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 D**

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

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

Case Number in R4BP3: BC-UG033301-51

Evaluating Competent Authority: Latvia

Date: 01/08/2022

contents

1 CONCLUSION

The biocidal products (wipes) within family *SALVESAFE D* with active substance *Lactic acid* (CAS No. 50-21-5, EC No. 200-018-0) at the concentration range 1.75-2.38% w/w are authorised for product type 2 and product type 4 as disinfectants not intended for direct application to humans or animals and food and feed area disinfectants, respectively.

Biocidal product family *SALVESAFE D* is claimed with bactericidal, yeasticidal activity and activity against enveloped viruses for hard non-porous surfaces in domestic, institutional, industrial area and medical area for non-professional, professional and industrial users.

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 D* 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 18 January 2018 until 18 January 2028.

A person placing on the market or using the biocidal products included in biocidal product family *SALVESAFE D* must comply with the conditions set out in authorisation letter issued by Latvian Competent Authority and Summary of Products Characteristics for biocidal product family.

List of approved changes and amendments:

Application type	eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
SA-AAT	LV	BC-QH053619-26	30.08.2019.	Amendment – post-authorisation condition is removed. Long term storage test data is submitted.	Section 2.2.6.1. pp. 32 Confidential Annex Section 3.5. pp. 50
SA-AAT	LV	BC-ES066400-34	17.08.2021.	Assessment of data on skin corrosion/irritation endpoints.	Section 2.2.6.1
SA-MAC	LV	BC-NF074758-24	01..08.2022.	New meta-SPC	Section 2.1.4

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 D	Latvia

2.1.1.1.1 Trade names of the products within the family SALVESAFE D

Trade name	Other trade name
SALVESAFE D0_P	SalveSafe Wipes
SALVESAFE D1_P	SalveSafe Wipes Sfle Ess
SALVESAFE D2_P	SalveSafe Wipes Pomme
SALVESAFE D3_P	SalveSafe Wipes Menthe Gl
SALVESAFE D4_P	SalveSafe Wipes Thé vert
SALVESAFE D5_P	SalveSafe Wipes Igloo
SALVESAFE D6_P	SalveSafe Wipes Icy
SALVESAFE D0_C	
SALVESAFE D1_C	Care GERM-WIPES
SALVESAFE D2_C	
SALVESAFE D3_C	
SALVESAFE D4_C	
SALVESAFE D5_C	
SALVESAFE D6_C	
SALVESAFE D0_GPPRO	Lingettes désinfectantes sans parfum OSANIS - Lingettes désinfectantes sans parfum
SALVESAFE D2_GPPRO	Lingettes désinfectantes Golden OSANIS - Lingettes désinfectantes Golden
SALVESAFE D3_GPPRO	HeroLAB Lingettes désinfectantes 40=80 HeroLAB PRO Lingettes désinfectantes 60=120 Lingettes désinfectantes Feuilles de menthe OSANIS - Lingettes désinfectantes Feuilles de menthe
SALVESAFE D4_GPPRO	Lingettes désinfectantes Igloo OSANIS - Lingettes désinfectantes Igloo
SALVESAFE D5_GPPRO	Les lingettes désinfectantes bubble b
SALVESAFE D6_GPPRO	Lingettes désinfectantes Chlorophylle OSANIS - Lingettes désinfectantes Chlorophylle
SALVESAFE D7_GPPRO	Lingettes désinfectantes Thé blanc et Thym OSANIS - Lingettes désinfectantes Thé blanc et Thym

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	SALVECO S.A.S.	
	Address	Avenue Pierre Mendès-France SAINT DIE DES VOSGES, F-88100, FRANCE	
Authorisation number for biocidal product family	EU-0017682-0000 (according to Asset number in R4BP3)		
Authorisation numbers of the biocidal products within family	SALVESAFE D0_P		EU-0017682-0001
	SALVESAFE D1_P		EU-0017682-0002

	SALVESAFE D2_P	EU-0017682-0003
	SALVESAFE D3_P	EU-0017682-0004
	SALVESAFE D4_P	EU-0017682-0005
	SALVESAFE D5_P	EU-0017682-0006
	SALVESAFE D6_P	EU-0017682-0007
	SALVESAFE D0_C	EU-0017682-0008
	SALVESAFE D1_C	EU-0017682-0009
	SALVESAFE D2_C	EU-0017682-0010
	SALVESAFE D3_C	EU-0017682-0011
	SALVESAFE D4_C	EU-0017682-0012
	SALVESAFE D5_C	EU-0017682-0013
	SALVESAFE D6_C	EU-0017682-0014
	SALVESAFE D0_GPPRO	EU-0017682-0015
	SALVESAFE D2_GPPRO	EU-0017682-0016
	SALVESAFE D3_GPPRO	EU-0017682-0017
	SALVESAFE D4_GPPRO	EU-0017682-0018
	SALVESAFE D5_GPPRO	EU-0017682-0019
	SALVESAFE D6_GPPRO	EU-0017682-0020
	SALVESAFE D7_GPPRO	EU-0017682-0021
Date of the authorisation	18 January 2018	
Expiry date of the authorisation	18 January 2028	

2.1.1.3 Manufacturer of the products of the family

Name of manufacturer (1)	FELT
Address of manufacturer	Z.L 10 RUE DU VERTUQUET, F-59960, NEUVILLE-EN-FERRAIN, FRANCE
Location of manufacturing sites	Z.L 10 RUE DU VERTUQUET, F-59960, NEUVILLE-EN-FERRAIN, FRANCE
Name of manufacturer (2)	EUROWIPES
Address of manufacturer	Rue du Grand Champ, F-28400, NOGENT-LE-ROTROU, France
Location of manufacturing sites	Rue du Grand Champ, F-28400, NOGENT-LE-ROTROU, France
Name of manufacturer (3)	SOCOMORE
Address of manufacturer	Avenue Paul Duplaix, F-56000, VANNES, France
Location of manufacturing sites	ZA de Gohelis-Ouest, F-56250, ELVEN, France

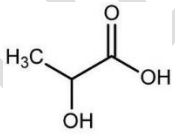
Name of manufacturer (4)	SOCOMORE
Address of manufacturer	Meenane, Watergrasshill, T56 VX37, Co. Cork, Ireland
Location of manufacturing sites	Meenane, Watergrasshill, T56 VX37, Co. Cork, Ireland

2.1.1.4 Manufacturer of the active substance

Active substance	Lactic acid
Name of manufacturer	JUNGBUNGZLAUER S.A
Address of manufacturer	Z. I Portuaire BP 32, 67390, Marckolsheim, France
Location of manufacturing sites	ST Alban Vorstadt 90 4002 Basel Switzerland

2.1.2 Product family composition and formulation

2.1.2.1 Identity of the active substance

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

2.1.2.2 Candidate for substitution

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

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

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%, w/w)**	
					min	**max**
Lactic acid	2-Hydroxypropanoic acid	Active substance	50-21-5	200-018-0	1.75	2.38

The composition of the biocidal product family *SALVESAFE D* 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 D* does not contain nanomaterials.

2.1.2.4 Information on technical equivalence

The active substance *Lactic acid* (CAS No. 50-21-5) is not included in the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012. The assessment of technical equivalence of the active substance listed in Annex I of the Regulation (EU) No 528/2012 is not applicable.

2.1.2.5 Information on the substance(s) of concern

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

2.1.2.6 Type of formulation

Ready-to-use impregnated wipes

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 D* 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	P102: Keep out of reach of children (for non-professional users)
Supplemental label elements	EUH210: Safety data sheet available on request (for professionals users)

2.1.4 Authorised use

2.1.4.1 Use description

Meta 1 – Disinfectant wipes for hard non-porous surfaces (professional users)

Use 1 – Disinfectant wipes for hard non-porous surfaces without direct contact with food or feeding stuffs

Product Type	Product type 2
Where relevant, an exact description of the authorised use	Ready-to-use multi-purpose cleaner disinfectant wipes for all washable hard non-porous surfaces with a bactericidal and yeasticidal efficacy in institutional and industrial area.
Target organisms (including development stage)	Bacteria and yeasts
Field of use	Indoor, outdoor

Application methods	**Type of method**: manual application: wiping **General description of the method:** Pull out single ready-to-use wipe. Wet the entire surface thoroughly and let stand at least 5 minutes. Allow to air dry.
Application rates and frequency	**The application rate:** Wipe surface with 1 ready-to-use wipe (180 x 200 mm) per m². **Frequency**: apply once, repeat if it is necessary.
Categories of users	Professional, industrial
Pack sizes and packaging material	Flow pack (PET/PE): 40-80 wipes (material: 100% polyester, wipe size: 180x200 mm)

Use 2 – Disinfectant wipes for hard non-porous surfaces which has contact with food and feeding stuffs

Product Type	Product type 4
Where relevant, an exact description of the authorised use	Ready-to-use multi-purpose cleaner disinfectant wipes for all washable hard non-porous surfaces with a bactericidal and yeasticidal efficacy in institutional and industrial area.
Target organisms (including development stage)	Bacteria and yeasts
Field of use	Indoor, outdoor
Application methods	**Type of method**: manual application: wiping **General description of the method:** Pull out single ready-to-use wipe. Wet the entire surface thoroughly and let stand at least 5 minutes. For food contact materials and surfaces rinse with water and let dry.
Application rates and frequency	**The application rate:** Wipe surface with 1 ready-to-use wipe (180 x 200 mm) per m². **Frequency**: apply once, repeat if it is necessary.
Categories of users	Professional, industrial
Pack sizes and packaging material	Flow pack (PET/PE): 40-80 wipes (material: 100% polyester, wipe size: 180x200 mm)

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

PT2: Pull out single ready-to-use wipe. Wet the entire surface thoroughly (1 wipe (180x200 mm)/m^2) and let stand at least 5 minutes. Allow to air dry. Apply once, repat if ii is necessary. Only wet wipes are efficacious, do not use wipes after dehydration. Close carefully a flow pack when not in use. **PT4:** Pull out single ready-to-use wipe. Wet the entire surface thoroughly (1 wipe (180x200 mm)/m^2) and let stand at least 5 minutes. For food contact materials and surfaces rinse with water and let dry. Apply once, repat if ii is necessary. Only wet wipes are efficacious, do not use wipes after dehydration. Close carefully a flow pack when not in use.

2.1.5.2 Risk mitigation measures

Not applicable.

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

No direct or indirect adverse effects are known. In case of contact with eyes, remove contact lenses if present and rinse the eye slowly and gently with clean water. Measures to protect the environment: Do not flush down the toilet. Do not dispose in the environment.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of wipes/packaging in accordance with national regulation.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: Products can be stored at room temperature up to 24 months. Conditions: Avoid cold, frost and heat. Recommended use: 3 months after the opening.

Meta 2 – Disinfectant wipes for hard non-porous surfaces (non-professional users)

Use 1 – Disinfectant wipes for hard non-porous surfaces without direct contact with food or feeding stuffs

Product Type	Product type 2
Where relevant, an exact description of the authorised use	Ready-to-use multi-purpose cleaner disinfectant wipes for all washable hard non-porous surfaces with a bactericidal and yeasticidal efficacy in domestic area.
Target organisms (including development stage)	Bacteria and yeasts
Field of use	Indoor, outdoor
Application methods	**Type of method**: manual application: wiping **General description of the method:** Pull out single ready-to-use wipe. Wet the entire surface thoroughly and let stand at least 5 minutes. Allow to air dry.
Application rates and frequency	**The application rate:** Wipe surface with 1 ready-to-use wipe (180 x 200 mm) per m². **Frequency**: apply once, repeat if it is necessary.
Categories of users	Non-professional
Pack sizes and packaging material	Flow pack (PET/PE): 40-80 wipes (material: 100% polyester, wipe size: 180x200 mm)

Use 2 – Disinfectant wipes for hard non-porous surfaces which has contact with food and feeding stuffs

Product Type	Product type 4
Where relevant, an exact description of the authorised use	Ready-to-use multi-purpose cleaner disinfectant wipes for all washable hard non-porous surfaces with a bactericidal and yeasticidal efficacy in domestic area.
Target organisms (including development stage)	Bacteria and yeasts
Field of use	Indoor, outdoor
Application methods	**Type of method**: manual application: wiping **General description of the method:** Pull out single ready-to-use wipe. Wet the entire surface thoroughly and let stand at least 5 minutes. For food contact materials and surfaces rinse with water and let dry.
Application rates and frequency	**The application rate:** Wipe surface with 1 ready-to-use wipe (180 x 200 mm) per m². **Frequency**: apply once, repeat if it is necessary.
Categories of users	Non-professional
Pack sizes and packaging material	Flow pack (PET/PE): 40-80 wipes (material: 100% polyester, wipe size: 180x200 mm)

2.1.5.6 Use-specific instructions for use

Section 2.1.6

2.1.5.7 Use-specific risk mitigation measures

Section 2.1.6

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

Section 2.1.6

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

Section 2.1.6

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

Section 2.1.6

2.1.6 General directions for use

2.1.6.1 Instructions for use

PT2: Pull out single ready-to-use wipe. Wet the entire surface thoroughly (1 wipe (180x200 mm)/m^2) and let stand at least 5 minutes. Allow to air dry. Apply once, repat if ii is necessary. Only wet wipes are efficacious, do not use wipes after dehydration. Close carefully a flow pack when not in use. **PT4:** Pull out single ready-to-use wipe. Wet the entire surface thoroughly (1 wipe (180x200 mm)/m^2) and let stand at least 5 minutes. For food contact materials and surfaces rinse with water and let dry. Apply once, repat if ii is necessary. Only wet wipes are efficacious, do not use wipes after dehydration. Close carefully a flow pack when not in use.

2.1.6.2 Risk mitigation measures

Not applicable.

2.1.6.3 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. In case of contact with eyes, remove contact lenses if present and rinse the eye slowly and gently with clean water. Measures to protect the environment: Do not flush down the toilet. Do not dispose in the environment.

2.1.6.4 Instructions for safe disposal of the product and its packaging

Dispose of wipes/packaging in accordance with national regulation.

2.1.6.5 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. Recommended use: 3 months after the opening.

Meta 3 – **Disinfectant wipes for hard non-porous surfaces (professional and non-professional users)**

Use 1 – Disinfectant wipes for hard non-porous surfaces without direct contact with food or feeding stuffs

Product Type	Product type 2
Where relevant, an exact description of the authorised use	Ready-to-use multi-purpose cleaner disinfectant wipes for all washable hard non-porous surfaces with a bactericidal, yeasticidal efficacy and virucidal activity only against enveloped viruses in institutional, industrial, medical and domestic area.
Target organisms (including development stage)	Bacteria, yeasts and enveloped viruses
Field of use	Indoor, outdoor
Application methods	**Type of method**: manual application: wiping **General description of the method:** Pull out single ready-to-use wipe. Wet the entire surface thoroughly and let stand at least 5 minutes. Allow to air dry.
Application rates and frequency	**The application rate:** ensure complete wetting on the surfaces. **Frequency**: apply once, repeat if it is necessary.
Categories of users	Industrial, professional and non-professional
Pack sizes and packaging material	**Packaging material:** Unidose bag in PAP/PE/ALU/PE, 1 wipe Flow pack in PET/PE, PET/PE-EVOH-PE, PA/PE-EVOH-PE, PE with hardclosure (PP or PE lid) or with resealable label (PE or PE/PET), 20 - 100 wipes Canister/Bucket in HDPE or PP with closure in PP or PET or PE, 80 - 500 wipes Bag in PA/PE-EVOH-PE or PA-ALU-OPA-PE, 80 - 500 wipes **Wipes material**: 100% Polyester, lyocell, viscose, viscose/Polyester, pulp (cellulose), pulp (cellulose)/Polyester or PP **Wipe size:** from 50*50 mm to 400*400 mm

Use 2 – Disinfectant wipes for hard non-porous surfaces which has contact with food and feeding stuffs

Product Type	Product type 4
Where relevant, an exact description of the authorised use	Ready-to-use multi-purpose cleaner disinfectant wipes for all washable hard non-porous surfaces with a bactericidal, yeasticidal efficacy and virucidal activity only against enveloped viruses in institutional, industrial, medical and domestic area.
Target organisms (including development stage)	Bacteria, yeasts and enveloped viruses
Field of use	Indoor, outdoor
Application methods	**Type of method**: manual application: wiping **General description of the method:** Pull out single ready-to-use wipe. Wet the entire surface thoroughly and let stand at least 5 minutes. For food contact materials and surfaces rinse with water and let dry.
Application rates and frequency	**The application rate:** Ensure complete wetting on the surfaces. **Frequency**: apply once, repeat if it is necessary.
Categories of users	Industrial, professional and non-professional
Pack sizes and packaging material	**Packaging material:** Unidose bag in PAP/PE/ALU/PE, 1 wipe Flow pack in PET/PE, PET/PE-EVOH-PE, PA/PE-EVOH-PE, PE with hardclosure (PP or PE lid) or with resealable label (PE or PE/PET), 20 - 100 wipes Canister/Bucket in HDPE or PP with closure in PP or PET or PE, 80 - 500 wipes Bag in PA/PE-EVOH-PE or PA-ALU-OPA-PE, 80 - 500 wipes **Wipes material**: 100% Polyester, lyocell, viscose, viscose/Polyester, pulp (cellulose), pulp (cellulose)/Polyester or PP **Wipe size:** from 50*50 mm to 400*400 mm

2.1.6.6 Use-specific instructions for use

Section 2.1.7

2.1.6.7 Use-specific risk mitigation measures

Section 2.1.7

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

Section 2.1.7

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

Section 2.1.7

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

Section 2.1.7

2.1.7 General directions for use

2.1.7.1 Instructions for use

Comply with the instructions for use. **PT2:** Pull out ready-to-use wipe. Ensure complete wetting on the surfaces and let stand at least 5 minutes. Allow to air dry. Apply once, repeat if it is necessary. Only wet wipes are efficacious, do not use wipes after dehydration. Close carefully a package when not in use. **PT4:** Pull out ready-to-use wipe. Ensure complete wetting on the surfaces and let stand at least 5 minutes. For food contact materials and surfaces rinse with water and let dry Apply once, repeat if it is necessary. Only wet wipes are efficacious, do not use wipes after dehydration. Close carefully a package when not in use.

2.1.7.2 Risk mitigation measures

Wash hands after use. Avoid the contact with eyes.

2.1.7.3 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. If medical advice is needed, have product container or label at hand. IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor. IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor. IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor. IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. Measures to protect the environment: Do not flush down the toilet. Do not dispose in the environment.

2.1.7.4 Instructions for safe disposal of the product and its packaging

Dispose of wipes/packaging in accordance with national regulation.

2.1.7.5 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. Keep out of reach of children and animals. Recommended use: 3 months after the opening.

2.1.8 Other information

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2.1.9 Packaging of the biocidal products

Type of packaging	**Volume of the packaging**	**Material of the packaging**	**Type and material of closure**	**User**	**Compatibility of the product with the proposed packaging materials (Yes/No)**	**Meta-SPC**
Flow pack	40-80 wipes (100% polyester) Wipe size: 180x200 mm (4.9 g liquid per one wipe). Size of packaging: 350x270 mm or 420x310 mm. Volume of the packaging: 1188 cm^3 or 3224 cm^3.	PET (11.8%)/ PE (88.2%)	PP Lid	Non-professional; Professional; Industrial	Yes	1 2
Unidose bag	1 wipe (polyester, lyocell, viscose, viscose/polyester, pulp (cellulose), pulp (cellulose)/polyester or polypropylene) wipe size from 50*50mm to 200*170mm (0.263g to 7.14g liquid per one wipe).	PAP/PE/ALU/ PE	-	Non-professional; Professional; Industrial	Yes	3

	Size of packaging: from 60*70mm to 100*70mm					
Flow pack	From 20 to 100 wipes (polyester, lyocell, viscose, viscose/polyester, pulp (cellulose), pulp (cellulose)/polyester or polypropylene, Wipe size from 200*100mm to 200*200mm (from 1.5g to 8.4g liquid per one wipe). Size of packaging: from 240*150mm to 520*310mm Volume of the packaging: from 300cm^3 to 4712cm^3	PET/PE, PET/PE-EVOH/PE, PA/PE-EVOH-PE, PE	Hard closure: PP or PE lid Resealable label: PE or PE/PET	Non-professional; Professional; Industrial	Yes	3
Canister/ Bucket	From 80 to 500 wipes (polyester, lyocell, viscose, viscose/polyester, pulp (cellulose), pulp (cellulose)/polyester or polypropylene Wipe size from 130*200 mm to 400*400 mm (from 2.73g to 17.8g liquid per one wipe). Size of packaging: from 75mm (diameter)*180 mm to 320mm (diameter) *450mm Volume of the packaging: from 0.8 to 36.19L	HDPE or PP	PP, PET, PE	Non-professional; Professional; Industrial	Yes	3
Bag	From 80 to 500 wipes	PA/PE-EVOH-PE or	-	Non-professional;	Yes	3

	(polyester, lyocell, viscose, viscose/polyester, pulp (cellulose), pulp (cellulose)/polyester or polypropylene, Wipe size from 130*200mm to 400*400mm (from 2.73g to 17.8g liquid per one wipe). Size of packaging: from 75*180mm to 320*450mm	PA-ALU-OPA-PE		Professional; Industrial		
PET – polyethylene terephthalate; PE – Polyethylene; PAP – Paper/Cardboard; ALU – Aluminum; EVOH – Ethylene-vinyl alcohol; PA – Polyamide; HDPE – Hight density polyethylene; PP – Polypropylene; OPA – Polyamide nylon						

2.1.10 Documentation

2.1.10.1 Data submitted in relation to product application

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

2.2 Assessment of the biocidal product family

2.2.1 Intended use

Table 1. **Disinfectant wipes for hard non-porous surfaces**

Product Type	**Product type 2** and **4**
Where relevant, an exact description of the authorised use	**Meta 1** - Ready-to-use multi-purpose cleaner disinfectant wipes for all washable hard non-porous surfaces (with and without contact with food and feeding stuffs) with a bactericidal and yeasticidal efficacy in institutional and industrial area. **Meta 2** - Ready-to-use multi-purpose cleaner disinfectant wipes for all washable hard non-porous surfaces (with and without contact with food and feeding stuffs) with a bactericidal and yeasticidal efficacy in domestic area. **Meta 3** - Ready-to-use multi-purpose cleaner disinfectant wipes for all washable hard non-porous surfaces with a bactericidal, yeasticidal efficacy and virucidal activity only against enveloped viruses in institutional, industrial, medical and domestic area.
Target organisms (including development stage)	**Meta 1** and **2** - Bacteria, yeasts **Meta 3** - Bacteria, yeasts and enveloped viruses
Field of use	Indoor, outdoor
Application methods	**Type of method**: manual application: wiping **Meta 1 and 2** **General description of the method:** **PT2:** Pull out single ready-to-use wipe. Wet the entire surface thoroughly (1 wipe (180 x 200 mm) / m²) and let stand at least 5 minutes. Allow to air dry. Apply once, repeat if it is necessary. Only wet wipes are efficacious, do not use wipes after dehydration. Close carefully a flow pack when not in use. **PT4:** Pull out single ready-to-use wipe. Wet the entire surface thoroughly (1 wipe (180 x 200 mm) / m²) and let stand at least 5 minutes. For food contact materials and surfaces rinse with water and let dry. Apply once, repeat if it is necessary. Only wet wipes are efficacious, do not use wipes after dehydration. Close carefully a flow pack when not in use. **Meta 3** **PT2:** Pull out ready-to-use wipe. Ensure complete wetting on the surfaces and let stand at least 5 minutes. Allow to air dry. Apply once, repeat if it is necessary. Only wet wipes are efficacious, do not use wipes after dehydration. Close carefully a package when not in use. **PT4:** Pull out ready-to-use wipe. Ensure complete wetting on the surfaces and let stand at least 5 minutes. For food contact materials and surfaces rinse with water and let dry. Apply once, repeat if it is necessary. Only wet wipes are efficacious,

	do not use wipes after dehydration. Close carefully a package when not in use.
Application rates and frequency	**The application rate:** Ensure complete wetting on the surfaces **Frequency**: apply once, repeat if it is necessary.
Categories of users	**Meta 1** - professional and industrial **Meta 2 -** Non-professional **Meta 3** - Non-professional, professional and industrial
Pack sizes and packaging material	Section 2.1.7.

2.2.2 Physical, chemical and technical properties

Biocidal product family *SALVESAFE D* is a family of ready-to-use impregnated wipes. Tests for all physical-chemical properties are performed with the liquids before it is applied to the carrier component. However, the product stability tests are carried out with the products as they are supplied to the user (impregnated wipes).

Property	Guideline and Method	Tested product	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	Biocidal product family SALVESAFE D	Impregnated wipes	Conf.PAR
Colour at 20 °C and 101.3 kPa	Visual	Biocidal product family SALVESAFE D	Colorless liquid on white absorbent wipes	Conf.PAR
Acidity / alkalinity at 20 °C	CIPAC MT 75.3	Biocidal product family SALVESAFE D	2.69-2.89	Conf.PAR
Relative density / bulk density at 20 °C	EEC Method A3	Biocidal product family SALVESAFE D	1.006-1.009	Conf.PAR

Property	Guideline and Method	Tested product	Results	Reference
Viscosity, 20°C and 40°C	OECD 114	Biocidal product family SALVESAFE D	< 50 mPa*s	Conf.PAR
Storage stability test – **accelerated storage**	Storage for 2 weeks at 54˚C±2°C (CIPAC MT46.3)	***Meta-SPC 1 and 2*** *Products Salvesafe D0_P – D6_P* and *Salvesafe D0_C – D6_C:* The storage stability tests are conducted for ready-to-use wipes (PE wipes) in the commercial packaging (PE/PET). The titration method is used for the detection and identification of *Lactic acid* in liquids extracted from wipes. **Meta-SPC 3**	Non-perfumed SALVESAFE D0_P and SALVESAFE D0_C Lactic acid at the start 1.76% w/w and at the end 1.73 % w/w Products with nominal Lactic acid concentration 2.38% w/w -> content at the start 2.34-2.47% w/w and at the end 2.46-2.49% w/w. Tested concentrations and it's changes are within allowed tolerance limit of the declared nominal content of active substance. All flow packs and wipes didn't change in appearance. No changes in pH, viscosity and density. Products with nominal Lactic acid	

Property	Guideline and Method	Tested product	Results	Reference
		Products Salvesafe D0_GPPRO – D7_GPPRO: The storage stability tests are conducted for ready-to-use wipes (Lyocell fabric material) in the commercial packaging (Polyester). HPLC method is used for the detection and identification of *Lactic acid* in liquids extracted from wipes.	concentration 1.76% w/w: content at the start 1.72-1.78% w/w and at the end 1.75-1.80 % w/w. Tested concentrations and it's changes are within allowed tolerance limit of the declared nominal content of active substance. All flow packs and wipes didn't change in appearance. No changes in pH, viscosity and density.	
		With aim to show that a material of wipes doesn't impact on properties two types of wipes materials were impregnated with two different formulations: without perfume (Salvesafe D0_GPPRO), and with perfume (Salvesafe D2_GPPRO). Physico-chemical parameters and active substance content were measured before and after the 14 days storage. After 14 days, the analyses were realized on liquid extracted from wipes. The following wipes materials were tested: Polyester and Lyocell. Lyocell is considered representative of cellulose-based fibers and associated	Products with nominal Lactic acid concentration 1.76% w/w: content at the start 1.76-1.78% w/w and at the end 1.79-1.80 % w/w. All flow packs and wipes didn't change in appearance. No changes in pH, viscosity and density.	

Property	Guideline and Method	Tested product	Results	Reference
		blends, and polyester is considered representative of polymer and associated blends.		
Storage stability test – **long term storage at ambient temperature**	Storage for 24 months at 23±4°C at day light	***Meta-SPC 1 and 2*** *Products Salvesafe D0_P – D6_P* and *Salvesafe D0_C – D6_C:* The storage stability tests are conducted for ready-to-use wipes in the commercial packaging: 40 wipes (100% polyester, wipe size: 180x200 mm) in PE packaging with PP Lid closure. Liquid was extracted from the wipes by pressing.	*Non-perfumed SALVESAFE D0_P* and *SALVESAFE D0_C* *Lactic acid* content at the start 1.76% w/w and at the end 1.86% w/w. Tested concentrations and it's changes are within allowed tolerance limit and changes < 10%. pH values at the start 2.80 and at the end 2.93. No variations in physical state, colour, density and viscosity. *Perfumed SALVESAFE D1_P – D6_P* and *SALVESAFE D1_C – D6_C* *Lactic acid* content at the start 2.34-2.47% w/w and at the end 2.47-2.56% w/w. Tested concentrations and it's changes are within allowed tolerance limit and changes < 10%. pH values at the start 2.69-2.75 and at the end 2.80-2.85. No variations in physical state, colour, density and viscosity.	Conf.PAR

Property	Guideline and Method	Tested product	Results	Reference
		Meta-SPC 3 *Products Salvesafe D0_GPPRO – D6_GPPRO:* in progress		
Storage stability test – **low temperature stability test for liquids**	The condition on storage "Avoid cold and frost" should be indicated on the label.			
Wettability	Not applicable			
Suspensibility, spontaneity and dispersion stability	Not applicable			
Wet sieve analysis and dry sieve test	Not applicable			
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable			
Particle size distribution, content of dust/fines, attrition, friability	Not applicable			
Persistent foaming	Not applicable			
Flowability/Pourability/Dustability	Not applicable			
Burning rate — smoke generators	Not applicable			
Burning completeness — smoke generators	Not applicable			
Composition of smoke — smoke generators	Not applicable			
Physical compatibility	Not applicable			
Chemical compatibility	Not applicable			
Degree of dissolution and dilution stability	Not applicable			

Conclusion on the physical, chemical and technical properties of the product
The data provided by the Applicant was acceptable. All products are ready to use impregnated wipes.

The storage test reports results show that biocidal products (ready-to-use wipes) in closed package are stable for two years at ambient temperature. The condition on storage "Avoid cold and frost" should be indicated on the label. Recommended period for use after opening of pack is 3 months.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Results	Reference
Explosives	-	Products do not contain substances with chemicals groups associated with explosive properties	-
Flammable gases	-	Products are a wipes	-
Flammable aerosols	-	Products are not an aerosols	-
Oxidising gases	-	Products are a wipes	-
Gases under pressure	-	Not applicable, not under pressure	-
Flammable liquids	-	Products are a wipes.	-
Flammable solids	-	The wipes are impregnated with non-flammable liquid. A liquid only contains non-flammable components. The flash point of all ingredients > 100°C.	-
Self-reactive substances and mixtures	-	Products contain no self-reacting substances	-
Pyrophoric liquids	-	Products are a wipes	-
Pyrophoric solids	-	The wipes are impregnated with non-pyrophoric liquid.	-
Self-heating substances and mixtures	-	Products are a wipes.	-
Substances and mixtures which in contact with water emit flammable gases	-	Products are a wipes.	-
Oxidising liquids	-	Products are a wipes.	-
Oxidising solids	-	The wipes are impregnated with non-oxidising liquid. A liquid doesn't contain substances with oxidizing properties.	-
Organic peroxides	-	Products are a wipes.	-
Corrosive to metals	UN manual of tests and criteria Part III, 37.4 (test C.1) Max Famille D (worst case product with maximal	Not classified as corrosive to metals. A representative product was tested on metal corrosion classification. The product shows a negative result for corrosion to metal. After 7 days of testing: Aluminium: max 0.5% Steel: max 1.8% The weight loss is below the threshold of 13.5%. Localised corrosion is observed on the steel sample partially immersed in the	Conf.PAR

Property	Guideline and Method	Results	Reference
	content of active substance and co-formulants)	liquid. The depth of the deepest intrusion was measured metallographically and measured to be 76 µm. The deepest intrusion does not exceed 120 µm after seven days exposure time. The data for is considered to sufficiently support all members in family.	
Auto-ignition temperatures of products (liquids and gases)	-	The products are known to be stable at room temperature	-
Relative self-ignition temperature for solids	-	Not applicable	-
Dust explosion hazard	-	Not applicable	-

Conclusion on the physical hazards and respective characteristics of the product
No classification and labelling for physico-chemical hazards is required.

2.2.4 Methods for detection and identification

Conclusion on the methods for detection and identification of the product
Analytical method for the determination of *Lactic acid* residues in body and animals fluids and tissues, environmental media (soil, air, water) and also treated food or feeding have not been submitted since the Applicant has indicated that these points are not relevant for the biocidal product family *SALVESAFE D*. Latvian CA accepts this approach, based on the following points: 1. *Lactic acid* is a naturally occurring alpha-hydroxy acid. *Lactic acid* is normally found in the blood and interstitial fluid of humans at a level of 10 mg/dl (U.S. EPA, 2008). *Lactic acid* and co-formulants are not classified as toxic or very toxic, analytical methods in body fluids and tissues are not required. 2. *Lactic acid* approved for use as a food additive (E270) according Regulation (EU) No. 1333/2008. *Lactic acid* meets the specifications for purity laid down in Regulation (EU) No. 231/2012. *Lactic acid* is present in a variety of foods, like yogurt containing 9 g/kg (Simpson BK., 2012), traditional cheese with 8 g/kg (Dolci P., 2008) and beef meat with a content of 1.4-5.0 g/kg (Nassos PS., 1988). Lactate is an endogenous substance (in carbohydrate and amino acid metabolism) and a natural component of very many foods, in particular fruits and fermented milk products. *Lactic acid* also occurs naturally in meats, fruits, tomato juice, beer, wine, molasses, blood and muscles of animals, and in the soil. *Lactic acid* has been approved in the EU as a food additive without an ADI or upper limit (Directive 95/2/EC), as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMA 2008). In 2011, the European Food Safety Authority (EFSA) delivered its agreement for the approval of *lactic acid* for uses to reduce microbial contamination of beef hides, carcasses, cuts and trimmings. More specifically, the approval was sought for treatments using *lactic acid* solution concentrations from 2% to 5% (w/w) at temperature of up to 55°C applied either by spraying or misting : "Considering the expected low

level of exposure deriving from the use of *Lactic acid* in carcasses, cuts and trimmings and the fact that it is an endogenous substance, it was concluded that the treatments, as described, will be of no safety concern, provided the substance used complies with the European Union specifications for food additives" (EFSA, 2011). According to the above mentioned, residues determination in food of plant and animal origin is not relevant.

3. *Lactic acid* also occurs naturally in the soil. Furthermore, *Lactic acid* is ubiquitous in the environment from natural and man-made sources making it impossible to determine the exact source. According to it, residues determination in air, water, soil are not considered to be relevant.

Biocidal product family *SALVESAFE D* does not contain substances of concerns.

2.2.5 Efficacy against target organisms

Information on effectiveness against target organisms submitted for the biocidal products within family *SALVESAFE D* is evaluated and the results are summarised in Section 3.3 of confidential Annex I.

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

Meta 1 and 2

The efficacy studies on bactericidal and yeasticidal claim had been performed for biocidal product with minimal concentration of *Lactic acid* and each co-formulants (reference biocidal product *SALVESAFE D0_P*). For phase 2, step 1 the liquid extracted from the wipe by a stomacher had been used in testing.

Meta 3

The efficacy studies on bactericidal, yeasticidal claim and efficacy against enveloped viruses had been performed for biocidal product with minimal concentration of *Lactic acid* and each co-formulants (reference biocidal product *SALVESAFE D0*). For phase 2, step 1 the liquid extracted from the wipe by a stomacher had been used in testing.

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

The used Standards based on laboratory suspension tests (phase 2, step 1) and test (phase 2, step 2) simulating practical conditions are appropriate to its intended use (temperature, soiling, contact time, concentrations, etc.) to support claims for evaluation of bactericidal and yeasticidal activity for family *SALVESAFE D*. The following Standards were used:

- EN 1650:2013, NF EN 1650:2019 – Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (phase 2, step 1);
- EN 1276:2010, NF EN 1276:2019 - 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 16615:2015 - Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with

mechanical action employing wipes in the medical area (4-field test) - Test method and requirements (phase 2, step 2).

- DIN EN 14476:2019-10 - Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1); German version EN 14476:2013+A2:2019
- DIN EN 16777:2019-03 - Chemical disinfectants and antiseptics – Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2, step 2); German version EN 16777:2018
- NF EN 13727:2015+A2 - Chemical antiseptics and disinfectants - Quantitative suspension test for the evaluation of bactericidal activity in medicine - Test method and prescriptions (Phase 2, Step 1)
- NF EN 13624:2013 - Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements - (Phase 2, step 1).

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

2.2.5.1 Function and field of use

All biocidal products within Meta 1 and 2 are ready-to-use wipes for disinfections of hard surfaces (in and without contact with food) in domestic, institutional and industrial area[1].

All biocidal products within Meta 3 are ready-to-use wipes for disinfections of hard surfaces (in and without contact with food) in domestic, institutional, industrial[2] and medical area.

Biocidal product family *SALVESAFE D* is claimed as disinfectants with a bactericidal and yeastidical action (Meta 1 and 2) and with a bactericidal, yeastidical and virucidal action against enveloped viruses (Meta 3). Only wet wipes are efficacious.

2.2.5.2 Effects on target organisms, including unacceptable suffering

The results of the efficacy studies are summarized in Section 3.3 of confidential Annex I, as well as, in below following Table under the point 2.2.5.4 within this Section.

Meta 1 and 2 Domestic, institutional and industrial area (initial application 2017)

To demonstrate the **bactericidal activity** quantitative suspension test according to the **EN 1276:2010** (method dilution-neutralization) against four reference strains: *Pseudomonas aeruginosa DSM 939, Enterococcus hirae DSM 3320, Staphylococcus aureus CIP 483* and *Escherichia coli DSM 682,* has been performed.

Activity against bacteria has been evaluated for liquid extracted from wipes at a 5 minutes contact time with desired concentrations of 80%, 50% and 1% at dirty conditions (3 g/l bovine albumin) and temperature 20 ± 1°C.

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

The results showed that the liquid extracted from wipes demonstrates > 5.00 log reduction for all tested bacterial species at the desired concentrations of 80%. Moreover, tests on *E. coli* demonstrated > 5.00 log reduction after 5 min contact time at 50% product concentration too (required ≥ 5.00).

Therefore, the biocidal product SALVESAFE D0_C with 1.75% w/w concentration of Lactic acid within family SALVESAFE D is a disinfectant with a bactericidal activity under defined test conditions and exposure 5 minutes according to claimed Standard and intended use.

To demonstrate the **yeasticidal activity** the quantitative suspension test according to the **EN 1650:2013** (method dilution-neutralization) against yeast *Candida albicans CIP 4872* has been performed.

Activity against yeast has been evaluated for liquid extracted from wipes at a 5 minutes contact time with desired concentrations of 80%, 50% and 1% at dirty conditions (3 g/l bovine albumin) and temperature 20 ± 1°C.

The results showed that the liquid extracted from wipes demonstrates > 4.00 log reduction for the tested yeast species at the desired concentration ≥ 80% (required ≥ 4.00).

Therefore, the biocidal product SALVESAFE D0_C with 1.75% w/w concentration of Lactic acid within family SALVESAFE D is a disinfectant with a yeasticidal activity under defined test conditions and exposure 5 minutes according to claimed Standard and intended use.

Simulation of **practical conditions** to establish whether the biocidal product (wipe) has a **bactericidal and yeasticidal activity** on hard surfaces the phase 2, step 2 was performed according to **EN 16615:2015**. The quantitative test on non-porous surfaces with mechanical action were used. Three bacterial species and one yeast were tested at dirty conditions (3 g/l bovine albumin + 3 ml/l sheep erythrocytes) and 20°C with a contact time of 5 minutes.

The results showed that the product commercial wipe 17.8 cm x 19 cm: 100% polyester impregnated with SALVESAFE D0_C demonstrates > 5.00 log reduction for all tested bacterial species and > 4.00 log reduction for yeast species at the tested concentration.

Therefore, the biocidal product SALVESAFE D0_C with 1.75% w/w concentration of Lactic acid within family SALVESAFE D is a disinfectant with a bactericidal and yeasticidal activity under the practical conditions according to claimed intended use.

Meta 3 Domestic, institutional, industrial and medical area (application on major changes 2022)

To demonstrate the **bactericidal activity** quantitative suspension test according to the **EN 1276:2019** against four reference bacteria strains has been performed.

Activity against bacteria has been evaluated for liquid extracted from wipes at 5 minutes contact time with desired concentrations of 80%, 50% and 1% at dirty conditions (3 g/l bovine albumin) and temperature 20 ± 1°C.

The results showed that the liquid extracted from wipes demonstrates > 5.00 log reduction for all tested bacterial species at the desired concentrations of 50% and 80%.

To demonstrate the **bactericidal activity** quantitative suspension test according to the **EN 13727:2015** against three reference bacteria strains has been performed.

Activity against bacteria has been evaluated for liquid extracted from wipes at a 5 minutes contact time with desired concentrations of 80%, 50% and 1% at dirty conditions (3 g/l bovine albumin with 3 mL/L sheep erythrocytes) and temperature 20 ± 1°C.

The results showed that the liquid extracted from wipes demonstrates > 5.00 log reduction for all tested bacterial species at the desired concentrations of 80%.

Therefore, the biocidal product SALVESAFE D0_C with 1.75% w/w concentration of Lactic acid within family SALVESAFE D is a disinfectant with a bactericidal activity under defined test conditions and exposure 5 minutes according to claimed Standard and intended use.

To demonstrate the **yeasticidal activity** the quantitative suspension test according to the **EN 1650:2019** against yeast has been performed.

Activity against yeast has been evaluated for liquid extracted from wipes at a 5 minutes contact time with desired concentrations of 80%, 50% and 1% at dirty conditions (3 g/l bovine albumin) and temperature 20 ± 1°C.

The results showed that the liquid extracted from wipes demonstrates > 4.00 log reduction for the tested yeast species at the desired concentration ≥ 80%.

To demonstrate the **yeasticidal activity** the quantitative suspension test according to the **EN 13624:2013** against yeast has been performed.

Activity against yeast has been evaluated for liquid extracted from wipes at a 5 minutes contact time with desired concentrations of 80%, 50% and 1% at dirty conditions (3 g/l bovine albumin with 3 mL/L sheep erythrocytes) and temperature 20 ± 1°C.

The results showed that the liquid extracted from wipes demonstrates > 4.00 log reduction for the tested yeast species at the desired concentration ≥ 80%.

Therefore, the biocidal product SALVESAFE D0_C with 1.75% w/w concentration of Lactic acid within family SALVESAFE D is a disinfectant with a yeasticidal activity under defined test conditions and exposure 5 minutes according to claimed Standard and intended use.

Simulation of **practical conditions** to establish whether the biocidal product (wipe) has a **bactericidal and yeasticidal activity** on hard surfaces the phase 2, step 2 was performed according to **EN 16615:2015**. The quantitative test on non-porous surfaces with mechanical action was used. Three bacterial species and one yeast were tested at dirty conditions (3 g/l bovine albumin + 3 ml/l sheep erythrocytes) and 20 °C with a contact time of 5 minutes.

The results showed that the standard wipe 17.5 cm x 28 cm: 55% pulp, 45% polyethyleneterephtalat (PET) impregnated with SALVESAFE D0_C solution demonstrates > 5.00 log reduction for all tested bacterial species and > 4.00 log reduction for yeast species at the tested concentration.

In addition, the results showed that commercial wipe 200 x 170 mm: Lyocell fiber impregnated with SALVESAFE D0_C demonstrates > 5.00 log reduction for all tested bacterial species and > 4.00 log reduction for yeast species at the tested concentration.

Therefore, the biocidal product SALVESAFE D0_C with 1.75% w/w concentration of Lactic acid within family SALVESAFE D is a disinfectant with a bactericidal and yeasticidal activity under the practical conditions according to claimed intended use.

To demonstrate the **virucidal activity against enveloped viruses** a quantitative suspension test according to the **EN 14476:2019** has been performed.

Activity against enveloped viruses has been evaluated for liquid extracted from wipes at a 5 minutes contact time with desired concentrations of 80%, 50%, 8% and 1% at dirty conditions (3 g/l bovine albumin with 3 mL/L sheep erythrocytes) and temperature 20 ± 1°C.

The results showed that the liquid extracted from wipes demonstrates > 5.00 log reduction for the tested virucidal specie at the desired concentration ≥ 80%.

To demonstrate the **virucidal activity against enveloped viruses** a quantitative non-porous surface test according to the **EN 16777:2019** has been performed.

Activity against enveloped viruses has been evaluated for liquid extracted from wipes at a 5 minutes contact time with desired concentrations of 100%, 80% and 1% at dirty conditions (3 g/l bovine albumin with 3 mL/L sheep erythrocytes) and temperature 20 ± 1°C.

The results showed that the liquid extracted from wipes demonstrates > 4.00 log reduction for the tested virucidal specie at the desired concentration ≥ 80%.

Therefore, the biocidal product SALVESAFE D0_C with 1.75% w/w concentration of Lactic acid within family SALVESAFE D is a disinfectant with an activity against enveloped viruses under defined test conditions and exposure 5 minutes according to claimed Standard and intended use.

2.2.5.3 Mode of action, including time delay

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

2.2.5.4 Efficacy data

Experimental data on the efficacy of the tested biocidal products against target organisms for supporting of the family

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Meta 1 and 2 (initial application 2017)							
Bactericide	PT2 and 4	SalveSafe Wipes (product extraction from the wipes, 1.75% w/w Lactic acid)	Pseudomonas aeruginosa DSM 939 Enterococcus hirae DSM 3320 Staphylococcus aureus CIP 483 Escherichia coli DSM 682	EN 1276:2010; (phase 2, step 1) Test method: dilution-neutralization /Quantitative suspension test	Tested product concentrations: 80%, 50%, 1%; contact times 5 minutes; dirty conditions with interfering substance: 3 g/l bovine albumin; test temperature 20 ± 1°C	Tested product demonstrated the bactericidal activity at concentrations of ≥ 80% in defined conditions (pass R > 5 log)	Conf.PAR

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Yeasticide	PT2 and 4	SalveSafe Wipes (product extraction from the wipes, 1.75% w/w Lactic acid)	Candida albicans CIP 4872	EN 1650:2013; (phase 2, step 1) Test method: dilution-neutralization /Quantitative suspension test	Tested product concentrations: 80% , 50%, 1%; contact times 5 minutes; dirty conditions with interfering substance: 3 g/l bovine albumin; test temperature 20 ± 1°C	Tested product demonstrated the yeasticidal activity at concentrations of ≥ 80% in defined conditions (pass R > 4 log)	Conf.PAR
Bactericide and Yeasticide	PT2 and 4	SalveSafe Wipes (commercial wipe, 1.75% w/w Lactic acid)	Pseudomonas aeruginosa ATCC 15442 Enterococcus hirae ATCC 10541 Staphylococcus aureus ATCC 6538 Candida albicans ATCC 10231	EN 16615:2015; (phase 2, step 2) Test method: dilution-neutralization / quantitative test on non-porous surfaces with mechanical action	Tested product concentrations: ready-to-use wipes, contact time - 5 minutes; dirty conditions with interfering substance: 3 g/l bovine albumin + 3 ml/l sheep erythrocytes; test temperature 20 ± 2.5°C	Tested product demonstrated the bactericidal and yeasticidal activity in defined conditions (pass R > 5 log and R > 4 log, respectively)	Conf.PAR
Meta 3 (MAC 2022)							
Bactericide	PT2 and PT4	SalveSafe D (product extraction from the wipes, 1.75% w/w Lactic acid)	*Staphylococcus aureus* DSM 799 *Enterococcus hirae* DSM 3320 *Pseudomonas aeruginosa* DSM 939 *Escherichia coli* DSM 682	EN 1276:2019; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 80%, 50%, 1% - Diluent: distilled water - Test method: dilution-neutralization - Contact time: 5 minutes - Soiling: 3 g/L BSA (dirty conditions) - Test temperature: 20°C	Tested product demonstrated bactericidal activity (logR > 5) at 80% product test concentration under defined conditions – 5 min, dirty conditions	Conf.PAR
Yeasticidal	PT2 and PT4	SalveSafe D (product extraction from the wipes, 1.75% w/w Lactic acid)	*Candida albicans* DSM 1386	EN 1650:2019; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 80%, 50%, 1% - Diluent: distilled water - Test method: dilution-neutralization - Contact time: 5 minutes - Soiling: 3 g/L BSA (dirty conditions) - Test temperature: 20°C	Tested product demonstrated yeasticidal activity (logR > 4) at 80% product test concentration under defined conditions – 5 min, dirty conditions	Conf.PAR

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Bactericide	PT2	SalveSafe D (product extraction from the wipes, 1.75% w/w Lactic acid)	*Staphylococcus aureus* DSM 799 *Enterococcus hirae* DSM 3320 *Pseudomonas aeruginosa* DSM 939	EN 13727+A2:2015; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 80%, 50%, 1% - Diluent: distilled water - Test method: dilution-neutralization - Contact time: 5 minutes - Soiling: 3 g/L BSA+3 ml/L sheep erythrocytes (dirty conditions) - Test temperature: 20°C	Tested product demonstrated bactericidal activity (logR > 5) at 50% and 80% product test concentration under defined conditions – 5 min, medical dirty conditions	Conf.PAR
Yeasticidal	PT2	SalveSafe D (product extraction from the wipes, 1.75% w/w Lactic acid)	*Candida albicans* DSM 1386	EN 13624:2013; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 80%, 50%, 1% - Diluent: distilled water - Test method: dilution-neutralization - Contact time: 5 minutes - Soiling: 3 g/L BSA+3 ml/L sheep erythrocytes (dirty conditions) - Test temperature: 20°C	Tested product demonstrated yeasticidal activity (logR > 4) at 80% product test concentration under defined conditions – 5 min, medical dirty conditions	Conf.PAR
Virucide against enveloped virus	PT2 and PT4	SalveSafe D (product extraction from the wipes, 1.75% w/w Lactic acid)	Modified vacciniavirus Ankara (MVA)	EN 14476:2019-10; Quantitative suspension test (phase 2, step 1)	- Tested product concentrations: 80%, 50%, 8.0% 1.0% - Diluent: distilled water - Interfering substance: 3 g/L BSA + 3.0 ml/l erythrocytes (dirty conditions) - Contact time: 5 minutes - Test temperature: 20°C	Tested product demonstrated virucidal activity against enveloped virus (> 4 log) at 80% product test concentrations after exposure time of 5 minutes under dirty conditions and 20°C.	Conf.PAR

Function	Field of use	Test product	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Virucide against enveloped virus	PT2 and PT4	SalveSafe D (product extraction from the wipes, 1.75% w/w Lactic acid)	Modified vacciniavirus Ankara (MVA)	EN 16777:2018; Quantitative non-porous surface test (phase 2, step 2)	- Tested product concentrations: 100%, 80%, 1.0% - Diluent: distilled water - Interfering substance: 3 g/L BSA + 3.0 ml/l erythrocytes (dirty conditions) - Contact time: 5 minutes - Test temperature: 20°C	Tested product demonstrated virucidal activity against enveloped virus (> 4 log) at 80% and 100% product test concentrations after exposure time of 5 minutes under dirty conditions and 20°C.	Conf.PAR
Bactericidal, yeasticidal	PT2 and PT4	SalveSafe D (liquid for disinfectant wipes, standard wipe, 1.75 % w/e lactic acid)	*Staphylococcus aureus* DSM 799 *Enterococcus hirae* DSM 3320 *Pseudomonas aeruginosa* DSM 939 *Candida albicans* DSM 1386	EN 16615:2015; Quantitative non-porous surface test with mechanical action (phase 2, step 2)	- Tested product concentrations: 100%, 1% - Diluent: distilled water - Test method: dilution-neutralization - Test surface PVC with PUR surface coating - Test wipe: (17,5 cmx28 cm: 55% pulp, 45% PET) - Contact time: 5 minutes - Soiling: 3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions) - Test temperature: 20°C	Tested product demonstrated bactericidal activity (logR > 5) at 100% product test concentration under defined conditions – 5 min, dirty conditions Tested product demonstrated yeasticidal activity (logR > 4) at 100% product test concentration under defined conditions – 5 min, dirty conditions	Conf.PAR
Bactericidal, yeasticidal	PT2 PT4	SalveSafe D (Lingettes désinfectantes, commercial wipe, 1.75% w/w Lactic acid))	*Staphylococcus aureus* DSM 799 *Enterococcus hirae* DSM 3320 *Pseudomonas aeruginosa* DSM 939 *Candida albicans* DSM 1386	EN 16615:2015; Quantitative non-porous surface test with mechanical action (phase 2, step 2)	- Tested product concentrations: 100% - Diluent: distilled water - Test method: dilution-neutralization - Test surface PVC with PUR surface coating - Test wipe: (200 mmx170mm: Lyocell fiber) - Contact time: 5 minutes - Soiling: 3 g/L BSA + 3 ml/L sheep erythrocytes (dirty conditions) - Test temperature: 20°C	Tested product demonstrated bactericidal activity (logR > 5) at 100% product test concentration under defined conditions – 5 min, dirty conditions Tested product demonstrated yeasticidal activity (logR > 4) at 100% product test concentration under defined conditions – 5 min, dirty conditions	Conf.PAR

Conclusion on the efficacy of the product
Biocidal product family *SALVESAFE D* is a group of products (wipes) with one active substance – *Lactic acid* at the concentration range 1.75-2.38 % w/w, similar use, but some differences in the content (different perfumes). The efficacy of full family is demonstrated using approach of worst-case testing. The efficacy studies had been performed for biocidal product with minimal *Lactic acid* concentration (1.75 % w/w), minimal concentration of each co-formulants and without perfume. It is not expected that negligible increasing of emulsifier content can negatively impact on efficacy. Therefore, the tested product covers all members within biocidal product family *SALVESAFE D*. For simulation of practical conditions according to EN 16615:2015 the commercial wipes are tested for meta-SPC 1 and 2 and standard wipe (from EN16615:2015) and commercial wipes are tested for meta-SPC 3. **Meta 1** All biocidal products within Meta 1 are ready-to-use wipes for disinfections of hard non-porous surfaces (in and without contact with food) in institutional and industrial area by professional users. The products are effective against bacteria and yeast at 5 minutes contact time. **Meta 2** All biocidal products within Meta 2 are ready-to-use wipes for disinfections of hard non-porous surfaces (in and without contact with food) in domestic area by non-professional users. The products are effective against bacteria and yeast at 5 minutes contact time. **Meta 3** All biocidal products within Meta 3 are ready-to-use wipes for disinfections of hard non-porous surfaces (in and without contact with food) in institutional, industrial, domestic and medical area by professional and non-professional users. The products are effective against bacteria, yeast and enveloped viruses at 5 minutes contact time.

2.2.5.5 Occurrence of resistance and resistance management

The efficacy of the biocidal product family *SALVESAFE D* has provided due the content of the active substance – *Lactic acid*. The resistance of target organisms to the biocidal product family *SALVESAFE D* actually could mean resistance to the *Lactic acid*. The possibility of the development of the resistance to *Lactic acid* was not evaluated due the fact that mentioned active substance is not included in the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012. The data on target organism's resistance had not been submitted by Applicant. However, Latvian CA revising the scientific literature (Theron MM., 2010) concludes that no clear scientific evidence exists that target organisms have developed resistance against the organics acid, such as *Lactic acid*.

2.2.5.6 Known limitations

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

2.2.5.7 Evaluation of the label claims

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

- Meta 1 and 2: bactericidal and yeasticidal activity at the contact time 5 minutes by full wetting of surface.
- Meta 3: bactericidal, yeasticidal and virucidal activity against enveloped viruses at the contact time 5 minutes by full wetting of surface.

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

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.	Conf.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	-	Conf.PAR

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not corrosive or irritating to skin.
Justification for the value/conclusion	According to the CLP criteria and additivity approach, classification is met with respect to local effects on the skin (irritation) for the individual products of the BPF and thus the BPF itself. The conclusion is made based on RAC opinion for L(+)-Lactic acid, content of individual components, generic cut-off values specified in CLP Annex I, Table 1.1 and generic concentration limits (GCL) specified in CLP Annex I, Table 3.2.3. The sum of the concentrations/GCL of individual components exceeds a concentration limit 1%. Upon Latvian CA request to support non-classification of the BPF, the Applicant provided study according to the OECD Test Guidance No. 404. The tested formulation contains 3.52% Lactic acid and surfactants at total concentration above the limit within family. As well, the tested formulation contains perfume at the concentration above the limit notified in family. Please refer to the Section 3.5 of the Confidential Annex for detailed composition of the tested formulation. 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 on a frame formula under dermatological control: - Evaluation of skin compatibility of a cosmetic product after repeated applications on elbow bend area for 5 consecutive days. The tested item had a close composition to products included in BPF. This study considered the test item non-irritant and showed a good skin tolerance.
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**	**Reference**
OECD guidelines 405 (GLP)	Conf.PAR	0.1 mL of biocidal product as supplied. Ocular examinations were performed 24, 48 and 72 hours following treatment	The ocular reactions observed have been slight to moderate and totally reversible.	Systemic analgesia and topical ocular anesthetic applied during test	Conf.PAR

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The biocidal product family *SALVESAFE D* does not have irritating effects on the eyes.
Justification for the value/conclusion	According to CLP regulation Annex I point 3.3.2.7 "Reversible effects on the eye (Category 2)", the substance shall be classified as Irrit. to eyes Cat. 2 if the substance produces at least in 2 of 3 tested animals the following effects: a) corneal opacity ≥ 1 and/or b) iritis ≥ 1, and/or c) conjunctival redness ≥ 2 and/or d) conjunctival oedema (chemosis) ≥ 2 (calculated as the mean scores following grading at 24, 48 and 72 hours after installation of the test material, and which fully reverses within an observation period of 21 days). The eye irritation test is performed for "dummy" perfumed formulation with 2.38% w/w *Lactic acid*, maximal concentration of a co-formulants. The tested product covers all perfumed biocidal product within family. The test showed mean individual values 0.3-1.0 for corneal opacity (value 1.0 observed only for one tested animal), 0-0.7 for iritis, 1.0-

	2.0 for conjunctival redness (value 2.0 observed only for one tested animal) and 0.3-1.0 for conjunctival oedema (chemosis). All effects were totally reversible within 21 days. According to CLP regulation no classification criteria are fulfilled. The biocidal product family *SALVESAFE D* 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 D* does not have irritating effects on respiratory tract.
Justification for the conclusion	The respiratory tract irritation effects of the biocidal products family *SALVESAFE D* 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 D* 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 D* does not have sensitization effects on skin.
Justification for the value/conclusion	The potential effect on dermal sensitization of the biocidal product family *SALVESAFE D* has not been investigated experimentally. Taking into account the information on classification of the *Lactic acid* and co-formulants, Latvian CA considers that the biocidal product family *SALVESAFE D* does not meet the criteria for classification for sensitisation.
Classification of the product according to CLP and DSD	Not relevant

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	The biocidal product family *SALVESAFE D* does not have respiratory sensitisation effects.
Justification for the value/conclusion	The respiratory sensitisation effects of the biocidal products family *SALVESAFE D* 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 D* 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 D* contains *Lactic acid* and no substance of concern. Latvian CA considers, that the biocidal product family *SALVESAFE D* 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 D* 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 D* 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 is not required for the use of the biocidal product family *SALVESAFE D*.

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 D* 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 D*, Latvian CA considers that detailed assessment of effects on the environment is not relevant.

However, Applicant had provided study with proposal to support rapidle degradability of "dummy" liquid formulation that covers composition of liquid extracted from the wipes within biocidal product family *SALVESAFE D*.

Aerobic biodegradability study is performed for a "dummy" perfumed formulation with 2.64% w/w Lactic acid and co-formulants with concentration above the family limit.

The results of the test show 63% carbon dioxide generation during 5 days and 100% after 25 days. The tested formulation is considered rapidly degradable in the environment in accordance with point 4.1.2.9.5 of Annex I CLP regulation as carbon dioxide generation is 60% of theoretical maximum during 10 days.

However, taking into account the formulation type (wipes) of the biocidal product family *SALVESAFE D*, Latvian CA considers that the following measures to protect the environment are appropriate: *Do not flush down the toilet. Do not dispose in the environment.*

2.2.8 Measures to protect man, animals and the environment

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

List of references

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