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 C**

Product types: PT1 (Human hygiene)

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

Case Number in R4BP3: BC-KQ030208-32

Evaluating Competent Authority: Latvia

Date: 16/May/2024

Contents

1 CONCLUSION

The ready-to-use biocidal products within family *SALVESAFE C*, formulated by SALVECO S.A.S. (France), with active substance *Lactic acid* (CAS No. 50-21-5, EC No. 200-018-0) at the concentration 1.75% w/w are authorised for product type 1 (disinfectants for human hygiene) as hygienic handrub.

Biocidal product family *SALVESAFE C* is claimed with bactericidal, yeasticidal and virucidal activity only against enveloped viruses in domestic, medical[1], institutional and industrial area for non-professional, professional and industrial users. The detailed list of target organisms and conclusion on efficacy is given in point 2.2.5.4 of Section 2.2.5.

The 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 C* 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.

In accordance with Article 17(4) of the Regulation (EU) 528/2012 the authorisation number is valid from 7 June 2017 until 7 June 2027.

A person placing on the market or using the biocidal products included in biocidal product family *SALVESAFE C* 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.

[1] Not surgical handrub

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 C	EU

2.1.1.1.1 Trade names of the products within the family SALVESAFE C

Trade name	Other trade name	meta SPC
SALVESAFE C0_C	• Mousse désinfectante mains • BACTIDOSE GREEN Mousse • La désinfection honnête - Mousse désinfectante mains • Milton Antibacterial hand sanitiser • Milton Mousse mains désinfectante • Mousse Désinfectante pour les Mains sans parfum • Mousse Désinfectante pour les Mains sans parfum by Biozeffi • Mousse Désinfectante pour les Mains sans parfum by Effibioz • Desinfizierender Handschaum, parfümfrei, by Effibioz • Hand Sanitising Foam fragrance free by Effibioz, • Mousse desinfectante para manos sin fragancia by Effibioz, • Mousse disinfettante mani Senza profumo by Effibioz • Mapa Mousse desinfectante para Manos sin fragrancia by Effibioz • Spontex Mousse desinfectante para Manos sin fragrancia by Effibioz	1
SALVESAFE C16_C	• Evercleanhand-rub • OSANIS – Mousse désinfectante mains parfum Feuilles de Menthe • OSANIS - Ontsmettend handschuim, geparfumeerd met munt • OSANIS - Schiuma disinfettante per le mani alla menta • OSANIS - Hand-Desinfektionsschaum Minzblattduft • OSANIS - Espuma desinfectante para manos hoja de menta; • OSANIS – Espuma desinfetante para as mãos folhas de menta; • OSANIS - Hand Disinfectant Foam Icy	
SALVESAFE C0_GPPRO	• OSANIS - Mousse désinfectante mains • BACTIDOSE GREEN Mousse Mains • Mousse Désinfectante pour les Mains Pro - sans parfum • Mousse Désinfectante pour les Mains Pro - sans parfum by Biozeffi • Mousse Désinfectante pour les Mains Pro sans parfum by Effibioz • Milton - Antibacterial hand sanitiser – Mousse mains désinfectante • OSANIS - Hand Disinfectant Foam • OSANIS - Espuma desinfetante para as mãos • OSANIS - Espuma desinfectante para manos • OSANIS – Ontsmettend handschuim	2

Trade name	Other trade name	meta SPC
	• OSANIS - Schiuma disinfettante per le mani • OSANIS - Hand-Desinfektionsschaum • BÉABA – Mousse désinfectante mains • BÉABA – Hand disinfecting foam • BÉABA – Espúma desinfectante de manos • BÉABA – Händedesinfektionsschaum • BÉABA – Handdesinfecterend schuim • BÉABA – Pianka do dezynfekcji rąk • BÉABA – Sredstvo za dezinfekciju ruku • BÉABA – Schiuma disinfettante mani • Fragrance free pro hand disinfectant foam by effibioz; • Pro schiuma disinfettante per le mani senza profumo by effibioz; • Hand desinfektionsschaum ohne parfüm by effibioz; • Ontsmettend handschuim zonder parfum by effibioz; • Espuma desinfectante para manos sin perfume by effibioz; • Espuma desinfetante para as mãos sem perfume by effibioz	
SALVESAFE C8_GPPRO	• Mousse Désinfectante pour les Mains Parfumée Golden • Mousse Désinfectante pour les Mains Parfumée Golden by Biozeffi • Mousse Désinfectante pour les Mains Parfumée Golden by Effibioz • Mousse Désinfectante pour les Mains Pro - Parfumée Golden • Mousse Désinfectante pour les Mains Pro Parfumée Golden by Biozeffi • Mousse Désinfectante pour les Mains Pro Parfumée Golden by Effibioz • Dettol Foam Hand Sanitiser • Dettol Anti-bacterial Hand Sanitiser • Dettol Hand Hygiene Foam • Sagrotan Desinfektion Handschaum • Sagrotan Desinfektion Handhygiene-Schaum • Sagrotan Desinfektion Handmousse • Hand disinfectant foam Golden • Schiuma disinfettante per le mani Golden • Hand desinfektionsschaum Golden • Ontsmettend handschuim Golden • Espuma desinfectante para manos Golden Espuma desinfetante para as mãos Golden	
SALVESAFE C9_GPPRO	-	
SALVESAFE C12_GPPRO	-	
SALVESAFE C16_GPPRO	• EverCleanHand-lotion • OSANIS - Mousse désinfectante mains parfumée • OSANIS – Hand Sanitiser Foam • BACCIDE Mousse Mains • Hand disinfectant foam Mint • Schiuma disinfettante per le mani Menta • Hand desinfektionsschaum Minze	

Trade name	Other trade name	meta SPC
	• Ontsmettend handschuim Munt • Espuma desinfectante para manos Menta • Espuma desinfetante para mãos Hortelã Mousse désinfectante pour les mains parfumée menthe	
SALVESAFE C17_GPPRO	• Mousse Désinfectante pour les Mains Parfumée Fleurs de printemps • Mousse Désinfectante pour les Mains Parfumée Fleurs de printemps by Biozeffi • Mousse Désinfectante pour les Mains Parfumée Fleurs de printemps by Effibioz • Mousse Désinfectante pour les Mains Pro - Parfumée Fleurs de printemps • Mousse Désinfectante pour les Mains Pro Parfumée Fleurs de printemps by Biozeffi Mousse Désinfectante pour les Mains Pro Parfumée Fleurs de printemps by Effibioz	
SALVESAFE C3_GPPRO	-	3
SALVESAFE C18_GPPRO	Même - La mousse désinfectante mains sensibles	

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-0016328-0000 (according to Asset number in R4BP3)	
Authorisation numbers of the biocidal products within family	SALVESAFE C0_C	EU-0016328-0016
	SALVESAFE C16_C	EU-0016328-0033
	SALVESAFE C0_GPPRO	EU-0016328-0034
	SALVESAFE C3_GPPRO	EU-0016328-0035
	SALVESAFE C8_GPPRO	EU-0016328-0036
	SALVESAFE C9_GPPRO	EU-0016328-0037
	SALVESAFE C12_GPPRO	EU-0016328-0038
	SALVESAFE C16_GPPRO	EU-0016328-0039
	SALVESAFE C17_GPPRO	EU-0016328-0040
	SALVESAFE C18_GPPRO	EU-0016328-0041
Date of the authorisation	7 June 2017	
Expiry date of the authorisation	7 June 2027	

2.1.1.3 Manufacturer of the products of the family

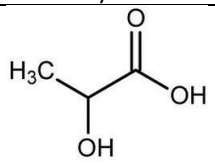
Name of manufacturer (1)	SALVECO S.A.S.
Address of manufacturer	Avenue Pierre Mendès-France SAINT DIE DES VOSGES, F-88100, FRANCE
Location of manufacturing sites	Avenue Pierre Mendès-France SAINT DIE DES VOSGES, F-88100, FRANCE
Name of manufacturer (2)	GESTRA S.A.S
Address of manufacturer	Allée Robert Schumann, 88110, RAON-L'ETAPE, France
Location of manufacturing sites	Allée Robert Schumann, 88110, RAON-L'ETAPE, France
Name of manufacturer (3)	Laboratoires Gilbert
Address of manufacturer	AVENUE DU GENERAL DE GAULLE, 14200, HEROUVILLE SAINT CLAIR, France
Location of manufacturing sites	AVENUE DU GENERAL DE GAULLE, 14200, HEROUVILLE SAINT CLAIR, 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	-
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)
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.75

The composition of the biocidal product family *SALVESAFE C* and composition of each biocidal product within family is described in the Section 3.2. of the confidential Annex I. The biocidal product family *SALVESAFE C* 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 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 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 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 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

2.1.4 Authorised uses

2.1.4.1 Meta 1

2.1.4.1.1 Hygienic handrub for non-professional users – 24 months

Product Type	Product type 1 - Human hygiene
Where relevant, an exact description of the authorised use	Hygienic handrub. Ready-to-use disinfectant for hands with a bactericidal, yeasticidal and virucidal (only against enveloped viruses) efficacy in domestic area.
Target organisms	Bacteria, yeasts and enveloped viruses
Field of use	Indoor, outdoor
Application methods	Manual application: spreading and foam application Place 3 ml on clean hands and wrists. Rub for at least 30 seconds. Do not rinse.
Application rates and frequency	The application rate 3 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

2.1.4.1.2 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

Shelf-life: Products can be stored at room temperature up to 24 months. Conditions: Protect from cold and heat.

2.1.4.2 Meta 2

2.1.4.2.1 Hygienic handrub for professional and non-professional users – 30 months

Product Type	Product type 1 - Human hygiene
Where relevant, an exact description of the authorised use	Hygienic handrub. Ready-to-use disinfectant for hands with a bactericidal, yeasticidal and virucidal (only against enveloped viruses) efficacy in medical, institutional, industrial and domestic area.
Target organisms	Bacteria, yeasts and enveloped viruses
Field of use	Indoor, outdoor
Application methods	Manual application: spreading and foam application Place 3 ml on clean hands and wrists. Rub for at least 30 seconds. Do not rinse.
Application rates and frequency	The application rate 3 ml. Frequency: apply once, repeat if renewed hand disinfection is needed.
Categories of users	Industrial, professional, 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

Shelf-life: Products can be stored at room temperature up to 30 months. Conditions: Protect from cold and heat.

2.1.4.3 Meta 3

2.1.4.3.1 Hygienic handrub for professional and non-professional users – 24 months

Product Type	Product type 1 - Human hygiene
Where relevant, an exact description of the authorised use	Hygienic handrub. Ready-to-use disinfectant for hands with a bactericidal, yeasticidal and virucidal (only against enveloped viruses) efficacy in medical, institutional, industrial and domestic area.
Target organisms	Bacteria, yeasts and enveloped viruses
Field of use	Indoor, outdoor
Application methods	Manual application: spreading and foam application Place 3 ml on clean hands and wrists. Rub for at least 30 seconds. Do not rinse.
Application rates and frequency	The application rate 3 ml. Frequency: apply once, repeat if renewed hand disinfection is needed.
Categories of users	Industrial, professional, non-professional
Pack sizes and packaging material	Section 2.1.7.

2.1.4.3.2 Use-specific instructions for use

Section 2.1.5

2.1.4.3.3 Use-specific risk mitigation measures

Section 2.1.5

2.1.4.3.4 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

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

Section 2.1.5

2.1.4.3.6 Where specific to the use, the 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: Protect from cold and heat.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Place 3 ml on clean hands and wrists. Rub for at least 30 seconds. Do not rinse. Apply once, repeat if renewed hand disinfection is needed.

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

Section 2.1.4

2.1.6 Other information

Professional and industrial users – medical, institutional and industrial area. Not surgical handrub. Non-professional users – domestic area.

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	0.01-5L	Plastic: PET, PE, PP	Cap, Dispensing Cap	Professional Non-professional	Yes
Drum	10-210L	Plastic: HDPE	Cap	Professional Industrial	Yes
Pouches	0.01-5L	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*					

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data was provided for the active substance *Lactic acid* or biocidal product family.

2.2 Assessment of the biocidal product family

2.2.1 Intended use

Hygienic handrub for non-professional and professional users

Product Type	Product Type 1 - Human hygiene
Where relevant, an exact description of the authorised use	Hygienic handrub. Ready-to-use disinfectant for hands with a bactericidal, yeasticidal and virucidal (only against enveloped viruses) 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. Virus: - *Vacciniavirus*, common name: enveloped virus.
Field of use	Indoor, outdoor
Application method(s)	Manual application: spreading and foam application General description of the method: Place 3 ml on clean hands and wrists. Rub for at least 30 seconds. Do not rinse.
Application rate	Apply once, repeat if renewed hand disinfection is needed.
Categories of users	Industrial, professional, non-professional

2.2.2 Physico-chemical properties and storage stability

SALVESAFE C is a family of water-based ready for use formulations containing 1.75% w/w *Lactic acid*. The physico-chemical data is shown in the below following Table 2.2.2.

Table 2.2.2. A summary of the physical and chemical properties of the biocidal product family SALVESAFE C

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 C with 1.75% w/w *Lactic acid*	Liquid	[redacted]
Colour at 20 °C and 101.3 kPa	Visual	Biocidal product family SALVESAFE C with 1.75% w/w *Lactic acid*	Colorless	[redacted]

[2] Not surgical handrub

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
				[redacted]
pH at 20 °C	CIPAC MT 75.3	Biocidal product family SALVESAFE C with 1.75% w/w Lactic acid	2.75-2.93 before storage 2.75-3.02 after accelerated storage	[redacted]
Relative density / bulk density at 20 °C	EC Method A.3	Biocidal product family SALVESAFE C with 1.75% w/w Lactic acid	1.005-1.007 before and after storage	[redacted]
Viscosity at 20 °C	OECD 114	Biocidal product family SALVESAFE C with 1.75% w/w Lactic acid	< 50 mPa*s before and after storage	[redacted]
Storage stability test – **accelerated storage**	Storage for 8 weeks at 40°C±1°C and 54°C±2°C during 14 days (CIPAC MT46.3)	*Lactic acid* content at the start 1.71-1.77% w/w and at the end 1.70-1.82% w/w. Tested concentrations and it's changes are within allowed tolerance limit of the declared nominal content of active substance (1.75% w/w). No variations in physical state, density and viscosity. pH values at the start and at the end of studies are indicated above.		[redacted]
Storage stability test – **long term storage at ambient temperature**	Storage for **24 months** at 23±4°C in PET bottle_HDPE pump head and HDPE bottle_HDPE cap	*SALVESAFE C0_C, SALVESAFE C16_C and SALVESAFE C3_GPPRO* *Lactic acid* content at the start 1.73-1.78% w/w and 1.77-1.87% w/w after 24 months. Tested concentrations are within allowed tolerance limit and changes below than 10%. pH values at the start 2.75-2.93 and at the end 2.80-2.99. No variations in physical state, density and viscosity. For product SALVESAFE C18_GPPRO the study is ongoing. However, considering [redacted] the deviations are not expected.		[redacted]

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
	Storage for **30 months** at 23±4°C in PET bottle_HDPE pump head and HDPE bottle_HDPE cap	Salvesafe C0_GPPRO, SALVESAFE C8_GPPRO, SALVESAFE C9_GPPRO, SALVESAFE C12_GPPRO, SALVESAFE C16_GPPRO and SALVESAFE C17_GPPRO Lactic acid content at the start 1.73-1.78% w/w and 1.75-1.88% w/w after 30 months. Tested concentrations are within allowed tolerance limit and changes below than 10%. pH values at the start 2.78-2.93 and at the end 2.85-2.94. No variations in physical state, density and viscosity.		[redacted]
Storage stability test – **low temperature stability test for liquids**	Not required: label mentions "Protect from cold".			
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Covered by data on long term storage stability test in original packaging.			
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 are 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	PET and HDPE is resistant to active substance (One from the resources https://www.calpaclab.com/chemical-compatibility-charts/). In additional, this point is covered by long term storage studies.			
Wettability	Not applicable since the biocidal products are liquid.			
Suspensibility, spontaneity and dispersion stability	Not applicable since the biocidal products are liquid.			
Wet sieve analysis and dry sieve test	Not applicable since the biocidal products are liquid.			
Emulsifiability, re-emulsifiability	Not applicable since the biocidal products are liquid.			

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
and emulsion stability				
Particle size distribution, content of dust/fines, attrition, friability	All products of the family are ready to use liquids. The products are not used in spray applications. The risk assessment is not requested under the simplified procedure. The MMAD is not relevant to demonstrate efficacy.			
Persistent foaming	Not applicable since the biocidal products are liquid.			
Flowability/Pourability/Dustability	Not applicable since the biocidal products are liquid.			
Burning rate — smoke generators	Not applicable since the biocidal products are liquid.			
Burning completeness — smoke generators	Not applicable since the biocidal products are liquid.			
Composition of smoke — smoke generators	Not applicable since the biocidal products are liquid.			
Physical compatibility	Not relevant. The products in this family are not intended to be used in conjunction with any other biocidal products.			
Chemical compatibility	Not relevant. The products in this family are not intended to be used in conjunction with any other biocidal products.			
Degree of dissolution and dilution stability	Not applicable since the biocidal products are ready to use liquid.			
Surface tension	Not conducted. None of the products of this biocidal product family contain aliphatic, aromatic or alicyclic hydrocarbons in a total concentration equal to or greater than 10%. A viscosity values show that the products do not need to be classified with respect to aspiration hazard.			

Conclusion on the physical, chemical and technical properties of the product
Latvian CA accepts that physico-chemical properties is without the risk envelope. Biocidal products SALVESAFE C0_C, SALVESAFE C16_C, SALVESAFE C3_GPPRO and SALVESAFE C18_GPPRO are stable for 24 months at ambient temperature/ Biocidal products Salvesafe C0_GPPRO, SALVESAFE C8_GPPRO, SALVESAFE C9_GPPRO, SALVESAFE C12_GPPRO, SALVESAFE C16_GPPRO and SALVESAFE C17_GPPRO is stable for 30 months at ambient temperature. The condition on storage "Protect from cold and heat" should be indicated on the label.

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.	-

Property	Guideline and Method	Results	Reference
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, products are a liquids	-
Flammable liquids	-	Content of water [redacted] The flashpoints of the main constituents are [redacted]. Only [redacted] perfumes classified as [redacted], but present at relatively low concentration [redacted] Therefore flashpoint of the mixture is expected to be [redacted].	-
Flammable solids	-	Not applicable, products are a liquids	-
Self-reactive substances and mixtures	-	Waiver: the products contain [redacted] water and none of the components is classified as self-reactive. No chemical groups present in the components associated with explosive or self-reactive properties, such as indicated in the Appendix 6 of the UN RTDG, Manual of Tests and Criteria.	-
Pyrophoric liquids	-	None of the components in the formulation are pyrophoric. The liquid is stable at ambient temperature for prolonged of time.	-
Pyrophoric solids	-	Products is ready-to-use liquid formulation.	-
Self-heating substances and mixtures	-	Waiver: According to CLP criteria, the surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore, liquids are not classified as self-heating. Furthermore, the products contains [redacted] water and none of the components is classified as self-heating. Not expected that the product would be a self-heating mixture. This is also confirmed by the stability testing.	-
Substances and mixtures which in contact with water emit flammable gases	-	Not applicable, products are stable aqueous solutions.	-

Property	Guideline and Method	Results	Reference
Oxidising liquids	-	No components with oxidizing properties in the products.	-
Oxidising solids	-	Not applicable, products are a liquids.	-
Organic peroxides	-	No components present with bivalent O-O structure present	-
Corrosive to metals	UN manual of tests and criteria Part III, 37.4 (test C.1) [redacted]	Not classified as corrosive to metals. A representative product [redacted] was tested on metal corrosion classification. The product shows a negative result for corrosion to metal. The weight loss after 7 days of testing: Aluminium: max 0.4% Steel: max 2.0% The weight loss is below the threshold of 13.5%. No localized corrosion was found on all samples except the steel sample which was immersed partially in the liquid. Measurements of the depth of localized attack: 95 µm. The deepest intrusion measures less than 120 µm. [redacted]	[redacted]
Auto-ignition temperatures of products (liquids and gases)	-	The products are known to be stable at room temperature and do not ignite spontaneously. The content of water is [redacted] therefore auto-ignition is not expected.	-
Relative self-ignition temperature for solids	-	Not applicable, products are a liquids.	-
Dust explosion hazard	-	Not applicable, products are a liquids.	-

[3] The composition of test item is presented in confidential annex to PAR.

Conclusion on the physical hazards and respective characteristics of the product
The products are not classified with regard to physical hazards according to the CLP Regulation 1272/2008.

2.2.4 Methods for detection and identification

Conclusion on the methods for detection and identification of the product
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 C*. Latvian CA accepts this approach, based on 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. Biocidal product family *SALVESAFE C* does not contain substances of concerns.

2.2.5 Efficacy against target organisms

Information on effectiveness against target organisms submitted for the biocidal products within family *SALVESAFE C* is evaluated and the results are summarised in Section 3.4 of confidential Annex I.

The biocidal product family *SALVESAFE C* is developed based on *Lactic acid* as an active substance which provides efficacy of the biocidal products.

The efficacy studies on bactericidal, yeasticidal and virucidal (only against enveloped viruses) claim had been performed for biocidal product [redacted] with 1.75% w/w *Lactic acid* concentration.

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. For supporting of virucidal claim against only enveloped viruses the modified *Vacciniavirus* Ankara from the Institute of Animal Hygiene and Veterinary Public Health of the University Leipzig was used for testing.

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 (temperature, soiling, contact time, concentrations, etc.) to support label claim for family *SALVESAFE C*. The following Standards were used for medical area according to EN 14885, Section 4.3:

- EN 1500:2013 – Chemical disinfectants and antiseptics – Hygienic handrub – Test method and requirements (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).
- EN 14476:2013 – Quantitative suspension test for the evaluation of virucidal activity in the medical area (phase 2, step 1).

The following Standards were used for domestic, institutional and industrial area according to EN 14885, Section 4.5:

- EN 1650:2008 – Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (phase 2, step 1);
- EN 1276:2010 - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (phase 2, step 1).

For intended use efficacy against reference target organisms has been successfully demonstrated for biocidal product family *SALVESAFE C*. Full details of the test conditions and test results are provided.

2.2.5.1 Function and field of use

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

Biocidal product family *SALVESAFE C* is claimed as hygienic handrub with a bactericidal, yeastidical and virucidal action only against enveloped viruses. The effectiveness is provided by Laboratory efficacy test reports according to European standards.

2.2.5.2 Effects on target organisms, including unacceptable suffering

The results of the efficacy studies are summarized in Section 3.4 of confidential Annex I, as well as, in below following Table under the point 2.2.5.4 within this Section.

The efficacy studies had been performed for representative biocidal product [redacted]

Medical area:

To demonstrate the bactericidal activity in medical area, 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 97%, 80%, 50%, 10% and 1% at clean conditions (0.3g/l albumin) and temperature 20 ± 1°C (Table 3.4.1 in Section 3.4 of confidential Annex I).

Tested concentrations (≥ 50%) of the product possess bactericidal efficacy against *Staphylococcus aureus ATCC 6538* and *Enterococcus hirae ATCC 10541*. The bactericidal infectivity reduction factor overpass > 5 log (required ≥ 5).

Tested concentrations (≥ 10%) of the product possess bactericidal efficacy against *Pseudomonas aeruginosa ATCC 15442* and *Escherichia coli K12 NCTC 10538*. The bactericidal infectivity reduction factor overpass > 5 log (required ≥ 5).

Therefore, the biocidal product with 1.75% w/w concentration of Lactic acid within family SALVESAFE C is a disinfectant with a bactericidal activity under defined test conditions and exposure 30 sec according to claimed Standard and intended use.

To demonstrate the yeasticidal activity in medical area, 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 97%, 80%, 50% and 10% at clean conditions (0.3g/l albumin) and temperature 20 ± 1°C (Table 3.4.2 in Section 3.4 of confidential Annex I).

Tested concentrations (≥ 50%) of the product possess yeasticidal efficacy. The yeasticidal infectivity reduction factor overpass > 4 log (required ≥ 4).

Therefore, the biocidal product with 1.75% w/w concentration of Lactic acid within family SALVESAFE C is a disinfectant with a yeasticidal activity under defined test conditions and exposure 30 sec according to claimed Standard and intended use.

To demonstrate the virucidal activity only against enveloped viruses in medical area, quantitative suspension test according to the **EN 14476:2013** against enveloped viruses (*Modified Vacciniavirus Ankara*) has been performed.

Biocidal product activity has been evaluated at a 30, 45, 60 and 90 sec contact time with desired product concentrations of 97%, 80% and 20%, at the temperature 20 ± 1°C and clean conditions (Table 3.4.3 in Section 3.4 of confidential Annex I).

Biocidal product was tested at 0.3g/l albumin (clean conditions for handrub). According to Clauses 5.2.2.8.4, 5.5.2 and 5.5.3 of the EN 14476 the concentration of interfering substance prior dilution is 0.3 g/100 ml for 20% and 80% product concentrations and 1.5 g/100 ml for 97% product concentration (ready-to-use).

Tested concentrations (80% and 20%) of the product possess virucidal efficacy against only enveloped viruses. The virucidal infectivity reduction factor overpass ≥ 4 log (required ≥ 4) at 45 sec contact time.

Tested concentration (ready to use, 97%) of the product possess virucidal efficacy against only enveloped viruses. The virucidal infectivity reduction factor overpass ≥ 4 log (required ≥ 4) at 30 sec contact time.

Therefore, the biocidal product with 1.75% w/w concentration of Lactic acid within family SALVESAFE C is a disinfectant with a virucidal activity against only enveloped viruses under defined test conditions and exposure 30 sec according to claimed Standard and intended use.

Domestic, institutional and industrial area:

To demonstrate the bactericidal activity in domestic, institutional and industrial area, additional quantitative suspension test according to the **EN 1276:2010** (method dilution-neutralization) against four reference strains: *Pseudomonas aeruginosa ATCC 15442, Enterococcus hirae ATCC 10541, Staphylococcus aureus ATCC 6538* and *Escherichia coli ATCC 10536,* has been performed.

Biocidal product activity against bacteria has been evaluated at a 30 sec contact time with desired product concentrations of 80%, 50%, 10% and 1% at clean conditions (0.3g/l albumin) and temperature 20 ± 1°C (Table 3.4.4. in Section 3.4 of confidential Annex I).

Tested concentrations (≥ 10%) of the product possess bactericidal efficacy. The bactericidal infectivity reduction factor overpass > 5 log (required ≥ 5).

Therefore, the biocidal product with 1.75% w/w concentration of Lactic acid within family SALVESAFE C is a disinfectant with a bactericidal activity under defined test conditions and exposure 30 sec according to claimed Standard and intended use.

To demonstrate the yeasticidal activity in domestic, institutional and industrial area, quantitative suspension test according to the **EN 1650:2008** (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 80%, 50% and 0.1% at clean conditions (0.3g/l albumin) and temperature 20 ± 1°C (Table 3.4.5 in Section 3.4 of confidential Annex I).

Tested concentrations (≥ 50%) of the product possess yeasticidal efficacy. The yeasticidal infectivity reduction factor overpass > 4 log (required ≥ 4).

Therefore, the biocidal product with 1.75% w/w concentration of Lactic acid within family SALVESAFE C is a disinfectant with a yeasticidal activity under defined test conditions and exposure 30 sec according to claimed Standard and intended use.

Medical, domestic, institutional and industrial area (practical conditions):

Simulation of practical conditions to establish whether the biocidal product reduces the release of transient microbial flora on hands was performed according to **EN 1500:2013** (method dilution-neutralization), phase 2, step 2; Hygienic handrub.

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

Preparation to procedure	soft soap from linseed oil
Reference procedure	2 x 30 sec contact time, 2 x 3 ml per person, 60% propan-2-ol, 20 ± 1 °C

Procedure with the tested product	30 sec contact time, 3 ml per person, 20 ± 1 °C

All acceptance criteria (EN 1500, Clause 5.7.1.) were met:

1. More than 18 volunteers (20 in the test);
2. The overall means of the lg prevalues were above 5.00;
3. Not more than 3 individual lg reductions of less than 3.00 were observed;
4. The absolute difference of mean differences were less than 2.00;
5. All weighted mean counts between 5 and 15 (Table 3.4.6 in Section 3.4 of confidential Annex I).

Hodges-Lehmann upper one-sided 97.5% confidence limit for the difference in lg R between reference product and tested product is less (0.41) than the inferiority margin (0.6). The results showed that at application volume of 3 ml/person of undiluted tested product for 30 sec is non-inferior to propan-2-ol 60%.

Therefore, the product with Lactic acid concentration 1.75% w/w, used for hand rubbing for 30 seconds, under a volume of 3 ml has an biocidal activity according to claimed Standard and intended use. The biocidal product family SALVESAFE C can be used as hygienic handrub.

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 *SALVESAFE C* is inhibiting of cells growth and biomass producing and finally cells are destroyed.

The results of the efficacy tests conclusively demonstrate that the biocidal products with the concentration of *Lactic acid* 1.75% w/w for a 30 sec contact time reached a sufficient effectiveness and passed the target organisms (bacteria, yeast and enveloped viruses) reduction factor. Biocidal products with the concentration of *Lactic acid* 1.75% w/w are achieved the claimed effect proposed by the Applicant for intended use as disinfectants for hands – hygienic handrub.

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 organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Bactericide	Hygienic handrub	Pseudomonas aeruginosa ATCC 15442, Enterococcus hirae ATCC 10541, Staphylococcus aureus ATCC 6538 Escherichia coli K12 NCTC 10538	EN 13727:2013; (phase 2, step 1) Test method: dilution-neutralization /Quantitative suspension test	Tested product concentrations: 97%, 80%, 50%, 10%; contact times 30 seconds; clean conditions with interfering substance: 0.3g/l albumin; test temperature 20 ± 1°C	Tested product demonstrated the bactericidal activity at concentrations of ≥ 50% in defined conditions (pass R > 5 log)	
Yeasticide	Hygienic handrub	Candida albicans ATTC 10231	EN 13624:2013; (phase 2, step 1) Test method: dilution-neutralization /Quantitative suspension test	Tested product concentrations: 97%, 80%, 50%, 10%; contact times 30 seconds; clean conditions with interfering substance: 0.3g/l albumin; test temperature 20± 1°C	Tested product demonstrated the yeasticidal activity at concentrations of ≥ 50% in defined conditions (pass R > 4 log)	
Virucide	Hygienic handrub	Modified Vacciniavirus Ankara	EN 14476:2013; phase 2, step 1; Quantitative suspension test	Tested product concentrations: 97%, 80%, 20%; contact times 30, 45, 60, 90 seconds; clean conditions with interfering substance: 1.5g/l and 0.3g/l albumin; test temperature 20 ± 1°C	Tested product demonstrated the virucidal activity against only enveloped viruses at concentrations of ≥ 97% in defined conditions (pass R ≥ 4 log)	
Bactericide	Hygienic handrub	Staphylococcus aureus ATCC 6538 Echerichia coli ATCC 10536 Pseudomonas aeruginosa ATCC 15442 Enterococcus hirae ATCC 10541	EN 1276:2010; (phase 2, step 1); Method: dilution-neutralization / Quantative suspension test	Tested product concentrations: 80%, 50%, 10%, 1%; contact times 30 seconds; clean conditions with interfering substance: 0.3g/l albumin; test temperature 20 ± 1°C	Tested product demonstrated the bactericidal activity at concentrations of ≥ 10% in defined conditions (pass R > 5 log)	

Function	Field of use	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Yeasticide	Hygienic handrub	Candida albicans ATTC 10231	EN 1650:2008; phase 2, step 1; Method: dilution-neutralization / Quantitative suspension test	Tested product concentrations: 80%, 50%, 0.1%; contact times 30 seconds; clean conditions with interfering substance: 0.3g/l albumin; test temperature 20 ± 1°C	Tested product demonstrated the bactericidal activity at concentrations of ≥ 50% in defined conditions (pass R > 4 log)	
Bactericide	Hygienic handrub	Escherichia coli K12 NCTC 10538	EN 1500:2013 (phase 2, step 2); method dilution-neutralization	Tested handrub: 30 sec contact time, 3 ml per person, 20 ± 1 °C. Reference handrub: 60% propan-2-ol: 2 x 30 sec contact time; 2 x 3 ml per person	The results showed that at application volume of 3 ml/person of undiluted tested product for 30 s the product is non-inferior to propan-2-ol 60%	

Conclusion on the efficacy of the product
Tested biocidal product family *SALVESAFE C* meets the bactericidal, yeasticidal and virucidal activity against only enveloped viruses under the specified test conditions according to appropriate EN Standard Method. Biocidal effectiveness has been demonstrated with a sufficiently high coefficients of reduction factor (log R). Biocidal product family *SALVESAFE C* is a group of products with one active substance at one concentration, similar use, [redacted]. The efficacy studies had been performed for biocidal product with main content of active substance and co-formulants [redacted]. The tested [redacted] covers all members within biocidal product family *SALVESAFE C.* [redacted] The results of the efficacy tests conclusively demonstrate that the biocidal products with *Lactic acid* concentration 1.75% w/w for a 30 sec contact time reached a sufficient effectiveness and passed the target organisms (bacteria, yeast, enveloped viruses) reduction factor.

2.2.5.5 Occurrence of resistance and resistance management

The efficacy of the biocidal product family *SALVESAFE C* has provided due the content of the active substance – *Lactic acid*. The resistance of target organisms to the biocidal product family *SALVESAFE C* actually could mean resistance to the *Lactic acid*. The possibility of the development of the resistance to *Lactic acid* was not evaluated due the fact that mentioned active substance is not included in the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012. The data on target organism's resistance had not been submitted by Applicant. 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

The limiting factors which may influence the efficacy testing procedure process have not been recorded in test reports. The efficacy studies of biocidal product within family *SALVESAFE C* had been performed in Laboratories which have a Good Laboratory Practice (GLP) statement in accordance with Standard procedure and Laboratories which have the certificate according to ISO 17025:2005.

2.2.5.7 Evaluation of the label claims

The biocidal product family *SALVESAFE C* is intended to be used in medical[4], domestic, institutional and industrial area as disinfectants for hands – hygienic handrub.

The evaluation of efficacy demonstrates that the biocidal products within family *SALVESAFE C* meet agreed criteria for reduction of bacteria, yeast and enveloped viruses population in presence of organic soiling.

The 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, yeasticidal and virucidal activity against only enveloped viruses at the contact time 30 sec".

The above mentioned label claim is acceptable to use in Latvia. The Applicant has to agree with concerned Member State for the use of terminology and translation of label claim in each language.

[4] Not surgical handrub

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 (GLP)	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	-	[redacted]

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 [redacted] 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. Study results showed 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 tests under dermatological control: - assessment of cutaneous tolerance of a test item after a 14-days application period on normal and sensitive skin; - study of acute skin compatibility of a test item after single application: 48-hour semi occlusive patch-test on sensitive skin. All of these studies considered the test item non-irritant and showed very good skin compatibility (details in confidential PAR).
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 405 (GLP)	Confidential PAR	0.1mL of product as supplied by the Applicant. Ocular examinations were performed 1, 24, 48 and 72 hours following treatment	All ocular effects slight to moderate 1 hour after treatment and totally reversible within 1-2 days. Test results presented in Section 3.5 of confidential Annex I	-	[redacted]

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The biocidal product family *SALVESAFE C* does not have irritating effects on the eye.
Justification for the value/conclusion	According to CLP regulation Annex I point 3.3.2.7 "Reversible effects on the eye (Category 2)", the substance shall be classified as Irrit. to eyes Cat. 2 if the substance produces at least in 2 of 3 tested animals the following effects: a) corneal opacity ≥ 1 and/or b) iritis ≥ 1, and/or c) conjunctival redness ≥ 2 and/or d) conjunctival oedema (chemosis) ≥ 2 (calculated as the mean scores following grading at 24, 48 and 72

	hours after installation of the test material, and which fully reverses within an observation period of 21 days). The eye irritation test is performed for [redacted]. [redacted](details in confidential PAR). Therefore, Latvian CA is in opinion that tested product is a worst case and covers all biocidal products within family. Eye irritation test for described "dummy" formulation conducted according to OECD guidelines 405. Study results showed mean individual values 0 for corneal opacity, 0 for iritis, 0 – 0.3 for conjunctival redness (only one animal showed conjunctival redness after 24 hours merely, effect was totally reversible within 2 days) and 0 for conjunctival oedema (chemosis). According to CLP regulation no classification criteria are fulfilled. The biocidal product family *SALVESAFE C* shall not be classified as eyes irritant.
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 C* does not have irritating effects on respiratory tract.
Justification for the conclusion	The respiratory tract irritation effects of the biocidal products family *SALVESAFE C* 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 the biocidal product family *SALVESAFE C* 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 C* does not have sensitization effects on skin.
Justification for the value/conclusion	The potential effect on dermal sensitization of the biocidal product family *SALVESAFE C* has not been investigated experimentally. Taking into account the information on classification of the *Lactic acid* and co-formulants, as well as, final concentration of sensitising substances in the final products, Latvian CA considers that the biocidal product family *SALVESAFE C* 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 C* does not have respiratory sensitisation effects.
Justification for the value/conclusion	The respiratory sensitisation effects of the biocidal products family *SALVESAFE C* 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 the biocidal product family *SALVESAFE C* 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 C* contains *Lactic acid* and no substance of concern. Based on the information on the hazards of the *Lactic acid* and co-formulants and their content in biocidal product family, Latvian CA considers, that the biocidal product family *SALVESAFE C* does not require classification for acute toxicity.

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 is not required for the use of the biocidal product family *SALVESAFE C*.

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 C 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 C family.

Safety data sheets have been submitted for active substance and each co-formulant. Based on composition the final products are not classified for environmental hazard according to CLP regulation.

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 C family is acceptable from an environmental perspective.

2.2.8 Measures to protect man, animals and the environment

The biocidal product family *SALVESAFE C* 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:**

Place 3 ml on clean hands and wrists. Rub for at least 30 seconds. Do not rinse. Apply once, repeat if renewed hand disinfection is needed.

2. **Label claim:**

Biocidal efficacy at 20°C: bactericidal, yeasticidal and virucidal activity against only enveloped viruses 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:**

Protect from cold and heat.

Biocidal products SALVESAFE C0_C, SALVESAFE C16_C, SALVESAFE C3_GPPRO and SALVESAFE C18_GPPRO are stable for 24 months at ambient temperature.

Biocidal products Salvesafe C0_GPPRO, SALVESAFE C8_GPPRO, SALVESAFE C9_GPPRO, SALVESAFE C12_GPPRO, SALVESAFE C16_GPPRO and SALVESAFE C17_GPPRO is stable for 30 months at ambient temperature.

List of 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. Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council
4. Simpson BK and *auth*., 2012. Food biochemistry and food processing. John Wiley & Sons, Inc.
5. Dolci P and *auth.,* 2008. Microbial dynamics of Castelmagno PDO, a traditional Italian cheese, with a focus on lactic acid bacteria ecology. International Journal of Food Microbiology, 122, pp. 302-311.
6. Nassos PS and *auth*., 1988. Lactic acid concentration as an indicator of acceptability in refrigerated or freeze-thawed ground beef. Applied and Environmental Microbiology, 54, pp. 822- 823.
7. European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners
8. EMA, 2008. Status of MRL Procedures MRL assessments in the context of Council Regulation (EEC) No 2377/90 http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004956.pdf
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)
10. Theron MM, J.F. Rykers Lues, 2010. Organics Acid and Food preservation, CRC Press.