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 B**

Product types: PT1 (Human hygiene)

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

Case Number in R4BP3: BC-LB024023-71

Evaluating Competent Authority: Latvia

Date: 8/June/2021

Contents

CONCLUSION

The ready-to-use biocidal products within family *SALVESAFE B*, 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 B* is claimed with bactericidal, yeasticidal and virucidal activity only against enveloped viruses in medical[1], institutional and industrial area for 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 B* 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 25 November 2016 until 25 November 2026.

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

1 ASSESSMENT REPORT

1.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier	**Country**
SALVESAFE B	Latvia

2.1.1.1.1 Trade names of the products within the family "SALVESAFE B"

Trade name	**Product type**
SALVESAFE B1	PT1
SALVESAFE B2	PT1

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-0014276-0000 (according to Asset number in R4BP3)		
Authorisation numbers of the biocidal products within family	SALVESAFE B1		EU-0014276-0002
	SALVESAFE B2		EU-0014276-0001
Date of the authorisation	25 November 2016		
Expiry date of the authorisation	25 November 2026		

2.1.1.3 Manufacturer of the products of the family

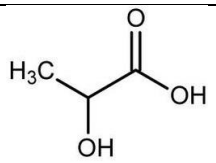
Name of manufacturer	SALVECO S.A.S.
Address of manufacturer	Avenue Pierre Mendès-France SAINT DIE DES VOSGES, F-88100, FRANCE
Location of manufacturing sites	Avenue Pierre Mendès-France SAINT DIE DES VOSGES, F-88100, FRANCE

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	Confidential PAR
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 B* and composition of each biocidal product within family is described in the Section 3.3. of Annex I in the confidential Product Assessment Report (PAR). The biocidal product family *SALVESAFE B* 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 the maximal concentration of the *Lactic acid* and co-formulants in the biocidal product family *SALVESAFE B* and 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	EUH210: Safety data sheet available on request.

2.1.4 Authorised use

2.1.4.1 Use description

Table 1. Use 1 – **Disinfectants for human hygiene (disinfectants for hands – hygienic handrub)**

Product Type	Product type 1
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 and industrial area.
Target organisms (including development stage)	Bacteria, yeasts and only enveloped viruses
Field of use	Indoor, outdoor
Application methods	**Type of method**: 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 rates and frequency	**The application rate** 3 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.

2.1.4.2 Use-specific instructions for use

Section 2.1.5

2.1.4.3 Use-specific risk mitigation measures

Section 2.1.5

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

Section 2.1.5

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

Section 2.1.5

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

Section 2.1.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

Place 3 ml of the product 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: In case of accident or if you feel unwell, seek medical advice immediately. 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

Biocidal product and 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, exposure to direct light.

2.1.6 Other information

Relevant label claim is indicated in Section 2.2.5.7 of PAR.

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	Yes
Drum	10-210L	Plastic: HDPE	Cap	Professional Industrial	Yes
IBC (Intermediate bulk container) *	1000L	Plastic: HDPE	Cap	Industrial	Yes
Pouches	0.05-5L	Plastic: LDPE, LLDPE	Cap pump	Professional	Yes
All used packaging must be secure, closed, tight, strong and durable. Packaging can be refilled only with product foreseen for that purpose. *PET – polyethylene terephthalate; PE – Polyethylene; HDPE* - High-density polyethylene; *LDPE - Low-density polyethylene; LLDPE - Linear low-density polyethylene* **Authorisation holder supplies to customer with agreement on repackaging (according to above mentioned table) for placing on the market.*					

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

Table 1. Disinfectants for human hygiene (disinfectants for hands – hygienic handrub)

Product Type	Product Type 1
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[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: virus.
Field of use	Indoor, outdoor
Application method(s)	**Type of method**: 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 and frequency	**The application rate** 3 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

2.2.2 Physical, chemical and technical properties

Biocidal product family *SALVESAFE B* is a family of water-based ready for use formulations. 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 B with 1.75% w/w Lactic acid	Liquid	Confidential PAR
Colour at 20 °C and 101.3 kPa	Visual	Biocidal product family SALVESAFE B with 1.75% w/w Lactic acid	Colorless (light yellow)	Confidential PAR

[2] Not surgical handrub

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Acidity / alkalinity at 20 °C	CIPAC MT 75.3	Biocidal product family SALVESAFE B with 1.75% w/w Lactic acid	2.00< pH < 3.00	Confidential PAR
Relative density / bulk density at 20 °C	EEC Method A3	Biocidal product family SALVESAFE B with 1.75% w/w Lactic acid	1.000≤density≤ 1.010	Confidential PAR
Viscosity	OECD 114	Biocidal product family SALVESAFE B with 1.75% w/w Lactic acid	<360 mPa·s	Confidential PAR
Storage stability test – **accelerated storage**	Storage for 8 weeks at 40°C±1°C (CIPAC MT46.3)	Biocidal products with 1.69% w/w and 1.71% w/w Lactic acid are used. The storage stability tests are conducted in commercial packaging (PET Bottle with HDPE pump head (foam dispenser)). For the detection and identification of the active substance Lactic acid titration method is used.	Lactic acid content at start 1.69% w/w and 1.71% w/w, at the end 1.71% w/w and 1.72% w/w, respectively. No variations in physical state, colour, density and viscosity.	Confidential PAR
Storage stability test – **long term storage at ambient temperature**	Storage for 24 months at ambient temperature	*SALVESAFE B1*: Initial concentration of Lactic acid was 1.79% w/w. The storage stability tests are conducted in commercial packaging: 1. Bottle / 50 mL / PET / HDPE pump head 2. Bottle /150 mL / LDPE / cap *SALVESAFE B2*: Initial concentration of Lactic acid was 1.78% w/w. The storage stability tests are conducted in commercial packaging: 1. Bottle / 50 mL / PET / HDPE pump head 2. Bottle /150 mL / LDPE / cap	1. Lactic acid content after storage was 1.85% w/w, pH 2.90; 2. Lactic acid content after storage was 1.82% w/w, pH 2.90. 1. Lactic acid content after storage was 1.79% w/w, pH 2.90; 2. Lactic acid content after storage was 1.87% w/w, pH 2.89.	Salveco Test report 2018/053 Salveco Test report 2018/054

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Storage stability test – **low temperature stability test for liquids**	The Applicant provided reports on tests performed for 3 months at 4°C±1°C for all biocidal products within family. No separation observed following storage at mentioned conditions. However, the test does not performed according to CIPAC MT 39.3 at 0±2°C at 7 days. The condition on storage "Avoid cold and frost" should be indicated on the label.			
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 and emulsion stability	Not applicable since the biocidal products are liquid			
Particle size distribution, content of dust/fines, attrition, friability	Not applicable since the biocidal products are liquid.			
Persistent foaming	Not conducted as the biocidal products are water based			
Flowability/Pourability/Dustability	Not conducted as the biocidal products are water based.			
Burning rate — smoke generators	Not conducted as the biocidal products are water based.			
Burning completeness — smoke generators	Not conducted as the biocidal products are water based.			
Composition of smoke — smoke generators	Not conducted as the biocidal products are water based.			
Physical compatibility	Not applicable. The biocidal products are not used together with other substances or mixtures.			
Chemical compatibility	Not applicable. The products are not used together with other products.			
Degree of dissolution and dilution stability	The products are ready-to-use liquids.			
Surface tension	Not conducted as the biocidal products are water based and the Applicant submitted a viscosity value which shows 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 are without the risk envelope. The biocidal product family *SALVESAFE B* is stable for two years at ambient temperature. The condition on storage "Avoid cold and frost" should be indicated on the label.

2.2.3 Physical hazards and respective characteristics

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 B* exhibit any hazardous physico-chemical properties. The biocidal products within family *SALVESAFE B* are water-based ready-to-use liquids, are not flammable and are not expected to have any explosive or oxidising properties. Latvian CA agrees that no classification and labelling for physico-chemical hazards is required for biocidal product family *SALVESAFE B*.

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 B*. 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 B* 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 B* is evaluated and the results are summarised in Section 3.2 of Annex I in confidential PAR.

The biocidal product family *SALVESAFE B* 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 with 1.75% w/w *Lactic acid* concentration and minimal concentration of each co-formulants (reference biocidal product *SALVESAFE B2*).

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 claims for evaluation of bactericidal activity and label claims for family *SALVESAFE B*. 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 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 and reference target organisms, efficacy has been successfully demonstrated for biocidal product family *SALVESAFE B*. 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 B* are ready-to-use solutions for human hygiene in medical, institutional and industrial area.

Biocidal product family *SALVESAFE B* 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 Tables 3.1-3.6 in Section 3.2 of Annex I in confidential PAR, as well as, in below following Table under the point 2.2.5.4 within this Section.

The efficacy studies had been performed for reference biocidal product *SALVESAFE B2* with 1.75% w/w *Lactic acid* concentration and minimal concentration of each co-formulants within family *SALVESAFE B.*

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 3.1 in Section 3.2 of Annex I in confidential PAR).

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 SALVESAFE B2 with 1.75% w/w concentration of Lactic acid within family SALVESAFE B 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 3.2 in Section 3.2 of Annex I in confidential PAR).

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

Therefore, the biocidal product SALVESAFE B2 with 1.75% w/w concentration of Lactic acid within family SALVESAFE B 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 3.3 in Section 3.2 of Annex I in confidential PAR).

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 SALVESAFE B2 with 1.75% w/w concentration of Lactic acid within family SALVESAFE B 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.

Institutional and industrial area:

To demonstrate the bactericidal activity in institutional and industrial area, 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 in Section 3.2 of Annex I in confidential PAR).

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

Therefore, the biocidal product SALVESAFE B2 with 1.75% w/w concentration of Lactic acid within family SALVESAFE B 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 in 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 3.5 in Section 3.2 of Annex I in confidential PAR).

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

Therefore, the biocidal product SALVESAFE B2 with 1.75% w/w concentration of Lactic acid within family SALVESAFE B is a disinfectant with a yeasticidal activity under defined test conditions and exposure 30 sec according to claimed Standard and intended use.

Medical, 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 3.6 in Section 3.2 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 biocidal product SALVESAFE B2 (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 B 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 B* 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 product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Bactericide	Hygienic handrub	SALVESAFE B2	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)	Confidential PAR
Yeasticide	Hygienic handrub	SALVESAFE B2	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)	Confidential PAR
Virucide	Hygienic handrub	SALVESAFE B2	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)	Confidential PAR
Bactericide	Hygienic handrub	SALVESAFE B2	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)	Confidential PAR

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Yeasticide	Hygienic handrub	SALVESAFE B2	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)	Confidential PAR
Bactericide	Hygienic handrub	SALVESAFE B2	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%	Confidential PAR

Conclusion on the efficacy of the product
Tested biocidal product family *SALVESAFE B* 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 B* is a group of products with one active substance at one concentration, similar use, but some differences in the content. The efficacy of full family is demonstrated using approach of worst case testing. The efficacy studies on bactericidal, yeasticidal and virucidal (only against enveloped viruses) claim had been performed for biocidal product with 1.75% w/w *Lactic acid* concentration and minimal concentration of each co-formulants. The tested product covers all members within biocidal product family *SALVESAFE B*. The results of the efficacy tests conclusively demonstrate that the biocidal products with *Lactic acid* concentration 1.75% 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 B* has provided due the content of the active substance – *Lactic acid*. The resistance of target organisms to the biocidal product family *SALVESAFE B* 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 B* had been performed in Laboratories which have a Good Laboratory Practice (GLP) statement in accordance with Standard procedure and 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 B* is intended to be used in medical[3], institutional and industrial area as disinfectants for hands – hygienic handrub.

The evaluation of efficacy demonstrates that the biocidal products within family *SALVESAFE B* 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 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.

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

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not corrosive or irritating to skin.
Justification for the value/conclusion	According to the CLP criteria and additivity approach, classification is met with respect to local effects on the skin (irritation) for the individual products of the BPF and thus the BPF itself. The conclusion is made based on RAC opinion for L(+)-Lactic acid, content of individual components, generic cut-off values specified in CLP Annex I, Table 1.1 and generic concentration limits (GCL) specified in CLP Annex I, Table 3.2.3. The sum of the concentrations/GCL of individual components exceeds a concentration limit 1%. Upon Latvian CA request to support non-classification of the BPF, the Applicant provided study according to the OECD Test Guidance No. 404. The tested formulation contains 3.52% Lactic acid and surfactants at total concentration above the limit within family. As well, the tested formulation contains perfume at the concentration above the limit notified in family. Therefore, the tested formulation can be considered as representative worst case and based on point 1.1.3.5 of CLP Latvian CA is in opinion that tested formulation covers all biocidal products within BPF.

	According to Table 3.2.2 of the CLP, the substances and mixtures shall be classified as Skin Irrit. 2 if mean score of ≥ 2.3 and ≤ 4.0 for erythema/eschar or for oedema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal is observed. 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 the biocidal product with maximal concentration of each co-formulants. 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	-	Confidential PAR

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The biocidal product family *SALVESAFE B* 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 test on biocidal product with the maximal Lactic acid and co-formulants concentration performed according to OECD guidelines 405 showed mean individual values 0 for corneal opacity, 0 for iritis, 0 – 0.3 for conjunctival redness and 0 for conjunctival oedema (chemosis) (Section 3.4 of Annex I in confidential PAR). No classification criteria are fulfilled, the biocidal product family *SALVESAFE B* shall not be classified as eyes irritant.
Classification of the product according to CLP and DSD	Not relevant

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	The biocidal product family *SALVESAFE B* does not have irritating effects on respiratory tract.
Justification for the conclusion	The respiratory tract irritation effects of the biocidal products family *SALVESAFE B* 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 B* does not meet the criteria for classification for respiratory tract irritation.
Classification of the product according to CLP and DSD	Not relevant

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	The biocidal product family *SALVESAFE B* does not have sensitization effects on skin.
Justification for the value/conclusion	The potential effect on dermal sensitization of the biocidal product family *SALVESAFE B* has not been investigated experimentally. Taking into account the information on classification of the *Lactic acid* and co-formulants, Latvian CA considers that the biocidal product family *SALVESAFE B* does not meet the criteria for classification for sensitisation.
Classification of the product according to CLP and DSD	Not relevant

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	The biocidal product family *SALVESAFE B* does not have respiratory sensitisation effects.
Justification for the value/conclusion	The respiratory sensitisation effects of the biocidal products family *SALVESAFE B* 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 B* does not meet the criteria for classification for respiratory sensitisation.
Classification of the product according to CLP and DSD	Not relevant

Acute toxicity

Biocidal product family *SALVESAFE B* contains *Lactic acid* and no substance of concern. Latvian CA considers, that the biocidal product family *SALVESAFE B* does not meet the classification criteria for acute toxicity.

2.2.6.2 Exposure assessment

The Applicant have not provided information regarding biocidal product family *SALVESAFE B* exposure on 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 the biocidal product family *SALVESAFE B* and data requirements for Simplified procedure according to Regulation (EU) 528/2012, Latvian CA considers that detailed exposure assessment is not relevant.

Latvian CA accepts that the personal protective equipment are not required for the use of the biocidal product family *SALVESAFE B*.

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 the biocidal product family *SALVESAFE B* and data requirements for Simplified procedure according to Regulation (EU) 528/2012, Latvian CA considers that detailed risk characterisation for human health is not relevant.

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 the biocidal product family *SALVESAFE B* and data requirements for Simplified procedure according to Regulation (EU) 528/2012, Latvian CA considers that detailed assessment of effects on the environment is not relevant.

However, the Applicant had provided the study on aerobic biodegradability of the biocidal product with the maximal each co-formulant and Lactic acid concentration according OECD

301 B guideline (Salveco Biodegradability Analyses Report RPRI10YBA467) as additional supporting information. The results of the performed test show the more than 60% carbon dioxide generation during 7 days and 100% after 36 days. In accordance with point 4.1.2.9 of Annex I CLP the mixtures are considered rapidly degradable in the environment if carbon dioxide generation is 60% of theoretical maximum during 28 days. Latvian CA accepts the outcome of the biodegradability study and considers that detailed exposure assessment is not required.

2.2.8 Measures to protect man, animals and the environment

The biocidal product family *SALVESAFE B* 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:**

EUH210: Safety data sheet available on request.

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, heat, exposure to direct light.
Shel-life - 24 months.

3 Annex I

3.1. List of studies for the biocidal product family *SALVESAFE B*

3.2. List of References

3.1. List of studies for the biocidal product family

Author(s)	Year	Title	Key study (Y/N)	Data Protection Claimed (Yes/No)	Owner
Confidential PAR	2016	Accelerated Storage Stability Salvesafe B1, Salveco Laboratory Unpublished	Y	Y	Salveco
Confidential PAR	2016	Accelerated Storage Stability Salvesafe B2, Salveco Laboratory Unpublished	Y	Y	Salveco
Hisiger s., Revol B.	2018	Long-Term Storage Stability Salvesafe B1, Salveco Laboratory, Test report No. 2018/053 Unpublished	Y	Y	Salveco
Hisiger s., Revol B.	2018	Long-Term Storage Stability Salvesafe B2, Salveco Laboratory, Test report No. 2018/054 Unpublished	Y	Y	Salveco
Confidential PAR	2016	Chemical analysis, Lactic acid content, Salvesafe Rub Foam T+8, Salvesafe Rub Foam - Icy T+8 Salveco Laboratory Unpublished	Y	Y	Salveco
Confidential PAR	2016	Chemical analysis, Lactic acid content, Salvesafe Rub Foam T0, Salvesafe Rub Foam - Icy T0 Salveco Laboratory Unpublished	Y	Y	Salveco
Confidential PAR	2016	Physico-chemical analysis Salvesafe B1, Salveco Laboratory Unpublished	Y	Y	Salveco
Confidential PAR	2016	Physico-chemical analysis Salvesafe B2, Salveco Laboratory Unpublished	Y	Y	Salveco
Confidential PAR	2011	Evaluation of ultimate aerobic biodegradability in aqueous medium following the OECD 301 B guideline Laboratoire d'Etudes et d'Expertises US Ecotoxicologie ISO / CEI 17025 Unpublished	Y	Y	Salveco
Confidential PAR	2016	Assessment of acute eye irritation, Physher Bio Developpement GLP Unpublished	Y	Y	Salveco
Confidential PAR	2016	Hygienic Handrub (EN1500) Chemila spol s.r.o. ISO/CEI 17025 Unpublished	Y	Y	Salveco
Confidential PAR	2015	Bactericidal and Yeasticidal Efficacy (EN 13727, EN13624) Hygiene Nord GmbH ISO/CEI 17025 Unpublished	Y	Y	Salveco
Confidential PAR	2016	Determination of yeasticidal efficacy (EN 1650) APEX Bio Solutions GLP Unpublished	Y	Y	Salveco
Confidential PAR	2016	Determination of bactericidal efficacy (EN 1276) APEX Bio Solutions	Y	Y	Salveco

Author(s)	Year	Title	Key study (Y/N)	Data Protection Claimed (Yes/No)	Owner
		GLP Unpublished			
Confidential PAR	2016	Efficacy against Modified Vacciniavirus Ankara (EN 14476), Labor Prof. Gisela Enders ISO / CEI 17025 Unpublished	Y	Y	Salveco
Confidential PAR	2007	Acute dermal irritation/corrosion test in the rabbit. Base 34 Version 7.6c M, Study No. 268/07-1698 EVIC France CLP Unpublished	Y	Y	Salveco
Confidential PAR	2018	Study of acute skin compatibility of a test item after single application: 48 hour semi-occlusive patch-test. Mousse Désinfectante Mains Salvesafe Rub V16.0. 1.01PS_48H. IDEA Clinic Unpublished	N	Y	Salveco
Confidential PAR	2016	Assessment of cutaneous tolerance of a test item after a 14 day application period. Salvesafe Rub. 1.02.D_14J IDEA Clinic Unpublished	N	Y	Salveco

3.2. 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.