 2.38% concentration of Lactic acid can be claimed for a disinfectant with a virucidal activity against enveloped viruses under the defined test conditions and exposure of 15 minutes according to the claimed Standard.

Toilet bowl disinfectant: The activity against enveloped viruses was evaluated with the Toilet Disinfectant at 15-minutes contact time, at concentrations of 100% under dirty conditions (3 g/L BSA + 3.0 ml/l erythrocytes). The tested product demonstrates > 4.0 log reduction for *Modified vacciniavirus Ankara (MVA)* at 100% concentration.

The biocidal product family with 2.38% concentration of Lactic acid can be claimed for a disinfectant with a virucidal activity against enveloped viruses under the defined test conditions and exposure of 15 minutes according to the claimed Standard.

Additional test organisms

An activity is demonstrated against specifically the strain ***Herpes simplex virus*** according to the methodology of a phase 2, step 1 test (EN 14476) at 20 °C, with a contact time of 15 minutes, in dirty conditions (3g/L BSA + 3mL/L erythrocytes). In these conditions, an activity against *Herpes simplex virus* is shown at the in-use concentration of 80 and 97%. The activity also supported according to the methodology of a phase 2, step 2 test (EN 16777) at 20 °C, with a contact time of 15 minutes, in dirty conditions (3g/L BSA + 3mL/L erythrocytes). In these conditions, an activity is shown at the in-use concentration of 100%.

An activity is demonstrated against specifically the strain ***Human coronavirus 229E*** according to the methodology of a phase 2, step 1 test (EN 14476) at 20 °C, with a contact time of 15 minutes, in dirty conditions (3g/L BSA). In these conditions, an activity against *Human coronavirus 229E* is shown at the in-use concentration of 80 and 97%. The activity also supported according to the methodology of a phase 2, step 2 test (EN 16777) at 20 °C, with a contact time of 15 minutes, in dirty conditions (3g/L BSA). In these conditions, an activity is shown at the in-use concentration of 100%.

An activity is demonstrated against specifically the strain ***H1N1 influenza virus*** according to the methodology of a phase 2, step 1 test (EN 14476) at 20 °C, with a contact time of 15 minutes, in dirty conditions (3g/L BSA). In these conditions, an activity against *H1N1 influenza virus* is shown at the in-use concentration of 97%. The activity also supported according to the methodology of a phase 2, step 2 test (EN 16777) at 20 °C, with a contact time of 15 minutes, in dirty conditions (3g/L BSA). In these conditions, an activity is shown at the in-use concentration of 100%.

An activity is demonstrated against specifically the strain ***Delta variant of Coronavirus SARS-CoV-2*** according to the methodology of a phase 2, step 1 test (EN 14476) at 20 °C, with a contact time of 15 minutes, in dirty conditions (3g/L BSA). In these conditions, an activity against *Delta variant of Coronavirus SARS-CoV-2* is shown at the in-use concentration of 80% and 97%.

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 (liquid) at ready-to-use format and with the concentration of 2.38% *Lactic acid* after a 15 minutes contact time 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
Bactericidal and yeasticidal efficacy (initial application 2019)							
Bactericide	Hard surface disinfection in domestic, institutional and industrial areas	Disinfectant (SALVESAFE G0)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* ATCC 10536	EN 1276:2009; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 97%, 80%, 50%, 1% - Diluent: water for injections - Test method: dilution-neutralization - Contact time: 15 minutes - Soiling: 3 g/L BSA (dirty conditions) - Test temperature: 20°C	Tested product demonstrated bactericidal activity at 80% product test concentration under defined conditions (pass R > 5 log)	Conf.PAR
Bactericide	Hard surface disinfection in domestic, institutional areas	Gel WC Disinfectant	*Pseudomonas aeruginosa* DSM 939	EN 1276:2010; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 80% - Diluent: distilled water - Test method: dilution-neutralization - Contact time: 15 minutes - Soiling: 3 g/L BSA (dirty conditions) - Test temperature: 20°C	Tested product demonstrated bactericidal activity on *P. aeruginosa* at 80 % product concentration under defined conditions (pass R > 5 log)	Conf.PAR
Yeasticide	Hard surface disinfection in domestic, institutional and industrial areas	Disinfectant (SALVESAFE G0)	*Candida albicans* ATCC 10231	EN 1650:2013; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 80%, 50%, 1% - Diluent: water for injections - Test method: dilution-neutralization - Contact time: 15 minutes - Soiling: 3 g/L BSA (dirty conditions) - Test temperature: 20°C	Tested product demonstrated yeasticidal activity at 80% product concentration under defined conditions (pass R > 4 log)	Conf.PAR

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Yeasticide	Hard surface disinfection in domestic, institutional areas	Gel WC Disinfectant	*Candida albicans* CIP 48.72	EN 1650:2013; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 80% - Diluent: distilled water - Test method: dilution-neutralization - Contact time: 15 minutes - Soiling: 3 g/L BSA (dirty conditions) - Test temperature: 20°C	Tested product demonstrated yeasticidal activity at 80% product concentration under defined conditions (pass R > 4 log)	Conf.PAR
Bactericide	Hard surface disinfection in domestic, institutional and industrial areas	Disinfectant (SALVESAFE G0)	*Staphylococcus aureus* CIP 4.83 *Pseudomonas aeruginosa* DSM 939 *Escherichia coli* DSM 682 *Enterococcus hirae* DSM 3320	EN 13697:2015 Quantitative non-porous surface test without mechanical action (phase 2, step 2)	- Tested product concentrations: 100%, 80%, 1% - Diluent: distilled water - Test method: dilution-neutralization - Contact time: 15 minutes - Soiling: 3 g/L BSA (dirty conditions) - Test temperature: 20°C	Tested product demonstrated bactericidal activity (R > 4 log) at 100% product concentration under defined conditions (dirty, 20°C, 15 min contact time)	Conf.PAR
Yeasticide	Hard surface disinfection in domestic, institutional and industrial areas	Disinfectant (SALVESAFE G0)	*Candida albicans* CIP 48.72	EN 13697:2015 Quantitative non-porous surface test without mechanical action (phase 2, step 2)	- Tested product concentrations: 100%, 80%, 1% - Diluent: distilled water - Test method: dilution-neutralization - Contact time: 15 minutes - Soiling: 3 g/L BSA (dirty conditions) - Test temperature: 20°C	Tested product demonstrated yeasticidal activity (R > 3 log) at 80% and 100% product concentrations under defined conditions (dirty, 20°C, 15 min contact time)	Conf.PAR

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Bactericide and Yeasticide	Hard surface disinfection in domestic, institutional areas	Gel WC Disinfectant	*Staphylococcus aureus* CIP 4.83 *Pseudomonas aeruginosa* DSM 939 *Escherichia coli* DSM 682 *Enterococcus hirae* DSM 3320 *Candida albicans* CIP 48.72	EN 13697:2015 Quantitative non-porous surface test without mechanical action (phase 2, step 2)	- Tested product concentrations: 100%, 80%, 1% - Diluent: distilled water - Test method: dilution-neutralization - Contact time: 15 minutes - Soiling: 3 g/L BSA (dirty conditions) - Test temperature: 20°C	Tested product demonstrated bactericidal activity (R > 4 log) at 100% product concentration under defined conditions (dirty, 20°C, 15 min contact time) Tested product demonstrated yeasticidal activity (R > 3 log) at 100% product concentration under defined conditions (dirty, 20°C, 15 min contact time)	Conf.PAR
Virucidal activity against enveloped viruses (application on major changes 2022)							
General claim against enveloped viruses							
Virucide	Hard surface disinfection in domestic, institutional and industrial areas (PT2)	Multi-surface Disinfectant cleaner (2.38 % w/v lactic acid)	Modified vacciniavirus Ankara (MVA)	EN 14476:2019-10; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 97%, 80%, 10%, 0.01% - Diluent: distilled water - Interfering substance: 3 g/L BSA + 3.0 ml/l erythrocytes (dirty conditions) - Contact time: 5 minutes - Test temperature: 20°C	Tested product demonstrated **virucidal activity against enveloped virus** (> 4 log) at 10%, 80% and 97% product test concentrations after exposure time of 5 minutes under dirty conditions and 20°C.	Conf.PAR
Virucide	Hard surface disinfection in domestic, institutional and industrial areas (PT2)	Toilet disinfectant (2.38 % w/v lactic acid)	Modified vacciniavirus Ankara (MVA)	EN 14476:2019-10; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 97% - Diluent: distilled water - Interfering substance: 3 g/L BSA + 3.0 ml/l erythrocytes (dirty conditions) - Contact time: 15 minutes - Test temperature: 20°C	Tested product demonstrated **virucidal activity against enveloped virus** (> 4 log) at 97% product test concentrations after exposure time of 15 minutes under dirty conditions and 20°C.	Conf.PAR

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Virucide	Hard surface disinfection in domestic, institutional and industrial areas (PT2)	Multi-surface Disinfectant cleaner (2.38 % w/v lactic acid)	Modified vacciniavirus Ankara (MVA)	EN 16777:2018; Quantitative non-porous surface test (phase 2, step 2)	- Tested product concentrations: 100%, 50%, 1% - Diluent: distilled water - Interfering substance: 3 g/L BSA + 3.0 ml/l erythrocytes (dirty conditions) - Contact time: 15 minutes - Test temperature: 18-25°C	Tested product demonstrated **virucidal activity against enveloped virus** (> 4 log) at 50% and 100% product test concentrations after exposure time of 15 minutes under dirty conditions and 18-25°C.	Conf.PAR
Virucide	Hard surface disinfection in domestic, institutional and industrial areas (PT2)	Toilet disinfectant (2.38 % w/v lactic acid)	Modified vacciniavirus Ankara (MVA)	EN 16777:2018; Quantitative non-porous surface test (phase 2, step 2)	- Tested product concentrations: 100% - Diluent: distilled water - Interfering substance: 3 g/L BSA + 3.0 ml/l erythrocytes (dirty conditions) - Contact time: 15 minutes - Test temperature: 18-25°C	Tested product demonstrated **virucidal activity against enveloped virus** (> 4 log) at 100% product test concentration after exposure time of 15 minutes under dirty conditions and 18-25°C.	Conf.PAR
Additional test organisms							
Virucide	Hard surface disinfection in domestic, institutional and industrial areas (PT2)	Disinfectant de surfaces (2.38 % w/v lactic acid)	*Herpes simplex virus* **(additional test organism)**	EN 14476+A2:2019; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 97%, 80%, 1% - Diluent: distilled water - Interfering substance: 3 g/L BSA + 3.0 ml/l erythrocytes (dirty conditions) - Contact time: 15 minutes - Test temperature: 20°C	Tested product demonstrated **virucidal activity against enveloped virus *Herpes simplex virus*** (> 4 log) at 80% and 97% product test concentrations after exposure time of 15 minutes under dirty conditions and 20°C.	Conf.PAR
Virucide	Hard surface disinfection in domestic, institutional and industrial areas (PT2)	Multi-surface Disinfectant cleaner (2.38 % w/v lactic acid)	*Human coronavirus* 229E strain **(additional test organism)**	EN 14476+A2:2019; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 97%, 10% - Diluent: distilled water - Interfering substance: 3 g/L BSA + 3.0 ml/l erythrocytes (dirty conditions) - Contact time: 15 minutes - Test temperature: 20°C	Tested product demonstrated **virucidal activity against enveloped virus *Human coronavirus* 229E** (> 4 log) at 97% product test concentration after exposure time of 15 minutes under dirty conditions and 20°C.	Conf.PAR

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Virucide	Hard surface disinfection in domestic, institutional and industrial areas (PT2)	Disinfectant de surfaces (2.38 % w/v lactic acid)	*Human coronavirus* HCoV-229E, H1N1 *influenza virus* **(additional test organisms)**	EN 14476+A2:2019; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 97%, 80%, 0.1% - Diluent: distilled water - Interfering substance: 3 g/L BSA - Contact time: 15 minutes - Test temperature: 20°C	Tested product demonstrated **virucidal activity against enveloped virus *Human coronavirus* HCoV-229E** (> 4 log) at 80% and 97% product test concentrations after exposure time of 15 minutes under defined test conditions (3 g/L BSA) and 20°C. Tested product demonstrated **virucidal activity against enveloped virus H1N1 *influenza virus*** (> 4 log) at 97% product test concentration after exposure time of 15 minutes under defined test conditions (3 g/L BSA) and 20°C.	Conf.PAR
Virucide	Hard surface disinfection in domestic, institutional and industrial areas (PT2)	Multi-surface Disinfectant (2.38 % w/v lactic acid)	Delta variant of Coronavirus SARS-CoV-2 **(additional test organism)**	EN 14476+A2:2019; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 80%, 1% - Diluent: distilled water - Interfering substance: 3 g/L BSA - Contact time: 15 minutes - Test temperature: 20°C	Tested product demonstrated **virucidal activity against enveloped virus Delta variant of Coronavirus SARS-CoV-2** (> 4 log) at 80% product test concentration after exposure time of 15 minutes under specific test conditions (3 g/L BSA) and 20°C.	Conf.PAR

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Virucide	Hard surface disinfection in domestic, institutional and industrial areas (PT2)	Multi-surface Disinfectant (2.38 % w/v lactic acid)	Delta variant of Coronavirus SARS-CoV-2 **(additional test organism)**	EN 14476+A2:2019; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 97% - Diluent: distilled water - Interfering substance: 3 g/L BSA - Contact time: 15 minutes - Test temperature: 20°C	Tested product demonstrated **virucidal activity against enveloped virus Delta variant of Coronavirus SARS-CoV-2** (> 4 log) at 97% product test concentration after exposure time of 15 minutes under specific test conditions (3 g/L BSA) and 20°C.	Conf.PAR
Virucide	Hard surface disinfection in domestic, institutional and industrial areas (PT2)	Disinfectant de surfaces (2.38 % w/v lactic acid)	*Herpes simplex virus* **(additional test organism**)	EN 16777:2018; Quantitative non-porous surface test (phase 2, step 2)	- Tested product concentrations: 100%, 80% and 0.1% - Diluent: distilled water - Interfering substance: 3 g/L BSA + 3 mL/L sheep erythrocytes - Contact time: 15 minutes - Test temperature: 20°C	Tested product demonstrated **virucidal activity against enveloped virus *Herpes simplex virus*** (> 4 log) at 100% product test concentrations after exposure time of 15 minutes under specific test conditions (3 g/L BSA+ 3 mL/L sheep erythrocytes) and 20°C.	Conf.PAR

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Virucide	Hard surface disinfection in domestic, institutional and industrial areas (PT2)	Disinfectant de surfaces (2.38 % w/v lactic acid)	*Human coronavirus* HCoV-229E, H1N1 *influenza virus* **(additional test organisms)**	EN 16777:2018; Quantitative non-porous surface test (phase 2, step 2)	- Tested product concentrations: 100%, 80% and 0.1% - Diluent: distilled water - Interfering substance: 3 g/L BSA - Contact time: 15 minutes - Test temperature: 20°C	Tested product demonstrated **virucidal activity against enveloped virus H1N1 *influenza virus*** (> 4 log) at 100% product test concentration after exposure time of 15 minutes under defined test conditions (3 g/L BSA) and 20°C. Tested product demonstrated **virucidal activity against enveloped virus *Human coronavirus* HCoV-229E** (> 4 log) at 100% product test concentration after exposure time of 15 minutes under defined test conditions (3 g/L BSA) and 20°C.	Conf.PAR

Conclusion on the efficacy of the product

The efficacy was demonstrated according to EN Standard Methods for phase 2, step 1 tests (EN 1276, EN 1650, EN 14476) and phase 2 step 2 test (EN 13697, EN 16777). The tested products cover the full range of BPF composition (minimal content of active substance and minimal / maximal content of co-formulants).

Ready-to use products meet the bactericidal and yeasticidal activity and virucidal activity against enveloped viruses for PT2 and PT4 - hard surface disinfection in domestic, institutional and industrial areas under the specified test requirements: temperature 20°C, contact time 15 minutes.

The BPF is also tested against Herpes simplex virus, Human coronavirus 229E, H1N1 influenza virus and Delta variant of Coronavirus SARS-CoV-2.

The efficacy is supported under general dirty conditions therefore, the pre-cleaning stage is not necessary.

The products are applied by spraying, foaming, pouring and mopping. According to instruction for use, mopping is intended for product's distribution onto surface. The products are not applied with mechanical action.

Therefore, it can be concluded that all products 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 G family is intended to be used as hard non-porous surface disinfectants in domestic, institutional and industrial areas.

The evaluation of efficacy demonstrates that the biocidal products within family meet agreed criteria for reduction of bacteria, yeast and enveloped viruses 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 multi-purpose disinfectants with bactericidal, yeasticidal efficacy and virucidal efficacy only against enveloped viruses for non-porous hard surfaces in contact and without contact with food and feed in domestic, institutional and industrial area[3]

- Ready to use disinfectants with bactericidal, yeasticidal efficacy and virucidal efficacy only against enveloped viruses for surfaces on the inside of toilet's bowl in domestic and institutional area.

[3] Products are not intended for use in medical area or for milk and meat industry.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

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	Erythema Animal 1: **0.7** Animal 2: **1.0** Animal 3: **0.3** Oedema 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. As well, the tested formulation contains perfume at the concentration above the limit notified in 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 tested item had a close composition to products included in BPF. 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 438 (GLP)	Confidential PAR	30 µL of biocidal product during 10 seconds. Examinations at 30, 75, 120, 180 and 240 minutes.	Combination of the three endpoints was 2 x II, 1 x IV. No predictions can be made.	n.a.	Confidential PAR
OECD guidelines 405 (GLP)	Confidential PAR	0.1 mL of biocidal product. Ocular examinations were performed 1, 24, 48 and 72 hours following treatment	The ocular reactions observed have been slight to moderate and totally reversible. Test results presented in Section 3.4 of the Confidential Annex	n.a.	Confidential PAR

Conclusion used in Risk Assessment – Eye irritation

Value/conclusion	Not causing severe damage or eye irritation
Justification for the value/conclusion	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 two studies according to the OECD Test Guidance No. 438 and OECD No. 405 for "dummy" formulation SALVESAFE G. The tested formulation contains 2.38% Lactic acid and surfactants at total concentration above the limit within family. As well, tested formulation contains perfume at the same concentration, but with a worst classification. Therefore, Latvian CA is in opinion that tested formulation covers all biocidal product within BPF. According to OECD Test Guidance No. 438 criteria the results obtained under these experimental conditions leads to the category "no prediction can be made". Additional testing was required to establish a definitive classification. According to OECD Test Guidance No. 405 and CLP criteria the tested product doesn't meet classification criteria.
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	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 BPR. For all products the exact composition is known. Please refer to the Section 3.2 of the Confidential Annex for detailed BPF composition and classification of individual components. 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 STOT-SE 3, H335.
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. Please refer to the Section 3.2. of the Confidential Annex for detailed BPF composition and classification of individual components. 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. According to information on co-formulant's classification and applying CLP criteria the content of sensitisers don't exceed the concentration limits for elicitation.
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. Please refer to the Section 3.2. of the Confidential Annex for detailed BPF composition and classification of individual components. 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 G* family.

Safety data sheets have been submitted for active substance and each co-formulant. *SALVESAFE G* family does not contain a component classified for acute toxicity. Therefore, *SALVESAFE G* 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 G* family contains *Lactic acid* as the active substance and four co-formulants as substances and ten perfumes as mixtures. 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 for all co-formulants and components of perfumes was performed by the Applicant. None of the co-formulants/perfumes component are subject to a decision regarding endocrine disrupting properties. See Section 3.5 of the Confidential Annex for more details.

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 G* 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 G* is acceptable from a human health perspective.

2.2.7 Risk assessment for the environment

2.2.7.1 Effects assessment on the environment

No studies are provided for *SALVESAFE G* family.

Safety data sheets have been submitted for active substance and each co-formulant. According to SDSs, *SALVESAFE G* family contains one co-formulant and 8 perfumes classified for environmental hazards.

Based on final content of "relevant components" in products, the products are not classified. Following to method described in Section 4.1.3.5.5 of CLP regulation, the sum

of the concentrations of these components multiplied by their corresponding M-factors is much lower than 25%.

Based on the data provided by the Applicant, there is no concern regarding the ED properties of the co-formulants used in the *SALVESAFE G* family. See Section 3.5 of the Confidential Annex for more details.

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 G* 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:**

Non-porous hard surfaces[4]:

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.

Pouring - 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.

Inner surfaces of toilet bowl:

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.

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

2. Label claim:

Non-porous hard surfaces:

Ready to use multi-purpose disinfectants with bactericidal, yeasticidal efficacy and virucidal activity against enveloped viruses for non-porous hard surfaces in contact and without contact with food and feed in domestic, institutional and industrial area.

Inner surfaces of toilet bowl:

Ready to use disinfectants with bactericidal, yeasticidal efficacy and virucidal activity against enveloped viruses for surfaces on the inside of toilet's bowl in domestic and institutional area.

3. Additional statements:

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.

4. 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.

5. Waste management measures:

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

6. Storage conditions and stability:

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

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. European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners
4. EMA, 2008. Status of MRL Procedures MRL assessments in the context of Council Regulation (EEC) No 2377/90
5. Theron MM, J.F. Rykers Lues, 2010. Organics Acid and Food preservation, CRC Press.