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 A**

Product types: PT1 (Human hygiene),
PT2 (Disinfectants and algaecides not intended for direct application to humans or animals) and
PT4 (Food and feed area)

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

Case Number in R4BP3: BC-EG005446-55

Evaluating Competent Authority: Latvia

Date: 21/September/2022
Initial 28/October/2014

Contents

1 CONCLUSION

The ready-to-use biocidal products within family "*SALVESAFE A*", 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 range 0.32-1.76% w/w are authorised for the following product types (PT): human hygiene disinfectants (PT 1), disinfectants and algaecides not intended for direct application to humans or animals (PT 2) and food and feed area disinfectants (PT 4).

Biocidal product family „*SALVESAFE A*" is claimed with bactericidal, yeasticidal and virucidal activity against one specific virus[1] in domestic, institutional and industrial area. 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 A"* 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 3rd November 2014 until 2nd November 2024.

A person placing on the market or using the biocidal products included in biocidal product family "*SALVESAFE A*" 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] against only *Influenza virus A/H1N1*

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 A	Latvia

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

Trade name	**Product type**	**Intended Use***
SALVESAFE A21M	PT2, PT4	Use 2 Use 4
SALVESAFE A23M	PT2, PT4	Use 2 Use 4
SALVESAFE A25M	PT2, PT4	Use 2 Use 4
SALVESAFE A27M	PT2	Use 3
SALVESAFE A28M	PT1, PT2, PT4	Use 1 Use 2 Use 4
SALVESAFE A29M	PT1, PT2, PT4	Use 1 Use 2 Use 4
SALVESAFE A30M	PT2, PT4	Use 2 Use 4
SALVESAFE A31M	PT2, PT4	Use 2 Use 4
SALVESAFE A32M	PT2, PT4	Use 2 Use 4
SALVESAFE A33M	PT1	Use 1
SALVESAFE A34M	PT2, PT4	Use 2 Use 4
SALVESAFE A35M	PT1	Use 1
SALVESAFE A36M	PT1	Use 1
SALVESAFE A44M	PT1	Use 1
SALVESAFE A43M	PT2, PT4	Use 2 Use 4
SALVESAFE A22M	PT2, PT4	Use 2 Use 4
SALVESAFE A46M	PT2, PT4	Use 2 Use 4
SALVESAFE A47M	PT2, PT4	Use 2 Use 4

SALVESAFE A48M	PT2, PT4	Use 2 Use 4
SALVESAFE A49M	PT2, PT4	Use 2 Use 4
SALVESAFE A50M	PT2, PT4	Use 2 Use 4
SALVESAFE A51M	PT2, PT4	Use 2 Use 4

* Use 1 – Disinfectants for human hygiene (disinfectants for hands); Use 2 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces); Use 3 – Algaecides; Use 4 – Food and feed area disinfectants (disinfectant for all washable hard surfaces).

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	LV/2014/SP/01 (EU-0006622-0000)		
Authorisation numbers of the biocidal products within family	**Trade name**	**Authorisation numbers in Latvia[2]**	**Authorisation numbers according Asset numbers in R4BP3**
	SALVESAFE A21M	LV/2014/SP/01-1P	EU-0006622-0007
	SALVESAFE A23M	LV/2014/SP/01-2P	EU-0006622-0001
	SALVESAFE A25M	LV/2014/SP/01-4P	EU-0006622-0005
	SALVESAFE A27M	LV/2014/SP/01-7P	EU-0006622-0002
	SALVESAFE A28M	LV/2014/SP/01-8P	EU-0006622-0008
	SALVESAFE A29M	LV/2014/SP/01-9P	EU-0006622-0009
	SALVESAFE A30M	LV/2014/SP/01-10P	EU-0006622-0011
	SALVESAFE A31M	LV/2014/SP/01-11P	EU-0006622-0010
	SALVESAFE A32M	LV/2014/SP/01-12P	EU-0006622-0012
	SALVESAFE A33M	LV/2014/SP/01-13P	EU-0006622-0015
	SALVESAFE A34M	LV/2014/SP/01-14P	EU-0006622-0013
	SALVESAFE A35M	LV/2014/SP/01-15P	EU-0006622-0014
	SALVESAFE A36M	Not applicable	EU-0006622-0016
	SALVESAFE A44M	Not applicable	EU-0006622-0017
	SALVESAFE A43M	Not applicable	EU-0006622-0018
	SALVESAFE A22M	Not applicable	EU-0006622-0019
	SALVESAFE A46M	Not applicable	EU-0006622-0020
	SALVESAFE A47M	Not applicable	EU-0006622-0021
	SALVESAFE A48M	Not applicable	EU-0006622-0022
	SALVESAFE A49M	Not applicable	EU-0006622-0023
	SALVESAFE A50M	Not applicable	EU-0006622-0024
	SALVESAFE A51M	Not applicable	EU-0006622-0025
Date of the authorisation	3rd November 2014		
Expiry date of the authorisation	2nd November 2024		

2.1.1.3 Manufacturer of the products of the family

Name of manufacturer 1	**SALVECO S.A.S.**

2 Authorisation numbers had been assigned before the agreement to use Asset No.

Address of manufacturer	Avenue Pierre Mendès-France SAINT DIE DES VOSGES, F-88100, FRANCE
Location of manufacturing sites	Avenue Pierre Mendès-France SAINT DIE DES VOSGES, F-88100, FRANCE
Name of manufacturer 2	**MULTIFILL BV BULKONTVANGST**
Address of manufacturer	Constructieweg 25A, 3641, SB Mijdrecht, The Netherlands
Location of manufacturing sites	Constructieweg 25A, 3641, SB Mijdrecht, The Netherlands
Name of manufacturer 3	**Diversey Netherlands Production BV**
Address of manufacturer	Rembrandtlaan 414, 7545, ZW Enschede, The Netherlands
Location of manufacturing sites	Rembrandtlaan 414, 7545, ZW Enschede, The Netherlands
Name of manufacturer 4	**Diversey UK Production Ltd**
Address of manufacturer	Cotes Park Industrial Estate, Somercotes, DE55 4PA, Alfreton, United Kingdom
Location of manufacturing sites	Cotes Park Industrial Estate, Somercotes, DE55 4PA, Alfreton, United Kingdom
Name of manufacturer 5	**Diversey Espana Production S.L.U**
Address of manufacturer	Avenida Conde Duque 5, 7 y 9, Poligono Industrial La Postura, 28343, Valdemoro (Madrid), Spain
Location of manufacturing sites	Avenida Conde Duque 5, 7 y 9, Poligono Industrial La Postura, 28343, Valdemoro (Madrid), Spain
Name of manufacturer 6	**Diversey Italy Production Srl**
Address of manufacturer	Strada Statale 235, 26010, Bagnolo Cremasco (CR), Italy
Location of manufacturing sites	Strada Statale 235, 26010, Bagnolo Cremasco (CR), Italy
Name of manufacturer 7	**Diversey Germany Production oHG**
Address of manufacturer	Morschheimer Strasse 12, 67292, Kirchheimbolanden, Germany
Location of manufacturing sites	Morschheimer Strasse 12, 67292, Kirchheimbolanden, Germany
Name of manufacturer 8	**FOREVER PRODUCTS SA**
Address of manufacturer	Rue de la Glacerie 122, 6180, Courcelles, Belgium
Location of manufacturing sites	Rue de la Glacerie 122, 6180, Courcelles, Belgium
Name of manufacturer 9	**Vandeputte**
Address of manufacturer	120 Boulevard Industriel 7700 Mouscron, Belgium
Location of manufacturing sites	120 Boulevard Industriel 7700 Mouscron, Belgium
Name of manufacturer 10	**Cheport spol s.r.o**
Address of manufacturer	Lhotsko 93 76312 Vizovice, Czech Republic
Location of manufacturing sites	Lhotsko 93 76312 Vizovice, Czech Republic
Name of manufacturer 11	**Emmegi Detergents SRL**
Address of manufacturer	Via Merlo Carlo Giuseppe, 3 20122 Milano, Italy
Location of manufacturing sites	Via marconi, 5 25030 Trenzano, Italy
Name of manufacturer 12	**GFL SA**
Address of manufacturer	Via Sorengo 1 6900 Lugano Switzerland

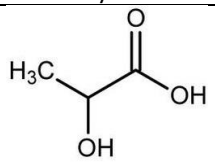
Location of manufacturing sites	Via del Benessere, 4 27010 Siziano, Italy
Name of manufacturer 13	**SUTTER INDUSTRIES SPA**
Address of manufacturer	Localita Leigozze 1, 15060, Borghetto Borbera AL, Italy
Location of manufacturing sites	Localita Leigozze 1, 15060, Borghetto Borbera AL, Italy
Name of manufacturer 14	**BRUNEL - ALTAÏR Group**
Address of manufacturer	ZI A - 132 Rue du Mont de Templemars, 59139, NOYELLES LES SECLIN, France
Location of manufacturing sites	ZI A - 132 Rue du Mont de Templemars, 59139, NOYELLES LES SECLIN, France
Name of manufacturer 15	**Bio Armor**
Address of manufacturer	Zone de la gare, 10/12 route du Pré Chevalier, 22940, Plaintel, France
Location of manufacturing sites	Zone de la gare, 10/12 route du Pré Chevalier, 22940, Plaintel, France

2.1.1.4 Manufacturers of the active substance

Active substance	Lactic acid
Name of manufacturer (1)	PURAC BIOQUIMICA
Address of manufacturer	Gran Vial 19-25, 08160, Montmelo, Spain
Location of manufacturing sites	Gran Vial 19-25, 08160, Montmelo, Spain
Name of manufacturer (2)	JUNGBUNGZLAUER S.A
Address of manufacturer	Z. I Portuaire BP 32, 67390, Marckolsheim, France
Location of manufacturing sites	Z. I Portuaire BP 32, 67390, Marckolsheim, France

2.1.2 Product family composition and formulation

2.1.2.1 Identity of the active substance

Main constituent	
ISO name	Lactic acid
IUPAC or EC name	2-Hydroxypropanoic acid
EC number	200-018-0
CAS number	50-21-5
Index number in Annex VI of CLP	-
Minimum purity / content	88% w/w
Structural formula	

2.1.2.2 Candidate for substitution

Lactic acid does not meet the conditions laid down in Article 10 of Regulation (EU) No. 528/2012, and therefore is not considered as a candidate for substitution.

Lactic acid is listed in Annex I of the Regulation (EU) No 528/2012 under the Category 1 - Substances authorised as food additives according to Regulation (EC) No 1333/2008.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%, w/w)**	
					Min	**Max**
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	0.32	1.76

The composition of the biocidal product family "SALVESAFE A" and composition of each biocidal product within family is described in the Section 3.3. of the confidential Annex I. The biocidal product family "SALVESAFE A" 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

Latvian CA is evaluated two subjects of possible concerns: relating classification of the biocidal product family "SALVESAFE A" and relating to efficacy of the biocidal product family "SALVESAFE A". The evaluation results are described in confidential PAR. The main conclusions are:

- due to the relatively low content of each co-formulant's in the biocidal product family "SALVESAFE A", classification resulting from co-formulant's toxicological and eco-toxicological profile is not triggered and they are not considered as a substances of concern;
- co-formulant's do not possess the biocidal function within family "SALVESAFE A" and should not be considered as active substances.

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 A" 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	Not applicable
Note	Not applicable

2.1.4 Authorised uses

2.1.4.1 Use description

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

Product Type	Product type 1
Where relevant, an exact description of the authorised use	Ready-to-use disinfectant for hands with a bactericidal, yeasticidal and virucidal efficacy against only *Influenza virus A/H1N1* in domestic, institutional and industrial area.
Target organisms (including development stage)	Bacteria, yeasts and virus (only *Influenza virus A/H1N1*)
Field of use	Indoor, outdoor
Application methods	**Type of method**: manual application: spreading, foam application, brush treatment. **General description of the method:** Wet hands and wrists with water. Place 3 mL of product in the hollow of the hand. Rub hands and wrists for at least 30 seconds. Rinse thoroughly with clean water.
Application rates and frequency	**The application rate** 3 mL **Frequency**: Apply once, repeat if renewed hand disinfection is needed.
Categories of users	Professional, non-professional and industrial
Pack sizes and packaging material	Section 2.1, point 2.1.7

Table 2. Use 2 – **Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces)**

Product Type	Product type 2
Where relevant, an exact description of the authorised use	Ready-to-use multi-purpose disinfectant with a bactericidal, yeasticidal and virucidal efficacy against only *Influenza virus A/H1N1* for hard surfaces in domestic, institutional and industrial area.
Target organism (including development stage)	Bacteria, yeasts and virus (only *Influenza virus A/H1N1*)
Field of use	Indoor, outdoor
Application methods	**Type of method**: manual application: spraying, spreading, foam application, brush treatment, dip treatment, immersion. **General description of the method:** Apply the product by fully wetting all surface for 5 minutes. Rub or brush if necessary.
Application rate and frequency	**The application rate** is to fully wet all surface. **Frequency**: Apply once. Repeat the application if necessary.
Categories of users	Professional, non-professional and industrial
Pack sizes and packaging material	Section 2.1, point 2.1.7

Table 3. Use 3 – **Algaecides not intended for direct application to humans or animals**

Product Type	Product type 2
Where relevant, an exact description of the authorised use	Ready-to-use solution with algaecide efficacy used as lichen and algae remover from hard surfaces: roofs, walls, concrete, stone, tiles, sport courts, playgrounds, greenhouses.
Target organism (including development stage)	Algae and lichen
Field of use	Outdoor
Application methods	**Type of method**: manual application: spraying, spreading, foam application, brush treatment, dip treatment, immersion. **General description of the method:** Use in the dry weather. Apply the product by wetting all surface. Allow the product functioning until complete drying. Do not rinse. Brush if necessary 2 days later to remove debris.
Application rate and frequency	**The application rate** is to fully wet all surface. **Frequency**: Apply once and then monitor the situation regularly. Repeat the application if necessary.
Categories of users	Professional, non-professional and industrial
Pack sizes and packaging material	Section 2.1, point 2.1.7

Table 4. Use 4 – **Food and feed area disinfectants (disinfectant for all washable hard surfaces)**

Product Type	Product type 4
Where relevant, an exact description of the authorised use	Ready-to-use multi-purpose disinfectant with a bactericidal, yeasticidal and virucidal efficacy against only *Influenza virus A/H1N1* for hard surfaces in domestic, institutional and industrial area.
Target organism (including development stage)	Bacteria, yeasts and virus (only *Influenza virus A/H1N1*)
Field of use	Indoor, outdoor
Application methods	**Type of method**: manual application, spraying, spreading, foam application, brush treatment, dip treatment, immersion. **General description of the method:** Apply the product by fully wetting all surface for 5 minutes. Rub or brush if necessary. Rinse thoroughly with clean water.
Application rate and frequency	**The application rate** is to fully wet all surface. **Frequency**: Apply once. Repeat the application if necessary.
Categories of users	Professional, non-professional and industrial
Pack sizes and packaging material	Section 2.1, point 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

Use 1: Wet hands and wrists with water. Place 3 mL of product in the hollow of the hand. Rub hands and wrists for at least 30 seconds. Rinse thoroughly with clean water. Use 2: Apply the product by fully wetting all surface for 5 minutes. Rub or brush if necessary. Use 3: Use in the dry weather. Apply the product by wetting all surface. Allow the product functioning until complete drying. Do not rinse. Brush if necessary 2 days later to remove debris. Use 4: Apply the product by fully wetting all surface for 5 minutes. Rub or brush if necessary. Rinse thoroughly with clean water.

2.1.5.2 Risk mitigation measures

Non-professional users: Keep out of reach of children. If medical advice is needed, have product container or label at hand. Professional and industrial users: Safety data sheet is available on request.

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 content/container according to 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 and heat.

2.1.6 Other information

Summary: ready-to-use water based disinfectants in domestic, institutional and industrial area. Bactericidal and yeasticidal claim for PT2 and PT4 is relevant for biocidal products with Lactic acid concentration ≥ 0.32% w/w and ≤ 1.76 % w/w. Bactericidal and yeasticidal claim for PT1 is relevant for biocidal products with Lactic acid concentration ≥ 1.75% w/w and ≤ 1.76 % w/w. Efficacy against *Influenza virus A/H1N1* for biocidal products claimed for PT1 with Lactic acid concentration ≥ 1.75% w/w and ≤ 1.76 % w/w. Efficacy against *Influenza virus A/H1N1* for biocidal products claimed for PT2 and PT4 with Lactic acid concentration ≥ 0.42% w/w and ≤ 1.76 % w/w. Efficacy against algae for biocidal product with Lactic acid concentration ≥ 1.69% w/w and ≤ 1.76 % w/w.

2.1.7 Packaging of the biocidal products

Type of packaging	Volume of the packaging	Use (acc. point 2.1.4)	Material of the packaging	Type and material of closure(s)	Intended user	Compatibility of the product with the proposed packaging materials (Yes/No)
Bag/Sack	0.01-5L	Use 1 Use 2 Use 3 Use 4	Plastic: HDPE, LDPE, PET, PE, PP	Cap	Industrial, Professional, Non-professional	Yes
Bottle	0.01-2L	Use 1 Use 2 Use 3 Use 4	Plastic: HDPE, LDPE, PET, PE, PP	Cap, Dispensing Cap	Industrial, Professional, Non-professional	Yes
Can/Tin	0.1-1L	Use 1 Use 2 Use 3 Use 4	Plastic: HDPE, LDPE, PET, PE, PP	Cap, Dispensing Cap	Industrial, Professional, Non-professional	Yes
Drum	10-210L	Use 1 Use 2 Use 3 Use 4	Plastic: HDPE, LDPE, PET, PE, PP	Cap	Industrial, Professional, Non-professional	Yes
IBC (intermediate bulk container)	1000L	Use 2 Use 3 Use 4	Plastic: HDPE, LDPE, PET, PE, PP	Cap	Industrial	Yes
Jerry can	1-80L	Use 1 Use 2 Use 3 Use 4	Plastic: HDPE, LDPE, PET, PE, PP	Cap, Dispensing cap	Industrial, Professional, Non-professional	Yes
Airspray	0.15-1L	Use 1 Use 2 Use 3 Use 4	Plastic: HDPE, LDPE, PET, PE, PP	Trigger Cap	Industrial, Professional, Non-professional	Yes
Pouches	0.05-5L	Use 1 Use 2 Use 4	Plastic: HDPE, LDPE, PET, PE, PP	Cap pump	Industrial, 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.						

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 uses as applied for by the Applicant

Table 1. Intended use 1 – **Disinfectants for human hygiene (disinfectant for hands)**

Product Type	Product Type 1
Where relevant, an exact description of the authorised use	Ready-to-use disinfectant for hands with a bactericidal, yeasticidal and virucidal efficacy against only *Influenza virus A/H1N1* in domestic, 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; - *Escherichia coli K-12*, common name: bacteria, facultative anaerobic, Gram-negative. Yeast: - *Candida albicans*, common name: yeast. Virus: - *Influenza virus A/H1N1*, common name: virus.
Field of use	Indoor, Outdoor
Application method(s)	Type of method: manual application: spreading, foam application, brush treatment. General description of the method: Wet hands and wrists with water. Place 3 mL of product in the hollow of the hand. Rub hands and wrists for at least 30 seconds. Rinse thoroughly with clean water.
Application rate and frequency	The application rate is 3 mL. Frequency: Apply once, repeat if renewed hand disinfection is needed.
Categories of users	Professional, non-professional and industrial
Pack sizes and packaging material	Section 2.1, point 2.1.7

Table 2. Intended use 2 – **Disinfectants not intended for direct application to humans or animals (disinfectant for all washable hard surfaces)**

Product Type	Product type 2
Where relevant, an exact description of the authorised use	Ready-to-use multi-purpose disinfectant with a bactericidal, yeasticidal and virucidal efficacy against only *Influenza virus A/H1N1* for hard surfaces in domestic, 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; - *Staphylococcus aureus methicillin- resistant*, common name: bacteria, facultative anaerobic, Gram-positive; - *Salmonella typhimurium*, common name: bacteria, facultative anaerobic, Gram-negative; - *Listeria monocytogenes*, common name: bacteria, facultative anaerobic, Gram-positive; - *Acinetobacter baumannii*, common name: bacteria, aerobic, Gram-negative; - *Legionella pneumophila*, common name: bacteria, aerobic, Gram-negative. Yeast: - *Candida albicans*, common name: yeast Virus: - *Influenza virus A/H1N1*, common name: virus.
Field of use	Indoor, outdoor
Application method(s)	Type of method: manual application: spraying, spreading, foam application, brush treatment, dip treatment, immersion. General description of the method: Apply the product by fully wetting all surface for 5 minutes. Rub or brush if necessary.
Application rate and frequency	The application rate is to fully wet all surface. Frequency: Apply once. Repeat the application if necessary.
Categories of users	Professional, non-professional and industrial
Pack sizes and packaging material	Section 2.1, point 2.1.7

Table 3. Intended use 3 – **Algaecides not intended for direct application to humans or animals**

Product Type	Product type 2
Where relevant, an exact description of the authorised use	Ready-to-use solution with algaecide efficacy used as lichen and algae remover from hard surfaces: roofs, walls, concrete, stone, tiles, sport courts, playgrounds, greenhouses.
Target organism (Test organisms)	Algae (laboratory test): - *Pseudokirchneriella subcapitata*, common name: algae, development stage: NC; - *Chlorella vulgari*, common name: algae, development stage: NC. Algae and lichen: (on-field study, the test organisms is not identified).
Field of use	Outdoor
Application method(s)	Type of method: manual application: spraying, spreading, foam application, brush treatment, dip treatment, immersion. General description of the method: Use in the dry weather. Apply the product by wetting all surface. Allow the product functioning until complete drying. Do not rinse. Brush if necessary 2 days later to remove debris.
Application rate and frequency	The application rate is to fully wet all surface. Frequency: Apply once and then monitor the situation regularly. Repeat the application if necessary.
Categories of users	Professional, non-professional and industrial

Pack sizes and packaging material	Section 2.1, point 2.1.7

Table 4. Intended use 4 – **Food and feed area disinfectants (disinfectant for all washable hard surfaces)**

Product Type	Product type 4
Where relevant, an exact description of the authorised use	Ready-to-use multi-purpose disinfectant with a bactericidal, yeasticidal and virucidal efficacy against only *Influenza virus A/H1N1* for hard surfaces in domestic, 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; - *Staphylococcus aureus methicillin- resistant*, common name: bacteria, facultative anaerobic, Gram-positive; - *Salmonella typhimurium*, common name: bacteria, facultative anaerobic, Gram-negative; - *Listeria monocytogenes*, common name: bacteria, facultative anaerobic, Gram-positive; - *Acinetobacter baumannii*, common name: bacteria, aerobic, Gram-negative; - *Legionella pneumophila*, common name: bacteria, aerobic, Gram-negative. Yeast: - *Candida albicans*, common name: yeast. Virus: - *Influenza virus A/H1N1*, common name: virus.
Field of use	Indoor, outdoor
Application method(s)	Type of method: manual application: spraying, spreading, foam application, brush treatment, dip treatment, immersion. General description of the method: Apply the product by fully wetting all surface for 5 minutes. Rub or brush if necessary. Rinse thoroughly with clean water.
Application rate and frequency	The application rate is to fully wet all surface. Frequency: Apply once. Repeat the application if necessary.
Categories of users	Professional, non-professional and industrial
Pack sizes and packaging material	Section 2.1, point 2.1.7

2.2.2 Physical, chemical and technical properties

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

Biocidal product family "SALVESAFE A" is a family of water-based ready for use formulations. The physico-chemical data are shown in the below following Table.

The Applicant submitted accelerated storage stability test for the biocidal product with minimal Lactic acid concentration (0.32% w/w) in the commercial packaging (500 mL, HDPE Bottle). The sample had been storage at 40°C during 4 months. The long-term studies (2 years) at ambient temperature for biocidal product SALVESAFE A21M (Lactic acid concentration 0.32% w/w) and dummy product with maximal content of all ingredients (Lactic acid concentration 1.76% w/w) have been submitted in March 2018. The samples were put in the worst cases commercial packaging.

Latvian CA considers that the outcome of the mentioned studies provides sufficient evidence that biocidal products within family "SALVESAFE A" are stable for 24 months at ambient temperature as no modification of tested products has been observed.

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 A" with 0.32-1.76% w/w Lactic acid	Liquid	Confidential PAR
Colour at 20 °C and 101.3 kPa	Visual	Biocidal products without dyes Biocidal with dyes	Colorless to light yellow blue	Confidential PAR
Acidity / alkalinity at 20 °C	CIPAC MT 75.3	Biocidal products family "SALVESAFE A" with 0.32-1.76% w/w Lactic acid	2.0<pH<3.5	Confidential PAR
Relative density / bulk density at 20 °C	EEC Method A3	Biocidal products family "SALVESAFE A" with 0.32-1.76% w/w Lactic acid	1.000≤density≤ 1.009	Confidential PAR
Storage stability test – **accelerated storage**	Storage for 4 months at 40◦C (simulation an CIPAC MT46.3) For the detection and identification of the active substance Lactic acid HPLC methods is used. Storage for 14 days at 54◦C (simulation an CIPAC MT46.3) For the detection and identification of the active	Initial dossier Product name: Salvesafe A21M The storage stability tests are conducted in commercial packaging (500 mL, HDPE bottle). The product can be considered as worst case-product. MIC application Salvesafe A50M	Lactic acid content at start 0.32% w/w, at the end 0.31% w/w. Lactic acid content $_{start}$ 0.418% w/w Lactic acid content $_{end}$ 0.423% w/w pH_{start} = 2.59 pH_{end} = 2.72 $Viscosity_{start}$ < 50 mPa*S	Confidential PAR

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	substance Lactic acid HPLC methods is used.	SalvesafeA51M	$Viscosity_{end}$ < 50 mPa*S Lactic acid content $_{start}$ 1.77% w/w Lactic acid content $_{end}$ 1.80% w/w pH_{start} = 2.21 pH_{end} = 2.29 $Viscosity_{start}$ < 50 mPa*S $Viscosity_{end}$ < 50 mPa*S	
Storage stability test – **long term storage at ambient temperature**	Storage for 24 months at ambient temperature	Biocidal product Salvesafe A21M is used. The storage stability tests are conducted in commercial packaging: 1. Airspray* bottle / 500 mL / PET / trigger head 2. Airspray* bottle / 750 mL / HDPE / trigger head 3. Bottle / 750 mL / HDPE / cap 4. Pouch /800 mL / LDPE / cap pump *The spray pattern and the nozzle observation are measured for trigger sprayers after 24 months storage Biocidal product with maximal content of all ingredients. Lactic acid concentration 1.76% w/w). The	1. Lactic acid content is 0.33% w/w, pH 2.89 2. Lactic acid content is 0.32% w/w, pH 2.86 3. Lactic acid content is 0.33% w/w, pH 2.89 4. Lactic acid content is 0.31% w/w, pH 2.85 The spray pattern is circular. The nozzle is not blocked. The leak is not observed. The amount of liquid delivered by spraying is without variation.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		storage stability tests are conducted in commercial packaging: 1. Airspray* bottle / 500 mL / PET / trigger head 2. Airspray* bottle / 750 mL / HDPE / trigger head 3. Bottle / 750 mL / HDPE / cap 4. Pouch /800 mL / LDPE / cap pump *The spray pattern and the nozzle observation are measured for trigger sprayers after 24 months storage	1. Lactic acid content is 1.74% w/w, pH 3.62 2. Lactic acid content is 1.74% w/w, pH 3.59 3. Lactic acid content is 1.74% w/w, pH 3.60 4. Lactic acid content is 1.75% w/w, pH 3.58 The spray pattern is circular. The nozzle is not blocked. The leak is not observed. The amount of liquid delivered by spraying is without variation.	
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" must 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			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
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.			
Viscosity	OECD 114	Biocidal products family "SALVESAFE A" with 0.32-1.76% w/w Lactic acid	<300 mPa·s	Confidential PAR

Conclusion on the physical, chemical and technical properties of the product
Latvian CA accepts that physico-chemical properties is without the risk envelope. Based on the accelerated storage data generated by the Applicant the test reports results show that biocidal product family "SALVESAFE A" will be stable for two years at ambient temperature. The condition on storage "Avoid cold and frost" must 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 A" exhibit any hazardous physico-chemical properties. The biocidal products within family "SALVESAFE A" 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 A".

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 and co-formulants 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 A". 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.
   However, the Applicant provided the results on residues of Lactic acid and co-formulants based on calculation method considering the maximal content of Lactic acid and co-formulants as a "worst" case" (SALVECO Product assessment Report, Section 10.5) as additional supporting information. Latvian CA agrees with outcome of the calculation method and at the same time, ADI and exposure level for Lactic acid is not limited.
3. Lactic acid also occurs naturally in the soil. Furthermore, Lactic acid is ubiquitous in the environment from natural and man-made sources making it impossible to determine the exact source. According to it, residues determination in air, water, soil are not considered to be relevant.

2.2.5 Efficacy against target organisms

Information on effectiveness against target organisms submitted for the biocidal products within family "SALVESAFE A" is evaluated and the results are summarised in Section 3.2 of the Annex I of the confidential PAR.

The biocidal product family "SALVESAFE A" is developed based on Lactic acid (concentration range 0.32-1.76% w/w), as an active substance which provides efficacy of the biocidal products.

The efficacy studies on bactericidal and yeasticidal claim for Product type 1 had been performed for biocidal products with 1.75% w/w Lactic acid concentration.

The efficacy studies on bactericidal and yeasticidal claim for Product type 2 and 4 had been performed for biocidal products with minimal concentration of Lactic acid (0.32% w/w).

The efficacy studies on virucidal claim against *Influenza virus A/H1N1* had been performed for biocidal products with 0.42% w/w and 1.75% w/w content of Lactic acid for Product types 2 and 4 and Product type 1, respectively.

The algaecide claim had been supported by studies using biocidal product with 1.69% w/w content of Lactic acid.

The information on biocidal products trade name's indicated in test reports and relevant trade name's within authorised biocidal product family are pointed out in Section 3.5. of the Annex I of the confidential PAR.

Efficacy studies for Product type 1, Product type 2 and Product type 4 had been performed without presence of "potential active" substance. Taking into account above mentioned, as well as, the wide use of "potential active" substance in cosmetic and detergents industry, Latvian CA considers that "potential active" substance should not be considered as "active" substance within authorised biocidal product family "SALVESAFE A". Nevertheless, Applicant submitted the additional test report on "potential active" substance efficacy (Masternak A., Hisiger S., 2014) that shows no effect on target organisms at concentrations including maximum concentration really used within family "SALVESAFE A"[3].

It was shown that the proposed functions for tested disinfectant products within family "SALVESAFE A" are claimed as bactericide and yeasticide, as well as virucide against only *Influenza virus A/H1N1* and algaecide. The tested disinfectant products represent a number of types of efficacy that are supported by results of bactericidal, yeastidical, virucidal and algaecidal tests appropriate to the area of application (PT 1, PT 2, PT 4) and are evaluated as effective against a range of *Gram positive* and *Gram negative bacteria*, including strains with pathogenic characteristic, yeast strain *Candida albicans*, specific *Influenza virus A/H1N1* type and two unicellular green *algae* species.

The choice of reference micro-organisms for testing is relevant, since the use of only one organism per test is limited and may not be fully representative. In current efficacy tests for products family "SALVESAFE A" bacterial strains and yeast strain used as test-organisms were selected from reference target organisms in the Table of Reference Organisms (*CA-May13-Doc.6.2.b – Guidance document on the evaluation of efficacy of disinfectants PT2*) and in accordance with Standard EN 14885 – Chemical disinfectants and antiseptics – application of European Standards for chemical disinfectants and antiseptics.

The *Influenza virus A/H1N1* was selected and used as "model enveloped strain" (specifically the Test Laboratory choice) and as a common worldwide representative virus causing pandemia annually. Whereas it has not been reference organism according to EN 14476, Applicant supports virucidal claim only against this one specific strain and does not cover the general virucidal claim.

The two unicellular green algae species were selected as test-organisms: *Pseudokirchneriella subcapitate* CCAP278/2 and *Chlorella vulgaris* CCAP211/118 both originating from SAMS Research Services Ltd, Scotland. Latvian CA has opinion that these algae strains were selected based on scientific evidence.

The efficacy testing of products within family "SALVESAFE A" is provided by using EN standards methodology. 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 antimicrobial activity and label claims for family "SALVESAFE A". Some of Standard methods (as Intern method, SOP) are accepted as appropriate to its use for the efficacy evaluation of biocidal products against algae. The following Standards were used:

- EN 1275:2006 – Quantitative suspension test for the evaluation of basic fungicidal activity of chemical disinfectants (phase 2, step 1);

[3] Described in confidential PAR

- 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);
- 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 1650:2010 –Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2, step 1);
- EN 14476:2013 – Quantitative suspension test for the evaluation of virucidal activity in the medical area (phase 2, step 1);
- EN 13697:2001 – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (phase 2, step 2).
- EN 1499:2013 – Chemical disinfectants and antiseptics – Hygienic handwash (phase 2, step 2);
- 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 13727:2013 - Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area (phase 2, step 1).

For all intended uses and reference target organisms, efficacy has been successfully demonstrated for products within family "SALVESAFE A". Full details of the test conditions and test results are provided. In addition appropriate observations and recording of changes that affect population of target organisms (for algae species) are reported and methods of recording the effect are given.

There are three main groups of the biocidal products were tested on efficacy:

1) Product type 1 - cleaner and disinfectants for hands;

2) Product type 2 and Product type 4 – hard surface disinfectants and

3) Product type 2 – algaecide.

2.2.5.1 Function and field of use

All biocidal products within family "SALVESAFE A" are ready-to-use solutions. The overall domestic, industrial and institutional area of use is:

- disinfectants for hands (Product type 1);
- disinfectants for all washable hard surfaces not intended for direct application to humans or animals and disinfectants for all washable hard surfaces in food and feed area (Product type 2 and 4) and
- algaecide for outdoor hard surfaces such as roofs, walls, concrete, stone, tiles, sport courts, playgrounds, greenhouses (Product type 2).

Product type 1 indicated for human hygiene as cleaner and disinfectant for hands. Ready-to-use solution used as disinfectant for hands with a bactericidal, yeastidical and virucidal action against only *Influenza virus A/H1N1*. The effectiveness is provided by Laboratory efficacy test reports according to European standards.

Product type 2 is indicated as multi-purpose disinfectant for all washable hard surfaces: houses, nursing homes, kindergartens, industrial premises and technical services, floors, rooms, furniture, toilets, bathrooms, worktops, garbage containers and not intended for direct application to humans or animals and without contact with food. Biocidal products

within family "SALVESAFE A" are manufactured for use as disinfectants with bactericidal, yeasticidal, virucidal action against only *Influenza virus A/H1N1*. The effectiveness is provided by Laboratory efficacy test reports according to European Standards.

Product type 2 is indicated as ready-to-use solution with algaecide efficacy used as lichen and algae remover from hard surfaces: roofs, walls, concrete, stone, tiles, sport courts, playgrounds, greenhouses. Biocidal product within family "SALVESAFE A" is manufactured for use as algaecide. The effectiveness is provided by Laboratory test report and on-field study.

Product type 4 is indicated as multi-purpose disinfectants for all washable hard surfaces: houses, nursing homes, kindergartens, industrial premises and technical services, floors, rooms, furniture, kitchens, worktops. The products can be used on surfaces in contact with food (from production premise/equipment to storage premises/equipment). Biocidal products within family "SALVESAFE A" are manufactured for use as disinfectants with bactericidal, yeasticidal, virucidal action against only *Influenza virus A/H1N1*. The effectiveness is provided by Laboratory efficacy test reports according to European standards.

The harmonisation of relevant biocidal products within family "SALVESAFE A" and product types is indicated in Section 2.1.1.1.1.

2.2.5.2 Effects on target organisms, including unacceptable suffering

Product type 1 - Disinfectants for human hygiene (disinfectants for hands)

The efficacy studies on bactericidal, yeasticidal claim and virucidal claim against only *Influenza virus A/H1N1* for Product type 1 had been performed for biocidal product with 1.75% w/w Lactic acid concentration.

The results of the efficacy studies are summarized in Tables 3.1-3.4 in Section 3.2 of the Annex I of the confidential PAR, as well as, in below following Table 2.1 under the point 2.2.5.4 within this Section.

The information on biocidal products trade name's indicated in test reports and relevant trade name's within authorised biocidal product family are pointed out in Section 3.5. of the Annex I of the confidential PAR.

The biocidal product Salvesafe Soap (relevant to SALVESAFE A28M) represents a biocidal product family "SALVESAFE A" with claimed intended use PT 1 – hands disinfectant.

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

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

Reference procedure	Hand washing for 60 seconds 5 ml soft soap
Procedure with the product tested	Hand washing for 30 seconds 3 ml tested product

A negative difference between reduction factor of reference and tested product indicates that product tested is more effective compared with soft soap. According to the Wilcoxon-Wilcox statistical test at the required probability level of p=0.01 this difference is considered significant.

Therefore, the product Salvesafe Soap that is relevant to SALVESAFE A28M (Lactic acid concentration 1.75% w/w), used for hand washing for 30 seconds, under a volume of 3 ml has an activity according to claimed Standard and intended use.

The biocidal product Salvesafe Soap X10 (relevant to SALVESAFE A28M) represents the biocidal product family "SALVESAFE A" with claimed intended use PT 1 – hands disinfectant. This hands disinfectant was tested in a quantitative suspension test according to the **EN 13727:2013** (method dilution-neutralization) on bactericidal efficacy against four reference strains:

Escherichia coli K12 NCTC10538;
Pseudomonas aeruginosa ATCC 15442;
Enterococcus hirae ATCC 10541 and
Staphylococcus aureus ATCC 6538.

Tested concentrations (≥ 25%) of the product under dirty conditions (BSA 3 g/l + sheep erythrocytes 3ml/l) at 20˚C and exposure time 30 sec possesses bactericidal efficacy. The bactericidal infectivity reduction factor overpass > 5 log (required ≥ 3).

Therefore, the biocidal product Salvesafe Soap X10 that is relevant to biocidal product SALVESAFE A28M with 1.75% w/w concentration of Lactic acid within family "SALVESAFE A" is a disinfectant with a bactericidal activity under defined test conditions and exposure 30 sec according to claimed Standard and intended use.

The biocidal product Salvesafe Soap X10 (relevant to SALVESAFE A28M) represents the biocidal product family "SALVESAFE A" with claimed intended use PT 1 – hands disinfectant. This hands disinfectant was tested in a quantitative suspension test according to the **EN 13624:2013** (method dilution-neutralization) on yeasticidal efficacy against one reference strain:

Candida albicans ATCC 10231.

Tested concentrations (≥ 25%) of the product under dirty conditions (BSA 3 g/l + sheep erythrocytes 3ml/l) at 20˚C and exposure time 30 sec possesses yeasticidal efficacy. The yeasticidal infectivity reduction factor overpass > 4 log (required ≥ 2).

Therefore, the biocidal product Salvesafe Soap X10 that is relevant to biocidal product SALVESAFE A28M with 1.75% w/w concentration of Lactic acid within family "SALVESAFE A" is a disinfectant with a yeasticidal activity under defined test conditions and exposure 30 sec according to claimed Standard and intended use.

The biocidal product Salvesafe Soap (relevant to SALVESAFE A28M) represents the biocidal product family "SALVESAFE A" with claimed intended use PT 1 – hands disinfectant. This hands disinfectant was tested in a quantitative suspension test according to the **EN 1276:2010** (method dilution-neutralization) on bactericidal efficacy against four reference strains:

Escherichia coli ATCC 10536;
Pseudomonas aeruginosa ATCC 15442;
Enterococcus hirae ATCC 10541 and
Staphylococcus aureus ATCC 6538.

Tested concentrations (≥ 80%) of the product under dirty conditions (BSA 3 g/l) at 20°C and exposure time 30 sec possesses bactericidal efficacy. The bactericidal infectivity reduction factor overpass > 5 log (required ≥ 5).

Therefore, the biocidal product Salvesafe Soap that is relevant to biocidal product SALVESAFE A28M with 1.75% w/w concentration of Lactic acid within family "SALVESAFE A" is a disinfectant with a bactericidal activity under defined test conditions and exposure 30 sec according to claimed Standard and intended use.

The biocidal product Salvesafe Soap (relevant to SALVESAFE A28M) represents the biocidal product family "SALVESAFE A" with claimed intended use PT 1 – hands disinfectant. This hands disinfectant was tested in a quantitative suspension test according to the **EN 1650:2013** (method dilution-neutralization) on yeasticidal efficacy against one reference strain:

Candida albicans ATCC 10231.

Tested concentrations (≥ 80%) of the product under dirty conditions (BSA 3 g/l) at 20˚C and exposure time 30 sec possesses yeasticidal efficacy. The yeasticidal infectivity reduction factor overpass > 4 log (required ≥ 4).

Therefore, the biocidal product Salvesafe Soap that is relevant to biocidal product SALVESAFE A28M with 1.75% w/w concentration of Lactic acid within family "SALVESAFE A" is a disinfectant with a yeasticidal activity under defined test conditions and exposure 30 sec according to claimed Standard and intended use.

The biocidal product Salvesafe Soap X10 (relevant to SALVESAFE A28M) represents the product family "SALVESAFE A" with claimed intended use PT 1 – hands disinfectant. The disinfectant was tested in a quantitative suspension test according to the **EN 14476:2013** on virucidal efficacy against "model viruses" *Influenza virus A/H1N1* (Brisbane/59/2007 Novartis Vaccines and Diagnostics GmbH &Co).

The efficacy test was performed under dirty conditions BSA 3 g/l + sheep erythrocytes 3 ml/l as interfering substance, at the product concentration 0.5%, 20%, 40% and 80% at 20°C and exposure time 30 sec. Tested product demonstrated the sufficient virucidal activity against *Influenza virus A/H1N1* at concentration 20% under defined test conditions. The virucidal infectivity reduction factor pass log > 4 (required ≥ 4) at the concentration ≥ 20%.

It is necessary note, that the efficacy is assessed directly in relation to this *Influenza virus A/H1N1* and cannot be extended to all types of viruses (enveloped and non-enveloped).

Therefore, the biocidal product Salvesafe Soap X10 that is relevant to biocidal product SALVESAFE A28M with concentration of Lactic acid 1.75% w/w within family "SALVESAFE A" has a sufficient virucidal activity just only against specific target virus strain Influenza virus A/H1N1 under the defined test conditions and exposure time 30 sec according to Standard and claimed intended use.

Product type 2 and Product type 4 - Disinfectants not intended for direct application to humans or animals and food and feed area disinfectants (Disinfectants for all washable hard surfaces)

The efficacy studies on bactericidal and yeasticidal claim for Product type 2 and 4 had been performed for biocidal products with minimal concentration of Lactic acid (0.32% w/w).

The efficacy studies on virucidal claim against *Influenza virus A/H1N1* had been performed for biocidal product with 0.42% w/w content of Lactic acid.

The results of the efficacy studies are summarized in Tables 3.5-3.8 in Section 3.2 of the Annex I of the confidential PAR, as well as, in below following Table 2.1 under the point 2.2.5.4 within this Section.

The information on biocidal products trade name's indicated in test reports and relevant trade name's within authorised biocidal product family are pointed out in Section 3.5. of the Annex I of the confidential PAR.

Biocidal product Nettoyant désinfectant TS 3% (relevant to SALVESAFE A21M), represents product family "SALVESAFE A" with claimed intended use PT 2 and PT 4 - surface disinfectants.

This disinfectant is tested on bactericidal efficacy in the quantitative suspended test against 4 reference target organisms:

Staphylococcus aureus ATCC 6538;
Pseudomonas aeruginosa ATCC 15442;
Enterococcus hirae ATCC 10541 and
Echerichia coli ATCC 10536.

According to the **EN 1276:2010** standard the product demonstrated a bactericidal activity from the concentration 70% and 80% against the 4 reference strains of bacteria under dirty conditions (BSA 3 g/l) at 20˚C and 5 min of exposure time. The bacterial infectivity reduction factor overpass > 5 log (required ≥ 5).

This disinfectant is tested on yeasticidal efficacy in the quantitative suspended test against one reference target organism:

Candida albicans ATCC 10231.

According to the **EN 1275:2006** standard the product demonstrated a yeasticidal activity from the concentration 70% and 80% against the strain of yeast *Candida albicans* under dirty conditions (BSA 3 g/l) at 20˚C and 5 min of exposure time. The yeasticidal infectivity reduction factor pass > 4 log (required ≥ 4).

The mentioned product is tested on bactericidal and yeasticidal efficacy in the non-porous surface test against following reference target organisms:

Staphylococcus aureus ATCC 6538;
Pseudomonas aeruginosa ATCC 15442;
Enterococcus hirae ATCC 10541;
Echerichia coli ATCC 10536 and

Candida albicans ATCC 10231.

According to the **EN 13697:2001** the product demonstrated a bactericidal activity from the concentration of 80% against the 4 reference strains of bacteria under dirty conditions (BSA 3 g/l) at 20˚C and 5 min of exposure time. The bactericidal infectivity reduction factor pass > 4 log (required ≥ 4). Also this product demonstrated yeasticidal activity from the concentration 80% against the yeast strain under dirty conditions (BSA 3 g/l) at 20˚C and 5 min of exposure time. The yeasticidal infectivity reduction factor pass > 3 log (required ≥ 3).

Therefore, the biocidal product Nettoyant désinfectant TS 3% that is relevant to biocidal product SALVESAFE A21M with minimal concentration of Lactic acid (0.32% w/w) within family "SALVESAFE A" is a disinfectant with a sufficiently high bactericidal and yeasticidal activity against the reference strains and under defined test conditions and exposure time 5 min according to claimed Standards and intended use.

The biocidal product B36 diluted to 1.5% (relevant to SALVESAFE A21M) represents product family "SALVESAFE A" with claimed intended use PT 2 and PT 4 – surface disinfectants.

This disinfectant is tested in the quantitative suspended test on bactericidal efficacy against additional target organisms (origin: Institute Pasteur, line ATCC).

Listeria monocytogenes CIP 100607;
Salmonella enterica serovar typhimurium CIP 58.58;
Methicillin resistant Staphylococcus aureus CIP 103514;
Acinetobacter baumanii CIP 70.34;
Legionella pneumophila CIP 103854.

It should be noted that, in the case of large-scale use of disinfectant, it may be necessary to evaluate the sensitivity of bacterial species causing nosocomial infections. These species often different from the proposed reference species. As in this case the target bacteria selected from other international collections (CIP, Institute Pasteur) is accepted.

According to the **EN 1276:2010** standard, the product demonstrated a bactericidal activity from the concentration 0.9% and 1% against the 4 reference strains of bacteria and concentration 1% against the *Legionella pneumophila* under dirty conditions (BSA 3 g/l) at 20˚C and 5 min of exposure time. The bacterial infectivity reduction factor > 5 log (required ≥ 5).

This disinfectant is tested in the quantitative suspended test on yeasticidal efficacy against one reference target organism:

Candida albicans ATCC 10231.

According to the **EN 1650:2008** standard, the product demonstrated a yeastidical activity from the concentration 1% against the strain of and *Candida albicans* under dirty conditions (BSA 3 g/l) at 20˚C and 5 min of exposure time. The yeasticidal infectivity reduction factor > 4 log (required ≥ 4).

Therefore, the biocidal product B36 diluted to 1.5% that is relevant to biocidal product SALVESAFE A21M with minimal concentration of Lactic acid (0.32% w/w) within family "SALVESAFE A" is a disinfectant with a sufficiently high bactericidal and yeasticidal activity under defined test conditions and exposure time 5 min according Standard and claimed intended use.

The biocidal product Cleaner Disinfectant Spray (relevant to SALVESAFE A30M) represents the product family "SALVESAFE A" with claimed intended use PT 2 and PT 4 – surface disinfectants. This disinfectant was tested in a suspension test according to the DIN **EN 14476:2013** on virucidal efficacy against "model viruses" *Influenza virus A/H1N1* (Brisbane/59/2007 Novartis Vaccines and Diagnostics GmbH&Co.KG).

The efficacy test was performed under dirty conditions (3.0 g/l BSA + 3.0 ml/l erythrocytes as interfering substance), in product concentration of 0.5%, 20%, 40% and 80% at 20˚C and exposure time 5 minutes. The virucidal activity against *Influenza virus A/H1N1* of biocidal product was determined by the difference of the logarithmic titre of the virus control minus the logarithmic titre of the test virus. Tested product demonstrated the sufficient virucidal activity against *Influenza virus A/H1N1* at concentration 20% under defined test conditions. The virucidal infectivity reduction factor pass log > 5 (required ≥ 4).

It is necessary note, that the efficacy is assessed directly in relation to *Influenza virus A/H1N1* and cannot be extended to all types of viruses (enveloped and non-enveloped).

Therefore, the biocidal product Cleaner Disinfectant Spray that is relevant to biocidal product SALVESAFE A30M with concentration of Lactic acid 0.42% w/w within family "SALVESAFE A" is a sufficient biocidal activity just only against specific target virus strain Influenza virus A/H1N1 under the defined test conditions and exposure time 5 min according to Standard and claimed intended use.

Product type 2 - Algaecides not intended for direct application to humans or animals

The algaecide claim had been supported by studies using biocidal product with 1.69% w/w content of Lactic acid.

The results of the efficacy study are summarized in Table 3.9 in Section 3.2 of the Annex I of the confidential PAR, as well as, in below following Table 2.1 under the point 2.2.5.4 within this Section.

The information on biocidal products trade name's indicated in test reports and relevant trade name's within authorised biocidal product family are pointed out in Section 3.5. of the Annex I of the confidential PAR.

The biocidal product Antimoss RTU (or Nettoyant Antimousse Prét-á-l'emploi that is relevant to SALVESAFE A27M) represents family "SALVESAFE A" with claimed intended use PT 2 - algaecide. The biocidal product is tested on algaecide efficacy against two unicellular green algae species: *Pseudokirchneriella subcapitate* CCAP278/2 and *Chlorella vulgaris* CCAP211/118 both from origin SAMS Research Services Ltd, Scotland. The selected test species are accepted.

Due to the absence of specific methodology of EU standard that is not yet introduced, Intern method of algaecide efficiency test is performed. This trial purpose is to measure the impact of the tested product on unicellular green algae growth after 24, 48, 72 hours without changing the medium in static trial and the fluorescence inhibition percentages are calculated in comparison with control assays average. Fluorescence is the parameter used for biomass measurement. The trial conditions, test method, data processing are described. In this type of test, a control treatment without biocide is included. Fluorescence evaluation given in RFU, is measured with fluoremeter Dynex Revelation MFX (excitation: 430 nm; emission 670 nm). The actual tested concentration equals 80% v/v of raw product.

In addition, a visual observation is done, with photography taken, that also is given valuable additional information on the efficacy of the product. According to the visual observation, algae are well developed with darken green color in the control assay and no green color was observed in the test assay with 80% product. Fluorescence analysis demonstrates an algaecide effectiveness on the *Chlorella vulgaris*, with a fluorescence decrease of 95% after 48h compared to the control assay. Fluorescence analysis demonstrate an algaecide effectiveness of the product Antimoss RTU on the *Pseudokirchneriella subcapitate*, with a fluorescence decrease of 98% after 48h compared to the control assay.

Applicant submitted the additional supporting on-field study as illustrative material on efficacy of the biocidal product against moss, algae and lichen. This study indicated that after treatment by spraying of roof infested with moss, downpipe infested with algae and wall infested with lichen, after 8 days the following observations are made: moss has turned yellow and it is no more sticked to the roof surface, algae on downpipe surface have turned black and lichen on wall has turned yellow and it is no more sticked to concrete surface.

Therefore, the biocidal product Antimoss RTU (Nettoyant Antimousse Prét-á-l'emploi), that is relevant to biocidal product SALVESAFE A27M with 1.69% w/w concentration of Lactic

acid within family "SALVESAFE A" is demonstrated an algaecide effectiveness with optimal exposure time 48 h.

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 A" is inhibition of cells grows 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 and yeast) reduction factor, as well as, for a 30 sec contact time reached a sufficient effectiveness and passed the *Influenza virus A/H1N1* reduction factor. Biocidal products with the concentration of Lactic acid ≥1.75% and ≤ 1.76% w/w are achieved the claimed effect proposed by the Applicant for intended use as disinfectants for hands.

The results of the efficacy tests conclusively demonstrate that the biocidal products with the concentration of Lactic acid 0.32% w/w for a 5 min contact time reached a sufficient effectiveness and passed the target organisms (bacteria and yeast) reduction factor, and with the concentration of Lactic acid 0.42% w/w reached a sufficient effectiveness against one viruses (only *Influenza virus A/H1N1*). Biocidal products with the concentration of Lactic acid ≥ 0.32% (0.42% for *Influenza virus A/H1N1)* and ≤ 1.76% w/w are achieved the claimed effect proposed by the Applicant for intended use as disinfectants for all washable hard surfaces not intended for direct application to humans or animals and disinfectants for all washable hard surfaces in food and feed area.

The results of the visual observation conclusively demonstrate that the biocidal product with concentration of Lactic acid ≥ 1.69% and ≤ 1.76% w/w for a 48 h contact time reached a sufficient effectiveness against lichen and algae and achieved the claimed effect proposed by the Applicant for intended use as algaecide for outdoor hard surfaces such as roofs, walls, concrete, stone, tiles, sport courts, playgrounds, greenhouses.

2.2.5.4 Efficacy data

Table 2.1. 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
Product type 1							
Bactericide	Cleaner and disinfectant for hands	Salvesafe Soap	*Escherichia coli K12 NCTC 10538*	EU 1499:2013 (phase 2, step 2); method dilution-neutralization	Reference procedure: Hand washing for 60 seconds 5 ml soft soap; Procedure with the product tested: Hand washing for 30 seconds 3 ml product.	Tested product demonstrated the bactericidal activity (exceeding that of the reference soft soap) in defined test conditions	Confidential PAR
Bactericide	Cleaner and disinfectant for hands	Salvesafe Soap X10	*Escherichia coli K12 NCTC 10538;* *Pseudomonas aeruginosa ATCC 15442;* *Enterococcus hirae ATCC 10541;* *Staphylococcus aureus ATCC 6538*	EN 13727:2013; (phase 2, step 1) Test method: dilution-neutralization; Quantitative suspension test	Tested product concentrations: 50%, 25% , 5%; contact times 30 seconds; dirty conditions with interfering substance: BSA 3 g/l + sheep erythrocytes 3ml/l; test temperature 20^0C ± 1°C	Tested product demonstrated the bactericidal activity at concentrations of ≥ 25% in defined conditions (pass R > 5 log)	Confidential PAR
Yeasticide	Cleaner and disinfectant for hands	Salvesafe Soap X10	*Candida albicans ATCC 10231*	EN 13624:2013; (phase 2, step 1) Test method: dilution-neutralization; Quantitative suspension test	Tested product concentrations: 50%, 25% , 5%; contact times 30 seconds; dirty conditions with interfering substance: BSA 3 g/l + sheep erythrocytes 3ml/l; test temperature 20^0C ± 1°C	Tested product demonstrated the yeasticidal activity in defined conditions (pass R > 4 log)	Confidential PAR
Bactericide	Cleaner and disinfectant for hands	Salvesafe Soap	*Escherichia coli ATCC 10536;* *Pseudomonas aeruginosa ATCC 15442;* *Enterococcus hirae ATCC 10541;* *Staphylococcus aureus ATCC 6538*	EN 1276:2010; (phase 2, step 1) Test method: dilution-neutralization; Quantitative suspension test	Tested product concentrations: 80%, 70% , 10%; contact times 30 seconds; dirty conditions with interfering substance: BSA 3 g/l; test temperature 20^0C ± 1°C	Tested product demonstrated the bactericidal activity at concentrations of ≥ 80% 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	Cleaner and disinfectant for hands	Salvesafe Soap	*Candida albicans ATCC 10231*	EN 1650:2013; (phase 2, step 1) Test method: dilution-neutralization; Quantitative suspension test	Tested product concentrations: 80%, 50% , 25%, 1%; contact times 30 seconds; dirty conditions with interfering substance: BSA 3 g/l; test temperature 20^0C ± 1°C	Tested product demonstrated the yeasticidal activity at concentrations of ≥ 80% in defined conditions (pass R > 4 log)	Confidential PAR
Virucide	Cleaner and disinfectant for hands	Salvesafe Soap X10	*Influenza virus A/H1N1*	EN 14476:2013/FprA1:2015 (phase 2, step 1) Quantitative suspension test	Tested product concentrations of the product: 80%, 40%, 20%, 0.5%; dirty conditions: BSA 3 g/l + sheep erythrocytes 3ml/l; exposure time: 30 seconds; test temperature 20^0C ± 1°C	Tested product demonstrated the virucidal activity at concentrations of ≥ 20% in defined test conditions (pass R > 4 log)	Confidential PAR
Product type 2 and 4							
Bactericide	Surfaces	Nettoyant Désinfectant TS 3%	*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	Dirty conditions: BSA 3 g/l; concentrations of the product: 80 %, 70%, 50%; exposure time: 5 minute; temperature during the assays 20^0C ± 1°C	Tested product demonstrated the bactericidal activity from concentrations 70% and 80% in defined test conditions; pass the reduction criteria R > 5 log	Confidential PAR
Yeasticide	Surfaces	Nettoyant Désinfectant TS 3%	*Candida albicans ATTC 10231*	EN 1275:2006; (phase 2, step 1); Method: dilution-neutralization; Quantitative suspension test	Dirty conditions: BSA 3 g/l; concentrations of the product: 80 %, 70%, 50%; exposure time: 5 minute; temperature during the assays 20^0C ± 1°C	Tested product demonstrated the yeasticidal activity from concentrations 70% and 80% in defined test conditions; pass the reduction criteria R > 4 log.	Confidential PAR

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Bactericide and yeasticide	Surfaces	Nettoyant Desinfectant TS	*Staphylococcus aureus ATCC 6538;* *Echerichia coli ATCC 10536;* *Pseudomonas aeruginosa ATCC 15442;* *Enterococcus hirae ATCC 10541;* *Candida albicans ATTC 10231*	EN 13697:2001; phase 2, step 2; Method: dilution-neutralization; Quantitative non-porous surface test	Dirty conditions: BSA 3 g/l; concentrations of the product: 80 %, 70%, 10%; Exposure time: 5 minute; Temperature during the assays 20^0C ± 1°C	Tested product demonstrated the bactericidal activity from concentration 80% in defined test conditions; pass reduction criteria R > 4 log. Tested product demonstrated the yeasticidal activity from concentration 80% in defined test conditions; pass the reduction criteria R > 3 log.	Confidential PAR
Bactericide	Surfaces	B36 product diluted to 1.5%	*Legionella pneumophila subsp. pneumophila* (CIP103854); *Listeria monocytognenes* (CIP 100607); *Salmonella enterica subsp. enterica serotype typhimurium* (CIP 58.58); *Staphylococcus aureus methicillin resistant* (CIP 103514); *Acinetobacter baumanii* (CIP 70.34)	EN 1276:2010; phase 2, step 1; Method: dilution-neutralization; Quantative suspension test	Dirty conditions: BSA 3 g/l; concentrations of the product: 1%, 0.9 %, 0.1%; exposure time: 5 minutes; temperature during the assays 20^0C ± 1°C	Tested product demonstrated the bactericidal activity from the 1% solution in defined test conditions; pass the reduction criteria 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	Surfaces	B36 product diluted to 1.5%	*Candida albicans ATTC 10231*	EN 1650:2008; phase 2, step 1; Method: dilution-neutralization; Quantitative suspension test	Dirty conditions: BSA 3 g/l; Final concentrations of the product: 1%, 0.75 % and 0,1%; Exposure time: 5 minutes; Temperature during the assays 20^0C ± 1°C	Tested product demonstrated the yeasticidal activity from concentration of 1% at 20^0C; pass reduction criteria R > 4 log.	Confidential PAR
Virucide	Surfaces	SURE™ Cleaner Disinfectant Spray	*Influenza virus A /H1N1*	EN 14476:2013/FprA1:2015; phase 2, step 1; Quantitative suspension test	Dirty conditions: 3.0 g/l BSA+3.0 ml/l erythrocytes; concentrations of the product: 0.5%, 20%, 40% , 80%; exposure time: 5 minutes; temperature during the assays 20^0C ± 1°C	Tested product demonstrated the virucidal activity from concentration 20% under defined test conditions; pass the reduction criteria R > 5 log	Confidential PAR
Product type 2							
Algaecide	Outdoor surfaces	Antimos RTU	*Pseudokirchneriella subcapitate* CCAP278/2 *Chorella vulgaris* CCAP211/118	Intern method of algaecide efficiency evaluation , ISO Test medium composition – Algae Test; Fluorescence inhibition test in static trial	Tested concentration equals 80% (v/v) of raw product; trial time 24-72 h; temperature 21-24 ^{0}C in thermostatic clamber; light: close to daylight (400-700 nm); trial volume 50 ml; aeration non; stirring continuous	Tested product demonstrated the algaecide activity as fluorescence inhibition (If) after 48h exposition in defined test conditions.	Confidential PAR

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Algaecide	Outdoor surfaces	Nettoyant Antimousse Prét-á-l' emploi	*Moss, Algae and Lichen*	On-field study	Tested concentration 100% (v/v) of raw product; observation after 8 days; temperature 22^0C; apply by spraying to wet all the surface. Without rinsing/rain.	Visual: moss has turned yellow and it is no more sticked to the roof surface, algae on downpipe surface have turned black and lichen on wall has turned yellow and it is no more sticked to concrete surface.	Confidential PAR
Additional test on Citric Acid							
Bactericide	Citric acid solution 50% (w/w)		*Staphylococcus aureus ATCC 6538;* *Echerichia coli ATCC 10536;* *Pseudomonas aeruginosa ATCC 15442;* *Enterococcus hirae ATCC 10541*	EN 1276:2010; phase 2, step 1 Test method: dilution-neutralization; Quantitative suspension test	Tested product concentrations: 1.6%, 1% , 0.5%, 0.2%; contact times 5 minutes +/- 10 seconds; dirty conditions with interfering substance: BSA 3 g/l; test temperature 20^0C ± 1 °C	It was demonstrated that Citric acid has no bactericidal activity at concentrations 0.8%, 0.5% , 0.25 %, 0.1% (R < 5 log)	Confidential PAR

Conclusion on the efficacy of the product
Tested biocidal product family "SALVESAFE A" meets the bactericidal, yeasticidal, virucidal against only *Influenza virus A/H1N1* and algaecide activity under the specified test conditions according to appropriate EN Standard Method. Microbiocidal effectiveness has been demonstrated with a sufficiently high coefficients of reduction factor (log R). Product type 1 - The results of the efficacy tests conclusively demonstrate that the biocidal products with Lactic acid concentration ≥ 1.75% and ≤ 1.76% w/w for a 30 sec contact time reached a sufficient effectiveness and passed the target organisms (bacteria, yeast and virus *Influenza virus A/H1N1*) reduction factor. Product type 2 and 4 - The results of the efficacy tests conclusively demonstrate that the biocidal product family "SALVESAFE A" with Lactic acid concentration ≥ 0.32% w/w and ≤ 1.76% w/w for a 5 min contact time reached a sufficient effectiveness and passed the target organisms (bacteria and yeast), as well as, biocidal product family "SALVESAFE A" with Lactic acid concentration ≥ 0.42% w/w and ≤ 1.76% w/w reached a sufficient effectiveness against *Influenza virus A/H1N1.* Product type 2 -The results of the visual observation conclusively demonstrate that the biocidal products with Lactic acid concentration ≥ 1.69% w/w and ≤ 1.76% w/w for a 48 h contact time reached a sufficient effectiveness against lichen and algae for outdoor hard surfaces.

2.2.5.5 Occurrence of resistance and resistance management

The efficacy of the biocidal product family "SALVESAFE A" have provided due the content of the active substance – Lactic acid. The resistance of target organisms to the biocidal product family "SALVESAFE A" 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 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 products within family "SALVESAFE A" had been performed in Laboratories which have a Good Laboratory Practice (GLP) statement in accordance with Standard procedure and conditions claimed in EN Standard Method ISO 17025:2005 and Laboratories which have the certificate according to ISO 17025:2005. Some efficacy studies were performed by SALVECO Microbiology Laboratory (Laboratory of Applicant). Based on congeniality of the outcomes of the studies, Latvian CA accepted the submitted test reports for consideration.

2.2.5.7 Evaluation of the label claims

The biocidal product family "SALVESAFE A" is intended to be used in domestic, industrial and institutional area as:

- disinfectants for hands (SALVESAFE A28M, SALVESAFE A29M, SALVESAFE A33M, SALVESAFE A35M, SALVESAFE A36M and SALVESAFE A44M);

- disinfectants for all washable hard surfaces not intended for direct application to humans or animals and disinfectants for all washable hard surfaces in food and feed area (SALVESAFE A21M, SALVESAFE A23M, SALVESAFE A25M, SALVESAFE A28M, SALVESAFE A29M, SALVESAFE A30M, SALVESAFE A31M, SALVESAFE A32M and SALVESAFE A34M) and

- algaecide for outdoor hard surfaces such as roofs, walls, concrete, stone, tiles, sport courts, playgrounds, greenhouses (SALVESAFE A27M).

The evaluation of efficacy demonstrates that the biocidal products within family "SALVESAFE A" meet agreed criteria for reduction of bacteria, yeast and virus (only *Influenza virus A/H1N1*) population in presence of organic soiling.

Therefore, biocidal product family "SALVESAFE A" is considered as disinfectants with proven efficacy against bacteria, yeast and against only *Influenza virus A/H1N1*. Latvian CA notes that biocidal product family "SALVESAFE A" does not meet the criteria on general virucidal claim.

The Latvian CA considers that the following label claims are supported:

- Product type 1 - disinfectants for hands – Biocidal efficacy at 20°C: bactericidal, yeasticidal and virucidal activity only against *Influenza virus A/H1N1* at the contact time 30 seconds.

- Product type 2 and 4 - disinfectants for all washable hard surfaces not intended for direct application to humans or animals and disinfectants for all washable hard surfaces in food and feed area – Biocidal efficacy at 20°C: bactericidal, yeasticidal and virucidal activity only against *Influenza virus A/H1N1* at the contact time 5 minutes.

- Product type 2 - algaecide for outdoor hard surfaces such as roofs, walls, concrete, stone, tiles, sport courts, playgrounds, greenhouses – Biocidal efficacy at 20°C: algaecide activity (48 h contact time).

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Summary table of animal studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 404 of April 24, 2002 for Testing of Chemicals. Acute Dermal Irritation/Corrosion.	Confidential PAR	Test item applied as it is, 0.5 ml for 4 hours	<u>Erythema</u> Animal 1: **0.7** Animal 2: **1.0** Animal 3: **0.3** <u>Oedema</u> Animal 1: **0** Animal 2: **0** Animal 3: **0** Fully reversible after 72 h No histopathological changes observed	-	Confidential PAR

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not corrosive or irritating to skin.
Justification for the value/conclusion	According to the CLP criteria and additivity approach, classification is met with respect to local effects on the skin (irritation) for the individual products of the BPF and thus the BPF itself. The conclusion is made based on RAC opinion for L(+)-Lactic acid, content of individual components, generic cut-off values specified in CLP Annex I, Table 1.1 and generic concentration limits (GCL) specified in CLP Annex I, Table 3.2.3. The sum of the concentrations/GCL of individual components exceeds a concentration limit 1%. Upon Latvian CA request to support non-classification of the BPF, the Applicant provided study according to the OECD Test Guidance No. 404. The tested formulation contains 3.52% Lactic acid and surfactants at total concentration above the limit within family. Therefore, the tested formulation can be considered as representative worst case and based on point 1.1.3.5 of CLP Latvian CA is in opinion that tested formulation covers all biocidal products within BPF. According to Table 3.2.2 of the CLP, the substances and mixtures shall be classified as Skin Irrit. 2 if mean score of ≥ 2.3 and ≤ 4.0 for erythema/eschar or for oedema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal is observed.

	According to the study, the range of average score for erythema from 0.3 to 1.0 and no signs of oedema. All effects were fully reversible after 72 h. Therefore, the tested product doesn't meet classification criteria. *Additional data* In order to support the good skin tolerance of the products, the Applicant took the initiative to perform the following test under dermatological control: - Study of acute skin compatibility of a test item after single application: 48-hour semi occlusive patch-test. The test item induced no reaction of irritation and has a very good skin compatibility after single application of the investigational product, under semi-occlusive patch on a panel of 11 subjects with sensitive skin on body.
Classification of the product according to CLP	Not relevant

Eye irritation

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD guidelines 405 (GLP)	Confidential PAR	0.1mL of biocidal product Nettoyant Desinfectant with maximal content of each substance. Ocular examinations were performed 24, 48 and 72 hours	The test results included in Section 3.4. of Annex I	-	Confidential PAR

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The biocidal product family "SALVESAFE A" 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 Nettoyant Desinfectant (biocidal product with the maximal active substance and co-formulant's concentration) performed on 3 female albino New Zealand rabbits according to OECD guidelines 405

	showed mean individual values 0-0,7 for corneal opacity, 0 for iritis, 0,7-2,3 for conjunctival redness (only one animal showed conjunctival redness ≥ 2 from 3 animals) and 0,3-1,3 for conjunctival oedema (chemosis). All effects were totally reversible within 21 days. Data represented in Section 3.3. of the confidential Annex I. No classification criteria are fulfilled, the biocidal product within family "SALVESAFE A" 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 A" does not have irritating effects on respiratory tract.
Justification for the conclusion	The respiratory tract irritation effects of the biocidal products family "SALVESAFE A" 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 A" 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 A" does not have sensitization effects on skin.
Justification for the value/conclusion	The potential effect on dermal sensitization of the biocidal product family "SALVESAFE A" has not been investigated experimentally. Taking into account the information on classification of the Lactic acid and co-formulants together with data on composition of formulation (Section 3.3 of Confidential Annex I), as well as Table 3.4.6 of Annex I of the CLP, Latvian CA considers that the biocidal product family "SALVESAFE A" does not meet the criteria for classification for sensitisation. The outcome of calculation method is mentioned in Section 2.1.2.5.
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 A" does not have respiratory sensitisation effects.
Justification for the value/conclusion	The respiratory sensitisation effects of the biocidal products family "SALVESAFE A" 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 A" 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 A" contains Lactic acid and no substance of concern. Latvian CA considers, that the biocidal product family "SALVESAFE A" 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 A" 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 A" 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 A".

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 A" 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 A" 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 RPRI09YBA04) as additional supporting information. The results of the performed test show the 97% carbon dioxide generation during 28 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. 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 A" 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:**

   1.1. *Disinfectants for human hygiene (disinfectant for hands):* Wet hands and wrists with water. Place 3 mL of product in the hallow of the hand. Rub hands and wrists for at least 30 seconds. Rinse thoroughly with clean water. Apply once, repeat if renewed hand disinfection is needed.

   1.2. *Disinfectants not intended for direct application to humans or animals (disinfectant for all washable hard surfaces):* Apply the product up to fully wet all the surface for 5 minutes. Rub or brush if necessary. Apply once and repeat the application if necessary.

   1.3. *Algaecides not intended for direct application to humans or animals:* Use in the dry weather. Apply the product by wetting all surface. Allow the product functioning until complete drying. Do not rinse. Brush if necessary 2 days later to remove debris. Apply once and then monitor the situation regularly. Repeat the application if necessary.

   1.4. *Food and feed area disinfectants (disinfectant for all washable hard surfaces):* Apply the product up to fully wetting all the surface for 5 minutes. Rub or brush if necessary. Rinse thoroughly with clean water. Apply once and repeat the application if necessary.

2. **The label claim must contain the following indications:**

   2.1. *Disinfectants for human hygiene (disinfectant for hands):* Biocidal efficacy at 20°C: bactericidal, yeasticidal and virucidal activity only against *Influenza virus A/H1N1* at the contact time 30 seconds";

   2.2. *Disinfectants not intended for direct application to humans or animals (disinfectant for all washable hard surfaces):* Biocidal efficacy at 20°C: bactericidal, yeasticidal and virucidal activity only against *Influenza virus A/H1N1* at the contact time 5 minutes;

   2.3. *Algaecides not intended for direct application to humans or animals:* Biocidal efficacy at 20°C: algaecide activity (48 h contact time);

2.4. *Food and feed area disinfectants (disinfectant for all washable hard surfaces):* Biocidal efficacy at 20°C: Biocidal efficacy at 20°C: bactericidal, yeasticidal and virucidal activity only against *Influenza virus A/H1N1* at the contact time 5 minutes.

3. The label must contain the following precautionary information:

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

Professional and industrial users:
- Safety data sheet is available on request.

4. Additional information on first aid instruction:

- If swallowed: Immediately call to 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 according to national regulation.

6. Storage conditions and stability:

- Avoid cold, frost and heat
- The shelf life of the product is 24 months.

7. Conditions for authorisation:

- Summary: ready-to-use water based disinfectants in domestic, institutional and industrial area.

- Bactericidal and yeasticidal claim for PT2 and PT4 is relevant for biocidal products with Lactic acid concentration ≥ 0.32% w/w and ≤ 1.76 % w/w.

- Bactericidal and yeasticidal claim for PT1 is relevant for biocidal products with Lactic acid concentration ≥ 1.75% w/w and ≤ 1.76 % w/w.

- Efficacy against *Influenza virus A/H1N1* for biocidal products claimed for PT1 with Lactic acid concentration ≥ 1.75% w/w and ≤ 1.76 % w/w.

- Efficacy against *Influenza virus A/H1N1* for biocidal products claimed for PT2 and PT4 with Lactic acid concentration ≥ 0.42% w/w and ≤ 1.76 % w/w.

- Efficacy against algae for biocidal product with Lactic acid concentration ≥ 1.69% w/w and ≤ 1.76 % w/w.

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.