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 F**

Product types: PT1 (Human hygiene)

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

Case Number in R4BP3: BC-SX042125-12

Evaluating Competent Authority: Latvia

Date: 11/February/2021

Contents

1 CONCLUSION

The ready-to-use biocidal products within family *SALVESAFE F* with active substance *Lactic acid* (CAS No. 50-21-5, EC No. 200-018-0) at the concentration range 1.75-2.38% w/w are authorised for product type 1 (disinfectants for human hygiene) as hygienic handwash.

SALVESAFE F is claimed with bactericidal and yeasticidal activity in domestic, medical[1], institutional and industrial area for professional, industrial and non-professional users.

The biocidal product family consists of 2 meta-SPC's. First meta-SPC intended for professional and industrial users and contains 13 products, second meta-SPC intended for non-professional users and contains 12 products. The structuring of the family into two meta-SPC was based on request from Applicant to separate products depend on category of users. However, the composition of each product intended for professional, industrial users is same to the products claimed for non-profession use. Therefore, in practice family contains only 13 products which have variations in composition.

Latvian CA considers that sufficient data have been provided to verify the outcome and conclusions, and permits the simplified authorisation of the biocidal product family *SALVESAFE F* according 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 *SALVESAFE F* 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 for biocidal product family.

In accordance with Article 17(4) of the Regulation (EU) 528/2012 the authorisation number is valid from 11th January 2019 until 11th January 2029.

[1] Not surgical handwash

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 F	EU

2.1.1.1.1 Trade names of the products

Trade name	**Category of Users (Suffix of meta SPC)**
SALVESAFE F0dil_GPRO	Professional, industrial (meta 1-1)
SALVESAFE F0_GPRO	Professional, industrial (meta 1-1)
SALVESAFE Fv0_GPRO	Professional, industrial (meta 1-1)
SALVESAFE F1_GPRO	Professional, industrial (meta 1-1)
SALVESAFE Fv1_GPRO	Professional, industrial (meta 1-1)
SALVESAFE F3_GPRO	Professional, industrial (meta 1-1)
SALVESAFE Fv3_GPRO	Professional, industrial (meta 1-1)
SALVESAFE F4_GPRO	Professional, industrial (meta 1-1)
SALVESAFE Fv4_GPRO	Professional, industrial (meta 1-1)
SALVESAFE F7_GPRO	Professional, industrial (meta 1-1)
SALVESAFE Fv7_GPRO	Professional, industrial (meta 1-1)
SALVESAFE F8_GPRO	Professional, industrial (meta 1-1)
SALVESAFE Fv8_GPRO	Professional, industrial (meta 1-1)
SALVESAFE F0_GP	Non-professional (meta 1-2)
SALVESAFE Fv0_GP	Non-professional (meta 1-2)
SALVESAFE F1_GP	Non-professional (meta 1-2)
SALVESAFE Fv1_GP	Non-professional (meta 1-2)
SALVESAFE F3_GP	Non-professional (meta 1-2)
SALVESAFE Fv3_GP	Non-professional (meta 1-2)
SALVESAFE F4_GP	Non-professional (meta 1-2)
SALVESAFE Fv4_GP	Non-professional (meta 1-2)
SALVESAFE F7_GP	Non-professional (meta 1-2)
SALVESAFE Fv7_GP	Non-professional (meta 1-2)
SALVESAFE F8_GP	Non-professional (meta 1-2)
SALVESAFE Fv8_GP	Non-professional (meta 1-2)

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-0019494-0000		
Authorisation numbers of the biocidal products within family	SALVESAFE F0dil_GPRO		EU-0019494-0001
	SALVESAFE F0_GPRO		EU-0019494-0002
	SALVESAFE Fv0_GPRO		EU-0019494-0003

	SALVESAFE F1_GPRO	EU-0019494-0004
	SALVESAFE Fv1_GPRO	EU-0019494-0005
	SALVESAFE F3_GPRO	EU-0019494-0008
	SALVESAFE Fv3_GPRO	EU-0019494-0009
	SALVESAFE F4_GPRO	EU-0019494-0010
	SALVESAFE Fv4_GPRO	EU-0019494-0011
	SALVESAFE F7_GPRO	EU-0019494-0016
	SALVESAFE Fv7_GPRO	EU-0019494-0017
	SALVESAFE F8_GPRO	EU-0019494-0018
	SALVESAFE Fv8_GPRO	EU-0019494-0019
	SALVESAFE F0_GP	EU-0019494-0020
	SALVESAFE Fv0_GP	EU-0019494-0021
	SALVESAFE F1_GP	EU-0019494-0022
	SALVESAFE Fv1_GP	EU-0019494-0023
	SALVESAFE F2_GP	EU-0019494-0024
	SALVESAFE Fv2_GP	EU-0019494-0025
	SALVESAFE F3_GP	EU-0019494-0026
	SALVESAFE Fv3_GP	EU-0019494-0027
	SALVESAFE F4_GP	EU-0019494-0028
	SALVESAFE Fv4_GP	EU-0019494-0029
	SALVESAFE F7_GP	EU-0019494-0034
	SALVESAFE Fv7_GP	EU-0019494-0035
	SALVESAFE F8_GP	EU-0019494-0036
	SALVESAFE Fv8_GP	EU-0019494-0037
Date of the authorisation	11th January 2019	
Expiry date of the authorisation	11th January 2029	

2.1.1.3 Manufacturer of the products of the family

Name of manufacturer 1	**SALVECO S.A.S.**
Address of manufacturer	Avenue Pierre Mendès-France SAINT DIE DES VOSGES, F-88100, FRANCE
Location of manufacturing sites	Avenue Pierre Mendès-France SAINT DIE DES VOSGES, F-88100, FRANCE
Name of manufacturer 2	**MULTIFILL BV BULKONTVANGST**

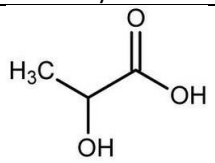
Address of manufacturer	Constructieweg 25A, 3641, SB Mijdrecht, The Netherlands
Location of manufacturing sites	Constructieweg 25A, 3641, SB Mijdrecht, The Netherlands
Name of manufacturer 3	**Diversey Netherlands Production BV**
Address of manufacturer	Rembrandtlaan 414, 7545, ZW Enschede, The Netherlands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

2.1.1.4 Manufacturer of the active substance

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

2.1.2 Product family composition and formulation

2.1.2.1 Identity of the active substance

Main constituent	
ISO name	Lactic acid
IUPAC or EC name	2-Hydroxypropanoic acid
EC number	200-018-0
CAS number	50-21-5
Index number in Annex VI of CLP	-
Minimum purity / content	88% w/w
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 (%, w/w)	
					min	max
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.75	2.38

SALVESAFE F 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 program for the systematic examination of all existing active substances contained in biocidal products referred to 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 applicable.

2.1.2.5 Information on the substance(s) of concern

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

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 CLP requirements, 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	For professional users: EUH210: Safety data sheet available on request For non-professional users: P101: If medical advice is needed, have product container or label at hand P102: Keep out of reach of children

2.1.4 Authorised uses

2.1.4.1 Use 1

Meta 1-1 Hygienic handwash for professional and industrial users

Product Type	Product type 1 - Human hygiene
Where relevant, an exact description of the authorised use	Hygienic handwash. Ready-to-use disinfectant for hands with a bactericidal and yeasticidal efficacy in medical, institutional and industrial area.
Target organisms	Bacteria and yeasts
Field of use	Indoor, outdoor
Application methods	Type of method: manual - foam application General description of the method: Wet hands and wrists with water. Place 2 ml of the product on the hallow of the hand. Rub hands and wrists for at least 30 seconds. Rinse thoroughly with clean water.
Application rates and frequency	The application rate: 2 ml Frequency: apply once, repeat if renewed hand disinfection is needed.
Categories of users	Professional, industrial
Pack sizes and packaging material	Section 2.1.7.

2.1.4.1.2 Use-specific instructions for use

Section 2.1.5

2.1.4.1.3 Use-specific risk mitigation measures

Section 2.1.5

2.1.4.1.4 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

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

Section 2.1.5

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

Section 2.1.5

2.1.4.2 Use 2

Meta 1-2 Hygienic handwash for non-professional users

Product Type	Product type 1 - Human hygiene
Where relevant, an exact description of the authorised use	Hygienic handwash. Ready-to-use disinfectant for hands with a bactericidal and yeasticidal efficacy in domestic area.
Target organisms	Bacteria and yeasts
Field of use	Indoor, outdoor
Application methods	Type of method: manual - foam application General description of the method: Wet hands and wrists with water. Place 2 ml of the product on the hallow of the hand. Rub hands and wrists for at least 30 seconds. Rinse thoroughly with clean water.
Application rates and frequency	The application rate: 2 ml Frequency: apply once, repeat if renewed hand disinfection is needed.
Categories of users	Non-professional
Pack sizes and packaging material	Section 2.1.7.

2.1.4.2.2 Use-specific instructions for use

Section 2.1.5

2.1.4.2.3 Use-specific risk mitigation measures

Section 2.1.5

2.1.4.2.4 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

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

Section 2.1.5

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

Section 2.1.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

Wet hands and wrists with water. Place 2 ml of the product on the hallow of the hand. Rub hands and wrists for at least 30 seconds. Rinse thoroughly with clean water.

2.1.5.2 Risk mitigation measures

Not applicable

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

No direct or indirect adverse effects are known. First aid instructions: If swallowed: immediately call a POISON CENTER or doctor/physician. In case of contact with eyes, remove contact lenses if present and rinse the eye slowly and gently with clean water.

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

Shelf-life: Products can be stored at room temperature up to 24 months. Conditions: Avoid cold, frost, heat.

2.1.6 Other information

Professional users – medical area - not surgical handwash.

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	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	0.01-2L	Plastic: HDPE, LDPE, PET, PE, PP	Cap, Dispensing Cap	Professional Non-professional	Yes
Drum	10-210L	Plastic: HDPE	Cap	Professional	Yes
Jerry can	1-80L	Plastic: HDPE, LDPE	Cap	Professional	Yes
Pouches	0.05-5L	Plastic: LDPE, LLDPE	Cap pump	Professional Non-professional	Yes
All used packaging must be secure, closed, tight, strong and durable. Packaging can be refilled only with product foreseen for that purpose (not mentioned on the label). *PET – polyethylene terephthalate; PE – Polyethylene; HDPE* - High-density polyethylene; *LDPE - Low-density polyethylene; LLDPE - Linear low-density polyethylene, PP - Polypropylene*					

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 use

Hygienic handwash for non-professional, professional and industrial users

Product Type	Product Type 1 - Human hygiene
Where relevant, an exact description of the authorised use	Hygienic handwash. Ready-to-use disinfectant for hands with a bactericidal and yeasticidal efficacy in domestic, medical[2], institutional and industrial area.
Target organism (Test organisms)	Bacteria: - *Pseudomonas aeruginosa*, common name: bacteria, aerobic, Gram-negative; - *Staphylococcus aureus*, common name: bacteria, facultative anaerobic, Gram-positive; - *Escherichia coli*, common name: bacteria, facultative anaerobic, Gram-negative; - *Enterococcus hirae*, common name: bacteria, facultative anaerobic, Gram-positive; Yeast: - *Candida albicans*, common name: yeast.
Field of use	Indoor, outdoor
Application method(s)	Type of method: manual - foam application General description of the method: Wet hands and wrists with water. Place 2 ml of the product on the hallow of the hand. Rub hands and wrists for at least 30 seconds. Rinse thoroughly with clean water.
Application rate	Apply once, repeat if renewed hand disinfection is needed.
Categories of users	Non-professional, professional, industrial

2.2.2 Physico-chemical properties and storage stability

Biocidal product family *SALVESAFE F* is a family of water-based ready for use formulations containing 1.75-2.38% *Lactic acid*. The physico-chemical data are shown in the below following Table.

Property	**Guideline and Method**	**Purity of the test substance % (w/w)**	**Results**	**Reference**
Physical state at 20 °C and 101.3 kPa	Visual	Biocidal product family SALVESAFE F	Liquids (homogenous solutions)	Salveco Analytical Test Reports
Colour at 20 °C and 101.3 kPa	Visual	Biocidal product family SALVESAFE F	clear, colourless	Salveco Analytical Test Reports
Acidity / alkalinity at 20 °C	CIPAC MT 75.3 Undiluted products	Biocidal product family SALVESAFE F	Before accelerated storage 2.27-2.57; after accelerated storage 2.26-2.67	Salveco Analytical Test Reports

[2] Not surgical handwash

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Relative density / bulk density at 20 °C	EC Method A.3 Undiluted products	Biocidal product family SALVESAFE F	Before accelerated storage 1.005-1.016 g/ml; after accelerated storage 1.005-1.017 g/ml	Salveco Analytical Test Reports
Viscosity at 20 °C	OECD 114 Undiluted products	F0dil_GPRO F0_GPRO F1_GPRO F3_GPRO F4_GPRO F7_GPRO F8_GPRO Fv0_GPRO Fv1_GPRO Fv3_GPRO Fv4_GPRO Fv7_GPRO Fv8_GPRO	< 50 mPa*s (after accelerated storage < 50 mPa*s) < 288 mPa*s (after accelerated storage < 293 mPa*s)	Salveco Analytical Test Reports
Storage stability test – **accelerated storage**	Storage at 54°C±2°C during 14 days (CIPAC MT46.3)	Biocidal products with initial concentration of *Lactic acid* around 1.72-1.81% are used. The storage stability tests are conducted in glass bottles. For the detection and identification of *Lactic acid* HPLC method is used.	*Lactic acid* content at the start 1.72-1.81% w/w and at the end 1.74-1.82%. Tested concentrations and it's changes are within allowed tolerance limit of the declared nominal minimal content of active substance 1.75%. The changes are less than 10%. No variations in physical state and colour. No significant variations for pH, density and viscosity.	Salveco Analytical Test Reports
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 1.72-1.81% are used. The storage stability tests are conducted in PET bottles. For the detection and identification of *Lactic acid*	*Lactic acid* content at the end 1.75-1.83%. Tested concentrations and it's changes are within allowed tolerance limit of the declared nominal minimal content of active substance 1.75%. The changes are less than 10%. No variations in physical state and colour. No significant variations for pH, density and viscosity.	Salveco Analytical Test Reports

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		HPLC method is used.		
Storage stability test – **low temperature stability test for liquids**	The Applicant did not provide a test reports according to CIPAC MT 39.3 at low temperature. The condition on storage "Avoid cold and frost" shall be indicated on the label.			
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. Since products are water based, humidity is not expected to have a significant effect on the content of active substance during storage.			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Long storage stability test will cover reactivity towards container material. However, based on composition of the products reactivity towards container material is not expected.			
Wettability	Not applicable since the biocidal products are liquids			
Suspensibility, spontaneity and dispersion stability	Not applicable since the biocidal products are liquids			
Wet sieve analysis and dry sieve test	Not applicable since the biocidal products are ready-to-use liquids			
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable since the biocidal products are liquids			
Particle size distribution, content of dust/fines, attrition, friability	Not applicable since the biocidal products are liquids. Spray application is not intended.			
Persistent foaming	The data are not required when the products are intended to be foam application.			
Flowability/Pourability/Dustability	Not applicable since the biocidal products are liquids.			
Burning rate — smoke generators	Not applicable since the biocidal products are liquids.			
Burning completeness —	Not applicable since the biocidal products are liquids.			

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
smoke generators				
Composition of smoke — smoke generators	Not applicable since the biocidal products are liquids.			
Spraying pattern — aerosols	The products are not an aerosol and are not sold in spray packaging			
Physical compatibility	Not relevant. The products in this family are not intended to be used in combination with any other biocidal products.			
Chemical compatibility	Not relevant. The products in this family are not intended to be used in combination with any other biocidal products.			
Degree of dissolution and dilution stability	The products are ready-to-use liquids.			

Conclusion on the physical, chemical and technical properties of the product
Latvian CA accepts that physico-chemical properties is without a risk envelope. The data mentioned above supports that members of the biocidal product family *SALVESAFE F* will be stable for two years at ambient temperature. The condition on storage "Avoid cold and frost" should be indicated on the label. Long term storage stability testing at ambient temperature is started in August 2018. An intermediate report will be available on August 2019 and the final test report on August 2020. The post-authorisation condition is set.

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	-
Flammable gases	-	Products are a liquids	-
Flammable aerosols	-	Products are not an aerosols	-
Oxidising gases	-	Products are a liquids	-
Gases under pressure	-	Not applicable, not under pressure	-
Flammable liquids	-	The mixture is not classified as flammable.	-
Flammable solids	-	Products are a liquids	-
Self-reactive substances and mixtures	-	Products contain no self-reacting substances	-
Pyrophoric liquids	-	No pyrophoric substances present	-
Pyrophoric solids	-	Products are a liquids	-
Self-heating substances and mixtures	-	No self-heating compounds present	-
Substances and mixtures which in contact with water emit flammable gases	-	Products are a stable aqueous solution, no flammable gas is emitted	-

Property	Guideline and Method	Results	Reference
Oxidising liquids	-	No substances with oxidizing properties in the products	-
Oxidising solids	-	Products are a liquids	-
Organic peroxides	-	No compounds present with bivalent O-O structure present	-
Corrosive to metals	Read-across with Salvesafe G (EU-0021241-0000) and Salvesafe E (EU-0020512-0000)	Not classified as corrosive to metals. More details in Confidential PAR.	-
Auto-ignition temperatures of products (liquids and gases)	-	The products are known to be stable at room temperature	-
Relative self-ignition temperature for solids	-	Not applicable	-
Dust explosion hazard	-	Not applicable	-

Conclusion on the physical hazards and respective characteristics of the product
The Applicant has indicated that neither the active substance – *Lactic acid* nor the co-formulants of the biocidal product family *SALVESAFE F* exhibit any hazardous physico-chemical properties. The biocidal products within family *SALVESAFE F* are water-based ready-to-use liquids, are not flammable and do not have any explosive or oxidising properties. Latvian CA agrees that no classification and labelling for physico-chemical hazards is required. The biocidal products are stable for 24 months at ambient temperature. The condition on storage "Avoid cold and frost" should be indicated on the label.

2.2.4 Methods for detection and identification

Analytical method for the determination of *Lactic acid* residues in body and animals fluids and tissues, environmental media (soil, air, water) and also treated food or feeding have not been submitted since the Applicant has indicated that these points are not relevant for the biocidal product family *SALVESAFE F*. As well as, this is no data requirements for an application in accordance with Article 25 of the Regulation (EU) No 528/2012.

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). *Lactic acid* and co-formulants are not classified as toxic or very toxic, analytical methods in body fluids and tissues are not required.
2. *Lactic acid* approved for use as a food additive (E270) according Regulation (EU) No. 1333/2008. *Lactic acid* meets the specifications for purity laid down in Regulation (EU) No. 231/2012. *Lactic acid* is present in a variety of foods, like yogurt containing 9 g/kg (Simpson BK., 2012), traditional cheese with 8 g/kg (Dolci P., 2008) and beef meat with a content of 1.4-5.0 g/kg (Nassos PS., 1988). Lactate is an endogenous substance (in carbohydrate and amino acid metabolism) and a natural component of very many foods, in particular fruits and fermented milk products. *Lactic acid* also occurs naturally in meats, fruits, tomato juice, beer, wine, molasses, blood and muscles of animals, and in the soil. *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). In 2011, the European Food Safety Authority (EFSA) delivered its agreement for the approval of *Lactic acid* for uses to reduce microbial contamination of beef hides, carcasses, cuts and trimmings. More specifically, the approval was sought for treatments using *Lactic acid* solution concentrations from 2% to 5% (w/w) at temperature of up to 55°C applied either by spraying or misting: "Considering the expected low level of exposure deriving from the use of *Lactic acid* in carcasses, cuts and trimmings and the fact that it is an endogenous substance, it was concluded that the treatments, as described, will be of no safety concern, provided the substance used complies with the European Union specifications for food additives" (EFSA, 2011). According to the above mentioned, residues determination in food of plant and animal origin is not relevant.

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. According to it, residues determination in air, water, soil are not considered to be relevant.

2.2.5 Efficacy against target organisms

SALVESAFE F is developed based on *Lactic acid* as an active substance.

The efficacy studies on bactericidal and yeasticidal claim had been performed for a product with 1.75% *Lactic acid*.

The choice of reference micro-organisms for testing is in accordance with EN standards methodology. In current efficacy tests bacterial strains and yeast strain used as test-organisms were selected in accordance with Standard EN 14885 – Chemical disinfectants and antiseptics – application of European Standards for chemical disinfectants and antiseptics.

The used Standards based on laboratory suspension tests (phase 2, step 1) or tests (phase 2, step 2) simulating practical conditions are appropriate to its intended use. The following Standards were used according to EN 14885, Section 4.3:

- EN 1499:2013/2017 – Chemical disinfectants and antiseptics – Hygienic handwash (phase 2, step 2);
- EN 13727:2013 - Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area (phase 2, step 1).
- EN 13624:2013 - Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area (phase 2, step 1).

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

2.2.5.1 Function and field of use

All biocidal products within family *SALVESAFE F* are ready-to-use water-based solutions for hand hygiene in medical, domestic, institutional and industrial area.

SALVESAFE F is claimed as hygienic handwash with a bactericidal and yeastidical action.

2.2.5.2 Effects on target organisms, including unacceptable suffering

The efficacy studies had been performed for reference biocidal product F0dil_GPRO with 1.75% w/w Lactic acid concentration with minimal content of all ingredients. The negative impact of surfactant's on efficacy is not expected based on a data presented within application of authorisation for similar biocidal product family Salvesafe A[3] and Salvesafe C[4]. In addition Applicant has provided a data to support no impact of emollient on efficacy.

To demonstrate the **bactericidal activity**, quantitative suspension test according to the **EN 13727:2013** (method dilution-neutralization) against four reference strains: *Pseudomonas aeruginosa ATCC 15442, Enterococcus hirae ATCC 10541, Staphylococcus aureus ATCC 6538* and *Escherichia coli K12 NCTC 10538*, has been performed.

Biocidal product activity against bacteria has been evaluated at a 30 sec contact time with desired product concentrations of 50%, 25% and 1% at dirty conditions (3 g/l bovine albumin + 3 g/l sheep erythrocytes) and temperature 20 ± 1°C.

Tested concentration (50%) of the product possess bactericidal efficacy against all target organisms. The bactericidal infectivity reduction factor overpass > 5 log (required ≥ 3).

Therefore, the biocidal product SALVESAFE F0dil_GPRO is a disinfectant with a bactericidal activity under defined test conditions according to claimed Standard and intended use.

To demonstrate the **yeasticidal activity**, quantitative suspension test according to the **EN 13624:2013** (method dilution-neutralization) against yeast (*Candida albicans ATCC 10231*) has been performed.

Biocidal product activity has been evaluated at a 30 sec contact time with desired product concentrations of 50%, 25% and 1% at dirty conditions (3 g/l bovine albumin + 3 g/l sheep erythrocytes) and temperature 20 ± 1°C.

Tested concentration (50%) of the product possess yeasticidal efficacy. The yeasticidal infectivity reduction factor overpass > 3 log (required ≥ 2).

Therefore, the biocidal product SALVESAFE F0dil_GPRO is a disinfectant with a yeasticidal activity under defined test conditions according to claimed Standard and intended use.

Practical conditions

The hand disinfectant was tested according to the **EN 1499:2013** (method dilution-neutralization), phase 2, step 2; Hygienic hand washing.

The test was performed to find out bactericidal efficacy against *Escherichia coli K12 NCTC 10538* strain according to the following experimental conditions:

Reference procedure	Hand washing for 60 seconds 5 ml soft soap
Procedure with the product tested	Hand washing for 30 seconds 2 ml tested product

Superiority test according to Wilcoxon`s matched-pairs test showed that the product is significantly more effective than the soft soap (rank sum = 0.00, p = 0.000) at the level of significance p = 0.01.

[3] EU-0006622-0000
[4] EU-0016328-0000

Therefore, the biocidal product Salve Safe Soap 10F used for hand washing for 30 seconds, under a volume of 2 ml has an activity according to claimed Standard and intended use.

2.2.5.3 Mode of action, including time delay

The dissociation degree of *Lactic acid* in solution depends on pH value. In contact of undissociated form of *Lactic acid* with biological material, such as micro-organisms, the Lactic acid is able to pass the cells membrane. At a relatively low pH, the *Lactic acid* inhibits the pathogens through the penetration of the undissociated form across the membrane which interferes with the metabolic functions of the pathogen. The decrease in the intracellular pH causes dissipation of the membrane and leads to membrane disruption. Therefore the mode of action for this product family is inhibiting of cells growth and biomass producing and finally cells are destroyed.

The results of the efficacy tests conclusively demonstrate that the biocidal product with the concentration of *Lactic acid* 1.75% for a 30 sec contact time reached a sufficient effectiveness and passed the target organisms (bacteria and yeasts) reduction factor.

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**
Bactericide	Hygienic handwash	SALVESAFE F0dil_GPRO (a.s. 1.75%)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* NCTC 10538	EN 13727:2012+A2:2015 (phase 2, step 1)	- Tested product concentrations: 50%, 25%, 1% - Diluent: hard water - Contact time: 30 seconds - Interfering substance: 3 g/l bovine albumin + 3 g/l sheep erythrocytes (dirty conditions) - Test method: dilution-neutralization - Test temperature: 20 ± 1°C	Tested product demonstrated bactericidal efficacy (logR > 5 log) at concentrations of ≥ 50% and logR > 3 for concentrations of ≥ 25% within 30 seconds contact time under dirty conditions.

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects
Yeasticide	Hygienic handwash	SALVESAFE F0dil_GPRO (a.s. 1.75%)	*Candida albicans* ATCC 10231	EN 13624:2013 (phase 2, step 1)	- Tested product concentrations: 50%, 25%, 1% - Diluent: hard water - Contact time: 30 seconds - Interfering substance: 3 g/l bovine albumin + 3 g/l sheep erythrocytes (dirty conditions) - Test method: dilution-neutralization - Test temperature: 20 ± 1°C	Tested product demonstrated yeasticidal efficacy (logR > 3 log) at concentrations of ≥ 50% within 30 seconds contact time under dirty conditions.
Bactericide	Hygienic handwash	SALVESAFE F0dil_GPRO (a.s. 1.75%)	*Escherichia coli* K12 NCTC 10538	EN 1499:2013/2017 (phase 2, step 2) Volunteer test	Tested product concentrations: 2 ml - 100% (undiluted) Contact time: 30 seconds Contamination fluid: $2.88x10^8$ cfu/ml Test method: dilution neutralization Test temp: 20±1°C Reference: 5 ml soft soap for 60s 15 volunteers	The test item is suitable for the hygienic handwash when hands are kept moist with 2ml (on wetted hands) of test product for a contact time of 30s The absolute difference between mean differences RP-PP and PP-RP was 0.69 (Abs = [-0.56–(-1.25)] < 2. Product was significantly more effective than the reference (rank sum = 0.000 (1-tailed) significance level p = 0.01)
Additional data						
Bactericide	Hygienic handwash	SalveSafeSoap (a.s. 1.75%) with emollient SalveSafeSoap (a.s. 1.75%) without emollient	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* NCTC 10536	prEN1276:2018 However, the current versions are EN 1276:2010. The status for 2018 version is still officially "Draft".	- Tested product concentrations: 50%, 25%, 1% - Diluent: hard water - Contact time: 30 seconds - Interfering substance: 3 g/l bovine albumin (dirty conditions) - Test method: dilution-neutralization - Test temperature: 20 ± 1°C	Tested product demonstrated bactericidal efficacy (logR > 5 log) at concentrations of ≥ 25% within 30 seconds contact time under dirty conditions.

Conclusion on the efficacy of the product
Biocidal product family SALVESAFE F is a group of products with one active substance, similar use, but some differences in the content. The efficacy of full family is demonstrated using approach of worst case testing. The efficacy studies had been performed for biocidal product with minimal concentration of active substance and each co-formulants, without presence of perfumes. The negative effect of co-formulants at maximal concentration is excluded. The tested product covers all members within family. The results of the efficacy tests conclusively demonstrate that the biocidal products for a 30 sec contact time reached a sufficient effectiveness against bacteria and yeast according to intended use.

2.2.5.5 Occurrence of resistance and resistance management

The possibility of the development of the resistance to *Lactic acid* was not evaluated. However, by 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

The biocidal product family *SALVESAFE F* is intended to be used in medical[5], domestic, institutional and industrial area as disinfectants for hands – hygienic handwash.

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

Latvian CA considers that the following label claim can be used on products label for non-professional, professional and industrial users:

- Biocidal efficacy at 20°C: bactericidal and yeasticidal activity at the contact time 30 sec.

[5] Not surgical handwash

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	<u>Erythema</u> Animal 1: **0.7** Animal 2: **1.0** Animal 3: **0.3** <u>Oedema</u> Animal 1: **0** Animal 2: **0** Animal 3: **0** Fully reversible after 72 h No histopathological changes observed	-	Confidential PAR

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not corrosive or irritating to skin.
Justification for the value/conclusion	According to the CLP criteria and additivity approach, classification is met with respect to local effects on the skin (irritation) for the individual products of the BPF and thus the BPF itself. The conclusion is made based on RAC opinion for L(+)-Lactic acid, content of individual components, generic cut-off values specified in CLP Annex I, Table 1.1 and generic concentration limits (GCL) specified in CLP Annex I, Table 3.2.3. The sum of the concentrations/GCL of individual components exceeds a concentration limit 1%. Upon Latvian CA request to support non-classification of the BPF, the Applicant provided study according to the OECD Test Guidance No. 404. The tested formulation contains 3.52% Lactic acid and surfactants at total concentration above the limit within family. 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 on sensitive skin. The tested item had a close composition to products included in BPF. This study considered the test item non-irritant and showed very good skin compatibility.
Classification of the product according to CLP	Not relevant

Eye corrosion and irritation

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

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The biocidal product family *SALVESAFE F* does not have irritating effects on the eye.
Justification for the value/conclusion	*SALVESAFE F* contains *Lactic acid* and co-formulants classified as H318 - Causes serious eye damage and co-formulants with classification H319 - Causes serious eye irritation. Taking into account the maximal content of *Lactic acid* and co-formulants the results of an additivity approach show that H318 statement should be applicable. However, Applicant provided the eyes irritation study according OECD No. 405 for "dummy" formulation with the concentration of co-formulant's and *Lactic acid* above notified limit for family. Based on test results and CLP regulation Annex I point 3.3.2.7 *SALVESAFE F* does not meet the criteria for classification for eye irritation
Classification of the product according to CLP	Not relevant

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	The biocidal product family *SALVESAFE F* does not have irritating effects on respiratory tract.
Justification for the conclusion	The respiratory tract irritation effects of the biocidal products family *SALVESAFE F* have not been investigated experimentally. Based on the information on the hazards of the *Lactic acid*, co-formulants and their content in biocidal product family, Latvian CA considers that *SALVESAFE F* does not meet the criteria for classification for respiratory tract irritation.
Classification of the product according to CLP	Not relevant

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	The biocidal product family *SALVESAFE F* does not have sensitization effects on skin.
Justification for the value/conclusion	The potential effect on dermal sensitization of the biocidal product family *SALVESAFE F* has not been investigated experimentally. *SALVESAFE F* contains perfumes classified as H317 - May cause an allergic skin reaction. Taking into account information on the maximal concentration of substances caused an allergic skin reaction of perfumes, the final result of calculated concentration of sensitising substances in the final biocidal product is lower than 0.1 %. Therefore, according to Table 3.4.5, Section 3.4, Part 3, Annex I of CLP regulation H317 and EUH208 statements are not applicable. Therefore, *SALVESAFE F* does not meet the criteria for classification for sensitisation.
Classification of the product according to CLP	Not relevant

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	The biocidal product family *SALVESAFE F* does not have respiratory sensitisation effects.
Justification for the value/conclusion	The respiratory sensitisation effects of the biocidal products family *SALVESAFE F* have not been investigated experimentally. Based on the information on the hazards of the *Lactic acid* and co-formulants and their content in biocidal product family, the Latvian CA considers that *SALVESAFE F* does not meet the criteria for classification for respiratory sensitisation.
Classification of the product according to CLP	Not relevant

Acute toxicity

Biocidal product family *SALVESAFE F* contains *Lactic acid* and no substance of concern. Based on the information on the hazards of the *Lactic acid* and co-formulants Latvian CA considers, that *SALVESAFE F* does not require classification for acute toxicity.

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 F* family contains *Lactic acid* as the active substance and six co-formulants as substances and five 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.

2.2.6.2 Exposure assessment

There are no substances of concern present and the product is not classified, therefore the Latvian CA considers that a 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 biocidal product family *SALVESAFE F*.

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 no classification of family, Latvian CA considers that authorisation of *SALVESAFE F* is acceptable from a human health perspective.

2.2.7 Risk assessment for the environment

2.2.7.1 Effects assessment on 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 F* is acceptable from an environmental perspective. The detailed exposure assessment is not required.

However, Applicant had provided additional studies with proposal to demonstrate rapidly degradability of the biocidal product family *SALVESAFE F*. Tested "dummy" formulation is considered rapidly degradable in the environment according to point 4.1.2.9.5 of Annex I CLP regulation as carbon dioxide generation is 60% of theoretical maximum during 10 days.

Based on the data provided by the Applicant, there is no concern regarding the ED properties of the co-formulants used in the SALVESAFE F family. See Section 3.6 of the Confidential Annex for more details.

2.2.8 Measures to protect man, animals and the environment

The biocidal product family *SALVESAFE F* is authorised under the specified use conditions which are summarized in Section 2.1.

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:**

Wet hands and wrists with water. Place 2 ml of product on the hallow of the hand. Rub hands and wrists for at least 30 seconds. Rinse thoroughly with clean water.

2. **Label claim:**

Bactericidal and yeasticidal activity at the contact time 30 sec.

3. **The label information must contain the following precautionary statements:**

For professional and industrial users:
EUH210: Safety data sheet available on request;

For non-professional users:
P101: If medical advice is needed, have product container or label at hand.
P102: Keep out of reach of children.

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

If swallowed: immediately call a POISON CENTER or doctor/physician.
In case of contact with eyes, remove contact lenses if present and rinse the eye slowly and gently with clean water.

5. **Waste management measures:**

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

6. **Storage conditions and stability:**

Avoid cold, frost and heat.
Shelf-life - 24 months.

2.3 List of References

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9. EFSA, 2011. Scientific Opinion on the evaluation of the safety and efficacy of lactic acid for the removal of microbial surface contamination of beef carcasses, cuts and trimmings. 9(7), 2317 (35 pp)
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