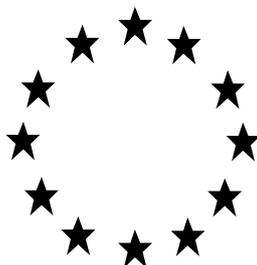


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A
BIOCIDAL PRODUCT FAMILY FOR UNION
AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



SALVECO SALVESAFE PRODUCTS

Product types 2, 3, 4

L-(+)-lactic acid as included in the Union list of approved active substances

Case Number in R4BP: BC-HC051278-51

Evaluating Competent Authority: France

Date: XX/XX/2021

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1 CONCLUSION

1.1 Conclusions of the evaluation

a) Summary of the evaluation and conclusions of the risk assessment

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product family.

General

The biocidal product family, SALVECO SALVESAFE PRODUCTS, is based on 0.627% to 31.33% of L (+) lactic acid (technical), is a product type 2, 3 and 4 intended for surface disinfection. The products of this biocidal family are liquids, to be applied for the disinfection against bacteria, yeast and enveloped virus by non-professional and professional users.

3 uses are claimed for the products of the BPF:

Use number	PT	Use description
1	2	Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in domestic, institutional, medical and industrial areas)
2	4	Food and feed area disinfectants (disinfectant for all washable hard surfaces in domestic, institutional and industrial (food industry) areas)
3	3	Disinfectants used to disinfect the materials and surfaces associated with the housing of animals (disinfectants for all washable hard surfaces in veterinary area)

The BPF SALVECO SALVESAFE PRODUCTS is composed of nine Meta-SPC with different AS concentrations:

Meta SPC	Uses	User category		Technical AS concentration
1	1 and 2	Pro / non pro	concentrate	15.66 to 31.33%
2	1 and 2	Pro / non pro	concentrate	15.66 to 31.33%
3	1 and 2	Pro	concentrate	7.83 to 31.33%
4	1 and 2	Pro	concentrate	7.83 to 31.33%
5	1, 2 and 3	Pro	concentrate	31.33%
6	1	Pro	concentrate	31.33%
7	1, 2 and 3	Pro	concentrate	31.33%
8	1 and 2	Pro / non pro	Ready to use	0.627 to 1.566%
9	1 and 2	Pro / non pro	Ready to use	0.627%

Physico-chemical properties

The physico-chemical properties of the biocidal product family SALVECO SALVESAFE PRODUCTS have been described and considered acceptable in the conditions of use detailed in the SPC.

For all Meta SPC of the family, the stability data indicate a shelf life of 2 years at ambient temperature when stored in commercial packaging material. All the products should be protected from frost.

Efficacy

The products of the family SALVECO SALVESAFE PRODUCTS have shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 for the following uses:

META-SPC 1

- Use 1: Disinfectants for all washable hard surfaces (PT 02) with dirty conditions (without mechanical action):

Household area:

- Mandatory target organisms:
 - Bacteria: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
- Other target organisms:
 - Enveloped viruses and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

Institutions and industry areas:

- Mandatory target organisms:
 - Bacteria, yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
- Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

Claimed application rate of 0.299% to 1.496% w/w L-(+)-lactic acid is then validated.

- Use 2: Disinfectants for all washable hard surfaces in domestic, institutional and industrial areas in contact with food (PT 04) in dirty conditions (without mechanical action) – for general disinfection:

- Mandatory target organisms:
 - Bacteria, yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

Claimed application rate of 0.299% to 1.496% w/w lactic acid is then validated.

META-SPC 2

- Use 1: Disinfectants for all washable hard surfaces (PT 02) in dirty conditions (without mechanical action)

Household area:

- Mandatory target organisms:
 - Bacteria: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
- Other target organisms:
 - Enveloped viruses and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

Institutions and industry areas:

- Mandatory target organisms:
 - Bacteria, yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
- Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

Claimed application rate of 0.299% to 1.496% w/w L-(+)-lactic acid is then validated.

- Use 2: Disinfectants for all washable hard surfaces in domestic, institutional and industrial areas in contact with food (PT 04) in dirty conditions (without mechanical action) – for general disinfection:

- Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

Claimed application rate of 0.299% to 1.496% w/w L-(+)-lactic acid is then validated.

META-SPC 3

- Use 1: Disinfectants for all washable hard surfaces in institutional and industrial areas (PT 02) in dirty conditions (without mechanical action) – for general disinfection:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
- Use 2: Disinfectants for all washable hard surfaces in institutional and industrial areas in contact with food (PT 04) in dirty conditions (without mechanical action) – for general disinfection:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

META-SPC 4

- Use 1: Disinfectants for all washable hard surfaces in institutional and industrial areas (PT 02) in dirty conditions (without mechanical action) – for general disinfection:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
- Use 2: Disinfectants for all washable hard surfaces in institutional and industrial areas in contact with food (PT 04) in dirty conditions (without mechanical action) – for general disinfection:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

META-SPC 5

- Use 1: Disinfectants for all washable hard surfaces (PT 02) in dirty conditions (without mechanical action):
Institutions and industry areas:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20 °C

Claimed application rate of 0.4485% w/w L-(+)-lactic acid is then validated.

Medical areas:

- Mandatory target organisms:
 - Bacteria, yeasts: 0.4485% w/w L-(+)-lactic acid, 5 min, 20°C
- Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

Claimed application rate of 0.4485% w/w L-(+)-lactic acid is then validated.

As no efficacy data have been provided to support the use by immersion in medical areas against fungi and viruses (mandatory target organisms), the application by immersion in medical area is not demonstrated.

Moreover, as only efficacy data against *E. hirae* was provided according to P2S2 test (EN 16615) and no tests with the other mandatory strains were provided, efficacy with mechanical action is not considered to be supported based on the efficacy data provided and only efficacy without mechanical action is validated.

- Use 2: Disinfectants for all washable hard surfaces in institutional and industrial areas in contact with food (PT 04) in dirty conditions (without mechanical action):
General disinfection and meat industries (except slaughterhouses):
 - Mandatory target organisms:

- Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
Claimed application rate of 0.4485% to 0.598% w/w L-(+)-lactic acid is then validated.
Milk industries:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.598% w/w L-(+)-lactic acid, 5 min, 20°CThe claimed application rate for this use are 0.4485% to 0.598% w/w L-(+)-lactic acid. Therefore, only the maximum application rate of 0.598% w/w L-(+)-lactic acid is validated for milk industries and the application rate of 0.4485% w/w L-(+)-lactic acid is not demonstrated.
- Use 3: Disinfectants for all washable non-porous hard surfaces in veterinary areas (PT 03) in clean conditions (without mechanical action):
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 30 min, 10 °CClaimed application rate of 0.299% w/w L-(+)-lactic acid is then validated.

META-SPC 6

- Use 1: Disinfectants for all washable hard surfaces in medical areas (PT 02) in dirty conditions (without mechanical action):
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.4485% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses: 0.4485% w/w L-(+)-lactic acid, 5 min, 20°C

As no efficacy data have been provided to support the use by immersion in medical areas against fungi and viruses (mandatory target organisms), the application by immersion in medical area is not demonstrated.

Moreover, as only efficacy data against *E. hirae* was provided according to P2S2 test (EN 16615) and no tests with the other mandatory strains were provided, efficacy with mechanical action is not considered to be supported based on the efficacy data provided and only efficacy without mechanical action is validated.

META-SPC 7

- Use 1: Disinfectants for all washable hard surfaces (PT 02) in clean and dirty conditions (without mechanical action)
Household area:
 - Mandatory target organisms:
 - Bacteria: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C*Institutions and industry areas:*
 - Mandatory target organisms:
 - Bacteria, yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

As only efficacy data against *E. hirae* was provided according to P2S2 test (EN 16615) and no tests with the other mandatory strains were provided efficacy with mechanical action (claimed for institutional area) is not considered to be supported based on the efficacy data provided and only efficacy without mechanical action is validated.

- Use 2: Disinfectants for all washable hard surfaces in domestic, institutional and industrial areas in contact with food (PT 04) in clean and dirty conditions (without mechanical action) – for general disinfection:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
- Use 3: Disinfectants for all washable hard non-porous surfaces in veterinary areas (PT 03) in clean conditions (without mechanical action):
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.748% w/w L-(+)-lactic acid, 30 min, 10°C

As no efficacy data has been provided against yeasts (mandatory target organism) with a contact time of 5 minutes, the efficacy for this contact time is not validated.

META-SPC 8

- Use 1: Disinfectants for all washable hard surfaces (PT 02) in dirty conditions (without mechanical action)
Household area:
 - Mandatory target organisms:
 - Bacteria: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C*Institutions and industry areas:*
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°CClaimed application rate of 0.598% or 1.496% w/w L-(+)-lactic acid (RTU products) is then validated.
- Use 2: Disinfectants for all washable hard surfaces in domestic, institutional and industrial areas in contact with food (PT 04) in dirty conditions (without mechanical action) – general disinfection:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°CClaimed application rate of 0.598% or 1.496% w/w L-(+)-lactic acid (RTU products) is then validated.

META-SPC 9

- Use 1: Disinfectants for all washable hard surfaces (PT 02) in dirty conditions (without mechanical action)
Household area:
 - Mandatory target organisms:
 - Bacteria: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C*Institutions and industry areas:*
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°CClaimed application rate of 0,598% w/w L-(+)-lactic acid (RTU products) is then validated.

- Use 2: Disinfectants for all washable hard surfaces in domestic, institutional and industrial areas in contact with food (PT 04) in dirty conditions (without mechanical action) – general disinfection:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20 °C
- Claimed application rate of 0.598% w/w L-(+)-lactic acid (RTU products) is then validated.

Please note that based on the composition of the family, some Meta SPC could claim products with less in use surfactants than the representative products tested in the efficacy studies (see confidential part of the PAR) and therefore for which no information on the impact on efficacy were provided.

Therefore, eCA consider that a general instructions for use should be added in the SPC for these Meta SPC (Meta SPC 1, Meta SPC 2, Meta SPC 3 and Meta SPC 4) indicated that "Minimum in use concentration of surfactants should be 0.29%."

Human health

Meta SPC 1 to 7:

Considering the dermal irritant and eye damaging properties of the products, the local risk is acceptable during hard surface disinfection for professional and non professional users considering the RMMs indicated in the SPC.

Meta SPC 8 and 9:

The risk is acceptable during hard surface disinfection for professional and non professional users.

Dietary risk assessment

By definition, PT 02 biocidal product is not intended for direct application to humans or animals and is not used for direct contact with food or feeding stuffs.

Regarding the intended uses on PT 03 and 04, residues in food, feed or drinking water might be expected. Nevertheless, based on the low concentration of L(+) lactic acid, the endogenous production and compared to naturally occurring levels in food, significant indirect exposure via intended uses is not expected.

Two co-formulants included in the SALVECO SALVESAFE PRODUCTS family were identified as substances of concern for human health. Nevertheless, based on the characteristics of these substances, it was not considered necessary to derive toxicological reference values. Therefore, risk for consumer via indirect exposure via food can be excluded.

Environment

No substance of concern has been defined for the environment.

Considering a worst case representative product with the maximum in-use concentration of L(+) lactic acid, all the indoor uses in PT02 and PT04 are considered acceptable for all the relevant compartments and for all the meta SPC.

Considering the indoor uses in PT03, the multi-purpose disinfectants for hard surfaces in veterinary area by immersion is considered unacceptable for the aquatic and terrestrial compartments via the release of manure/slurry to the environment. Therefore, the following

RMM should be applied to consider this intended use acceptable: ***Do not discharge the biocidal product nor the diluted solution of the biocidal product to the manure deposit. Baths containing the product need to be removed to a sewer connected to a sewage treatment plant.*** However, according to the WG I 2022, it was stated that a qualitative assessment is sufficient in case of indirect release to surface water. Therefore, the risks for PT03 uses (in veterinary area) are considered acceptable and no RMM is needed.

Considering the outdoor uses in PT02 – PT03 and PT04, these applications lead to risk ratios higher than 1 for the terrestrial compartment in case of direct release to soil. However, according to the WGIII2021, the risks are considered acceptable based on the argumentation on the natural occurrence of this substance in soil.

In order to reduce unnecessary releases to the environment and for spraying application, the following RMMs should be applied: "For outdoor uses, do not apply the product in case rain is expected within 24 hrs" and "For outdoor uses, avoid transfer to other areas by wind (drift)".

b) Presentation of the biocidal product family including classification and labelling

Classification of product family (meta SPC 1, 2, 3, 4, 5, 6 & 7)	
Hazard category	Skin Irrit. 2 Eye Dam. 1
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage

Classification of product family (meta SPC 8 & 9)	
Hazard category	N.A.
Hazard statement	N.A.

The description of the structure of the family is available in the SPC. The hazard and precautionary statements of the biocidal product family according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substance L-(+)-lactic acid contained in the biocidal product family does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is (are) not considered (a) candidate(s) for substitution. Therefore, a comparative assessment of the biocidal product family is not required.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

The conformity to the uniform principles, as defined in the Regulation (EU) n°528/2012, for the biocidal product family SALVECO SALVESAFE PRODUCTS is reported in the table below, for each use.

Meta-SPC	PT	Target organism	Application rates	Use condition	Conclusion	
1	2	Bacteria	0.299% to 1.496% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor & Outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping Non professional & Professional	Acceptable	
		Yeast				
		Enveloped virus				
	4	Bacteria				
		Yeast				
2	2	Bacteria	0.299% to 1.496% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor & Outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping Non professional & Professional	Acceptable	
		Yeast				
		Enveloped virus				
	4	Bacteria				
		Yeast				
3	2	Bacteria	0.299% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor & Outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping Professional	Acceptable	
		Yeast				
		Enveloped virus				
	4	Bacteria				
		Yeast				
4	2	Bacteria	0.299% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor & Outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping Professional	Acceptable	
		Yeast				
		Enveloped virus				
	4	Bacteria				
		Yeast				
5	2	Bacteria	0.4485% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor & Outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping without mechanical action Professional	Application by immersion in medical areas not acceptable: efficacy not demonstrated against fungi and virus (mandatory target organisms)	
		Yeast				
		Enveloped virus				
	4	2	Bacteria	0.4485% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor & Outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping without mechanical action Professional	Acceptable
			Yeast			
		4	Bacteria			
			Enveloped virus			

	4	Bacteria	0.4485% to 0.598% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor & Outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping Professional	Minimum application rate not acceptable for milk industries: efficacy not demonstrated.
		Bacteria	General disinfection and meat industries: 0.4485% to 0.598% w/w L-(+)-lactic acid, 5 min, 20°C Milk industries: 0.598% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor & Outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping Professional	Acceptable
		Yeast			
	3	Bacteria	0.299% w/w L-(+)-lactic acid, 30 min, 10°C		Acceptable
		Yeast			
6	2	Bacteria	0.4485% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor & Outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping without mechanical action Professional	Application by immersion in medical areas not acceptable: efficacy not demonstrated against fungi and virus (mandatory target organisms)
		Yeast			
		Enveloped virus			
		Bacteria	0.4485% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor & Outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, mopping without mechanical action Professional	Acceptable
		Yeast			
		Enveloped virus			
7	2	Bacteria	0.299% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor & Outdoor Application by Wiping, moping or brushing, spraying, soaking or dipping (immersion) without mechanical action	Acceptable
		Yeast			
		Enveloped virus			

				Clean carefully the surfaces before application of the product. Professional	
	4	Bacteria	0.299% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor & Outdoor	Acceptable
		Yeast		Application by Wiping, mopping or brushing, spraying, soaking or dipping (immersion)	
		Enveloped virus		Professional & Industrial	
	3	Bacteria	0.748% w/w L-(+)-lactic acid, 5 min, 10°C	Indoor & Outdoor	Not acceptable: Efficacy not demonstrated with contact time of 5min.
		Yeast		Application by Wiping, mopping or brushing, spraying, soaking or dipping (immersion) Professional	
		Bacteria	0.748% w/w L-(+)-lactic acid, 30 min, 10°C	Indoor & Outdoor	Acceptable
		Yeast		Application by Wiping, mopping or brushing, spraying, soaking or dipping (immersion) Professional	
8	2	Bacteria	0.598 % to 1.496% L-(+)-lactic acid, : 5 min, 20°C	Indoor & Outdoor	Acceptable
		Yeast		Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping	
		Enveloped virus		Non professional & Professional	
	4	Bacteria			
		Yeast			
9	2	Bacteria	0.598% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor & Outdoor	Acceptable
		Yeast		Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping	
		Enveloped virus		Non professional & Professional	
	4	Bacteria			
		Yeast			

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended use(s) of the biocidal product family have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance(s) in the biocidal product family are met.

The physico-chemical properties of the biocidal product family are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised use(s), according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product family SALVECO SALVESAFE PRODUCTS is sufficiently effective;
2. the biocidal product family SALVECO SALVESAFE PRODUCTS has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. the biocidal product family has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product family has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
 - the fate and distribution of the biocidal product in the environment,
 - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
 - the impact of the biocidal product on non-target organisms,
 - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the use(s) described in the SPC, may be authorised.

1.2 BPC opinion on the Union authorisation of the biocidal product/biocidal product family

As the conditions of Article 19(1) are met it is proposed that biocidal product family shall be authorised¹, for the use(s) described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

¹ This is without prejudice of any specific conditions that might apply in the territory of Member State(s) in accordance with Article 44(5) of the BPR.

2 ASSESSMENT REPORT

PART I - FIRST INFORMATION LEVEL

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier ²	Country (if relevant)
SALVECO SALVESAFE PRODUCTS	FRANCE

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		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products of the family

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

Name of manufacturer 2	GESTRA S.A.S.
Address of manufacturer	Allée Robert Schumann RAON-L'ETAPE, F-88110, FRANCE
Location of manufacturing sites	Allée Robert Schumann RAON-L'ETAPE, F-88110, FRANCE

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	L-(+)-lactic acid
Name of manufacturer	PURAC BIOCHEM BV
Address of manufacturer	Gran Vial 19-25, 08160 – Montmelo, Spain

² Please fill in here the identifying product name from R4BP.

Location of manufacturing sites	Gran Vial 19-25, 08160 – Montmelo, Spain
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Active substance	L-(+)-lactic acid
Name of manufacturer	JUNGBUNGZLAUER S.A
Address of manufacturer	Z. I Portuaire BP 32, 67390, Marckolsheim, France
Location of manufacturing sites	Z. I Portuaire BP 32, 67390, Marckolsheim, France

2.1.2 Product family composition and formulation

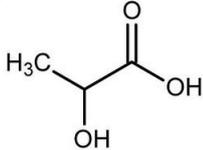
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes

No

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	L-(+)-lactic acid
IUPAC or EC name	(2S)-2-hydroxypropanoic acid
EC number	201-196-2
CAS number	79-33-4
Index number in Annex VI of CLP	-
Minimum purity / content	minimum purity of the active substance as manufactured \geq 95.5% w/w
Structural formula	

2.1.2.2 Candidate(s) for substitution

L-(+)-lactic acid is not candidate for substitution in accordance with Article 10 of BPR.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family²

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance*	79-33-4	201-196-2	0.598	29.9
		Technical active substance**			0.627	31.33
<i>Content in the biocidal product family of the TK containing the active substance</i>					0.68	34
Poly(oxy-1,2-ethanediyl), .alpha.-(carboxymethyl)-.omega.-(octyloxy)-		Surfactant	53563-70-5		0.252	28.8
D-glucopyranose, oligomeric, C10-16		Surfactant	110615-47-9		0.07	8.23

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
(even numbered)-alkyl glycosides						

*based on the content of active substance in the TK used for the formulation of the biocidal product (88% w/w for L-(+)-lactic acid).

**based on the minimum purity of active substance: 95.5% w/w for L-(+)-lactic acid.

2.1.2.4 Information on technical equivalence

The first source of L-(+)-lactic acid is the same as evaluated for inclusion in the EU list of approved active substances.

The second source (Jungbunzlauer S.A.) is considered technically equivalent compared to the reference source.

2.1.2.5 Information on the substance(s) of concern

Two co-formulants included in the SALVECO SALVESAFE PRODUCTS family were identified as substances of concern for human health.

Please see sections 2.1.2.3 above, 2.12.6.1 below and the confidential annex for further details.

2.1.2.6 Assessment of endocrine disruption (ED) properties of the biocidal product family

The biocidal product contains the active substance "L-(+)-Lactic Acid", which is not considered to have endocrine disrupting properties.

None of the co-formulants contained in the SALVECO SALVESAFE PRODUCTS family are regulatory identified as endocrine disruptors or have significant ED properties.

For further details, please refer to the Confidential Annex.

2.1.2.7 Type of formulation

SL – Soluble Concentrate (meta SPC 1 to 7), AL – Any other liquids (meta SPC 8 and 9)

PART II - SECOND INFORMATION LEVEL - META SPC 1

2.2.1 Meta SPC 1 administrative information

2.2.1.1 Meta SPC identifier

Identification	META SPC 1
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2.2.1.2 Suffix to the authorisation number

1	
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2.2.1.3 Product type(s)

Product type(s)	2
	4

2.2.2 Meta SPC 1 composition

2.2.2.1 Qualitative and quantitative information on the composition of the meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid	(2S)-2-hydroxypropionic acid	Pure active substance	79-33-4	201-196-2	14.96	29.9
		Technical active substance			15.66	31.33
<i>Content in the biocidal product family of the TK containing the active substance</i>					17	34
Poly(oxy-1,2-ethanediyl), .alpha.-(carboxymethyl)-.omega.-(octyloxy)-		Surfactant	53563-70-5		13.5	27
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		3.52	8.23

2.2.2.2 Type(s) of formulation of the meta SPC 1

SL – Soluble Concentrate

2.2.3 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Skin Irrit. 2 Eye Dam. 1
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H315: Causes skin irritation H318: Causes serious eye damage
Precautionary statements	P101: If medical advice is needed, have product container or label at hand P102: Keep out of reach of children P103: Read carefully and follow all instructions P264: Wash ... thoroughly after handling P280: Wear protective gloves/ protective clothing/eye protection/face protection /... P302 + P352: IF ON SKIN: Wash with plenty of water/... P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310: Immediately call a POISON CENTER/doctor/... P321: Specific treatment (see ... on this label). P332 + P313: If skin irritation occurs: Get medical advice/ attention P362 + P364: Take off contaminated clothing and wash it before reuse
Note	P280 is not applicable for the non-professional user.

2.2.4 Authorised use(s) of the META SPC 1

2.2.4.1 Use description

Table 1. Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in domestic, institutional, medical and industrial areas).

Product Type	PT2
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast Enveloped virus
Field of use	Indoor Outdoor in domestic, institutional, medical and industrial areas

Application method(s)	Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping - without mechanical action
Application rate(s) and frequency	Mandatory target organisms: <ul style="list-style-type: none"> Bacteria: 0.299% to 1.496% w/w L-(+)-lactic acid, 5 min, 20°C Other target organisms: <ul style="list-style-type: none"> Enveloped viruses and yeasts: 0.299% to 1.496% w/w L-(+)-lactic acid, 5 min, 20°C
Category(ies) of users	Non professional Professional
Pack sizes and packaging material	Package size for non professional is restricted to maximum 3 L and packaging above 1 L should be equipped with a handle Refill caps: 20 - 100mL HDPE Bottles: 0.5 - 5L HDPE or PET Jerry can: 1-80L HDPE (only for professional users) Drum: 10-210L HDPE (only for professional users) IBC: 1000L HDPE (only for professional users)

2.2.4.1.1 Use-specific instructions for use

-

2.2.4.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.2.4.2 Use description

Table 2. Use # 2 – Food and feed area disinfectants (disinfectant for all washable hard surfaces in domestic, institutional and food industry areas.

Product Type	PT 4
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Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor Outdoor in domestic, institutional and food industry areas (general disinfection)
Application method(s)	Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping - without mechanical action
Application rate(s) and frequency	Mandatory target organisms: <ul style="list-style-type: none">• Bacteria and yeast: 0.299% to 1.496% w/w L-(+)-lactic acid, 5 min, 20°C
Category(ies) of users	Non professional Professional
Pack sizes and packaging material	Package size for non professional is restricted to maximum 3 L and packaging above 1 L should be equipped with a handle Refill caps: 20 - 100mL HDPE Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE (only for professional users) Drum: 10-210L HDPE (only for professional users) IBC: 1000L HDPE (only for professional users)

2.2.4.2.1 Use-specific instructions for use

-

2.2.4.2.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.2.5 General directions for use of the meta SPC 1

2.2.5.1 Instructions for use

- Apply the product by fully wetting all surface for 5 minutes (apply approx. 18 sprays /m² or 20 mL/m² or fully cover the object to be disinfected).
- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.
- Read carefully and follow all instructions
- The authorisation holder should give indications of application of the product (dilution, quantity applied on surfaces, etc.) on the label in order to guarantee the efficacy of the product during its application. The volume of product to be diluted and the specified volume of water should be clearly indicated on the label (e.g. take 10 mL of product and dilute in 1L water).

2.2.5.2 Risk mitigation measures

- (For professional only) Wear protective chemical resistant gloves, chemical goggles and a coverall when handling the concentrate product (during dilution) - PPE material to be specified by the authorisation holder within the product information.
- Wash hands after use of the concentrate product.
- Avoid contact with eyes.
- Avoid splashes and spills during mixing and loading (dilution).
- (For non-professional only) A child-proof closure is required.
- Keep out of reach of children and non-target animals/pets.
- For outdoor uses, do not apply the product in case rain is expected within 24 hrs. For outdoor uses by spray, avoid transfer to other areas by wind (drift).

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

- If medical advice is needed, have product container or label at hand
- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor:
The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.
- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

2.2.5.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

- Keep out of reach of children and non-target animals/pets.
- Shelf-life: 2 years.
- Protect from frost.

2.2.6 Other information

- Minimum in use concentration of surfactants should be 0.29%.

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

2.2.7 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE FAM1_1				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	29.9
		Technical active substance			31.33
<i>Content in the biocidal product of the TK containing the active substance</i>					34
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		27
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		8.23
Trade name(s)	SALVESAFE FAM1_5				

Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	19.95
		Technical active substance			20.89
<i>Content in the biocidal product of the TK containing the active substance</i>					22.67
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		18
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		5.49

Trade name(s)	SALVESAFE FAM1_9 OSANIS – Nettoyant désinfectant concentré				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	14.96
		Technical active substance			15.66
<i>Content in the biocidal product of the TK containing the active substance</i>					17
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		13.5
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		4.11

Trade name(s)	SALVESAFE FAM1_13 MILTON - Dégraissant désinfectant				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	29.9
		Technical active substance			31.33
<i>Content in the biocidal product of the TK containing the active substance</i>					34
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		27
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		3.52

PART II - SECOND INFORMATION LEVEL - META SPC 2

2.3.1 Meta SPC 2 administrative information

2.3.1.1 Meta SPC identifier

Identification	META SPC 2
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2.3.1.2 Suffix to the authorisation number

2	
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2.3.1.3 Product type(s)

Product type(s)	2
	4

2.3.2 Meta SPC 2 composition

2.3.2.1 Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid	(2S)-2-hydroxypropionic acid	Pure active substance	79-33-4	201-196-2	14.96	29.9
		Technical active substance			15.66	31.33
<i>Content in the biocidal product family of the TK containing the active substance</i>					17	34
Poly(oxy-1,2-ethanediyl), .alpha.-(carboxymethyl)-.omega.-(octyloxy)-		Surfactant	53563-70-5		13.5	27
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		3.52	8.23

2.3.2.2 Type(s) of formulation of the meta SPC 2

SL – Soluble Concentrate

2.3.3 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Skin Irrit. 2 Eye Dam. 1
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H315: Causes skin irritation H318: Causes serious eye damage

Classification	
Precautionary statements	P101: If medical advice is needed, have product container or label at hand P102: Keep out of reach of children P103: Read carefully and follow all instructions P264: Wash ... thoroughly after handling P280: Wear protective gloves/ protective clothing/eye protection/face protection/... P302 + P352 IF ON SKIN: Wash with plenty of water/... P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310: Immediately call a POISON CENTER/doctor/... P321: Specific treatment (see ... on this label). P332 + P313: If skin irritation occurs: Get medical advice/ attention P362 + P364: Take off contaminated clothing and wash it before reuse
Note	For fragrance Cool Mint: EUH208 – « Contains Eucalyptol, Carvone and Limonene. May produce an allergic reaction » For fragrance Pure: EUH208 – « Contains Methyl salicylate and Eugenol. May produce an allergic reaction » For fragrance Eucalyptus Leaves: EUH208 – « Contains Eucalyptol. May produce an allergic reaction » P280 is not applicable for the non-professional user.

2.3.4 Authorised use(s) of the META SPC 2

2.3.4.1 Use description

Table 3. Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in domestic, institutional, medical and industrial areas).

Product Type	PT 2
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast Enveloped virus
Field of use	Indoor Outdoor in domestic, institutional, medical and industrial area
Application method(s)	Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping - without mechanical action
Application rate(s) and frequency	Mandatory target organisms: <ul style="list-style-type: none"> Bacteria: 0.299% to 1.496% w/w L-(+)-lactic acid, 5 min, 20°C Other target organisms:

	<ul style="list-style-type: none"> Enveloped viruses and yeasts: 0.299% to 1.496% w/w L-(+)-lactic acid, 5 min, 20°C
Category(ies) of users	Non professional Professional
Pack sizes and packaging material	Package size for non professional is restricted to maximum 3 L and packaging above 1 L should be equipped with a handle Refill caps: 20 - 100mL HDPE Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE (only for professional users) Drum: 10-210L HDPE (only for professional users) IBC: 1000L HDPE (only for professional users)

2.3.4.1.1 Use-specific instructions for use

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2.3.4.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.3.4.2 Use description

Table 4. Use # 2 – Food and feed area disinfectants (disinfectant for all washable hard surfaces in domestic, institutional and food industry areas.

Product Type	PT4
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor Outdoor in domestic, institutional and food industry areas (general disinfection)

Application method(s)	Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping - without mechanical action
Application rate(s) and frequency	Mandatory target organisms: <ul style="list-style-type: none">• Bacteria and yeast: 0.299% to 1.496% w/w L-(+)-lactic acid, 5 min, 20°C
Category(ies) of users	Non professional Professional
Pack sizes and packaging material	Package size for non professional is restricted to maximum 3 L and packaging above 1 L should be equipped with a handle Refill caps: 20 - 100mL HDPE Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE (only for professional users) Drum: 10-210L HDPE (only for professional users) IBC: 1000L HDPE (only for professional users)

2.3.4.2.1 Use-specific instructions for use

-

2.3.4.2.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.3.5 General directions for use of the meta SPC 2

2.3.5.1 Instructions for use

- Apply the product by fully wetting all surface for 5 minutes (apply approx. 18 sprays /m² or 20 mL/m² or fully cover the object to be disinfected).
- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.

- Read carefully and follow all instructions.
- The authorisation holder should give indications of application of the product (dilution, quantity applied on surfaces, etc.) on the label in order to guarantee the efficacy of the product during its application. The volume of product to be diluted and the specified volume of water should be clearly indicated on the label (e.g. take 10 mL of product and dilute in 1L water).

2.3.5.2 Risk mitigation measures

- (For professional only) Wear protective chemical resistant gloves, chemical goggles and a coverall when handling the concentrate product (during dilution) - PPE material to be specified by the authorisation holder within the product information.
- Wash hands after use of the concentrate product.
- Avoid contact with eyes
- Avoid splashes and spills during mixing and loading (dilution).
- (For non-professional) A child-proof closure is required.
- Keep out of reach of children and non-target animals/pets.
- For outdoor uses, do not apply the product in case rain is expected within 24 hrs.
- For outdoor uses by spray, avoid transfer to other areas by wind (drift).

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

- If medical advice is needed, have product container or label at hand
- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor:
The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid
- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

2.3.5.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

- Keep out of reach of children and non-target animals/pets.
- Shelf-life: 2 years.
- Protect from frost.

2.3.6 Other information

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| - Minimum in use concentration of surfactants should be 0.29%. |
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PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2**2.3.7** Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE FAM1_2				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	29.9
		Technical active substance			31.33
<i>Content in the biocidal product of the TK containing the active substance</i>					34
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		27
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		8.23

Trade name(s)	SALVESAFE FAM1_3				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Pure active substance	79-33-4	201-196-2	29.9

	(2S)-2-hydroxypropanoic acid	Technical active substance			31.33
<i>Content in the biocidal product of the TK containing the active substance</i>					34
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		27
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		8.23

Trade name(s)	SALVESAFE FAM1_4				
Authorisation number	MAISON VERTE - Recharge pour spray désinfectant multi-usages MAISON VERTE PRO - Recharge pour spray désinfectant multi-usages MAISON VERTE PRO - Recharge pour spray désinfectant salle de bain SANIVERT - Recharge pour spray désinfectant multi-usages YOU - Recharge désinfectant toutes surfaces YOU - Recharge désinfectant WC SANILAK - Recharge Nettoyant désinfectant multi-usages Eucalyptus SANILAK - Recharge Nettoyant désinfectant sanitaires Eucalyptus SANILAK - Recharge Nettoyant désinfectant cuisine Eucalyptus YOU - Refill All purpose disinfecting cleaner				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	29.9
		Technical active substance			31.33
<i>Content in the biocidal product of the TK containing the active substance</i>					34
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.		Surfactant	53563-70-5		27

omega.- (octyloxy)-					
D-glucopyranose, oligomeric, C10-16 (even numbered)- alkyl glycosides		Surfactant	110615- 47-9		8.23

Trade name(s)		SALVESAFE FAM1_6			
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	19.95
		Technical active substance			20.89
<i>Content in the biocidal product of the TK containing the active substance</i>					22.67
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		18
D-glucopyranose, oligomeric, C10-16 (even numbered)- alkyl glycosides		Surfactant	110615- 47-9		5.49

Trade name(s)		SALVESAFE FAM1_7			
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	19.95
		Technical active substance			20.89
<i>Content in the biocidal product of the TK containing the active substance</i>					22.67

Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		18
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		5.49

Trade name(s)	SALVESAFE FAM1_8				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	19.95
		Technical active substance			20.89
<i>Content in the biocidal product of the TK containing the active substance</i>					22.67
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		18
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		5.49

Trade name(s)	SALVESAFE FAM1_10				
Authorisation number	SANILAK - Nettoyant désinfectant concentré Menthe SANILAK - Recharge Nettoyant désinfectant sols et surfaces Menthe				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)

L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	14.96
		Technical active substance			15.66
<i>Content in the biocidal product of the TK containing the active substance</i>					17
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		13.5
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		4.11

Trade name(s)	SALVESAFE FAM1_11				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	14.96
		Technical active substance			15.66
<i>Content in the biocidal product of the TK containing the active substance</i>					17
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		13.5
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		4.11

Trade name(s)	SALVESAFE FAM1_12
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Authorisation number	MAISON VERTE - Recharge pour sol désinfectant multi-surfaces MAISON VERTE PRO - Recharge pour désinfectant sol MAISON VERTE PRO - Recharge pour désinfectant Multi-surfaces SANIVERT - Recharge désinfectant multi-surfaces YOU - Recharge désinfectant sols & surfaces SANILAK - Nettoyant désinfectant concentré Eucalyptus SANILAK - Recharge Nettoyant désinfectant sols et surfaces Eucalyptus				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	14.96
		Technical active substance			15.66
<i>Content in the biocidal product of the TK containing the active substance</i>					17
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		13.5
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		4.11

Trade name(s)	SALVESAFE FAM1_14				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	29.9
		Technical active substance			31.33
<i>Content in the biocidal product of the TK containing the active substance</i>					34
Poly(oxy-1,2-ethanediyl), .alpha.		Surfactant	53563-70-5		27

.- (carboxymethyl)- omega.- (octyloxy)-					
D-glucopyranose, oligomeric, C10-16 (even numbered)- alkyl glycosides		Surfactant	110615- 47-9		8.23

Trade name(s)		SALVESAFE FAM1_15			
Authorisation number		TECH'LAB - Concentré détergent désinfectant sols & surfaces			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	14.96
		Technical active substance			15.66
<i>Content in the biocidal product of the TK containing the active substance</i>					17
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)- omega.- (octyloxy)-		Surfactant	53563-70- 5		13.5
D-glucopyranose, oligomeric, C10-16 (even numbered)- alkyl glycosides		Surfactant	110615- 47-9		4.11

Trade name(s)		SALVESAFE FAM1_16			
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	14.96
		Technical active substance			15.66

<i>Content in the biocidal product of the TK containing the active substance</i>					17
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		13.5
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		4.11

PART II - SECOND INFORMATION LEVEL - META SPC 3

2.4.1 Meta SPC 3 administrative information

2.4.1.1 Meta SPC identifier

Identification	META SPC 3
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2.4.1.2 Suffix to the authorisation number

3	
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2.4.1.3 Product type(s)

Product type(s)	2
	4

2.4.2 Meta SPC 3 composition

2.4.2.1 Qualitative and quantitative information on the composition of the meta SPC 3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid	(2S)-2-hydroxypropionic acid	Pure active substance	79-33-4	201-196-2	7.48	29.9
		Technical active substance			7.83	31.33
<i>Content in the biocidal product family of the TK containing the active substance</i>					8.5	34
Poly(oxy-1,2-ethanediyl), .alpha.-		Surfactant	53563-70-5		6.75	27

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
(carboxymethyl)-.om ega.-(octyloxy)-						
D-glucopyranose, oligomeric, C10-16 (even numbered)- alkyl glycosides		Surfactant	110615-47-9		1.32	3.52

2.4.2.2 Type(s) of formulation of the meta SPC 3

SL – Soluble Concentrate

2.4.3 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 3

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Skin Irrit. 2 Eye Dam. 1
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H315: Causes skin irritation H318: Causes serious eye damage
Precautionary statements	P264: Wash ... thoroughly after handling P280: Wear protective gloves/ protective clothing/eye protection/face protection /... P302 + P352: IF ON SKIN: Wash with plenty of water/... P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310: Immediately call a POISON CENTER/doctor/... P321: Specific treatment (see ... on this label). P332 + P313: If skin irritation occurs: Get medical advice/ attention P362 + P364: Take off contaminated clothing and wash it before reuse
Note	

2.4.4 Authorised use(s) of the META SPC 3

2.4.4.1 Use description

Table 5. Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in institutional, and industrial areas).

Product Type	PT 2
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast Enveloped virus
Field of use	Indoor Outdoor in institutional and industrial area
Application method(s)	Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping - without mechanical action
Application rate(s) and frequency	Mandatory target organisms: <ul style="list-style-type: none"> Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C Other target organisms: <ul style="list-style-type: none"> Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
Category(ies) of users	Professional
Pack sizes and packaging material	Refill caps: 20 – 100mL HDPE Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE Drum: 10-210L HDPE IBC: 1000L HDPE

2.4.4.1.1 Use-specific instructions for use

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2.4.4.1.2 Use-specific risk mitigation measures

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

-

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

-

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

-

2.4.4.2 Use description

Table 6. Use # 2 – Food and feed area disinfectants (disinfectant for all washable hard surfaces in institutional and industrial areas).

Product Type	PT 4
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor Outdoor in institutional and industrial area (general)
Application method(s)	Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping - without mechanical action
Application rate(s) and frequency	Mandatory target organisms: <ul style="list-style-type: none"> • Bacteria and yeast: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
Category(ies) of users	Professional
Pack sizes and packaging material	Refill caps: 20 – 100mL HDPE Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE Drum: 10-210L HDPE IBC: 1000L HDPE

2.4.4.2.1 Use-specific instructions for use

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2.4.4.2.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.4.5 General directions for use of the meta SPC 3

2.4.5.1 Instructions for use

- Apply the product by fully wetting all surface for 5 minutes (apply approx. 18 sprays /m² or 20 mL/m² or fully cover the object to be disinfected).
- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.
- The authorisation holder should give indications of application of the product (dilution, quantity applied on surfaces, etc.) on the label in order to guarantee the efficacy of the product during its application. The volume of product to be diluted and the specified volume of water should be clearly indicated on the label (e.g. take 10 mL of product and dilute in 1L water).

2.4.5.2 Risk mitigation measures

- Wear protective chemical resistant gloves, chemical goggles and a coverall when handling the concentrate product (during dilution) - PPE material to be specified by the authorisation holder within the product information.
- Wash hands after use of the concentrate product.
- Avoid contact with eyes.
- Avoid splashes and spills during mixing and loading (dilution).
- For outdoor uses, do not apply the product in case rain is expected within 24 hrs. For outdoor uses by spray, avoid transfer to other areas by wind (drift).

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

- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor:
The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid
- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

2.4.5.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

- Shelf-life: 2 years.
- Protect from frost.

2.4.6 Other information

- Minimum in use concentration of surfactants should be 0.29%.

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

2.4.7 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE FAM2_1				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	14.96
		Technical active substance			15.66
<i>Content in the biocidal product of the TK containing the active substance</i>					17
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		13.5
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		1.76

Trade name(s)	SALVESAFE FAM2_2				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)

L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	29.9
		Technical active substance			31.33
<i>Content in the biocidal product of the TK containing the active substance</i>					34
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		27
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		3.52

Trade name(s)	SALVESAFE FAM2_6				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	7.48
		Technical active substance			7.83
<i>Content in the biocidal product of the TK containing the active substance</i>					8.5
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		6.75
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		1.32

PART II - SECOND INFORMATION LEVEL - META SPC 4

2.5.1 Meta SPC 4 administrative information**2.5.1.1** Meta SPC identifier

Identification	META SPC 4
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2.5.1.2 Suffix to the authorisation number

4	
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2.5.1.3 Product type(s)

Product type(s)	2
	4

2.5.2 Meta SPC 4 composition**2.5.2.1** Qualitative and quantitative information on the composition of the meta SPC 4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid	(2S)-2-hydroxypropionic acid	Pure active substance	79-33-4	201-196-2	7.48	29.9
		Technical active substance			7.83	31.33
<i>Content in the biocidal product family of the TK containing the active substance</i>					8.5	34
Poly(oxy-1,2-ethanediyl), .alpha.-(carboxymethyl)-.omega.-(octyloxy)-		Surfactant	53563-70-5		6.75	27
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		1.32	5.28

2.5.2.2 Type(s) of formulation of the meta SPC 4

SL – Soluble Concentrate

2.5.3 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 4**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

Classification	
Hazard category	Skin Irrit. 2 Eye Dam. 1
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H315: Causes skin irritation H318: Causes serious eye damage
Precautionary statements	P264: Wash ... thoroughly after handling P280: Wear protective gloves/ protective clothing/eye protection/face protection /... P302 + P352: IF ON SKIN: Wash with plenty of water/... P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310: Immediately call a POISON CENTER/doctor/... P321: Specific treatment (see ... on this label). P332 + P313: If skin irritation occurs: Get medical advice/ attention P362 + P364: Take off contaminated clothing and wash it before reuse
Note	For fragrance Cool Mint: EUH208 – « Contains Eucalyptol, Carvone and Limonene. May produce an allergic reaction » For fragrance Pure: EUH208 – « Contains Methyl salicylate and Eugenol. May produce an allergic reaction » For fragrance Eucalyptus Leaves: EUH208 – « Contains Eucalyptol. May produce an allergic reaction »

2.5.4 Authorised use(s) of the META SPC 4

2.5.4.1 Use description

Table 7. Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in institutional and industrial areas).

Product Type	PT2
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast Enveloped virus
Field of use	Indoor Outdoor in institutional and industrial area
Application method(s)	Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping - without mechanical action

Application rate(s) and frequency	<p>Mandatory target organisms:</p> <ul style="list-style-type: none"> Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C <p>Other target organisms:</p> <ul style="list-style-type: none"> Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
Category(ies) of users	Professional
Pack sizes and packaging material	<p>Refill caps: 20 – 100mL HDPE</p> <p>Bottles: 0,5 - 5L HDPE or PET</p> <p>Jerry can: 1-80L HDPE</p> <p>Drum: 10-210L HDPE</p> <p>IBC: 1000L HDPE</p>

2.5.4.1.1 Use-specific instructions for use

-

2.5.4.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.5.4.2 Use description

Table 8. Use # 2 – Food and feed area disinfectants (disinfectant for all washable hard surfaces in institutional and industrial areas).

Product Type	PT4
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor Outdoor in institutional and industrial area (general)

Application method(s)	Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping - without mechanical action
Application rate(s) and frequency	Mandatory target organisms: <ul style="list-style-type: none">• Bacteria and yeast: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
Category(ies) of users	Professional
Pack sizes and packaging material	Refill caps: 20 – 100mL HDPE Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE Drum: 10-210L HDPE IBC: 1000L HDPE

2.5.4.2.1 Use-specific instructions for use

-

2.5.4.2.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.5.5 General directions for use of the meta SPC 4

2.5.5.1 Instructions for use

- Apply the product by fully wetting all surface for 5 minutes (apply approx. 18 sprays /m² or 20 mL/m² or fully cover the object to be disinfected).
- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.
- The authorisation holder should give indications of application of the product (dilution, quantity applied on surfaces, etc.) on the label in order to guarantee the efficacy of the product during its application. The volume of product to be diluted and the specified volume of water should be clearly indicated on the label (e.g. take 10 mL of product and dilute in 1L water).

2.5.5.2 Risk mitigation measures

- Wear protective chemical resistant gloves, chemical goggles and a coverall when handling the concentrate product (during dilution) - PPE material to be specified by the authorisation holder within the product information.
- Wash hands after use of the concentrate product.
- Avoid contact with eyes.
- Avoid splashes and spills during mixing and loading (dilution).
- For outdoor uses, do not apply the product in case rain is expected within 24 hrs.
- For outdoor uses by spray, avoid transfer to other areas by wind (drift).

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

- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor:
The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid
- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

2.5.5.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

- Shelf-life: 2 years.
- Protect from frost.

2.5.6 Other information

- Minimum in use concentration of surfactants should be 0.29%.

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4

2.5.7 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE FAM2_3				
Authorisation number	ATOOUT-VERT - DD303 SANILAK - Recharge Nettoyant Désinfectant Multi-usages Menthe, SANILAK - Recharge Nettoyant Désinfectant Sanitaires Menthe, SANILAK - Recharge Nettoyant Désinfectant Cuisine Menthe				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	29.9
		Technical active substance			31.33
<i>Content in the biocidal product of the TK containing the active substance</i>					34
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		27
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		5.28

Trade name(s)	SALVESAFE FAM2_4				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	29.9
		Technical active substance			31.33
<i>Content in the biocidal product of the TK containing the active substance</i>					34
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.		Surfactant	53563-70-5		27

omega.- (octyloxy)-					
D-glucopyranose, oligomeric, C10-16 (even numbered)- alkyl glycosides		Surfactant	110615- 47-9		5.28

Trade name(s)	SALVESAFE FAM2_5				
Authorisation number	ATOUT-VERT - DDP38				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2- hydroxypropanoi c acid	Pure active substance	79-33-4	201-196-2	7.48
		Technical active substance			7.83
<i>Content in the biocidal product of the TK containing the active substance</i>					8.5
Poly(oxy-1,2- ethanediyl), .alpha .- (carboxymethyl)-. omega.- (octyloxy)-		Surfactant	53563-70- 5		6.75
D-glucopyranose, oligomeric, C10-16 (even numbered)- alkyl glycosides		Surfactant	110615- 47-9		1.32

PART II - SECOND INFORMATION LEVEL - META SPC 5

2.6.1 Meta SPC 5 administrative information

2.6.1.1 Meta SPC identifier

Identification	META SPC 5
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2.6.1.2 Suffix to the authorisation number

5	
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2.6.1.3 Product type(s)

Product type(s)	2
	3
	4

2.6.2 Meta SPC 5 composition**2.6.2.1** Qualitative and quantitative information on the composition of the meta SPC 5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid	(2S)-2-hydroxypropionic acid	Pure active substance	79-33-4	201-196-2	29.9	29.9
		Technical active substance			31.33	31.33
<i>Content in the biocidal product family of the TK containing the active substance</i>					34	34
Poly(oxy-1,2-ethanediyl), .alpha.-(carboxymethyl)-.omega.-(octyloxy)-		Surfactant	53563-70-5		28.8	28.8
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		3.52	3.52

2.6.2.2 Type(s) of formulation of the meta SPC 5

SL – Soluble Concentrate

2.6.3 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 5**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

Classification	
Hazard category	Skin Irrit. 2 Eye Dam. 1
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage
Labelling	
Signal words	Danger

Classification	
Hazard statements	H315: Causes skin irritation H318: Causes serious eye damage
Precautionary statements	P264: Wash ... thoroughly after handling P280: Wear protective gloves/ protective clothing/eye protection/face protection /... P302 + P352: IF ON SKIN: Wash with plenty of water/... P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310: Immediately call a POISON CENTER/doctor/... P321: Specific treatment (see ... on this label). P332 + P313: If skin irritation occurs: Get medical advice/ attention P362 + P364: Take off contaminated clothing and wash it before reuse
Note	

2.6.4 Authorised use(s) of the META SPC 5

2.6.4.1 Use description

Table 9. Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in institutional, medical, and industrial areas).

Product Type	PT2
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast Enveloped virus
Field of use	Indoor Outdoor in institutional, medical and industrial area
Application method(s)	Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion (except for medical areas), mopping - without mechanical action
Application rate(s) and frequency	Mandatory target organisms: <ul style="list-style-type: none"> Bacteria and yeasts: 0.4485% w/w L-(+)-lactic acid, 5 min, 20°C Other target organisms: <ul style="list-style-type: none"> Enveloped viruses: 0.4485% w/w L-(+)-lactic acid, 5 min, 20°C The concentrated product is to be diluted at 1.5% v/v before use as indicated on label.
Category(ies) of users	Professional
Pack sizes and packaging material	Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE

	Drum: 10-210L HDPE IBC: 1000L HDPE
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2.6.4.1.1 Use-specific instructions for use

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2.6.4.1.2 Use-specific risk mitigation measures

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

-

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

-

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

-

2.6.4.2 Use description

Table 10. Use # 2 – Food and feed area disinfectants (disinfectant for all washable hard surfaces in institutional and industrial (food industry) areas.

Product Type	PT4
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor Outdoor In institutional and industrial (food industry (general, meat (except slaughterhouses) and milk industries)) area
Application method(s)	Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping - without mechanical action
Application rate(s) and frequency	General disinfection and meat industries Mandatory target organisms: <ul style="list-style-type: none"> • Bacteria and yeast: 0.4485% to 0.598% w/w L-(+)-lactic acid, 5 min, 20°C Milk industries Mandatory target organisms: <ul style="list-style-type: none"> • Bacteria and yeast: 0.598% w/w L-(+)-lactic acid, 5 min, 20°C

Category(ies) of users	Professional
Pack sizes and packaging material	Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE Drum: 10-210L HDPE IBC: 1000L HDPE

2.6.4.2.1 Use-specific instructions for use

-

2.6.4.2.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.6.4.3 Use description

Table 11. Use # 3 – Disinfectants used to disinfect the materials and surfaces associated with the housing of animals (disinfectants for all washable hard surfaces in veterinary area).

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor Outdoor
Application method(s)	Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping - without mechanical action
Application rate(s) and frequency	Mandatory target organisms: <ul style="list-style-type: none"> Bacteria and yeast: 0.299% w/w L-(+)-lactic acid, 30 min, 10°C

	The concentrated product is to be diluted at 1% v/v before use as indicated on label.
Category(ies) of users	Professional
Pack sizes and packaging material	Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE Drum: 10-210L HDPE IBC: 1000L HDPE

2.6.4.3.1 Use-specific instructions for use

- Clean carefully the surfaces before application of the product.

2.6.4.3.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.6.5 General directions for use of the meta SPC 5

2.6.5.1 Instructions for use

- Apply the product by fully wetting all surface for 5 to 30 minutes (apply approx. 18 sprays /m² or 20 mL/m² or fully cover the object to be disinfected).
- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.
- The authorisation holder should give indications of application of the product (dilution, quantity applied on surfaces, etc.) on the label in order to guarantee the efficacy of the product during its application. The volume of product to be diluted and the specified volume of water should be clearly indicated on the label (e.g. take 10 mL of product and dilute in 1L water).

2.6.5.2 Risk mitigation measures

- Wear protective chemical resistant gloves, chemical goggles and a coverall when handling the concentrate product (during dilution) - PPE material to be specified by the authorisation holder within the product information.
- Wash hands after use of the concentrate product.

- Avoid contact with eyes.
- Avoid splashes and spills during mixing and loading (dilution).
- For outdoor uses, do not apply the product in case rain is expected within 24 hrs.
- For outdoor uses by spray, avoid transfer to other areas by wind (drift).

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

- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor:
The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid
- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

2.6.5.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

- Shelf-life: 2 years.
- Protect from frost.

2.6.6 Other information

- The product is a foaming formulation.

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5

2.6.7 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE FAM3_1				
Authorisation number	EKO CLEAN DESINFECTANT EKO GERM D				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)

L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	29.9
		Technical active substance			31.33
<i>Content in the biocidal product of the TK containing the active substance</i>					34
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		28.8
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		3.52

PART II - SECOND INFORMATION LEVEL - META SPC 6

2.7.1 Meta SPC 6 administrative information

2.7.1.1 Meta SPC identifier

Identification	META SPC 6
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2.7.1.2 Suffix to the authorisation number

6	
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2.7.1.3 Product type(s)

Product type(s)	2
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2.7.2 Meta SPC 6 composition

2.7.2.1 Qualitative and quantitative information on the composition of the meta SPC 6

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Pure active substance	79-33-4	201-196-2	29.9	29.9

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
	(2S)-2-hydroxypropanoic acid	Technical active substance			31.33	31.33
<i>Content in the biocidal product family of the TK containing the active substance</i>					34	34
Poly(oxy-1,2-ethanediyl), .alpha.-(carboxymethyl)-.omega.-(octyloxy)-		Surfactant	53563-70-5		28.8	28.8
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		5.28	5.28

2.7.2.2 Type(s) of formulation of the meta SPC 6

SL – Soluble Concentrate

2.7.3 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 6

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Skin Irrit. 2 Eye Dam. 1
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H315: Causes skin irritation H318: Causes serious eye damage

Classification	
Precautionary statements	P264: Wash ... thoroughly after handling P280: Wear protective gloves/ protective clothing/eye protection/face protection /... P302 + P352: IF ON SKIN: Wash with plenty of water/... P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310: Immediately call a POISON CENTER/doctor/... P321: Specific treatment (see ... on this label). P332 + P313: If skin irritation occurs: Get medical advice/ attention P362 + P364: Take off contaminated clothing and wash it before reuse
Note	EUH208 – "Contains Eucalyptol and Carvone. May produce an allergic reaction".

2.7.4 Authorised use(s) of the META SPC 6

2.7.4.1 Use description

Table 12. Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in medical area).

Product Type	PT2
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast Enveloped virus
Field of use	Indoor Outdoor in medical area
Application method(s)	Spraying, spreading, wiping, foam application, brush treatment, dip treatment, mopping - without mechanical action
Application rate(s) and frequency	Mandatory target organisms: <ul style="list-style-type: none"> Bacteria and yeast: 0.4485% w/w L-(+)-lactic acid, 5 min, 20°C Other target organisms: <ul style="list-style-type: none"> Enveloped viruses: 0.4485% w/w L-(+)-lactic acid, 5 min, 20°C The concentrated product is to be diluted at 1.5 % before use as indicated on label.
Category(ies) of users	Professional
Pack sizes and packaging material	Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE Drum: 10-210L HDPE IBC: 1000L HDPE

2.7.4.1.1 Use-specific instructions for use

-

2.7.4.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.7.5 General directions for use of the meta SPC 6

2.7.5.1 Instructions for use

- Apply the product by fully wetting all surface for 5 minutes (apply approx. 18 sprays /m² or 20 mL/m² or fully cover the object to be disinfected).
- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.
- The authorisation holder should give indications of application of the product (dilution, quantity applied on surfaces, etc.) on the label in order to guarantee the efficacy of the product during its application. The volume of product to be diluted and the specified volume of water should be clearly indicated on the label (e.g. take 10 mL of product and dilute in 1L water).

2.7.5.2 Risk mitigation measures

- Wear protective chemical resistant gloves, chemical goggles and a coverall when handling the concentrate product (during dilution) - PPE material to be specified by the authorisation holder within the product information.
- Wash hands after use of the concentrate product.
- Avoid contact with eyes.
- Avoid splashes and spills during mixing and loading (dilution).
- For outdoor uses, do not apply the product in case rain is expected within 24 hrs.
- For outdoor uses by spray, avoid transfer to other areas by wind (drift).

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

- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.

Call 112/ambulance for medical assistance.

Information to Healthcare personnel/doctor:

- The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid
- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor

2.7.5.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

- Shelf-life: 2 years.
- Protect from frost.

2.7.6 Other information

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PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6

2.7.7 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE FAM3_2				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	29.9
		Technical active substance			31.33
<i>Content in the biocidal product of the TK containing the active substance</i>					34

Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		28.8
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		5.28

PART II - SECOND INFORMATION LEVEL - META SPC 7

2.8.1 Meta SPC 7 administrative information

2.8.1.1 Meta SPC identifier

Identification	META SPC 7
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2.8.1.2 Suffix to the authorisation number

7	
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2.8.1.3 Product type(s)

Product type(s)	2
	3
	4

2.8.2 Meta SPC 7 composition

2.8.2.1 Qualitative and quantitative information on the composition of the meta SPC 7

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid	(2S)-2-hydroxypropionic acid	Pure active substance	79-33-4	201-196-2	29.9	29.9
		Technical active substance			31.33	31.33
<i>Content in the biocidal product family of the TK containing the active substance</i>					34	34
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		24.93	24.93

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		3.52	3.52

2.8.2.2 Type(s) of formulation of the meta SPC 7

SL – Soluble Concentrate

2.8.3 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 7

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Skin Irrit. 2 Eye Dam. 1
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H315: Causes skin irritation H318: Causes serious eye damage
Precautionary statements	P264: Wash ... thoroughly after handling P280: Wear protective gloves/ protective clothing/eye protection/face protection /... P302 + P352: IF ON SKIN: Wash with plenty of water/... P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310: Immediately call a POISON CENTER/doctor/... P321: Specific treatment (see ... on this label). P332 + P313: If skin irritation occurs: Get medical advice/ attention P362 + P364: Take off contaminated clothing and wash it before reuse
Note	

2.8.4 Authorised use(s) of the META SPC 7

2.8.4.1 Use description

Table 15. Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in domestic, institutional and industrial areas.

Product Type	PT 2
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast Enveloped virus
Field of use	Indoor Outdoor in domestic, institutional and industrial area
Application method(s)	Wiping, moping or brush, spraying, soaking or dipping (immersion) - without mechanical action
Application rate(s) and frequency	Mandatory target organisms: <ul style="list-style-type: none"> Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C Other target organisms: <ul style="list-style-type: none"> Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C The concentrated product is to be diluted at 1% v/v before use as indicated on label.
Category(ies) of users	Professional
Pack sizes and packaging material	Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE Drum: 10-210L HDPE IBC: 1000L HDPE Soft container: 1.5, 2.5L LDPE

2.8.4.1.1 Use-specific instructions for use

[Empty box]

2.8.4.1.2 Use-specific risk mitigation measures

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

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

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

-

2.8.4.2 Use description

Table 16. Use # 2 – Food and feed area disinfectants (disinfectant for all washable hard surfaces in domestic, institutional and industrial (food industry) areas.

Product Type	PT 4
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast Enveloped virus
Field of use	Indoor Outdoor in domestic, institutional and food industry areas (general disinfection)
Application method(s)	Wiping, moping or brush, spraying, soaking or dipping (immersion) - without mechanical action
Application rate(s) and frequency	Mandatory target organisms: <ul style="list-style-type: none"> Bacteria and yeast: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C Other target organisms: <ul style="list-style-type: none"> Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C The concentrated product is to be diluted at 1% v/v before use as indicated on label.
Category(ies) of users	Professional Industrial

Pack sizes and packaging material	Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE Drum: 10-210L HDPE IBC: 1000L HDPE Soft container: 1.5, 2.5L LDPE
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2.8.4.2.1 Use-specific instructions for use

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2.8.4.2.2 Use-specific risk mitigation measures

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

-

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

-

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

-

2.8.4.3 Use description

Table 17. Use # 3 – Disinfectants used to disinfect the materials and surfaces associated with the housing of animals (disinfectants for all washable hard surfaces in veterinary area).

Product Type	PT 3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor Outdoor
Application method(s)	Wiping, moping or brush, spraying, soaking or dipping (immersion) - without mechanical action
Application rate(s) and frequency	Mandatory target organisms: <ul style="list-style-type: none"> Bacteria and yeast: 0.748% w/w L-(+)-lactic acid, 30 min, 10°C

	The concentrated product is to be diluted at 2.5% v/v before use as indicated on label.
Category(ies) of users	Professional
Pack sizes and packaging material	Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE Drum: 10-210L HDPE IBC: 1000L HDPE Soft container: 1.5, 2.5L LDPE

2.8.4.3.1 Use-specific instructions for use

Clean carefully the surfaces before application of the product.

2.8.4.3.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.8.5 General directions for use of the meta SPC 7

2.8.5.1 Instructions for use

- Apply the product by fully wetting all surface for 5 to 30 minutes (apply approx. 18 sprays /m² or 20 mL/m² or fully cover the object to be disinfected).
- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.
- The authorisation holder should give indications of application of the product (dilution, quantity applied on surfaces, etc.) on the label in order to guarantee the efficacy of the product during its application. The volume of product to be diluted and the specified volume of water should be clearly indicated on the label (e.g. take 10 mL of product and dilute in 1L water).

2.8.5.2 Risk mitigation measures

- Wear protective chemical resistant gloves, chemical goggles and a coverall when handling the concentrate product (during dilution) - PPE material to be specified by the authorisation holder within the product information.
- Wash hands after use of the concentrate product.

- Avoid contact with eyes.
- Avoid splashes and spills during mixing and loading (dilution).
- For outdoor uses, do not apply the product in case rain is expected within 24 hrs.
- For outdoor uses by spray, avoid transfer to other areas by wind (drift).

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

- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor:
The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid
- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

2.8.5.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

- Shelf-life: 2 years.
- Protect from frost.

2.8.6 Other information

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PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 7

2.8.7 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE 15
Authorisation number	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	29.9
		Technical active substance			31.33
<i>Content in the biocidal product of the TK containing the active substance</i>					34
Poly(oxy-1,2-ethanediyl), .alpha.- (carboxymethyl)-.omega.- (octyloxy)-		Surfactant	53563-70-5		24.93
D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides		Surfactant	110615-47-9		3.52

PART II - SECOND INFORMATION LEVEL - META SPC 8

2.9.1 Meta SPC 8 administrative information

2.9.1.1 Meta SPC identifier

Identification	META SPC 8
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2.9.1.2 Suffix to the authorisation number

8	
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2.9.1.3 Product type(s)

Product type(s)	2
	4

2.9.2 Meta SPC 8 composition

2.9.2.1 Qualitative and quantitative information on the composition of the meta SPC 8

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Pure active substance	79-33-4	201-196-2	0.598	1.496

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
	(2S)-2-hydroxypropionic acid	Technical active substance			0.627	1.566
<i>Content in the biocidal product family of the TK containing the active substance</i>					0.68	1.7

2.9.2.2 Type(s) of formulation of the meta SPC 8

AL – Any other liquids

2.9.3 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 8

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	-
Hazard statement	-
Labelling	
Signal words	-
Hazard statements	-
Precautionary statements	-
Note	

2.9.4 Authorised use(s) of the META SPC 8

2.9.4.1 Use description

Table 18. Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in domestic, institutional and industrial areas).

Product Type	PT 2
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast Enveloped virus
Field of use	Indoor Outdoor in domestic, institutional and industrial areas

Application method(s)	Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion - without mechanical action
Application rate(s) and frequency	Ready to use products. Contact time: 5 min, 20°C
Category(ies) of users	Non professional Professional
Pack sizes and packaging material	Sprays (SP05): 0.5L - 0.75L HDPE or PET Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE (only for professional users) Drum: 10-210L HDPE (only for professional users) IBC: 1000L HDPE (only for professional users)

2.9.4.1.1 Use-specific instructions for use

-

2.9.4.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.9.4.2 Use description

Table 19. Use # 2 – Food and feed area disinfectants (disinfectant for all washable hard surfaces in domestic, institutional and industrial areas).

Product Type	PT 4
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor Outdoor

	in domestic, institutional and industrial (food industry (general)) areas
Application method(s)	Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion - without mechanical action
Application rate(s) and frequency	Ready to use products. Contact time: 5 min, 20°C
Category(ies) of users	Non professional Professional
Pack sizes and packaging material	Sprays (SP05): 0.5L - 0.75L HDPE or PET Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE (only for professional users) Drum: 10-210L HDPE (only for professional users) IBC: 1000L HDPE (only for professional users)

2.9.4.2.1 Use-specific instructions for use

-

2.9.4.2.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.9.5 General directions for use of the meta SPC 8

2.9.5.1 Instructions for use

- Apply the product by fully wetting all surface for 5 minutes (apply approx. 18 sprays /m² or 20 mL/m² or fully cover the object to be disinfected).
- Comply with the instructions for use.
- Apply only on non porous surfaces.
- Inform the registration holder if the treatment is ineffective.
- Read carefully and follow all instructions.

2.9.5.2 Risk mitigation measures

- For outdoor uses, do not apply the product in case rain is expected within 24 hrs.

- For outdoor uses by spray, avoid transfer to other areas by wind (drift).

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

- 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.

2.9.5.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

- Keep out of reach of children and non-target animals/pets.
- Shelf-life: 2 years.
- Protect from frost.

2.9.6 Other information

-

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 8

2.9.7 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE FAM5_1				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	0.598
		Technical active substance			0.627

<i>Content in the biocidal product of the TK containing the active substance</i>	0.68
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Trade name(s)	SALVESAFE FAM5_2				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	0.598
		Technical active substance			0.627
<i>Content in the biocidal product of the TK containing the active substance</i>					0.68

Trade name(s)	SALVESAFE FAM5_3 SANILAK - Nettoyant désinfectant multi-usages Eucalyptus SANILAK - Nettoyant désinfectant sanitaires Eucalyptus SANILAK - Nettoyant désinfectant cuisine Eucalyptus				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	0.598
		Technical active substance			0.627
<i>Content in the biocidal product of the TK containing the active substance</i>					0.68

Trade name(s)	SALVESAFE FAM5_4				
Authorisation number	YOU - All purpose disinfecting cleaner MAISON VERTE - Désinfectant MAISON VERTE PRO - Désinfectant Multi-usages MAISON VERTE PRO - Désinfectant Salle de Bain SANIVERT - Désinfectant YOU - Nettoyant désinfectant toutes surfaces YOU - Désinfectant WC détartrant				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)

L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	0.598
		Technical active substance			0.627
<i>Content in the biocidal product of the TK containing the active substance</i>					0.68

Trade name(s)	SALVESAFE FAM5_5				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	1.496
		Technical active substance			1.566
<i>Content in the biocidal product of the TK containing the active substance</i>					1.7

Trade name(s)	SALVESAFE FAM5_6 SANILAK - Nettoyant désinfectant sols et surfaces				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	1.496
		Technical active substance			1.566
<i>Content in the biocidal product of the TK containing the active substance</i>					1.7

Trade name(s)	SALVESAFE FAM5_7 SANILAK - Nettoyant désinfectant sols et surfaces Eucalyptus				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)

L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	1.496
		Technical active substance			1.566
<i>Content in the biocidal product of the TK containing the active substance</i>					1.7

Trade name(s)	SALVESAFE FAM5_8 MAISON VERTE - Désinfectant Multi-surfaces MAISON VERTE PRO - Désinfectant Sol MAISON VERTE PRO - Désinfectant Multi-surfaces SANIVERT - Désinfectant Multi-surfaces YOU - Désinfectant sols & surfaces				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	1.496
		Technical active substance			1.566
<i>Content in the biocidal product of the TK containing the active substance</i>					1.7

PART II - SECOND INFORMATION LEVEL - META SPC 9

2.10.1 Meta SPC 9 administrative information

2.10.1.1 Meta SPC identifier

Identification	META SPC 9
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2.10.1.2 Suffix to the authorisation number

9	
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2.10.1.3 Product type(s)

Product type(s)	2
	4

2.10.2 Meta SPC 9 composition**2.10.2.1** Qualitative and quantitative information on the composition of the meta SPC 9

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid	(2S)-2-hydroxypropionic acid	Pure active substance	79-33-4	201-196-2	0.598	0.598
		Technical active substance			0.627	0.627
<i>Content in the biocidal product family of the TK containing the active substance</i>					0.68	0.68

2.10.2.2 Type(s) of formulation of the meta SPC 9

AL – Any other liquids

2.10.3 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 9**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

Classification	
Hazard category	-
Hazard statement	-
Labelling	
Signal words	-
Hazard statements	-
Precautionary statements	-
Note	

2.10.4 Authorised use(s) of the META SPC 9**2.10.4.1** Use description

Table 20. Use # 1 – Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in domestic, institutional and industrial areas).

Product Type	PT 2
---------------------	------

Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast Enveloped virus
Field of use	Indoor Outdoor in domestic, institutional and industrial area
Application method(s)	Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping - without mechanical action
Application rate(s) and frequency	Ready to use products. Contact time: 5 min, 20°C
Category(ies) of users	Non professional Professional
Pack sizes and packaging material	Sprays (SP05): 0.5L - 0.75L HDPE or PET Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE (only for professional users) Drum: 10-210L HDPE (only for professional users) IBC: 1000L HDPE (only for professional users)

2.10.4.1.1 Use-specific instructions for use

-

2.10.4.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.10.4.2 Use description

Table 21. Use # 2 – Food and feed area disinfectants (disinfectant for all washable hard surfaces in domestic, institutional and industrial areas).

Product Type	PT 4
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Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor Outdoor in domestic, institutional and industrial (general) area
Application method(s)	Spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping - without mechanical action
Application rate(s) and frequency	Ready to use products. Contact time: 5 min, 20°C
Category(ies) of users	Non professional Professional
Pack sizes and packaging material	Sprays (SP05): 0.5L - 0.75L HDPE or PET Bottles: 0,5 - 5L HDPE or PET Jerry can: 1-80L HDPE (only for professional users) Drum: 10-210L HDPE (only for professional users) IBC: 1000L HDPE (only for professional users)

2.10.4.2.1 Use-specific instructions for use

-

2.10.4.2.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.10.5 General directions for use of the meta SPC 9

2.10.5.1 Instructions for use

- Apply the product by fully wetting all surface for 5 minutes (apply approx. 18 sprays /m² or 20 mL/m² or fully cover the object to be disinfected).

- Read carefully and follow all instructions.
- Apply only on non porous surfaces.

2.10.5.2 Risk mitigation measures

- For outdoor uses, do not apply the product in case rain is expected within 24 hrs.
- For outdoor uses by spray, avoid transfer to other areas by wind (drift).

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

- 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.

2.10.5.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

- Keep out of reach of children and non-target animals/pets.
- Shelf-life: 2 years.
- Protect from frost.

2.10.6 Other information

-

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 9

2.10.7 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	SALVESAFE FAM6_1				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Pure active substance	79-33-4	201-196-2	0.598

	(2S)-2-hydroxypropanoic acid	Technical active substance			0.627
<i>Content in the biocidal product of the TK containing the active substance</i>					0.68

Trade name(s)	SALVESAFE FAM6_2				
Authorisation number	SANILAK - Nettoyant désinfectant multi-usages Menthe SANILAK - Nettoyant désinfectant sanitaires Menthe SANILAK - Nettoyant désinfectant cuisine Menthe				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	0.598
		Technical active substance			0.627
<i>Content in the biocidal product of the TK containing the active substance</i>					0.68

Trade name(s)	SALVESAFE FAM6_3				
Authorisation number					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	0.598
		Technical active substance			0.627
<i>Content in the biocidal product of the TK containing the active substance</i>					0.68

2.11.1 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Refill caps	20-100mL	HDPE	Sealed cap	Professional,	yes

				Non-professional	
Bottles	0.5-5L	HDPE or PET or RPET or RPET/PET (50/50) or RPET/PET (25/75)	Cap, dispensing cap	Professional, Non-professional	yes
Sprays	0.5-0.75L	HDPE or PET or RPET or RPET/PET (50/50) or RPET/PET (25/75)	Trigger cap (trigger spray model SP05)	Professional, Non-professional	yes
Jerry can	1-80L	HDPE	Cap, dispensing cap	Professional	yes
Drum	10-210L	HDPE	Cap	Professional	yes
IBC	1000L	HDPE	Cap	Professional	yes
Soft container	1.5L 2.5L	LDPE	Cap pump	Professional	yes

2.11.2 Documentation

2.11.2.1 Data submitted in relation to product application

A list of studies performed on products is provided in the PAR in Annex 3.1. No new study is provided related to active substance.

2.11.2.2 Access to documentation

Diversey/CEHTRA studies being confidential from SALVECO S.A.S, the mention of the LoA in the efficacy section of the PAR will substitute the missing report in the SALVECO IUCLID dossier.

2.11.2.3 Similar conditions of use

Not relevant.

2.12 Assessment of the biocidal product family

2.12.1 Intended use(s) as applied for by the applicant

Table 15. Intended use # 1 **Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in institutional, medical, and industrial areas)**

Product Type(s)	Product Type 2 - Disinfectants and algacides not intended for direct application to humans or animals.
Where relevant, an exact description of the authorised use	Multi-purpose disinfectant with a bactericidal, yeasticidal and virucidal efficacy against enveloped viruses for hard non-porous surfaces in domestic, institutional, medical and industrial area.
Target organism (including development stage)	<p>Bacteria:</p> <ul style="list-style-type: none"> - <i>Pseudomonas aeruginosa</i>, common name: bacteria, aerobic, Gram-negative; - <i>Staphylococcus aureus</i>, common name: bacteria, facultative anaerobic, Gram-positive; - <i>Escherichia coli</i>, common name: bacteria, facultative anaerobic, Gram-negative; - <i>Enterococcus hirae</i>, common name: bacteria, facultative anaerobic, Gram-positive; <p>Yeast:</p> <ul style="list-style-type: none"> - <i>Candida albicans</i>, common name: yeast. <p>Viruses:</p> <ul style="list-style-type: none"> - Modified Vaccinia virus, common name : Envelopped virus <p>No data on development stages</p>
Field of use	Indoor, Outdoor
Application method(s)	<p>Type of method: concentrated products will be diluted at 1, 1.5, 2, 3, 4, 10% before use or used as ready-to-use as indicated on the label</p> <p>Manual application: spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping.</p> <p>General description of the method: Apply the product by fully wetting all surface (apply approx. 18 sprays/m² or 20 mL/m²) for 5 minutes. Rub or brush if necessary.</p>
Application rate(s) and frequency	<p>The application rate is 0.299% to 1.496% (w/w) active substance.</p> <p>Frequency: Apply once by fully wetting all surface. Repeat the application if necessary.</p>
Category(ies) of user(s)	Non-professional, professional
Pack sizes and packaging material	See part 2.1.7

Table 16. Intended use # 2 – **Disinfectants used to disinfect the materials and surfaces associated with the housing of animals (disinfectants for all washable hard surfaces in veterinary area)**

Product Type(s)	Product Type 3 - Veterinary hygiene biocidal products
Where relevant, an exact description of the authorised use	Multi-purpose disinfectant with bactericidal and yeasticidal efficacy for hard non-porous surfaces in veterinary area.
Target organism (including development stage)	<p>Bacteria:</p> <ul style="list-style-type: none"> - <i>Pseudomonas aeruginosa</i>, common name: bacteria, aerobic, Gram-negative; - <i>Staphylococcus aureus</i>, common name: bacteria, facultative anaerobic, Gram-positive; - <i>Enterococcus hirae</i>, common name: bacteria, facultative anaerobic, Gram-positive; - <i>Proteus vulgaris</i>, common name: bacteria, facultative anaerobic, Gram-negative <p>Yeast:</p> <ul style="list-style-type: none"> - <i>Candida albicans</i>, common name: yeast. <p>No data on development stages</p>
Field of use	Indoor, Outdoor
Application method(s)	<p>Type of method: The concentrated products to be diluted at 1% or 2.5% before use as indicated on the label</p> <p>Manual application: SAL: spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping.</p> <p>DIV: Soaked wipe, sponge, mop or brush, Spraying, Soaking or dipping (immersion), No rinsing required</p> <p>General description of the method: Apply the product once by fully wetting the surface (apply approx. 18 sprays/m² or 20 mL/m²) for 5 to 30 minutes. Rub or brush if necessary or let air dry</p>
Application rate(s) and frequency	<p>The application rate is 0.299 to 0.748 % (w/w) active substance.</p> <p>Frequency: Apply once by fully wetting all surface. Repeat the application if necessary</p>
Category(ies) of user(s)	Professional
Pack sizes and packaging material	See part 2.1.7

Table 17. Intended use # 3 – **Food and feed area disinfectants (disinfectant for all washable hard surfaces in institutional and industrial areas)**³

Product Type(s)	Product Type 4 - Food and feed area
Where relevant, an exact description of the authorised use	Multi-purpose concentrated disinfectant with a bactericidal and yeasticidal efficacy for hard non-porous surfaces in domestic, institutional and industrial (food industry) area, including meat industry and milk industry.
Target organism (including development stage)	Bacteria: <ul style="list-style-type: none"> - <i>Pseudomonas aeruginosa</i>, common name: bacteria, aerobic, Gram-negative; - <i>Staphylococcus aureus</i>, common name: bacteria, facultative anaerobic, Gram-positive; - <i>Escherichia coli</i>, common name: bacteria, facultative anaerobic, Gram-negative; - <i>Enterococcus hirae</i>, common name: bacteria, facultative anaerobic, Gram-positive; Yeast: <ul style="list-style-type: none"> - <i>Candida albicans</i>, common name: yeast. No data on development stages
Field of use	Indoor, outdoor
Application method(s)	Type of method: Concentrated products will be diluted at 1, 1.5, 2, 3, 4, 10% before use or be used as ready-to-use as indicated on the label Manual application: spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping. General description of the method: Apply the product once by fully wetting the surface (apply approx. 18 sprays/m ² or 20 mL/m ²) for 5 minutes. Rub or brush if necessary
Application rate(s) and frequency	The application rate is 0.299 to 1.496% (w/w) active substance. Frequency: Apply once by wetting all surface. Repeat the application if necessary
Category(ies) of user(s)	Non-professional, professional
Pack sizes and packaging material	See part 2.1.7

2.12.2 Physical, chemical and technical properties

Tests have been performed in order to cover all the products of the family.

- Meta SPC1: the 4 products of the meta SPC1 have similar pattern of composition.

³ Copy this section as many times as necessary (one table per use).

- Meta SPC2: the 12 products of the meta SPC2 have similar pattern of composition.

The representative product for the meta SPCs 1 and 2 is product **SALVESAFE_FAM1_2**; This product is identified as the worst case for the meta SPC1 and meta SPC2 because it contains the highest quantity of every ingredient.

Accelerated storage stability has been performed on each product of these meta SPCs.

- Meta SPC3: the 3 products of the meta SPC3 have similar pattern of composition.
- Meta SPC4: the 3 products of the meta SPC4 have similar pattern of composition.

The representative product for the meta SPCs 3 and 4 is product **SALVESAFE FAM2_3**; This product is identified as the worst case for the meta SPC3 and meta SPC4 because it contains the highest quantity of every ingredient.

Accelerated storage stability has been performed on each product of these meta SPCs (except SALVESAFE FAM2_6 which is covered by SALVESAFE FAM2_5. This product has the same composition, the only difference being the presence of a perfume).

- Meta SPC5 contains 1 product SALVESAFE FAM3_1.
- Meta SPC6 contains 1 product SALVESAFE_FAM3_2.

The representative product for the meta SPCs 5 and 6 is product **SALVESAFE FAM3_2**; This product is identified as the worst case for the meta SPC5 and meta SPC6 because it contains the highest quantity of every ingredient.

- Meta SPC7: The representative product for this meta SPC is product **SALVESAFE15** (the only product of the meta SPC).
- Meta SPC8: the 8 products of the meta SPC8 have similar pattern of composition. The representative product for this meta SPC is product **SALVESAFE_FAM5_8**.

Accelerated storage stability has been performed on each product of this meta SPC, and long term storage stability has been performed on 4 products of the Meta SPC.

- Meta SPC9: the 3 products of the meta SPC9 have similar pattern of composition. The representative product for this meta SPC is product **SALVESAFE_FAM6_2**; This sample is identified as the worst case for the meta-family because it contains the highest quantity of every ingredient.

Accelerated storage stability has been performed on each product of this meta SPC.

Two substances of concern could be present in the products of the family: Poly(oxy-1,2-ethanediyl), .alpha.-(carboxymethyl)-.omega.-(octyloxy)- and D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides. These substances are not expected to increase during storage of the products. Therefore, they have not been included in the storage stability/shelf life studies.

	Number of products	Minimum of pure AS content in final product % w/w	Maximum of pure AS content in final product % w/w	Representative product for studies.	In use concentrations of each meta SPC (in use concentration)

					of the product *
Meta SPC1	4	14.96	29.9	SALVESAFE_FAM1_2	1% - 10% (2%)
Meta SPC2	12	14.96	29.9	SALVESAFE_FAM1_2	1% - 10% (2%)
Meta SPC3	3	7.48	29.9	SALVESAFE FAM2_3	1% - 4% (1%)
Meta SPC4	3	7.48	29.9	SALVESAFE FAM2_3	1% - 4% (1%)
Meta SPC5	1	29.9	29.9	SALVESAFE_FAM3_2	1% - 2% (1.5%)
Meta SPC6	1	29.9	29.9	SALVESAFE_FAM3_2	1.5%
Meta SPC7	1	29.9	29.9	SALVESAFE 15	1%
Meta SPC8	8	0.598	1.496	SALVESAFE_FAM5_8	Ready to use
Meta SPC9	3	0.598	0.598	SALVESAFE_FAM6_2	Ready to use

*In use concentrations for each product have been reported in the BPF overview table in the confidential annex.

For spray characteristics, the MMDA was performed after accelerated storage and after long term storage on one product (SALVESAFE_FAM5_3) among those packaged in bottle with spray triggers: SALVESAFE FAM5_1, SALVESAFE FAM5_2, SALVESAFE FAM5_3, SALVESAFE FAM5_4, SALVESAFE FAM6_1, SALVESAFE FAM6_2 and SALVESAFE FAM6_3. This product is considered worse case for spray characteristics based on the surface tension of all products and their similar composition.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
Physical state, Colour and Odour at 20 °C and 101.3 kPa	Visual				
Meta SPC1 and 2		29.9 SALVESAFE FAM1_2	Yellow liquid with mint odour	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 1_2 Salveco Study N° 2019/039	Acceptable
		29.9 SALVESAFE FAM1_1	Yellow liquid with characteristic odour	Test report n°2019/072	Acceptable
		29.9 SALVESAFE FAM1_3	Yellow liquid with spicy odour	Test report n°2019/074	Acceptable
		29.9 SALVESAFE FAM1_4	Yellow liquid with fresh odour	Test report n°2019/075	Acceptable
		19.95 SALVESAFE FAM1_5	Yellow liquid with characteristic odour	Test report n°2019/076	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
		19.95 SALVESAFE FAM1_6	Yellow liquid with mint odour	Test report n°2019/077	Acceptable
		19.95 SALVESAFE FAM1_7	Yellow liquid with spicy odour	Test report n°2019/078	Acceptable
		19.95 SALVESAFE FAM1_8	Yellow liquid with fresh odour	Test report n°2019/079	Acceptable
		14.96 SALVESAFE FAM1_9	Yellow liquid with characteristic odour	Test report n°2019/080	Acceptable
		14.96 SALVESAFE FAM1_10	Yellow liquid with mint odour	Test report n°2019/081	Acceptable
		14.96 SALVESAFE FAM1_11	Yellow liquid with spicy odour	Test report n°2019/082	Acceptable
		14.96 SALVESAFE FAM1_12	Yellow liquid with fresh odour	Test report n°2019/083	Acceptable
		29.9 SALVESAFE FAM1_13	Yellow liquid with characteristic odour	Test report n°2019/084	Acceptable
		29.9 SALVESAFE FAM1_14	Yellow liquid with spicy odour	Test report n°2019/085	Acceptable
		14.96 SALVESAFE FAM1_15	Yellow liquid with mint odour	Test report n°2019/086	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
		14.96 SALVESAFE FAM1_16	Yellow liquid with spicy odour	Test report n°2019/087	Acceptable
Meta SPC3 and 4		29.9 SALVESAFE FAM2_3	Yellow liquid with mint odour	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 2_3 Salveco Study N° 2019/056	Acceptable
		14.96 SALVESAFE FAM2_1	Yellow liquid with characteristic odour	Test report n°2019/088	Acceptable
		29.9 SALVESAFE FAM2_2	Yellow liquid with characteristic odour	Test report n°2019/089	Acceptable
		29.9 SALVESAFE FAM2_4	Yellow liquid with spicy odour	Test report n°2019/091	Acceptable
		7.48 SALVESAFE FAM2_5	Yellow liquid with mint odour	Test report n°2019/092	Acceptable
Meta SPC 5		29.9 SALVESAFE FAM3_1	Yellow liquid with characteristic odour	Test report n°2019/059	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
Meta SPC 6		29.9 SALVESAFE FAM3_2	Yellow liquid with mint odour	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 3_2 Salveco Study N° 2019/060	Acceptable
Meta SPC7		29.9 SALVESAFE 15	Yellow liquid with characteristic odour	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_15 Salveco Study N° 2019/017	Acceptable
Meta SPC8		1.496 ALVESAFE FAM5_8	Light yellow liquid with fresh odour	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_5_8 Salveco Study N° 2019/068	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
		0.598 ALVESAFE FAM5_1	Colourless liquid with characteristic odour	Test report n°2019/095	Acceptable
		0.598 ALVESAFE FAM5_2	Colourless liquid with characteristic odour	Test report n°2019/096	Acceptable
		0.598 ALVESAFE FAM5_3	Colourless liquid with fresh odour	Test report n°2019/097	Acceptable
		0.598 ALVESAFE FAM5_4	Colourless liquid with fresh odour	Test report n°2019/098	Acceptable
		1.496 ALVESAFE FAM5_5	Colourless liquid with characteristic odour	Test report n°2019/099	Acceptable
		1.496 ALVESAFE FAM5_6	Light yellow liquid with characteristic odour	Test report n°2019/100	Acceptable
		1.496 ALVESAFE FAM5_7	Colourless liquid with fresh odour	Test report n°2019/101	Acceptable
Meta SPC9		0.598 SALVESAFE FAM6_2	Colourless liquid with mint odour	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 6_2 Salveco	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
				Study N° 2019/070	
		0.598 SALVESAFE FAM6_1	Colourless liquid with characteristic odour	Test report n°2019/103	Acceptable
		0.598 SALVESAFE FAM6_3	Colourless liquid with spicy odour	Test report n°2019/105	Acceptable
Acidity / alkalinity	pH: CIPAC MT 75.3 Acidity: CIPAC MT 191 (as % w/w of H ₂ SO ₄)				
Meta SPC1 and 2		29.9 SALVESAFE FAM1_2	T ₀ pH: 1.67 T ₀ acidity: 18.4% H ₂ SO ₄ w/w	REVOL B. 2019. PHYSICO-CHEMICAL ANALYSIS-Salvesafe_FAM1_2 Salveco Study N° 2019/039	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
		29.9 SALVESAFE FAM1_1	T ₀ pH: 1.64 T ₀ acidity: 17.5% H ₂ SO ₄ w/w	Test report n°2019/072	Acceptable
		29.9 SALVESAFE FAM1_3	T ₀ pH: 1.69 T ₀ acidity: 17.9% H ₂ SO ₄ w/w	Test report n°2019/074	Acceptable
		29.9 SALVESAFE FAM1_4	T ₀ pH: 1.69 T ₀ acidity: 17.7% H ₂ SO ₄ w/w	Test report n°2019/075	Acceptable
		19.95 SALVESAFE FAM1_5	T ₀ pH: 1.88 T ₀ acidity: 12.1% H ₂ SO ₄ w/w	Test report n°2019/076	Acceptable
		19.95 SALVESAFE FAM1_6	T ₀ pH: 1.79 T ₀ acidity: 12.2% H ₂ SO ₄ w/w	Test report n°2019/077	Acceptable
		19.95 SALVESAFE FAM1_7	T ₀ pH: 1.74 T ₀ acidity: 12.3% H ₂ SO ₄ w/w	Test report n°2019/078	Acceptable
		19.95 SALVESAFE FAM1_8	T ₀ pH: 1.78 T ₀ acidity: 12.2% H ₂ SO ₄ w/w	Test report n°2019/079	Acceptable
		14.96 SALVESAFE FAM1_9	T ₀ pH: 1.83 T ₀ acidity: 9.3% H ₂ SO ₄ w/w	Test report n°2019/080	Acceptable
		14.96 SALVESAFE FAM1_10	T ₀ pH: 1.83 T ₀ acidity: 9.4% H ₂ SO ₄ w/w	Test report n°2019/081	Acceptable
		14.96 SALVESAFE FAM1_11	T ₀ pH: 1.83 T ₀ acidity: 9.5% H ₂ SO ₄ w/w	Test report n°2019/082	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
		14.96 SALVESAFE FAM1_12	T ₀ pH: 1.83 T ₀ acidity: 9.4% H ₂ SO ₄ w/w	Test report n°2019/083	Acceptable
		29.9 SALVESAFE FAM1_13	T ₀ pH: 1.49 T ₀ acidity: 18.1% H ₂ SO ₄ w/w	Test report n°2019/084	Acceptable
		29.9 SALVESAFE FAM1_14	T ₀ pH: 1.69 T ₀ acidity: 17.9% H ₂ SO ₄ w/w	Test report n°2019/085	Acceptable
		14.96 SALVESAFE FAM1_15	T ₀ pH: 1.83 T ₀ acidity: 9.4% H ₂ SO ₄ w/w	Test report n°2019/086	Acceptable
		14.96 SALVESAFE FAM1_16	T ₀ pH: 1.83 T ₀ acidity: 9.5% H ₂ SO ₄ w/w	Test report n°2019/087	Acceptable
Meta SPC3 and 4		29.9 SALVESAFE FAM2_3	T ₀ pH: 1.59 T ₀ acidity: 17.6% H ₂ SO ₄ w/w	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 2_3 Salveco Study N° 2019/056	Acceptable
		14.96 SALVESAFE FAM2_1	T ₀ pH: 1.75 T ₀ acidity: 9.3% H ₂ SO ₄ w/w	Test report n°2019/088	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
		29.9 SALVESAFE FAM2_2	T ₀ pH: 1.52 T ₀ acidity: 18.6% H ₂ SO ₄ w/w	Test report n°2019/089	Acceptable
		29.9 SALVESAFE FAM2_4	T ₀ pH: 1.55 T ₀ acidity: 18.1% H ₂ SO ₄ w/w	Test report n°2019/091	Acceptable
		7.48 SALVESAFE FAM2_5	T ₀ pH: 1.87 T ₀ acidity: 4.6% H ₂ SO ₄ w/w	Test report n°2019/092	Acceptable
Meta SPC 5		29.9 SALVESAFE FAM3_1	T ₀ pH: 1.47 T ₀ acidity: 17.8 % H ₂ SO ₄ w/w	Test report n°2019/093	Acceptable
Meta SPC 6		29.9 SALVESAFE FAM3_2	T ₀ pH: 1.55 T ₀ acidity: 18.6 % H ₂ SO ₄ w/w	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 3_2 Salveco Study N° 2019/060	Acceptable
Meta SPC7		29.9 SALVESAFE 15	T ₀ pH: 1.49 T ₀ acidity: 17.4 % H ₂ SO ₄ w/w	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_15 Salveco	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
				Study N° 2019/017	
Meta SPC8		1.496 ALVESAFE FAM5_8	T ₀ pH: 2.27 T ₀ acidity: 0.8% H ₂ SO ₄ w/w	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_5_8 Salveco Study N° 2019/068	Acceptable
		0.598 ALVESAFE FAM5_1	T ₀ pH: 2.47 T ₀ acidity: 0.4% H ₂ SO ₄ w/w	Test report n°2019/095	Acceptable
		0.598 ALVESAFE FAM5_2	T ₀ pH: 2.47 T ₀ acidity: 0.4% H ₂ SO ₄ w/w	Test report n°2019/096	Acceptable
		0.598 ALVESAFE FAM5_3	T ₀ pH: 2.46 T ₀ acidity: 0.4% H ₂ SO ₄ w/w	Test report n°2019/097	Acceptable
		0.598 ALVESAFE FAM5_4	T ₀ pH: 2.49 T ₀ acidity: 0.4% H ₂ SO ₄ w/w	Test report n°2019/098	Acceptable
		1.496 ALVESAFE FAM5_5	T ₀ pH: 2.30 T ₀ acidity: 0.8% H ₂ SO ₄ w/w	Test report n°2019/099	Acceptable
		1.496	T ₀ pH: 2.30 T ₀ acidity: 0.8% H ₂ SO ₄ w/w	Test report n°2019/100	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
		ALVESAFE FAM5_6			
		1.496 ALVESAFE FAM5_7	T ₀ pH: 2.29 T ₀ acidity: 0.8% H ₂ SO ₄ w/w	Test report n°2019/101	Acceptable
Meta SPC9		0.598 SALVESAFE FAM6_2	T ₀ pH: 2.50 T ₀ acidity: 0.3 % H ₂ SO ₄ w/w	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 6_2 Salveco Study N° 2019/070	Acceptable
		0.598 SALVESAFE FAM6_1	T ₀ pH: 2.54 T ₀ acidity: 0.4 % H ₂ SO ₄ w/w	Test report n°2019/103	Acceptable
		0.598 SALVESAFE FAM6_3	T ₀ pH: 2.53 T ₀ acidity: 0.4 % H ₂ SO ₄ w/w	Test report n°2019/105	
Relative density / bulk density	EC Method A.3 OECD 109 Density meter Anton PAAR,				

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
Meta SPC1 and 2		29.9 SALVESAFE FAM1_2	$D^{20}_4 = 1.109$ at 20°C	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 1_2 Salveco Study N° 2019/039	Acceptable
Meta SPC3 and 4		29.9 SALVESAFE FAM2_3	$D^{20}_4 = 1.102$ at 20°C	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 2_3 Salveco Study N° 2019/056	Acceptable
Meta SPC 5		29.9 SALVESAFE FAM3_1	$D^{20}_4 = 1.100$ at 20°C	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 3_1 Salveco Study N° 2019/059	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
Meta SPC 6		29.9 SALVESAFE FAM3_2	$D^{20}_4 = 1.104$ at 20°C	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 3_2 Salveco Study N° 2019/060	Acceptable
Meta SPC7		29.9 SALVESAFE 15	$D^{20}_4 = 1.098$ at 20°C	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_15 Salveco Study N° 2019/017	Acceptable
Meta SPC8		1.496 ALVESAFE FAM5_8	$D^{20}_4 = 1.006$ at 20°C	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_5_8 Salveco Study N°	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
				2019/068	
Meta SPC9		0.598 SALVESAFE FAM6_2	$D^{20}_4 = 1.001$ at 20°C	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 6_2 Salveco Study N° 2019/070	Acceptable
Storage stability test – accelerated storage	CIPAC MT 46.3 Stability 54°C during 2 weeks				
Meta SPC1 and 2		29.9 SALVESAFE FAM1_2	<u>Appearance of the product:</u> T₀ : liquid, yellow, mint T_{2weeks} : liquid, yellow, mint <u>Appearance of packaging:</u> Glass bottle 125 mL <u>Active substance content:</u> T ₀ = 29.75 % w/w T _{2 weeks} = 30.03 %w/w Variation : +0.28%w/w	REVOL B. 2019. ACCELERATED STORAGE STABILITY for 14 days at 54 +/- 2°C Salvesafe_FAM 1_2 Salveco Study N° 2019/073	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
			<p>pH T₀=1.69 pH T_{2 weeks} =1.69</p> <p>Acidity T₀=18.4% H₂SO₄ w/w Acidity T_{2 weeks} =18.7% H₂SO₄ w/w</p> <p>Persistent foaming (2% dilution) T₀ = 36 mL Persistent foaming (2% dilution) T_{2 weeks} = 31 mL</p> <p>Dilution stability (2% dilution) T₀ : clear solution Dilution stability (2% dilution) T_{2 weeks} : clear solution</p>		
		29.9 SALVESAFE FAM1_1	<u>Packaging tested : glass bottle 125 mL</u>	Test report n°2019/072	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Characteristic	Characteristic		
			pH at 20°C	CIPAC MT 75.3	1.64	1.72		
			Acidity	CIPAC MT 191	17.5 % w/w	18.1 % w/w		
			Dilution stability	CIPAC MT 41	Clear solution	Clear solution		
			Persistent foaming	CIPAC MT 47.2	33 mL	36 mL		
			Lactic acid content	Validated HPLC proprietary method	30.14 g/100g	30.63 g/100g		
			2% dilution for dilution stability					
		29.9 SALVESAFE FAM1_3	Packaging tested : glass bottle 125 mL				Test report n°2019/074	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Spicy	Spicy		
			pH at 20°C	CIPAC MT 75.3	1.69	1.66		
			Acidity	CIPAC MT 191	17.9 % w/w	18.7 % w/w		
			Dilution stability	CIPAC MT 41	Clear solution	Clear solution		
			Persistent foaming	CIPAC MT 47.2	33 mL	37 mL		
			Lactic acid content	Validated HPLC proprietary method	30.34 g/100g	31.00 g/100g		
			2% dilution for dilution stability					
		29.9 SALVESAFE FAM1_4	Packaging tested: glass bottle 125 mL				Test report n°2019/075	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh		
			pH at 20°C	CIPAC MT 75.3	1.69	1.69		
			Acidity	CIPAC MT 191	17.7 % w/w	18.5 % w/w		
			Dilution stability	CIPAC MT 41	Clear solution	Clear solution		
			Persistent foaming	CIPAC MT 47.2	36 mL	38 mL		
			Lactic acid content	Validated HPLC proprietary method	29.93 g/100g	30.81 g/100g		
			2% dilution for dilution stability					
		19.95 SALVESAFE FAM1_5	Packaging tested: glass bottle 125 mL				Test report n°2019/076	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Characteristic	Characteristic		
			pH at 20°C	CIPAC MT 75.3	1.88	1.83		
			Acidity	CIPAC MT 191	12.1 % w/w	12.7 % w/w		
			Dilution stability	CIPAC MT 41	Clear solution	Clear solution		
			Persistent foaming	CIPAC MT 47.2	52 mL	49 mL		
			Lactic acid content	Validated HPLC proprietary method	20.03 g/100g	20.45 g/100g		
			3% dilution for dilution stability					
		19.95 SALVESAFE FAM1_6	Packaging tested: glass bottle 125 mL				Test report n°2019/077	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Mint	Mint		
			pH at 20°C	CIPAC MT 75.3	1.79	1.84		
			Acidity	CIPAC MT 191	12.2 % w/w	12.7 % w/w		
			Dilution stability	CIPAC MT 41	Clear solution	Clear solution		
			Persistent foaming	CIPAC MT 47.2	44 mL	49 mL		
			Lactic acid content	Validated HPLC proprietary method	20.11 g/100g	20.63 g/100g		
			3% dilution for dilution stability					
		19.95 SALVESAFE FAM1_7	Packaging tested: glass bottle 125 mL				Test report n°2019/078	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Spicy	Spicy		
			pH at 20°C	CIPAC MT 75.3	1.74	1.80		
			Acidity	CIPAC MT 191	12.3 % w/w	12.7 % w/w		
			Dilution stability	CIPAC MT 41	Clear solution	Clear solution		
			Persistent foaming	CIPAC MT 47.2	50 mL	45 mL		
			Lactic acid content	Validated HPLC proprietary method	20.22 g/100g	20.56 g/100g		
			3% dilution for dilution stability					
		19.95 SALVESAFE FAM1_8	Packaging tested: glass bottle 125 mL				Test report n°2019/079	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh		
			pH at 20°C	CIPAC MT 75.3	1.78	1.80		
			Acidity	CIPAC MT 191	12.2 % w/w	12.8 % w/w		
			Dilution stability	CIPAC MT 41	Clear solution	Clear solution		
			Persistent foaming	CIPAC MT 47.2	47 mL	50 mL		
			Lactic acid content	Validated HPLC proprietary method	20.13 g/100g	20.63 g/100g		
			3% dilution for dilution stability					
		14.96 SALVESAFE FAM1_9	Packaging tested: glass bottle 125 mL				Test report n°2019/080	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Characteristic	Characteristic		
			pH at 20°C	CIPAC MT 75.3	1.83	1.88		
			Acidity	CIPAC MT 191	9.3 % w/w	9.6 % w/w		
			Dilution stability	CIPAC MT 41	Clear solution	Clear solution		
			Persistent foaming	CIPAC MT 47.2	43 mL	39 mL		
			Lactic acid content	Validated HPLC proprietary method	15.07 g/100g	15.45 g/100g		
			10% dilution for dilution stability					
		14.96 SALVESAFE FAM1_10	Packaging tested: glass bottle 125 mL				Test report n°2019/081	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Mint	Mint		
			pH at 20°C	CIPAC MT 75.3	1.83	1.89		
			Acidity	CIPAC MT 191	9.4 % w/w	9.7 % w/w		
			Dilution stability	CIPAC MT 41	Clear solution	Clear solution		
			Persistent foaming	CIPAC MT 47.2	37 mL	42 mL		
			Lactic acid content	Validated HPLC proprietary method	14.95 g/100g	15.20 g/100g		
			10% dilution for dilution stability					
		14.96 SALVESAFE FAM1_11	Packaging tested: glass bottle 125 mL				Test report n°2019/082	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Spicy	Spicy		
			pH at 20°C	CIPAC MT 75.3	1.83	1.81		
			Acidity	CIPAC MT 191	9.5 % w/w	9.9 % w/w		
			Dilution stability	CIPAC MT 41	Clear solution	Clear solution		
			Persistent foaming	CIPAC MT 47.2	42 mL	39 mL		
			Lactic acid content	Validated HPLC proprietary method	14.92 g/100g	15.21 g/100g		
			10% dilution for dilution stability					
		14.96 SALVESAFE FAM1_12	Packaging tested: glass bottle 125 mL				Test report n°2019/083	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh		
			pH at 20°C	CIPAC MT 75.3	1.83	1.86		
			Acidity	CIPAC MT 191	9.4 % w/w	9.6 % w/w		
			Dilution stability	CIPAC MT 41	Clear solution	Clear solution		
			Persistent foaming	CIPAC MT 47.2	43 mL	40 mL		
			Lactic acid content	Validated HPLC proprietary method	14.90 g/100g	15.18 g/100g		
			10% dilution for dilution stability					
		29.9 SALVESAFE FAM1_13	Packaging tested: glass bottle 125 mL				Test report n°2019/084	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Characteristic	Characteristic		
			pH at 20°C	CIPAC MT 75.3	1.49	1.57		
			Acidity	CIPAC MT 191	18.1 % w/w	19.0 % w/w		
			Dilution stability	CIPAC MT 41	Slightly opalescent solution	Slightly opalescent solution		
			Persistent foaming	CIPAC MT 47.2	32 mL	38 mL		
			Lactic acid content	Validated HPLC proprietary method	30.17 g/100g	30.99 g/100g		
			1% dilution for dilution stability					
		29.9 SALVESAFE FAM1_14	Packaging tested: glass bottle 125 mL				Test report n°2019/085	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Spicy	Spicy		
			pH at 20°C	CIPAC MT 75.3	1.69	1.66		
			Acidity	CIPAC MT 191	17.9 % w/w	18.7 % w/w		
			Dilution stability	CIPAC MT 41	Clear solution	Clear solution		
			Persistent foaming	CIPAC MT 47.2	33 mL	37 mL		
			Lactic acid content	Validated HPLC proprietary method	30.34 g/100g	31.00 g/100g		
			1% dilution for dilution stability					
		14.96 SALVESAFE FAM1_15	Packaging tested: glass bottle 125 mL				Test report n°2019/086	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Mint	Mint		
			pH at 20°C	CIPAC MT 75.3	1.83	1.89		
			Acidity	CIPAC MT 191	9.4 % w/w	9.7 % w/w		
			Dilution stability	CIPAC MT 41	Clear solution	Clear solution		
			Persistent foaming	CIPAC MT 47.2	42 mL	38 mL		
			Lactic acid content	Validated HPLC proprietary method	14.95 g/100g	15.20 g/100g		
			2% dilution for dilution stability					
		14.96 SALVESAFE FAM1_16	Packaging tested: glass bottle 125 mL				Test report n°2019/087	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Spicy	Spicy		
			pH at 20°C	CIPAC MT 75.3	1.83	1.81		
			Acidity	CIPAC MT 191	9.5 % w/w	9.9 % w/w		
			Dilution stability	CIPAC MT 41	Clear solution	Clear solution		
			Persistent foaming	CIPAC MT 47.2	41 mL	37 mL		
			Lactic acid content	Validated HPLC proprietary method	14.92 g/100g	15.21 g/100g		
			2% dilution for dilution stability					
Meta SPC3 and 4		29.9 SALVESAFE FAM2_3	<u>Appearance of the product:</u> T₀: liquid, yellow, mint T_{2weeks}: liquid, yellow, mint <u>Appearance of packaging:</u>				REVOL B. 2019. ACCELERATED STORAGE STABILITY for 14 days at 54	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
			<p>Glass bottle 125 mL</p> <p><u>Active substance content:</u> $T_0 = 29.67\% \text{ w/w}$ $T_{2 \text{ weeks}} = 30.65\% \text{ w/w}$ Variation : +0.98% w/w</p> <p>pH $T_0 = 1.55$ pH $T_{2 \text{ weeks}} = 1.60$</p> <p>Acidity $T_0 = 17.8\% \text{ H}_2\text{SO}_4 \text{ w/w}$ Acidity $T_{2 \text{ weeks}} = 18.6\% \text{ H}_2\text{SO}_4 \text{ w/w}$</p> <p>Persistent foaming (1% dilution) $T_0 = 51 \text{ mL}$ Persistent foaming (1% dilution) $T_{2 \text{ weeks}} = 54 \text{ mL}$</p> <p>Dilution stability (1% dilution) T_0 : clear solution Dilution stability (1% dilution) $T_{2 \text{ weeks}}$: clear solution</p>	+/- 2°C Salvesafe_FAM 2_3 Salveco Study N° 2019/090	
		14.96 SALVESAFE FAM2_1	Packaging tested: glass bottle 125 mL	Test report n°2019/088	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Characteristic	Characteristic		
			pH at 20°C	CIPAC MT 75.3	1.75	1.82		
			Acidity	CIPAC MT 191	9.3 % w/w	9.5 % w/w		
			Dilution stability	CIPAC MT 41	Slightly opalescent solution	Slightly opalescent solution		
			Persistent foaming	CIPAC MT 47.2	41 mL	43 mL		
			Lactic acid content	Validated HPLC proprietary method	14.98 g/100g	15.38 g/100g		
			2% dilution for dilution stability					
		29.9 SALVESAFE FAM2_2	Packaging tested: glass bottle 125 mL				Test report n°2019/089	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Characteristic	Characteristic		
			pH at 20°C	CIPAC MT 75.3	1.52	1.54		
			Acidity	CIPAC MT 191	18.6 % w/w	19.1 % w/w		
			Dilution stability	CIPAC MT 41	Slightly opalescent solution	Slightly opalescent solution		
			Persistent foaming	CIPAC MT 47.2	35 mL	41 mL		
			Lactic acid content	Validated HPLC proprietary method	30.07 g/100g	30.36 g/100g		
			<u>1% dilution for dilution stability</u>					
		29.9 SALVESAFE FAM2_4	Packaging tested: glass bottle 125 mL				Test report n°2019/091	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Spicy	Spicy		
			pH at 20°C	CIPAC MT 75.3	1.55	1.64		
			Acidity	CIPAC MT 191	18.1 % w/w	18.8 % w/w		
			Dilution stability	CIPAC MT 41	Clear solution	Clear solution		
			Persistent foaming	CIPAC MT 47.2	52 mL	50 mL		
			Lactic acid content	Validated HPLC proprietary method	30.08 g/100g	30.45 g/100g		
			<u>1% dilution for dilution stability</u>					
		7.48 SALVESAFE FAM2_5	Packaging tested: glass bottle 125 mL				Test report n°2019/092	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Mint	Mint		
			pH at 20°C	CIPAC MT 75.3	1.87	1.99		
			Acidity	CIPAC MT 191	4.6 % w/w	4.8 % w/w		
			Dilution stability	CIPAC MT 41	Slightly opalescent solution	Slightly opalescent solution		
			Persistent foaming	CIPAC MT 47.2	39 mL	43 mL		
			Lactic acid content	Validated HPLC proprietary method	7.70 g/100g	7.79 g/100g		
			4% dilution for dilution stability					
Meta SPC 5		29.9 SALVESAFE FAM3_1	Packaging tested: Glass bottle 125 mL				Test report n°2019/093	Acceptable The product of Meta SPC 5 is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	As the produced foam is >60mL, it should be indicated that the product is a foaming formulation.	
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Characteristic	Characteristic		
			pH at 20°C	CIPAC MT 75.3	1.47	1.42		
			Acidity	CIPAC MT 191	17.8 % w/w	18.4 % w/w		
			Dilution stability	CIPAC MT 41	Clear solution	Clear solution		
			Persistent foaming	CIPAC MT 47.2	70 mL	67 mL		
			Lactic acid content	Validated HPLC proprietary method	29.96 g/100g	30.73 g/100g		
			2% dilution for dilution stability					
Meta SPC 6		29.9 SALVESAFE FAM3_2	<u>Appearance of the product:</u> T₀: liquid, yellow, mint T_{2weeks}: liquid, yellow, mint <u>Appearance of packaging:</u>				REVOL B. 2019. ACCELERATED STORAGE STABILITY for 14 days at 54	Acceptable The product of Meta SPC 6 is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
			<p>Glass bottle 125 mL</p> <p><u>Active substance content:</u> $T_0 = 29.97\% \text{ w/w}$ $T_{2 \text{ weeks}} = 30.48\% \text{ w/w}$ Variation : +0.51%</p> <p>pH $T_0 = 1.53$ pH $T_{2 \text{ weeks}} = 1.59$</p> <p>Acidity $T_0 = 18.8\% \text{ H}_2\text{SO}_4 \text{ w/w}$ Acidity $T_{2 \text{ weeks}} = 19.2\% \text{ H}_2\text{SO}_4 \text{ w/w}$</p> <p>Persistent foaming (2% dilution) $T_0 = 53 \text{ mL}$ Persistent foaming (2% dilution) $T_{2 \text{ weeks}} = 47 \text{ mL}$</p> <p>Dilution stability (2% dilution) T_0 : clear solution Dilution stability (2% dilution) $T_{2 \text{ weeks}}$: clear solution</p>	+/- 2°C Salvesafe_FAM 3_2 Salveco Study N° 2019/094	
Meta SPC7		29.9 SALVESAFE 15	<p><u>Appearance of the product:</u> T_0: liquid, yellow, characteristic $T_{2 \text{ weeks}}$: liquid, yellow, characteristic</p> <p><u>Appearance of packaging:</u> Glass bottle 125 mL</p> <p><u>Active substance content:</u> $T_0 = 29.99\% \text{ w/w}$</p>	REVOL B. 2019. ACCELERATED STORAGE STABILITY for 14 days at 54 +/- 2°C Salvesafe_15 Salveco Study N°	Acceptable The product of Meta SPC 7 is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
			<p>T_{2 weeks} = 30.67 %w/w Variation : +0.68%w/w</p> <p>pH T₀=1.44 pH T_{2 weeks} =1.51</p> <p>Acidity T₀=17.4% H₂SO₄ w/w Acidity T_{2 weeks} =18.2% H₂SO₄ w/w</p> <p>Persistent foaming (1% dilution) T₀ = 28mL Persistent foaming (1% dilution) T_{2 weeks} = 32mL</p> <p>Dilution stability (1% dilution) T₀ : slightly opalescent solution Dilution stability (1% dilution) T_{2 weeks} : slightly opalescent solution</p>	2019/019	
Meta SPC8		1.496 ALVESAFE FAM5_8	<p><u>Appearance of the product:</u> T₀: liquid, light yellow, fresh T_{2weeks}: liquid, light yellow, fresh</p> <p><u>Appearance of packaging:</u> Glass bottle 125 mL</p> <p><u>Active substance content:</u> T₀= 1.51 % w/w T_{2 weeks} = 1.46 %w/w Variation : -0.05 %w/w</p>	<p>REVOL B. 2019. ACCELERATED STORAGE STABILITY for 14 days at 54 +/- 2°C</p> <p>Salvesafe_5_8 Salveco Study N° 2019/102</p>	<p>Acceptable</p> <p>The product is stable after 14 days at 54°C.</p>

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment																												
			pH T ₀ =2.29 pH T _{2 weeks} =2.44 Acidity T ₀ =0.8% H ₂ SO ₄ w/w Acidity T _{2 weeks} =0.8% H ₂ SO ₄ w/w																														
		0.598 ALVESAFE FAM5_1	Packaging tested: glass bottle 125 mL <table border="1"> <thead> <tr> <th>Property</th> <th>Guideline and Method</th> <th>Results at T+0 (initial state)</th> <th>Results at T+14 days</th> </tr> </thead> <tbody> <tr> <td>Physical state at 20 °C and 101.3 kPa</td> <td>Visual</td> <td>Liquid</td> <td>Liquid</td> </tr> <tr> <td>Colour at 20 °C and 101.3 kPa</td> <td>Visual</td> <td>Colourless</td> <td>Colourless</td> </tr> <tr> <td>Odour at 20°C and 101.3 kPa</td> <td>Olfactory</td> <td>Characteristic</td> <td>Characteristic</td> </tr> <tr> <td>pH at 20°C</td> <td>CIPAC MT 75.3</td> <td>2.47</td> <td>2.56</td> </tr> <tr> <td>Acidity</td> <td>CIPAC MT 191</td> <td>0.4 % w/w</td> <td>0.4 % w/w</td> </tr> <tr> <td>Lactic acid content</td> <td>Validated HPLC proprietary method</td> <td>0.575 g/100g</td> <td>0.622 g/100g</td> </tr> </tbody> </table>	Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days	Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless	Odour at 20°C and 101.3 kPa	Olfactory	Characteristic	Characteristic	pH at 20°C	CIPAC MT 75.3	2.47	2.56	Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w	Lactic acid content	Validated HPLC proprietary method	0.575 g/100g	0.622 g/100g	Test report n°2019/095	Acceptable The product is stable after 14 days at 54°C.
Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days																														
Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid																														
Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless																														
Odour at 20°C and 101.3 kPa	Olfactory	Characteristic	Characteristic																														
pH at 20°C	CIPAC MT 75.3	2.47	2.56																														
Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w																														
Lactic acid content	Validated HPLC proprietary method	0.575 g/100g	0.622 g/100g																														

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment																												
		0.598 ALVESAFE FAM5_2	Packaging tested: glass bottle 125 mL <table border="1"> <thead> <tr> <th>Property</th> <th>Guideline and Method</th> <th>Results at T+0 (initial state)</th> <th>Results at T+14 days</th> </tr> </thead> <tbody> <tr> <td>Physical state at 20 °C and 101.3 kPa</td> <td>Visual</td> <td>Liquid</td> <td>Liquid</td> </tr> <tr> <td>Colour at 20 °C and 101.3 kPa</td> <td>Visual</td> <td>Colourless</td> <td>Colourless</td> </tr> <tr> <td>Odour at 20°C and 101.3 kPa</td> <td>Olfactory</td> <td>Characteristic</td> <td>Characteristic</td> </tr> <tr> <td>pH at 20°C</td> <td>CIPAC MT 75.3</td> <td>2.47</td> <td>2.60</td> </tr> <tr> <td>Acidity</td> <td>CIPAC MT 191</td> <td>0.4 % w/w</td> <td>0.4 % w/w</td> </tr> <tr> <td>Lactic acid content</td> <td>Validated HPLC proprietary method</td> <td>0.578 g/100g</td> <td>0.614 g/100g</td> </tr> </tbody> </table>	Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days	Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless	Odour at 20°C and 101.3 kPa	Olfactory	Characteristic	Characteristic	pH at 20°C	CIPAC MT 75.3	2.47	2.60	Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w	Lactic acid content	Validated HPLC proprietary method	0.578 g/100g	0.614 g/100g	Test report n°2019/096	Acceptable The product is stable after 14 days at 54°C.
Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days																														
Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid																														
Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless																														
Odour at 20°C and 101.3 kPa	Olfactory	Characteristic	Characteristic																														
pH at 20°C	CIPAC MT 75.3	2.47	2.60																														
Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w																														
Lactic acid content	Validated HPLC proprietary method	0.578 g/100g	0.614 g/100g																														
		0.598 ALVESAFE FAM5_3	Packaging tested: glass bottle 125 mL	Test report n°2019/097	Acceptable The product is stable after 14 days at 54°C. The MMAD performed on this product covers all																												

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		products with a pure active substance content of 0.598% (those that will be packaged in bottles with spray heads).
			Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless		
			Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh		
			pH at 20°C	CIPAC MT 75.3	2.46	2.44		
			Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w		
			Lactic acid content	Validated HPLC proprietary method	0.581 g/100g	0.617 g/100g		
	CIPAC method MT 187		<p>The MMAD was determined using a laser diffraction technique:</p>					
			<p>Before storage, the formulation produces a spray with a mean droplet size Dv(50) of about 117,71 µm and a value of Vol%<50µm about 1,60%.</p>					
			<p>After storage, the formulation produces a spray with a mean droplet size Dv(50) of about 109,44 µm and a value of Vol%<50µm about 1,48%.</p>					
		0.598	Packaging tested: glass bottle 125 mL				Test report n°2019/098	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
		ALVESAFE FAM5_4	Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		The product is stable after 14 days at 54°C.
Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid					
Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless					
Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh					
pH at 20°C	CIPAC MT 75.3	2.49	2.48					
Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w					
Lactic acid content	Validated HPLC proprietary method	0.591 g/100g	0.628 g/100g					
		1.496 ALVESAFE FAM5_5	Packaging tested: <u>glass bottle 125 mL</u>				Test report n°2019/099	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless		
			Odour at 20°C and 101.3 kPa	Olfactory	Characteristic	Characteristic		
			pH at 20°C	CIPAC MT 75.3	2.30	2.40		
			Acidity	CIPAC MT 191	0.8 % w/w	0.8 % w/w		
			Lactic acid content	Validated HPLC proprietary method	1.42 g/100g	1.50 g/100g		
		1.496 ALVESAFE FAM5_6	<u>Packaging tested: glass bottle 125 mL</u>				Test report n°2019/100	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Light yellow	Light yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Characteristic	Characteristic		
			pH at 20°C	CIPAC MT 75.3	2.30	2.44		
			Acidity	CIPAC MT 191	0.8 % w/w	0.8 % w/w		
			Lactic acid content	Validated HPLC proprietary method	1.43 g/100g	1.49 g/100g		
		1.496 ALVESAFE FAM5_7	<u>Packaging test: Glass bottle 125 mL</u>				Test report n°2019/101	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results				Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless		
			Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh		
			pH at 20°C	CIPAC MT 75.3	2.29	2.31		
			Acidity	CIPAC MT 191	0.8 % w/w	0.8 % w/w		
			Lactic acid content	Validated HPLC proprietary method	1.44 g/100g	1.54 g/100g		
Meta SPC9		0.598 SALVESAFE FAM6_2	<p><u>Appearance of the product:</u> T₀: liquid, colourless, mint T_{2weeks}: liquid, colourless, mint</p> <p><u>Appearance of packaging:</u> Glass bottle 125 mL</p> <p><u>Active substance content:</u> T₀ = 0.589 % w/w T_{2 weeks} = 0.620 %w/w</p>				REVOL B. 2019. ACCELERATED STORAGE STABILITY for 14 days at 54 +/- 2°C Salvesafe_FAM 6_2 Salveco Study N°	Acceptable The product is stable after 14 days at 54°C.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment																												
			Variation : +0.031w/w pH T ₀ =2.53 pH T _{2 weeks} =2.56 Acidity T ₀ =0.4% H ₂ SO ₄ w/w Acidity T _{2 weeks} =0.4% H ₂ SO ₄ w/w	2019/104																													
		0.598 SALVESAFE FAM6_1	Packaging tested: Glass bottle 125 mL <table border="1"> <thead> <tr> <th>Property</th> <th>Guideline and Method</th> <th>Results at T+0 (initial state)</th> <th>Results at T+14 days</th> </tr> </thead> <tbody> <tr> <td>Physical state at 20 °C and 101.3 kPa</td> <td>Visual</td> <td>Liquid</td> <td>Liquid</td> </tr> <tr> <td>Colour at 20 °C and 101.3 kPa</td> <td>Visual</td> <td>Colourless</td> <td>Colourless</td> </tr> <tr> <td>Odour at 20°C and 101.3 kPa</td> <td>Olfactory</td> <td>Characteristic</td> <td>Characteristic</td> </tr> <tr> <td>pH at 20°C</td> <td>CIPAC MT 75.3</td> <td>2.54</td> <td>2.46</td> </tr> <tr> <td>Acidity</td> <td>CIPAC MT 191</td> <td>0.4 % w/w</td> <td>0.4 % w/w</td> </tr> <tr> <td>Lactic acid content</td> <td>Validated HPLC proprietary method</td> <td>0.581 g/100g</td> <td>0.624 g/100g</td> </tr> </tbody> </table>	Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days	Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless	Odour at 20°C and 101.3 kPa	Olfactory	Characteristic	Characteristic	pH at 20°C	CIPAC MT 75.3	2.54	2.46	Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w	Lactic acid content	Validated HPLC proprietary method	0.581 g/100g	0.624 g/100g	Test report n°2019/103	Acceptable The product is stable after 14 days at 54°C.
Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days																														
Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid																														
Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless																														
Odour at 20°C and 101.3 kPa	Olfactory	Characteristic	Characteristic																														
pH at 20°C	CIPAC MT 75.3	2.54	2.46																														
Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w																														
Lactic acid content	Validated HPLC proprietary method	0.581 g/100g	0.624 g/100g																														

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment																												
		0.598 SALVESAFE FAM6_3	Packaging tested: Glass bottle 125 mL <table border="1"> <thead> <tr> <th>Property</th> <th>Guideline and Method</th> <th>Results at T+0 (initial state)</th> <th>Results at T+14 days</th> </tr> </thead> <tbody> <tr> <td>Physical state at 20 °C and 101.3 kPa</td> <td>Visual</td> <td>Liquid</td> <td>Liquid</td> </tr> <tr> <td>Colour at 20 °C and 101.3 kPa</td> <td>Visual</td> <td>Colourless</td> <td>Colourless</td> </tr> <tr> <td>Odour at 20°C and 101.3 kPa</td> <td>Olfactory</td> <td>Spicy</td> <td>Spicy</td> </tr> <tr> <td>pH at 20°C</td> <td>CIPAC MT 75.3</td> <td>2.53</td> <td>2.49</td> </tr> <tr> <td>Acidity</td> <td>CIPAC MT 191</td> <td>0.4 % w/w</td> <td>0.4 % w/w</td> </tr> <tr> <td>Lactic acid content</td> <td>Validated HPLC proprietary method</td> <td>0.594 g/100g</td> <td>0.629 g/100g</td> </tr> </tbody> </table>	Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days	Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless	Odour at 20°C and 101.3 kPa	Olfactory	Spicy	Spicy	pH at 20°C	CIPAC MT 75.3	2.53	2.49	Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w	Lactic acid content	Validated HPLC proprietary method	0.594 g/100g	0.629 g/100g	Test report n°2019/105	Acceptable The product is stable after 14 days at 54°C.
Property	Guideline and Method	Results at T+0 (initial state)	Results at T+14 days																														
Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid																														
Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless																														
Odour at 20°C and 101.3 kPa	Olfactory	Spicy	Spicy																														
pH at 20°C	CIPAC MT 75.3	2.53	2.49																														
Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w																														
Lactic acid content	Validated HPLC proprietary method	0.594 g/100g	0.629 g/100g																														
Storage stability test – long term storage at ambient temperature	Storage for 24 months at ambient temperature																																
Meta SPC1 and 2		29.9 SALVESAFE FAM1_2	5 packagings have been tested for stability. Results are presented below: PET Bottle (500 mL):	REVOL B. 2019. LONG TERM STORAGE	Acceptable The product is stable after 2																												

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
	<p>Visual and olfactory method</p> <p>Validated HPLC proprietary method</p> <p>CIPAC MT 75.3</p> <p>CIPAC MT 191</p> <p>CIPAC MT 47.2</p>		<p><u>Appearance of the product:</u> T₀: liquid, yellow, mint T_{12 months}: liquid, yellow, mint T_{24 months}: liquid, yellow, mint</p> <p><u>Active substance content:</u> T₀= 29.74 % w/w T_{12 months} = 30.07%w/w T_{24 months} = 30.12%w/w Variation: +0.38 %w/w</p> <p>pH T₀=1.67 pH T_{12 months} =1.68 pH T_{24 months} =1.70</p> <p>Acidity T₀=18.4% H₂SO₄ w/w Acidity T_{12 months} =18.6% H₂SO₄ w/w Acidity T_{24 months} =18.9% H₂SO₄ w/w</p> <p>Persistent foaming (2% dilution) after 1 min T₀ = 38 mL Persistent foaming (2% dilution) after 1 min T_{12 months} = 41 mL Persistent foaming (2% dilution) after 1 min T_{24 months} = 36 mL</p> <p><u>Packaging :</u> Weight loss: T₀=538.5 g</p>	<p>STABILITY FOR 2 YEAR AT 23 +/- 4°C Salvesafe_FAM 1_2 Salveco Study N° 2019/106</p> <p>TEST REPORT N°2021/023 (in R-PET bottle)</p>	<p>years at ambient temperature in the 5 packagings tested.</p> <p>These studies covers products of Meta SPC 1 and 2 having an AS content of 29.9%. Other products of Meta SPC 1 and 2 are covered by the study provided for the product SALVESAFE FAM5_8 of Meta SPC 8 (having an AS content of 1.49%).</p>

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
	<p>Visual and olfactory method</p> <p>Validated HPLC proprietary method</p> <p>CIPAC MT 75.3</p> <p>CIPAC MT 191</p>		<p>T_{24 months}=538.7 g</p> <p>Bottle observation: T₀: No leakage, no deformations T_{24 months}: No leakage, no deformations</p> <p>No visual variation was observed on the packaging</p> <p>HDPE Bottle (500 mL):</p> <p><u>Appearance of the product:</u> T₀: liquid, yellow, mint T_{12 months}: liquid, yellow, mint T_{24 months}: liquid, yellow, mint</p> <p><u>Active substance content:</u> T₀= 29.74 % w/w T_{12 months} = 29.85%w/w T_{24 months} = 29.95%w/w Variation: +0.21 %w/w</p> <p>pH T₀=1.67 pH T_{12 months} =1.65 pH T_{24 months} =1.71</p> <p>Acidity T₀=18.4% H₂SO₄ w/w Acidity T_{12 months} =18.6% H₂SO₄ w/w Acidity T_{24 months} =18.7% H₂SO₄ w/w</p>		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
	<p>CIPAC MT 47.2</p> <p>Visual and olfactory method</p> <p>Validated HPLC proprietary method</p>		<p>Persistent foaming (2% dilution) after 1 min T₀ = 38 mL Persistent foaming (2% dilution) after 1 min T_{12 months} = 38 mL Persistent foaming (2% dilution) after 1 min T_{24 months} = 41 mL</p> <p>Packaging : Weight loss: T₀=535.9 T_{24 months}=536.0</p> <p>No visual variation was observed on the packaging</p> <p>Dilution stability (2% dilution) T₀ : Clear solution Dilution stability (2% dilution) T_{30 months} : Clear solution</p> <p><u>HDPE Refill sealed cap (20 mL):</u></p> <p><u>Appearance of the product:</u> T₀: liquid, yellow, mint T_{12 months}: liquid, yellow, mint T_{24 months}: liquid, yellow, mint</p> <p><u>Active substance content:</u> T₀= 29.74 % w/w T_{12 months} = 29.96%w/w T_{24 months} = 30.07%w/w Variation: +0.33 %w/w</p> <p>pH T₀=1.67</p>		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
	CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 47.2		pH T _{12 months} =1.72 pH T _{24 months} =1.73 Acidity T ₀ =18.4% H ₂ SO ₄ w/w Acidity T _{12 months} =18.5% H ₂ SO ₄ w/w Acidity T _{24 months} =18.8% H ₂ SO ₄ w/w Persistent foaming (2% dilution) after 1 min T ₀ = 38mL Persistent foaming (2% dilution) after 1 min T _{12 months} = 31mL Persistent foaming (2% dilution) after 1 min T _{24 months} = 35mL Packaging : Weight loss: T ₀ =30.5 g T _{24 months} =30.4 g Bottle observation: T ₀ : No leakage, no deformations T _{24 months} : No leakage, no deformations No visual variation was observed on the packaging <u>HDPE Refill sealed cap (100 mL):</u> <u>Appearance of the product:</u> T ₀ : liquid, yellow, mint T _{12 months} : liquid, yellow, mint		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
	Visual and olfactory method Validated HPLC proprietary method CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 47.2		<p>T_{24 months}: liquid, yellow, mint</p> <p><u>Active substance content:</u> T₀ = 29.74 % w/w T_{12 months} = 29.93%w/w T_{24 months} = 30.04%w/w Variation: +0.30 %w/w</p> <p>pH T₀ = 1.67 pH T_{12 months} = 1.70 pH T_{24 months} = 1.72</p> <p>Acidity T₀ = 18.4% H₂SO₄ w/w Acidity T_{12 months} = 18.4% H₂SO₄ w/w Acidity T_{24 months} = 18.9% H₂SO₄ w/w</p> <p>Persistent foaming (2% dilution) after 1 min T₀ = 38mL Persistent foaming (2% dilution) after 1 min T_{12 months} = 36mL Persistent foaming (2% dilution) after 1 min T_{24 months} = 37mL</p> <p>Packaging : Weight loss: T₀ = 136.9 g T_{24 months} = 137.1 g</p> <p>Bottle observation: T₀: No leakage, no deformations</p>		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			T ₂₄ months: No leakage, no deformations No visual variation was observed on the packaging <u>R-PET bottle (500 mL)</u>						
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+12 months	Results T+24 months		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Yellow	Yellow	Yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Mint	Mint	Mint		
			pH at 20°C	CIPAC MT 75.3	1.66	1.63	1.64		
			Acidity	CIPAC MT 191	18.3 % w/w	18.5 % w/w	18.6 % w/w		
			Persistent foaming	CIPAC MT 47.2	35 mL	39 mL	33 mL		
			Lactic acid content	Validated HPLC proprietary method	30.01 g/100g	30.64 g/100g	30.45 g/100g		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T + 0 months (prior to storage)	Results at T + 12 months	Results at 24 months		
			Packaging weight	Weighting	538.8 g	537.4 g	536.9 g		
			Bottle observation	Visual	No leakage, no deformations	No leakage, no deformations	No leakage deformation		
Meta SPC3 and 4	Visual and olfactory method Validated HPLC proprietary method	29.9 SALVESAFE FAM2_3	HDPE Bottle (500 mL): <u>Appearance of the product:</u> T ₀ : liquid, yellow, mint T _{12 months} : liquid, yellow, mint T _{24 months} : liquid, yellow, mint <u>Active substance content:</u> T ₀ = 29.65% w/w T _{12 months} = 30.13%w/w T _{24 months} = 30.52%w/w Variation: +0.87 %w/w pH T ₀ = 1.59 pH T _{12 months} = 1.66					REVOL B. 2019. LONG TERM STORAGE STABILITY FOR 2 YEAR AT 23 +/- 4°C Salvesafe_FAM 2_3 Salveco Study N° 2019/107	Acceptable The product is stable after 2 years at ambient temperature in the commercial packaging. This study covers products of Meta SPC 3 and 4 having an AS content of 29.9%.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
	CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 47.2		pH T _{24 months} = 1.68 Acidity T ₀ = 17.6% H ₂ SO ₄ w/w Acidity T _{12 months} = 17.9% H ₂ SO ₄ w/w Acidity T _{24 months} = 18.4% H ₂ SO ₄ w/w Persistent foaming (1% dilution) T ₀ = 53 mL Persistent foaming (1% dilution) T _{12 months} = 57 mL Persistent foaming (1% dilution) T _{24 months} = 50 mL Dilution stability (1% dilution) T ₀ : clear solution Dilution stability (1% dilution) T _{30 months} : clear solution Packaging : Weight loss: T ₀ = 534.1 g T _{24 months} = 533.7 g Bottle observation: T ₀ : No leakage, no deformations T _{24 months} : No leakage, no deformations No visual variation was observed on the packaging		Other products of Meta SPC 3 and 4 are covered by the study provided for the product SALVESAFE FAM5_8 of Meta SPC 8 (having an AS content of 1.49%).
Meta SPC5 and 6		29.9 SALVESAFE FAM3_2	HDPE Bottle (500 mL): <u>Appearance of the product:</u> T ₀ : liquid, yellow, mint T _{12 months} : liquid, yellow, mint	REVOL B. 2019. LONG TERM STORAGE STABILITY FOR	Acceptable The product is stable after 2 years at ambient

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
	<p>Visual and olfactory method</p> <p>Validated HPLC proprietary method</p> <p>CIPAC MT 75.3</p> <p>CIPAC MT 191</p> <p>CIPAC MT 47.2</p>		<p>T_{24 months}: liquid, yellow, mint</p> <p><u>Active substance content:</u> T₀= 29.90% w/w T_{12 months} = 30.06%w/w T_{24 months} = 30.34%w/w Variation: +0.44 %w/w</p> <p>pH T₀=1.55 pH T_{12 months} =1.57 pH T_{24 months} =1.63</p> <p>Acidity T₀=18.6% H₂SO₄ w/w Acidity T_{12 months} =19.0% H₂SO₄ w/w Acidity T_{24 months} =19.1% H₂SO₄ w/w</p> <p>Persistent foaming (2% dilution) T₀ = 50 mL Persistent foaming (2% dilution) T_{12 months} = 55 mL Persistent foaming (2% dilution) T_{24 months} = 48 mL</p> <p>Dilution stability (2% dilution) T₀ : clear solution Dilution stability (2% dilution) T_{30 months} : clear solution</p> <p>Packaging : Weight loss: T₀=560.7 g T_{24 months}=560.9 g</p> <p>Bottle observation:</p>	<p>2 YEAR AT 23 +/- 4°C - Salvesafe_FAM 3_2 Salveco Study N° 2019/108</p>	<p>temperature in the commercial packaging.</p> <p>This study covers products of Meta SPC 5 and 6.</p>

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
			<p>T₀: No leakage, no deformations T_{24 months}: No leakage, no deformations</p> <p>No visual variation was observed on the packaging</p>		
Meta SPC7	<p>Visual and olfactory method</p> <p>Validated HPLC proprietary method</p> <p>CIPAC MT 75.3</p> <p>CIPAC MT 191</p>	29.9 SALVESAFE 15	<p>HDPE bottle (500 mL):</p> <p><u>Appearance of the product:</u> T₀: liquid, yellow, characteristic T_{12 months}: liquid, yellow, characteristic T_{24 months}: liquid, yellow, characteristic</p> <p><u>Active substance content:</u> T₀= 29.90% w/w T_{12 months} = 30.18%w/w T_{24 months} = 30.42%w/w Variation: +0.52 %w/w</p> <p>pH T₀=1.49 pH T_{12 months} =1.53 pH T_{24 months} =1.56</p> <p>Acidity T₀=17.4% H₂SO₄ w/w Acidity T_{12 months} =17.9% H₂SO₄ w/w Acidity T_{24 months} =18.1% H₂SO₄ w/w</p> <p>Persistent foaming T₀ = 30 mL Persistent foaming T_{12 months} = 36 mL Persistent foaming T_{24 months} = 27 mL</p>	<p>REVOL B. 2019. LONG TERM STORAGE STABILITY FOR 2 YEAR AT 23 +/- 4°C - Salvesafe_15 Salveco Study N° 2019/018</p>	<p>Acceptable</p> <p>The product is stable after 2 years at ambient temperature in the commercial packaging.</p>

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
	CIPAC MT 47.2		<p>Dilution stability (1% dilution) T₀ : slightly opalescent solution</p> <p>Dilution stability (1% dilution) T_{30 months} : slightly opalescent solution</p> <p>Packaging : Weight loss: T₀=534.8 g T_{24 months}=534.7 g</p> <p>Bottle observation: T₀: No leakage, no deformations T_{24 months}: No leakage, no deformations</p> <p>No visual variation was observed on the packaging</p>		
Meta SPC8	Visual and olfactory method Validated HPLC	1.496 SALVESAFE FAM5_8	<p>PET bottle (500 mL):</p> <p><u>Appearance of the product:</u> T₀: liquid, light yellow, fresh T_{12 months}: liquid, light yellow, fresh T_{24 months}: liquid, light yellow, fresh</p> <p><u>Active substance content:</u> T₀= 1.45% w/w T_{12 months} = 1.51%w/w T_{24 months} = 1.52%w/w Variation: +0.07 %w/w</p>	REVOL B. 2019. LONG TERM STORAGE STABILITY FOR 2 YEAR AT 23 +/- 4°C - Salvesafe_5_8 Salveco Study N° 2019/112	Acceptable The product is stable after 2 years at ambient temperature in the commercial packagings (PET and HDPE bottles).

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
	proprietary method CIPAC MT 75.3 CIPAC MT 191		pH T ₀ =2.27 pH T _{12 months} = 2.28 pH T _{24 months} = 2.30 Acidity T ₀ =0.8% H ₂ SO ₄ w/w Acidity T _{12 months} =0.8% H ₂ SO ₄ w/w Acidity T _{24 months} =0.8% H ₂ SO ₄ w/w <u>Packaging :</u> Weight loss: T ₀ =544.4 g T _{24 months} =544.4 g Bottle observation: T ₀ : No leakage, no deformations T _{24 months} : No leakage, no deformations No visual variation was observed on the packaging <u>HDPE bottle (500 mL):</u> <u>Appearance of the product:</u> T ₀ : liquid, light yellow, fresh T _{12 months} : liquid, light yellow, fresh T _{24 months} : liquid, light yellow, fresh <u>Active substance content:</u> T ₀ = 1.45% w/w T _{12 months} = 1.49 %w/w		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
	<p>Visual and olfactory method</p> <p>Validated HPLC proprietary method</p> <p>CIPAC MT 75.3</p> <p>CIPAC MT 191</p>		<p>T_{24 months} = 1.50 %w/w Variation: +0.05 %w/w</p> <p>pH T₀ = 2.27 pH T_{12 months} = 2.23 pH T_{24 months} = 2.32</p> <p>Acidity T₀ = 0.8% H₂SO₄ w/w Acidity T_{12 months} = 0.8% H₂SO₄ w/w Acidity T_{24 months} = 0.8% H₂SO₄ w/w</p> <p>Packaging : Weight loss: T₀ = 561.2 g T_{24 months} = 559.8 g</p> <p>Bottle observation: T₀: No leakage, no deformations T_{24 months}: No leakage, no deformations</p> <p>No visual variation was observed on the packaging</p>		
		1.496 SALVESAFE FAM5_8	Packaging tested: R-PET bottle (500 mL)	Test report n°2021/027, Baptiste REVOL	Acceptable The product is stable after 2 years at ambient temperature in the commercial

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+12 months	Result T+24 months		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Liquid		packagings (R-PET).
			Colour at 20 °C and 101.3 kPa	Visual	Light yellow	Light yellow	Light yellow		
			Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh	Fresh		
			pH at 20°C	CIPAC MT 75.3	2.27	2.36	2.36		
			Acidity	CIPAC MT 191	0.8 % w/w	0.8 % w/w	0.8 % w/w		
			Lactic acid content	Validated HPLC proprietary method	1.46 g/100g	1.49 g/100g	1.50 g/100g		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T + 0 months (prior to storage)	Results at T + 12 months	Results at T - months		
			Packaging weight	Weighting	535.3 g	534.7 g	533.8 g		
			Bottle observation	Visual	No leakage, no deformations	No leakage, no deformations	No leakage, deformation		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
		0.598 SALVESAFE FAM5_3	PET bottle (500mL) with a PP spray head					Test Report n° 2019/109	Acceptable The product is stable after 2 years at ambient temperature in the commercial packagings (PET and HDPE bottles). In Meta SPC 8, only products with a pure active substance content of 0.598% will be packaged in bottles with spray heads. The determination of the droplets distribution has been reported below.
Property	Guideline and Method	Results at T+0 (initial state)	Results at T+12 months	Results at T+24 months					
Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Liquid					
Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless	Colourless					
Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh	Fresh					
pH at 20°C	CIPAC MT 75.3	2.46	2.48	2.55					
Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w	0.4 % w/w					
Lactic acid content	Validated HPLC proprietary method	0.567 g/100g	0.589 g/100g	0.592 g/100g					

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T + 0 months (prior to storage)	Results at T + 12 months	Results at T + 24 months		
			Packaging weight	Weighting	548.8 g	548.9 g	548.6 g		
			Bottle observation	Visual	No leakage, no deformations	No leakage, no deformations	No leakage, no deformations		
			Amount of spray delivered	Weighting	1.19 g	1.25 g	1.29 g		
			Spray pattern	Visual	Circular spray pattern	Circular spray pattern	Circular spray pattern		
			Nozzle observation	Visual	No blockage or leak	No blockage or leak	No blockage or leak		
			HDPE bottle (500 mL) with a PP spray head						

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (Initial state)	Results at T+12 months	Results at T+24 months		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless	Colourless		
			Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh	Fresh		
			pH at 20°C	CIPAC MT 75.3	2.46	2.49	2.53		
			Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w	0.4 % w/w		
			Lactic acid content	Validated HPLC proprietary method	0.567 g/100g	0.591 g/100g	0.597 g/100g		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T + 0 months (prior to storage)	Results at T + 12 months	Results at T + 24 months		
			Packaging weight	Weighting	576.4 g	576.1 g	576.3 g		
			Bottle observation	Visual	No variation	No variation	No variation		
			Amount of spray delivered	Weighting	1.10 g	1.04 g	1.19 g		
			Spray pattern	Visual	Circular spray pattern	Circular spray pattern	Circular spray pattern		
			Nozzle observation	Visual	No blockage or leak	No blockage or leak	No blockage or leak		
		0.598 SALVESAFE FAM5_3	<u>R-PET bottle (500 mL) with a PP spray head</u>					Test report n° 2021/024, Baptiste REVOL	Acceptable The product is stable after 2

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+12 months	Results at T+24 months		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Liquid		years at ambient temperature in the commercial packagings (R-PET).
			Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless	Colourless		
			Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh	Fresh		
			pH at 20°C	CIPAC MT 75.3	2.45	2.55	2.55		
			Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w	0.4 % w/w		
			Lactic acid content	Validated HPLC proprietary method	0.596 g/100g	0.590 g/100g	0.608 g/100g		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T + 0 months (prior to storage)	Results at T + 12 months	Results at T months		
			Packaging weight	Weighting	536.5 g	535.3 g	534.7 g		
			Bottle observation	Visual	No leakage, no deformations	No leakage, no deformations	No leakage, deformation		
			Amount of spray delivered	Weighting	1.20 g	1.22 g	1.21 g		
			Spray pattern	Visual	Circular spray pattern	Circular spray pattern	Circular spray pattern		
			Nozzle observation	Visual	No blockage or leak	No blockage or leak	No blockage or leak		
	CIPAC method MT 187	0.598 SALVESAFE FAM5_3	The MMAD was determined using a laser diffraction technique, after a storage of 29 months at 23°C:					Katia Cavallin SIR number 15924. Sample "before aging".	Acceptable The MMAD performed on this

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment																																			
		Batch 8911102019	<p><u>Before storage, the formulation produces a spray with a mean droplet size Dv(50) of about 117,71 µm and a value of Vol% < 50µm about 1,60%.</u></p> <p><u>After storage, the formulation produces a spray with a mean droplet size Dv(50) of about 105,69 µm and a volume fraction smaller 50 µm of about 8.12%.</u></p>	Katia Cavallin, 2021, SIR number: 17125 Sample "after aging".	product after long term storage covers all products with a pure active substance content of 0.598% (those that will be packaged in bottles with spray heads).																																			
		0.598 SALVESAFE FAM5_4	<p>PET bottle (500 mL) with a PP spray head</p> <table border="1"> <thead> <tr> <th>Property</th> <th>Guideline and Method</th> <th>Results at T+0 (initial state)</th> <th>Results at T+12 months</th> <th>Results at T+24 months</th> </tr> </thead> <tbody> <tr> <td>Physical state at 20 °C and 101.3 kPa</td> <td>Visual</td> <td>Liquid</td> <td>Liquid</td> <td>Liquid</td> </tr> <tr> <td>Colour at 20 °C and 101.3 kPa</td> <td>Visual</td> <td>Colourless</td> <td>Colourless</td> <td>Colourless</td> </tr> <tr> <td>Odour at 20°C and 101.3 kPa</td> <td>Olfactory</td> <td>Fresh</td> <td>Fresh</td> <td>Fresh</td> </tr> <tr> <td>pH at 20°C</td> <td>CIPAC MT 75.3</td> <td>2.48</td> <td>2.53</td> <td>2.54</td> </tr> <tr> <td>Acidity</td> <td>CIPAC MT 191</td> <td>0.4 % w/w</td> <td>0.4 % w/w</td> <td>0.4 % w/w</td> </tr> <tr> <td>Lactic acid content</td> <td>Validated HPLC proprietary method</td> <td>0.566 g/100g</td> <td>0.589 g/100g</td> <td>0.599 g/100g</td> </tr> </tbody> </table>	Property	Guideline and Method	Results at T+0 (initial state)	Results at T+12 months	Results at T+24 months	Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Liquid	Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless	Colourless	Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh	Fresh	pH at 20°C	CIPAC MT 75.3	2.48	2.53	2.54	Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w	0.4 % w/w	Lactic acid content	Validated HPLC proprietary method	0.566 g/100g	0.589 g/100g	0.599 g/100g	Test report n°2019/110	Acceptable The product is stable after 2 years at ambient temperature in the commercial packagings (PET and HDPE bottles).
Property	Guideline and Method	Results at T+0 (initial state)	Results at T+12 months	Results at T+24 months																																				
Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Liquid																																				
Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless	Colourless																																				
Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh	Fresh																																				
pH at 20°C	CIPAC MT 75.3	2.48	2.53	2.54																																				
Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w	0.4 % w/w																																				
Lactic acid content	Validated HPLC proprietary method	0.566 g/100g	0.589 g/100g	0.599 g/100g																																				

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T + 0 months (prior to storage)	Results at T + 12 months	Results at T + 24 months		
			Packaging weight	Weighting	548.1 g	548.5 g	548.0 g		
			Bottle observation	Visual	No leakage, no deformations	No leakage, no deformations	No leakage, no deformations		
			Amount of spray delivered	Weighting	1.18 g	1.14 g	1.16 g		
			Spray pattern	Visual	Circular spray pattern	Circular spray pattern	Circular spray pattern		
			Nozzle observation	Visual	No blockage or leak	No blockage or leak	No blockage or leak		
			HDPE bottle (500 mL) with a PP spray head						

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+12 months	Results at T+24 months		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless	Colourless		
			Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh	Fresh		
			pH at 20°C	CIPAC MT 75.3	2.48	2.49	2.54		
			Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w	0.4 % w/w		
			Lactic acid content	Validated HPLC proprietary method	0.566 g/100g	0.575 g/100g	0.586 g/100g		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T + 0 months (prior to storage)	Results at T + 12 months	Results at T + 24 months		
			Packaging weight	Weighting	576.4 g	576.1 g	576.3 g		
			Bottle observation	Visual	No variation	No variation	No variation		
			Amount of spray delivered	Weighting	0.99 g	1.04 g	1.10 g		
			Spray pattern	Visual	Circular spray pattern	Circular spray pattern	Circular spray pattern		
			Nozzle observation	Visual	No blockage or leak	No blockage or leak	No blockage or leak		
		0.598 SALVESAFE FAM5_4	<u>R-PET bottle (500 mL) with a PP spray head</u>					Test report n° 2021/025, Baptiste REVOL	Acceptable The product is stable after 2 years at ambient

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+12 months	Results at T+24 months		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Liquid		temperature in the commercial packagings (R-PET).
			Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless	Colourless		
			Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh	Fresh		
			pH at 20°C	CIPAC MT 75.3	2.48	2.57	2.57		
			Acidity	CIPAC MT 191	0.4 % w/w	0.4 % w/w	0.4 % w/w		
			Lactic acid content	Validated HPLC proprietary method	0.591 g/100g	0.608 g/100g	0.613 g/100g		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T + 0 months (prior to storage)	Results at T + 12 months	Results at T + 24 months		
			Packaging weight	Weighting	552.5 g	552.0 g	551.1 g		
			Bottle observation	Visual	No leakage, no deformations	No leakage, no deformations	No leakage, no deformation		
			Amount of spray delivered	Weighting	1.17 g	1.21 g	1.22 g		
			Spray pattern	Visual	Circular spray pattern	Circular spray pattern	Circular spray pattern		
			Nozzle observation	Visual	No blockage or leak	No blockage or leak	No blockage or leak		
		1.496 SALVESAFE FAM5_7	PET bottle (500 mL)					Test report n°2019/111	Acceptable The product is stable after 2 years at ambient temperature in

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+12 months	Results at T+24 months		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Liquid		the commercial packagings (PET and HDPE bottles).
			Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless	Colourless		
			Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh	Fresh		
			pH at 20°C	CIPAC MT 75.3	2.26	2.35	2.39		
			Acidity	CIPAC MT 191	0.8 % w/w	0.9 % w/w	0.8 % w/w		
			Lactic acid content	Validated HPLC proprietary method	1.45 g/100g	1.48 g/100g	1.53 g/100g		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T + 0 months (prior to storage)	Results at T + 12 months	Results at T + 24 months		
			Packaging weight	Weighting	528.3 g	528.6 g	528.1 g		
			Bottle observation	Visual	No leakage, no deformations	No leakage, no deformations	No leakage, no deformations		
			HDPE bottle (500 mL)						

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+12 months	Results at T+24 months		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless	Colourless		
			Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh	Fresh		
			pH at 20°C	CIPAC MT 75.3	2.26	2.29	2.33		
			Acidity	CIPAC MT 191	0.8 % w/w	0.8 % w/w	0.9 % w/w		
			Lactic acid content	Validated HPLC proprietary method	1.45 g/100g	1.49 g/100g	1.51 g/100g		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T + 0 months (prior to storage)	Results at T + 12 months	Results at T + 24 months		
			Packaging weight	Weighting	530.1 g	530.6 g	529.9 g		
			Bottle observation	Visual	No leakage, no deformations	No leakage, no deformations	No leakage, no deformations		
		1.496 SALVESAFE FAM5_7	R-PET bottle (500 mL)					Test report n° 2021/026, Baptiste REVOL	Acceptable The product is stable after 2 years at ambient temperature in the commercial packagings (R-PET).

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+12 months	Results at T+24 months		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless	Colourless		
			Odour at 20°C and 101.3 kPa	Olfactory	Fresh	Fresh	Fresh		
			pH at 20°C	CIPAC MT 75.3	2.26	2.28	2.33		
			Acidity	CIPAC MT 191	0.8 % w/w	0.8 % w/w	0.8 % w/w		
			Lactic acid content	Validated HPLC proprietary method	1.53 g/100g	1.47 g/100g	1.48 g/100g		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T + 0 months (prior to storage)	Results at T + 12 months	Results at T + 24 months		
			Packaging weight	Weighting	532.6 g	531.9 g	530.8 g		
			Bottle observation	Visual	No leakage, no deformations	No leakage, no deformations	No leakage, deformation		
Meta SPC9		0.598 SALVESAFE FAM6_2	<p><u>PET bottle (500 ml) with a PP spray head:</u></p> <p>Appearance of the product: T₀: liquid, colourless, mint T_{12 months}: liquid, colourless, mint T_{24 months}: liquid, colourless, mint</p> <p>Active substance content: T₀= 0.568% w/w T_{12 months} = 0.601%w/w T_{24 months} = 0.611%w/w Variation: +0.043 %w/w</p> <p>pH T₀=2.50 pH T_{12 months} = 2.60</p>					REVOL B. 2019. LONG TERM STORAGE STABILITY FOR 2 YEAR AT 23 +/- 4°C - Salvesafe_FAM 6_2 Salveco Study N° 2019/113	Acceptable The product is stable after 2 years at ambient temperature in the commercial packagings (PET and HDPE bottles).

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
			<p>pH T_{24 months} = 2.63</p> <p>Acidity T₀=0.3% H₂SO₄ w/w Acidity T_{12 months} =0.4% H₂SO₄ w/w Acidity T_{24 months} =0.4% H₂SO₄ w/w</p> <p><u>Packaging :</u> Weight loss: T₀=553.9 g T_{24 months}=553.6 g No visual variation was observed on the packaging</p> <p>Bottle observation: T₀: No leakage, no deformations T_{24 months}: No leakage, no deformations</p> <p>Amount of spray delivered: T₀=1.12 g T_{24 months}=1.21 g</p> <p>Spray pattern : T₀=Circular spray pattern T_{24 months}=Circular spray pattern</p> <p>Nozzle observation : T₀=No blockage or leak T_{24 months}=No blockage or leak</p> <p>HDPE bottle (500 mL) with a PP spray head:</p>		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
			<p><u>Appearance of the product:</u> T₀: liquid, colourless, mint T_{12 months}: liquid, colourless, mint T_{24 months}: liquid, colourless, mint</p> <p><u>Active substance content:</u> T₀= 0.568% w/w T_{12 months} = 0.591 %w/w T_{24 months} =0.599 %w/w Variation: +0.031 %w/w</p> <p>pH T₀=2.50 pH T_{12 months} =2.55 pH T_{24 months} =2.61</p> <p>Acidity T₀=0.3% H₂SO₄ w/w Acidity T_{12 months} =0.4% H₂SO₄ w/w Acidity T_{24 months} =0.4% H₂SO₄ w/w</p> <p>Packaging : Weight loss: T₀=582.8 g T_{24 months}=582.9 g</p> <p>Bottle observation: T₀: No leakage, no deformations T_{24 months}: No leakage, no deformations</p>		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
			<p>No visual variation was observed on the packaging</p> <p>Amount of spray delivered: T₀=1.12 g T_{24 months}=1.07 g</p> <p>Spray pattern : T₀=Circular spray pattern T_{24 months}=Circular spray pattern</p> <p>Nozzle observation : T₀=No blockage or leak T_{24 months}=No blockage or leak</p>		
		0.598 SALVESAFE FAM6_2	<u>R-PET bottle (500 mL) with PP spray head</u>	Test report n° 2021/028	Acceptable The product is stable after 2 years at ambient temperature in the commercial packagings (R-PET).

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T+0 (initial state)	Results at T+12 months	Results at T+24 months		
			Physical state at 20 °C and 101.3 kPa	Visual	Liquid	Liquid	Liquid		
			Colour at 20 °C and 101.3 kPa	Visual	Colourless	Colourless	Colourless		
			Odour at 20°C and 101.3 kPa	Olfactory	Mint	Mint	Mint		
			pH at 20°C	CIPAC MT 75.3	2.50	2.55	2.54		
			Acidity	CIPAC MT 191	0.4% w/w	0.4 % w/w	0.4 % w/w		
			Lactic acid content	Validated HPLC proprietary method	0.583 g/100g	0.594 g/100g	0.609 g/100g		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results					Reference	eCA assessment
			Property	Guideline and Method	Results at T + 0 months (prior to storage)	Results at T + 12 months	Results at T - months		
			Packaging weight	Weighting	559.9 g	558.6 g	558.2 g		
			Bottle observation	Visual	No leakage, no deformations	No leakage, no deformations	No leakage, deformation		
			Amount of spray delivered	Weighting	1.25g	1.24 g	1.23 g		
			Spray pattern	Visual	Circular spray pattern	Circular spray pattern	Circular spr pattern		
			Nozzle observation	Visual	No blockage or leak	No blockage or leak	No blockage leak		
Storage stability test – low temperature stability test for liquids	The conditions on storage “Avoid cold, frost” is indicated on the label for each meta SPC.							Acceptable The products should be protected from frost.	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
Effects on content of the active substance and technical characteristics of the biocidal product - light			No particular effect has been observed in literature concerning effect of light on L-(+)-lactic acid. See results of long term storage, which is performed at room temperature in transparent or translucent packagings for confirmation. Besides, the UV-spectrum of L-(+)-lactic acid shows that no absorbance in the wavelength range of 290-800 nm takes place. Therefore, L-(+)-lactic acid cannot undergo direct photolysis in sunlight.		Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - temperature and humidity			Humidity: product is water-based and packaging is closed. No effect of humidity is expected. Temperature: No effect is expected in normal conditions of storage. See results of accelerated storage for confirmation.		Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material			No reactivity towards container material has been observed during storage stability studies.		Acceptable
Wettability			Not relevant		Not relevant

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
Suspensibility, spontaneity and dispersion stability					
Wet sieve analysis and dry sieve test					
Emulsifiability, re-emulsifiability and emulsion stability					
Disintegration time					
Particle size distribution, content of dust/fines, attrition, friability					
Persistent foaming	CIPAC MT 47.2		The risk assessment was carried out for all types of applications at the maximum in-use concentration.		
Meta SPC1 and 2		29.9 SALVESAFE FAM1_2	At 2% dilution: 38 mL after 1 min	REVOL B. 2019. PHYSICO-CHEMICAL ANALYSIS-Salvesafe_FAM 1_2 Salveco Study N° 2019/039	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
		29.9 SALVESAFE FAM1_1	At 2% dilution: 33 mL after 1 min	Test report n°2019/072	Acceptable
		29.9 SALVESAFE FAM1_3	At 2% dilution: 33 mL after 1 min	Test report n°2019/074	Acceptable
		29.9 SALVESAFE FAM1_4	At 2% dilution: 36 mL after 1 min	Test report n°2019/075	Acceptable
		19.95 SALVESAFE FAM1_5	At 3% dilution: 52 mL after 1 min	Test report n°2019/076	Acceptable
		19.95 SALVESAFE FAM1_6	At 3% dilution: 44 mL after 1 min	Test report n°2019/077	Acceptable
		19.95 SALVESAFE FAM1_7	At 3% dilution: 50 mL after 1 min	Test report n°2019/078	Acceptable
		19.95 SALVESAFE FAM1_8	At 3% dilution: 47 mL after 1 min	Test report n°2019/079	Acceptable
		14.96 SALVESAFE FAM1_9	At 10% dilution: 43 mL after 1 min	Test report n°2019/080	Acceptable
		14.96 SALVESAFE FAM1_10	At 10% dilution: 37 mL after 1 min	Test report n°2019/081	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
		14.96 SALVESAFE FAM1_11	At 10% dilution: 42 mL after 1 min	Test report n°2019/082	Acceptable
		14.96 SALVESAFE FAM1_12	At 10% dilution: 43 mL after 1 min	Test report n°2019/083	Acceptable
		29.9 SALVESAFE FAM1_13	At 1% dilution: 32 mL after 1 min	Test report n°2019/084	Acceptable
		29.9 SALVESAFE FAM1_14	At 1% dilution: 33 mL after 1 min	Test report n°2019/085	Acceptable
		14.96 SALVESAFE FAM1_15	At 2% dilution: 42 mL after 1 min	Test report n°2019/086	Acceptable
		14.96 SALVESAFE FAM1_16	At 2% dilution: 41 mL after 1 min	Test report n°2019/087	Acceptable
Meta SPC3 and 4		29.9 SALVESAFE FAM2_3	At 1% dilution: 53 mL after 1 min	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 2_3 Salveco Study N° 2019/056	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
		14.96 SALVESAFE FAM2_1	At 2% dilution: 41 mL after 1 min	Test report n°2019/088	Acceptable
		29.9 SALVESAFE FAM2_2	At 1% dilution: 35 mL after 1 min	Test report n°2019/089	Acceptable
		29.9 SALVESAFE FAM2_4	At 1% dilution: 52 mL after 1 min	Test report n°2019/091	Acceptable
		7.48 SALVESAFE FAM2_5	At 4% dilution: 39 mL after 1 min	Test report n°2019/092	Acceptable
Meta SPC 5		29.9 SALVESAFE FAM3_1	At 2% dilution: 70 mL after 1 min	Test report n°2019/093	The produced foam is >60mL, the product is a foaming formulation.
Meta SPC 6		29.9 SALVESAFE FAM3_2	At 2% dilution: 50 mL after 1 min	REVOL B. 2019. PHYSICO-CHEMICAL ANALYSIS- Salvesafe_FAM 3_2 Salveco Study N° 2019/060	Acceptable
Meta SPC7		29.9	At 1% dilution: 30 mL after 1 min	REVOL B. 2019.	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
		SALVESAFE 15		PHYSICO-CHEMICAL ANALYSIS-Salvesafe_15 Salveco Study N° 2019/017	
Meta SPC8			Not relevant as the products are ready to use.		Acceptable
Meta SPC9					
Flowability/Pourability/Dustability	Not applicable for SL formulation				Not relevant
Burning rate – smoke generators					Not relevant
Burning completeness – smoke generators					Not relevant
Composition of smoke – smoke generators					Not relevant
Spraying pattern – aerosols	NA – not aerosols. The spraying pattern has been studied for spray products (meta SPC5 and SPC6) in the frame of long term stability studies. Please refer to these studies.				Acceptable
Physical compatibility	Not relevant as the products of the family are not intended for application with other products.				Not relevant
Chemical compatibility	Not relevant as the products of the family are not intended for application with other products.				Not relevant

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
Degree of dissolution and dilution stability	The dilution stability has been studied for solution that need to be diluted before use in the accelerated storage studies (meta SPC 1, 2, 3 and 4).				Acceptable
Surface tension	Method A.5 Platinum plate Kruss tensiometer		Distilled water has a surface tension of 72.75 mN/m at 20°C; substances showing a surface tension lower than 60 mN/m under the conditions of this method should be regarded as being surface-active materials (see method A.5 Surface tension 2008).		
Meta SPC1 and 2		29.9 SALVESAFE FAM1_2	Product tested at 2%: 28.1 mN/m The substance is considered as a surface-active.	REVOL B. 2019. PHYSICO-CHEMICAL ANALYSIS- Salvesafe_FAM 1_2 Salveco Study N° 2019/039	Acceptable
Meta SPC3 and 4		29.9 SALVESAFE FAM2_3	Product tested at 1%: 27.9 mN/m The substance is considered as a surface-active.	REVOL B. 2019. PHYSICO-CHEMICAL ANALYSIS- Salvesafe_FAM 2_3 Salveco Study N° 2019/056	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
Meta SPC 5		29.9 SALVESAFE FAM3_1	Product tested at 2%: 28.5 mN/m The substance is considered as a surface-active.	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 3_2 Salveco Study N° 2019/059	Acceptable
Meta SPC 6		29.9 SALVESAFE FAM3_2	Product tested at 2%: 28.6 mN/m The substance is considered as a surface-active.	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 3_2 Salveco Study N° 2019/060	Acceptable
Meta SPC7		29.9 SALVESAFE 15	Product tested at 1% 27.8 mN/m The substance is considered as a surface-active.	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_15 Salveco	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
				Study N° 2019/017	
Meta SPC8		1.496 ALVESAFE FAM5_8	Product tested at 100% 29.0 mN/m The substance is considered as a surface-active.	REVOL B. 2019. PHYSICO-CHEMICAL ANALYSIS-Salvesafe_5_8 Salveco Study N° 2019/068	Acceptable
Meta SPC9		0.598 SALVESAFE FAM6_2	Product tested at 100% 28.3 mN/m The substance is considered as a surface-active.	REVOL B. 2019. PHYSICO-CHEMICAL ANALYSIS-Salvesafe_FAM6_2 Salveco Study N° 2019/070	Acceptable
Viscosity	OECD 114 Viscometer Lamy		The only data provided in the studies are reported below.		
Meta SPC1 and 2		29.9 SALVESAFE FAM1_2	At 20°C= <50 mPa.s At 40°C= <50 mPa.s	REVOL B. 2019. PHYSICO-	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
				CHEMICAL ANALYSIS- Salvesafe_FAM 1_2 Salveco Study N° 2019/039	
Meta SPC3 and 4		29.9 SALVESAFE FAM2_3	At 20°C= <50 mPa.s At 40°C= <50 mPa.s	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 2_3 Salveco Study N° 2019/056	Acceptable
Meta SPC 5 and 6		29.9 SALVESAFE FAM3_2	At 20°C= <50 mPa.s At 40°C= <50 mPa.s	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 3_2 Salveco Study N° 2019/060	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment
Meta SPC7		29.9 SALVESAFE 15	At 20°C= <50 mPa.s At 40°C= <50 mPa.s	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_15 Salveco Study N° 2019/017	Acceptable
Meta SPC8		1.496 ALVESAFE FAM5_8	At 20°C= <50 mPa.s At 40°C= <50 mPa.s	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_5_8 Salveco Study N° 2019/068	Acceptable
Meta SPC9		0.598 SALVESAFE FAM6_2	At 20°C= <50 mPa.s At 40°C= <50 mPa.s	REVOL B. 2019. PHYSICO- CHEMICAL ANALYSIS- Salvesafe_FAM 6_2 Salveco Study N° 2019/070	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	eCA assessment

Conclusion on the physical, chemical and technical properties of the product

The products of the family are SL or AL formulations. All studies above have been performed in accordance with the current requirements.

The products showed no changes when stored for 2 weeks at 54 +/- 2°C. The appearance of the products, pH, acidity, dilution stability, persistent foaming and active substance content were tested. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packagings (PET, HDPE, R-PET). Considering the types of formulation of the products (SL and AL) these results can be extrapolated to other packaging material. The 2 substances of concern (Poly(oxy-1,2-ethanediyl), .alpha.-(carboxymethyl)-.omega.-(octyloxy)- and D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides) have not been included in the storage stability/shelf life studies as they are not expected to increase during storage of the products.

Low temperature stability test was waived as the label recommends "Avoid cold, frost". Therefore, the products should be protected from frost.

The product of Meta SPC 5 is a foaming formulation.

Their technical characteristics are acceptable for SL or AL formulations.

2.12.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	FR evaluation
Explosives	Structure analysis		<p>Consideration of the structure indicates that L-(+)-lactic acid does not have explosive or oxidising properties.</p> <p>According to Regulation (EC) N°1272/2008 (CLP) criteria and screening procedure (as listed in appendix 6 to the UN Recommendations on the Transport of Dangerous Goods - Manual of Tests and Criteria (6th revised edition, 2015) or in the ECHA endpoint specific guidance on information requirements. (R.7a, v6.0, July 2017, §R.7.1.11), no chemical group associated with explosive properties was identified in the list of constituents of the products.</p> <p>The product is a water-based formulation.</p> <p>Therefore, explosive properties are not anticipated for the products and the acceptance procedure for Class 1 explosives shall not apply. No further testing was considered.</p> <p>See confidential PAR for the detailed expert judgment based on the composition</p>	<p>RAC opinion on L-(+)-lactic acid adopted 9 March 2018.</p> <p>CLH-O-0000001412-86-191/F</p>	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	FR evaluation
Flammable gases			Not relevant as the products of the BPF are liquid		Not relevant
Flammable aerosols			Not relevant as the products of the BPF are liquid		Not relevant
Oxidising gases			Not relevant as the products of the BPF are liquid		Not relevant
Gases under pressure			Not relevant as the products of the BPF are liquid		Not relevant
Flammable liquids Meta SPC1 to 9	Pensky Martens	SALVE SAFE FAM1_ 2 (Meta SPC 2)	The product considered as the worst case in term of composition (SALVESAFE FAM1_2) has been tested for flammability. No flash point observed up to 100°C. The products of the BPF are not flammable according to CLP regulation.	██████████ ██████████ Study N° RNC20-03649.001	Acceptable. The SALVESAFE FAM1_2 has been considered as the worst case as it contains the max content of active substance, surfactants and perfume of the BPF. Moreover the perfume present in this product is the only one classified as Flammable Cat 3 based on its

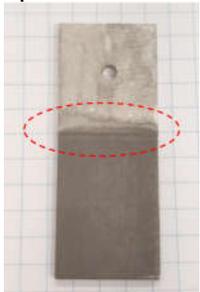
Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	FR evaluation
					FDS (Perfume Cool mint) Products in BPF are not considered as flammable.
Flammable solids			Not relevant as the products of the BPF are liquid		Not relevant
Self-reactive substances and mixtures	DSC METTLER TOLEDO DSC1	SALVE SAFE FAM1_2, SALVE SAFE FAM1_3 and SALVE SAFE FAM1_4 (Meta SPC 2)	According to Guidance on the application of the CLP criteria, "substances and mixtures must be considered for classification in this hazard class unless there are no chemical groups present in the molecule associated with explosive or self-reactive properties. Examples of such groups are given in Tables A6.1 and A6.2 in Appendix 6 of the UN RTDG, Manual of Tests and Criteria". See confidential PAR Moreover, DSC test have been performed support the absence of classification. 3 formulations were tested to cover the family. These formulations have the maximum content of perfume and considered as worst case products to cover all the perfumes of the family: SALVESAFE FAM1_2, SALVESAFE FAM1_3 and SALVESAFE FAM1_4.	[REDACTED] DSC Analysis	Acceptable Products of the BPF are not considered as self-reactive substances.

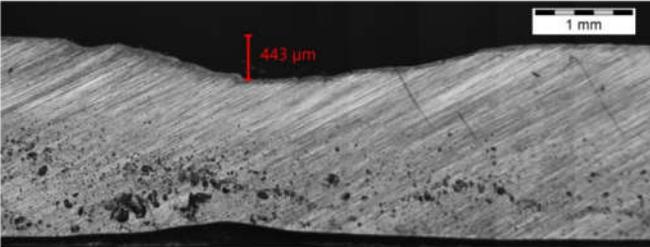
Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	FR evaluation
			The 3 DSC curves show an endothermic peak visible around 100°C that corresponds to the evaporation of water. No exothermic peak is visible up to 550°C.		
Pyrophoric liquids			Applicant has been producing and working with this type of formula for more than 10 years, without any notified pyrophoric effect. Applicant experience with this kind of product includes stability studies at a temperature of 54°C over weeks, which never spontaneously ignited when in contact with air. Moreover, the provided study for auto-flammability does not show ignition of the sample before 415°C.		Acceptable. Products in BPF are aqueous solutions
Pyrophoric solids			Not relevant as the product is a liquid		Not relevant
Self-heating substances and mixtures			According to Annex I 2.11.4.2 of the CLP Regulation, a self-heating substance or mixture is a liquid or solid substance or mixture, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat. This substance or mixture differs from a pyrophoric liquid or solid in that it will ignite only		Acceptable

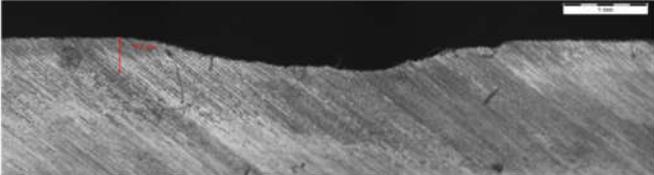
Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	FR evaluation
			<p>when in large amounts (kilograms) and after long periods of time (hours or days). In general, the phenomenon of self-heating applies only to solids. The test item is not included in the scope of this definition. Considering that the test procedure needs not be applied if the product is completely molten at 160°C and that the test method is not applicable to liquids, the products are not considered in this hazard class. Moreover, test item is water-based. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore, the liquids of the family are not classified as self-heating.</p>		
Substances and mixtures which in contact with water emit flammable gases			Not relevant as the product is a liquid with a large amount of water.		Not relevant
Oxidising liquids	Structure analysis		<p>No experimental study is available on the product.</p> <p>Consideration of the structure indicates that L-(+)-lactic acid does not have oxidising properties.</p>		Acceptable Products of the BPF are not considered as oxidising liquids.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	FR evaluation
			<p>the detailed compositions of perfumes are known and no halogen element are present and the oxygen element are linked to Carbone element or to Hydrogen element. Concerning the surfactants, their compositions is known and allows to justify the absence of oxidising property. (See confidential PAR)</p> <p>Therefore, the BPF does not have oxidising properties.</p>		
Oxidising solids			Not relevant as the product is a liquid		Not relevant
Organic peroxides	Composition analysis		The product does not contain organic peroxides		Acceptable
Corrosive to metals	UN Manual of Test and Criteria (ST/SG/AC.10/11/Rev5, 2009); Test C.1.		<p>RAC concludes that the substance L-(+)-lactic acid does not require classification for corrosivity to metals. Furthermore four tests have been provided on 2 products: one is considered is the worst case of Metas SPC 1 to 7 (MAX CONC AMM) and one is considered is the worst case of Metas SPC 8 and 9 (MAX PAE AMM). The composition of both formulations is reported in the confidential annex.</p> <p><u>Test description:</u></p>	RAC opinion on L-(+)-lactic acid adopted 9 March 2018. CLH-O-0000001412-86-191/F	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	FR evaluation												
			<p>Test coupons: Aluminium and steel Test temperature: 55°C (± 1°C) Duration of test: 168h ± 1h (7days) and 672h ± 1h (28 days)</p> <p>Three test coupons were prepared of each material (aluminium and steel) with following approximate dimensions: 50x 20 x 2 mm with a 3 mm diameter hole. For each test, one specimen is dipped into the solution, another one only halfway and a third one hangs in the gas phase. When localized corrosion occurs, the depth of the deepest hole will be estimated with the light microscope or determined by metallographic examination.</p> <p>Results of the four studies are reported below.</p>														
Metas 1-7 (MAX CONC AMM)	UN Manual of Test and Criteria (ST/SG/AC.10/11/Rev5, 2009); Test method of Part III,		<p>Results of formulation "MAX CONC AMM" (worst case of Metas SPC 1 to 7) after 7 days</p> <table border="1" data-bbox="792 1209 1473 1378"> <thead> <tr> <th>Material</th> <th>Position</th> <th>mass loss [%]</th> </tr> </thead> <tbody> <tr> <td>steel</td> <td>100% vapour</td> <td>0.2</td> </tr> <tr> <td>steel</td> <td>50%/50%</td> <td>0.9</td> </tr> <tr> <td>steel</td> <td>100% liquid</td> <td>1.8</td> </tr> </tbody> </table>	Material	Position	mass loss [%]	steel	100% vapour	0.2	steel	50%/50%	0.9	steel	100% liquid	1.8	<div style="background-color: black; width: 100%; height: 100%;"></div> <p>Report N° JC_20/235-1_final_200622</p>	<p>Acceptable</p> <p>Due to the test result after 7 days close to the limits, a new study after 28 days was</p>
Material	Position	mass loss [%]															
steel	100% vapour	0.2															
steel	50%/50%	0.9															
steel	100% liquid	1.8															

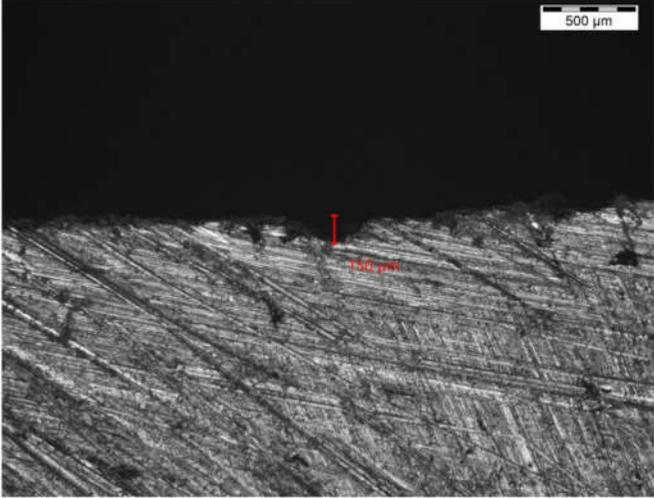
Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	FR evaluation						
	sub-section 37.4		Aluminium 100% vapour 0.0	Corrosion_formulation_worst_case_Metas1-7	requested to confirm the non classification of meta SPC 1-7						
			Aluminium 50%/50% 6.2								
			Aluminium 100% liquid 11.8								
			<p>Localised corrosion is observed on the aluminium sample partially immersed in the liquid.</p>  <p>The deepest intrusion measures 107 µm.</p>								
			Results of formulation "MAX CONC AMM" (worst case of Metas SPC 1 to 7) after 28 days								
<table border="1"> <thead> <tr> <th data-bbox="792 1241 987 1283">Material</th> <th data-bbox="987 1241 1227 1283">Position</th> <th data-bbox="1227 1241 1473 1283">mass loss [%]</th> </tr> </thead> <tbody> <tr> <td data-bbox="792 1283 987 1324">steel</td> <td data-bbox="987 1283 1227 1324">100% vapour</td> <td data-bbox="1227 1283 1473 1324">0.0</td> </tr> <tr> <td data-bbox="792 1324 987 1366">steel</td> <td data-bbox="987 1324 1227 1366">50%/50%</td> <td data-bbox="1227 1324 1473 1366">4.1</td> </tr> </tbody> </table>	Material	Position	mass loss [%]	steel	100% vapour	0.0	steel	50%/50%	4.1	Metal corrosion test on product Max Conc AMM for 28 days, Report: 21/431-1, [REDACTED]	Acceptable This test (performed at a prolonged time exposure of 28 days) confirmed
Material	Position	mass loss [%]									
steel	100% vapour	0.0									
steel	50%/50%	4.1									

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	FR evaluation												
			<table border="1"><tr><td>steel</td><td>100% liquid</td><td>3.4</td></tr><tr><td>Aluminium</td><td>100% vapour</td><td>0.0</td></tr><tr><td>Aluminium</td><td>50%/50%</td><td>6.5</td></tr><tr><td>Aluminium</td><td>100% liquid</td><td>13.1</td></tr></table> <p>The loss of mass does not exceed the maximum of 51.5% during 28 days of exposure.</p> <p>Localised corrosion is observed on both samples partially immersed in the liquid. The depth of intrusion was measured metallographically. The deepest intrusion on aluminium was measured to be 443 µm.</p>  <p><i>Aluminium, partially immersed. Measurement of localised corrosion: 443 µm</i></p> <p>The deepest intrusion on steel was measured to be 411 µm.</p>	steel	100% liquid	3.4	Aluminium	100% vapour	0.0	Aluminium	50%/50%	6.5	Aluminium	100% liquid	13.1		that products of Meta SPC 1 to 7 are not classified corrosive to metals.
steel	100% liquid	3.4															
Aluminium	100% vapour	0.0															
Aluminium	50%/50%	6.5															
Aluminium	100% liquid	13.1															

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	FR evaluation															
			 <p data-bbox="981 663 1339 679"><i>Steel, partially immersed. Measurement of localised corrosion: 411 µm</i></p> <p data-bbox="801 692 1467 791">The deepest intrusion (443 µm) does not exceed the maximum of 480 µm depth after 28 days of exposure.</p> <p data-bbox="801 831 1467 999">The formulation evaluated as the worst case of Metas SPC 1 to 7 (MAX CONC AMM) was found to be not corrosive to metals considering the mass loss and the deepest intrusion measured also after 28 days.</p> <p data-bbox="801 1007 1435 1067">Therefore, the products in these metas are not classified corrosive to metals.</p>																	
Metas 8-9 (MAX PAE AMM)	UN Manual of Test and Criteria (ST/SG/AC.10/11/Rev5, 2009); Test method of Part III,		<p data-bbox="801 1078 1424 1139">Results of formulation "MAX PAE AMM" (worst case of Metas SPC 8 and 9) after 7 days</p> <table border="1" data-bbox="801 1177 1467 1378"> <thead> <tr> <th>Material</th> <th>Position</th> <th>mass loss [%]</th> </tr> </thead> <tbody> <tr> <td>steel</td> <td>100% vapour</td> <td>0.2</td> </tr> <tr> <td>steel</td> <td>50%/50%</td> <td>1.3</td> </tr> <tr> <td>steel</td> <td>100% liquid</td> <td>1.7</td> </tr> <tr> <td>Aluminium</td> <td>100% vapour</td> <td>0.0</td> </tr> </tbody> </table>	Material	Position	mass loss [%]	steel	100% vapour	0.2	steel	50%/50%	1.3	steel	100% liquid	1.7	Aluminium	100% vapour	0.0	<p data-bbox="1480 1078 1742 1246">[Redacted]</p> <p data-bbox="1480 1254 1693 1353">Report N° JC_20/235-2_final_200622</p>	<p data-bbox="1765 1078 1912 1107">Acceptable</p> <p data-bbox="1765 1182 1995 1383">Due to the test result after 7 days close to the limits, a new study after 28 days was</p>
Material	Position	mass loss [%]																		
steel	100% vapour	0.2																		
steel	50%/50%	1.3																		
steel	100% liquid	1.7																		
Aluminium	100% vapour	0.0																		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	FR evaluation						
	sub-section 37.4		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Aluminium</td> <td style="width: 30%;">50%/50%</td> <td style="width: 50%;">0.2</td> </tr> <tr> <td>Aluminium</td> <td>100% liquid</td> <td>0.4</td> </tr> </table> <p>Localised corrosion is observed on the steel sample hanged in the vapour and on the steel sample partially immersed in the liquid. The deepest intrusion was observed on the steel sample partially immersed in the liquid.</p>  <p>The deepest intrusion measures 109 µm.</p> <p>.Therefore, the products in these metas are not classified corrosive to metals.</p>	Aluminium	50%/50%	0.2	Aluminium	100% liquid	0.4	Corrosion_formulation_worst_case_Metas 8-9	requested to confirm the non classification of meta SPC 8 and 9
Aluminium	50%/50%	0.2									
Aluminium	100% liquid	0.4									
			Results of formulation "MAX PAE AMM" (worst case of Metas SPC 8 and 9) after 28 days	Metal corrosion test on product	Acceptable						

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	FR evaluation																					
			<table border="1"><thead><tr><th data-bbox="801 480 981 512">Material</th><th data-bbox="981 480 1234 512">Position</th><th data-bbox="1234 480 1464 512">mass loss [%]</th></tr></thead><tbody><tr><td data-bbox="801 512 981 555">steel</td><td data-bbox="981 512 1234 555">100% vapour</td><td data-bbox="1234 512 1464 555">0.3</td></tr><tr><td data-bbox="801 555 981 598">steel</td><td data-bbox="981 555 1234 598">50%/50%</td><td data-bbox="1234 555 1464 598">2.4</td></tr><tr><td data-bbox="801 598 981 641">steel</td><td data-bbox="981 598 1234 641">100% liquid</td><td data-bbox="1234 598 1464 641">11.0</td></tr><tr><td data-bbox="801 641 981 684">Aluminium</td><td data-bbox="981 641 1234 684">100% vapour</td><td data-bbox="1234 641 1464 684">0.0</td></tr><tr><td data-bbox="801 684 981 727">Aluminium</td><td data-bbox="981 684 1234 727">50%/50%</td><td data-bbox="1234 684 1464 727">0.1</td></tr><tr><td data-bbox="801 727 981 770">Aluminium</td><td data-bbox="981 727 1234 770">100% liquid</td><td data-bbox="1234 727 1464 770">2.3</td></tr></tbody></table> <p data-bbox="801 770 1464 834">The loss of mass does not exceed the maximum of 51.5% during 28 days of exposure.</p> <p data-bbox="801 874 1464 1042">Localised corrosion is observed on the steel sample partially immersed in the liquid. The depth of intrusion was measured metallographically. The deepest intrusion on steel was measured to be 150 µm.</p>	Material	Position	mass loss [%]	steel	100% vapour	0.3	steel	50%/50%	2.4	steel	100% liquid	11.0	Aluminium	100% vapour	0.0	Aluminium	50%/50%	0.1	Aluminium	100% liquid	2.3	Max PAE AMM for 28 days, Report: 21/431-2, [REDACTED]	This test (performed at a prolonged time exposure of 28 days) confirmed that products of Meta SPC 8 and 9 are not classified corrosive to metals.
Material	Position	mass loss [%]																								
steel	100% vapour	0.3																								
steel	50%/50%	2.4																								
steel	100% liquid	11.0																								
Aluminium	100% vapour	0.0																								
Aluminium	50%/50%	0.1																								
Aluminium	100% liquid	2.3																								

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	FR evaluation
			 <p data-bbox="981 983 1339 999"><i>Steel, partially immersed. Measurement of localised corrosion: 150 µm</i></p> <p data-bbox="801 1010 1462 1110">The deepest intrusion (150 µm) does not exceed the maximum of 480 µm depth after 28 days of exposure.</p> <p data-bbox="801 1150 1462 1318">The formulation evaluated as the worst case of Metas SPC 8 and 9 (MAX PAE AMM) was found to be not corrosive to metals considering the mass loss and the deepest intrusion measured after 28 days.</p> <p data-bbox="801 1326 1462 1386">Therefore, the products in these metas are not classified corrosive to metals.</p>		

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference	FR evaluation
Auto-ignition temperatures of products (liquids and gases)	Method DIN 51794	Batch: 16540 05202 0 Product SALVE SAFE FAM1_2 (Meta SPC 2)	The flash point measured is above 100°C. Moreover, the products are known to be stable at room temperature and do not ignite spontaneously. This waiving is supported by the result of a study, stating an auto-ignition temperature of 415°C. The tested product is considered to be the worst case product of the family based on the composition.	Report N° R/20/20704	Acceptable
Relative self-ignition temperature for solids			Not relevant as the product is a liquid		Not relevant
Dust explosion hazard			Not relevant as the product is a liquid		Not relevant

Conclusion on the physical hazards and respective characteristics of the product

The products are neither flammable nor auto-flammable. They have no explosive, no self-reactive, no self-heating, no pyrophoric and no oxidizing properties. They are not classified as corrosive to metals (H290).

2.12.4 Methods for detection and identification

A product with the maximum active substance content over the BPF has been tested (29.9%). Analytical methods for other products can be read across from these data.

Principle of the method:

The samples are diluted with a 2M H₃PO₄ solution on a high precision scale and left overnight at 54°C.

The precise weights are measured to calculate the exact dilution of the sample. Analysis are performed using HPLC with UV/PDA detection. Quantification is done with a calibration curve by external standard method.

Validation of the method:

-Specificity: The specificity of the HPLC method was tested with the preparation of 2 formulations, one containing the active substance (L-(+)-Lactic acid - AcL), and the other with the same composition, but without L-(+)-lactic acid. The spectrum determined with HPLC shows that no peak is observed when the formulation is prepared without the active substance at the expected retention time.

Peaks observed at 2.8 and 5.8 min do not contribute to more than 3 % of the total quantity of active substance measured (see chromatograms in experimental report).

-Confirmation of identity: In order to confirm that the peak observed at 5 min accurately represents the L-(+)-lactic acid in the sample, the UV absorption spectrum was analysed. Confirmation of identity can be realised using the measured spectrum during the analysis and compared with the UV spectrum for a L-(+)-lactic acid standard and a spectra library for L-(+)-Lactic acid. The UV analysis is realised on a range of 200 – 300 nm, knowing that the L-(+)-lactic acid maximum UV absorption peak is 208 – 210 nm. The 3D UV spectra can be acquired, as well as the chromatogram measured at 210 nm for quantification.

-Linearity: The calibration curve used for the analysis can be adapted according to the dilution of the tested samples. However, the following rules are always applied when choosing the concentrations:

The L-(+)-lactic acid used for the calibration curve is pharmaceutical grade, with a certificate of analysis giving the exact L-(+)-lactic acid content.

The calibration curve always includes at least 5 different concentrations, with one repetition for each point (the concentrations are chosen in the range: 0.125 g/100g – 6.500 g/100g).

Dilutions factors have been provided to show that the linearity of the method covers all the products of the family. Moreover, dilutions may be adapted if needed, but the final concentration for testing should be in the range 0.13 – 2.5 g/100g.

The lowest concentration used in the calibration curve is never more than 20 % superior to the minimal L-(+)-lactic acid content measured.

The maximum concentration used in the calibration curve is never more than 20 % inferior to the maximal L-(+)-lactic acid content measured.

-Repeatability: The repeatability and the determination of the confidence interval were calculated considering two main sources of variations on the final result: (i) variation due to HPLC analysis, and (ii) variation due to sample preparation.

In order to evaluate the variation due to the HPLC analysis, a sample was injected 10 times in a row. The coefficient of variation (CV) of the L-(+)-lactic acid peak area is equal to 0,068 %. Considering this result, the error due to the HPLC can be neglected.

In order to evaluate the variation due to sample preparation, five different samples were prepared, following the complete sample preparation procedure using one initial formulation. Each sample was injected into the HPLC in order to quantify the active content. The coefficient of variation is equal to 1.3 %. The tolerance limit for this sample, according to BPR Guidance, is 5 %. Thus, considering experimental variations, the L-(+)-lactic acid content can be determined with a sufficient repeatability in this method.

Analyte concentration	RSD Horwitz	RSD Experimental
30 g/100g	1.6	1.3

-Recovery:

Spike concentration	Area determined with HPLC	Calculated concentration (g/100g)	Recovery
34.11	37349448	34.48	101.10%
50.16	54249255	50.08	99.83%
64.05	35279931	65.14	101.70%
73.24	40328110	74.46	101.66%
80.29	44190768	81.59	101.62%

The mean recovery is equal to 101.18%, with a RSD of 0.78%. For this sample at 29.9 g/100g of active content, the recovery should be included in the interval [98 – 102] %; which is the case in our analysis.

Analytical methods provided for substances of concern

- **Poly(oxy-1,2-ethanediyl), .alpha.-(carboxymethyl)-.omega.-(octyloxy)- (CAS 53563-70-5) – SOEC**
- **D-glucopyranose, oligomeric, C10-16 (CAS 110615-47-9) - APG**

Principle of the method:

Samples are diluted in ultra-pure water. Samples are stored at room temperature prior to direct injection. Analysis are performed using LC/MS system. For the preparation of the unknown samples, an initial dilution by a factor 10000 is performed by weighing the sample (using high precision scale) and subsequent dilutions by adding ultra-pure water into a volumetric flask. Quantification is done with a calibration curve by external standard method.

Validation of the method:

-Specificity:

The specificity of the method was tested with the preparation of 3 formulations: (i) APG and SOEC, (ii) SOEC without APG, (iii) APG without SOEC.

Formulations prepared for specificity testing

	Formulation 1	Formulation 2	Formulation 3
APG (g/L)	91.3	0	91.3

SOEC (g/L)	299.4	299.4	0
Component A(g/L)	331.8	331.8	331.8
Component B (g/L)	24.8	24.8	24.8
Component C (g/L)	14.4	14.4	14.4

Components A, B and C correspond to the co-formulants used in the family.

The different spectrum obtained with LC/MS show that both APG and SOEC can be accurately identified.

Signal for SOEC at $m/z = 343.33$ can be observed during the analysis of the APG compound in formulation 1 which contains the two components. In formulation 1 and 2, a low signal corresponding to SOEC is also present at $m/z = 343.33$ at a retention time of 3.35 min. However, integration with a corrected baseline can be made, and APG can thus be correctly identified and quantified. This interference does not contribute to more than 3% of the total peak area.

No interferences from other substances are observed during the analysis of the SOEC compound at $m/z = 519.50$.

Chromatograms of APG standard, SOEC standard and of the 3 formulations were provided.

-Confirmation of identity: From the first part, it is demonstrated that peaks can be identified with good accuracy. The mass signatures of APG and SOEC were analysed using standard solutions. For the analysis of the MS signature, standard of APG and standard of SOEC were diluted in ultrapure water at a concentration of 0.1 g/L as explained in the section sample preparation and injected separately in the LC/MS system.

Based on these results, m/z signal at 519.50 will be used for quantification of SOEC and m/z signal at 343.33 will be used for quantification of APG.

-Linearity:

The calibration curve is prepared using a mixture of standard APG and SOEC in water.

Linearity of the calibration curve used for the analysis was determined from 9 different concentrations between 0.01 and 0.4g/L for SOEC, and between 0.001 and 0.03 g/L for APG.

For SOEC, the equation and the R^2 of the calibration curve are as follows: $y = 10973703x$; $R^2 = 0,9994$.

ForAPG, the equation and the R^2 of the calibration curve are as follows: $y = 1182706,1407x$; $R^2 = 0,9989$.

-Repeatability:

In order to test for repeatability, the following representative formulation was injected in the system, and the amounts of APG and SOEC were quantified. Components A, B and C correspond to the co-formulants used in the family.

	Formulation (g/L)
Co-formulant A	331.8
SOEC	299.4
APG	91.3
Co-formulant B	24.8
Co-formulant C	14.4

Five different samples were prepared, following the procedure for unknown sample detailed in "sample preparation". Each of the sample was injected into the LC/MS system in order to quantify the SoC content. The concentrations were calculated using two calibration curves, one analysed before the samples (calibration 1), and one after (calibration 2). The samples were analysed on two different days for SOEC content.

The expected theoretical value is 299.4 g/L for SOEC. When considering values for serie 1, the mean is equal to 297.7 g/L with a standard deviation of 18.8 g/L and a coefficient of variation of 6.2 %. When considering values for serie 2, the mean is equal to 292.2 g/L with a standard deviation of 12.8 g/L and a coefficient of variation of 4.4%.

Quantification of SOEC content in formulation, 5 preparations on two different days

Sample number	Serie 1		Serie 2	
	Area	Concentration (g/L)	Area	Concentration (g/L)
1	263483	306.5	253856	284.6
2	235897	281.7	262109	301.6
3	277548	324.3	250629	282.2
4	270526	280.6	282658	282.5
5	281069	295.4	306046	310.0
Mean	265705	297.7	271059	292.2
Standard deviation	17979	18.3	23195	12.8
Coefficient of variation (%)	6.8	6.2	8.6	4.4

The samples were also analysed for APG content on two different days.

The expected theoretical value is 91.3 g/L for APG. When considering values for serie 1, the mean is equal to 86.7 g/L with a standard deviation of 6.7 g/L and a coefficient of variation of 7.8%. When considering values for serie 2, the mean is equal to 90.0 g/L with a standard deviation of 5.7 g/L and a coefficient of variation of 6.4%.

Quantification of APG content in formulation, 5 preparations on two different days

Sample number	Serie 1		Serie 2	
	Area	Concentration (g/L)	Area	Concentration (g/L)
1	11488	93.3	10007	89.7
2	9252	77.1	10819	99.5
3	11372	92.7	9405	84.7
4	12025	87.0	10843	86.7
5	11408	83.7	11053	89.5
Mean	11109	86.7	10425	90.0
Standard deviation	1071	6.7	696	5.7
Coefficient of variation (%)	9.6	7.8	6.7	6.4

-Recovery:

Spiked samples were prepared using standard of SOEC or APG diluted in water. The spiked samples were prepared by adding a small volume of diluted standard SOEC or APG in formulations. Two spikes concentrations were prepared for both APG and SOEC. In each case, one sample was not spiked, and used as a control to calculate the spike

concentration. The concentration in the control for SOEC is equal to 297.8 g/L. The concentration in control for APG is equal to 86.6 g/L.

Recovery calculations

	Concentration in the blank (mg/L)	Total concentration in the sample (mg/L)	Theoretical spike concentration (mg/L)	Calculated spike concentration (mg/L)	Recovery (%)	Mean recovery (%)
SOEC content	29.8	83.2	52.9	53.4	100.9	101.6
		125.6	93.7	95.8	102.3	
APG content	8.6	18.8	10.1	10.2	100.8	102.7
		29.9	20.3	21.2	104.6	

For SOEC, the mean recovery is equal to 101.6%, with a RSD of 0.97%.

For APG, the mean recovery is equal to 102,7%, with a RSD of 2,62%.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
<i>L-(+)-Lactic acid</i>	HPLC	N=5 Range: 34.11 g/100g - 80.29 g/100g	R ² =0.9999 7 points (0.131% - 2.496%)	Blank and placebo do not interfere with the peak of active ingredient.	99.83- 101.66%	101.18%	RSD = 0.78 %	Salveco, Validation of HPLC method for the quantification of L-(+)-lactic acid. Revol, 2019.	
<i>Poly(oxy-1,2-ethanediyl), .alpha.-(carboxymethyl)-.omega.-(octyloxy)- (CAS 53563-70-5)</i>	LC/MS	N=9 Range: 0,01 g/L - 0,4 g/L	R ² =0.9994	both APG and SOEC can be accurately identified	100.9 - 102,3%	101,6%	RSD = 0.97 %	Salveco validation method, Revol, B. 2020 Report N02020/054	

<i>D-glucofuranose, oligomeric, (C10-16 CAS 110615-47-9)</i>	LC/MS	N=9 Range: 0,001 g/L – 0,03 g/L	R ² =0.9989	both APG and SOEC can be accurately identified	100.8 – 104,6%	102,7%	RSD = 2.62 %		Salveco validation method, Revol, B. 2020 Report N02020/054
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Relevant residues in food of plant and animal origin and in the environmental compartments arising from the application of L(+) lactic acid are not expected. Therefore, residue analytical methods for L(+) lactic acid in food of plant and animal origin, in soil, air, drinking and surface water are not required. Since L(+)lactic acid is not classified as toxic or very toxic, analytical methods in body fluids and tissues are not required.

Conclusion on the methods for detection and identification of the product

An HPLC-UV method of analysis of active substance L-(+)-lactic acid was developed, and validated according to the SANCO/ 3030/99 rev 4 in the frame of this dossier.

Analytical method for determination of the two substances of concern SOEC (Poly(oxy-1,2-ethanediyl), .alpha.-(carboxymethyl)-.omega.-(octyloxy)-) and APG (D-glucofuranose, oligomeric, C10-16 (even numbered)-alkyl glycosides) in the test item were provided and validated.

Regarding other methods of analysis, a letter of access to active substance data has been submitted by the applicant.

2.12.5 Efficacy against target organisms

2.12.5.1 Function and field of use

MG 01: Disinfectants.

PT2: Disinfectants and algaecides not intended for direct application to humans or animals.

PT3: Veterinary hygiene.

PT4: Food and feed area.

The biocidal product family of SALVECO SALVESAFE PRODUCTS based on the active substance L-(+)-lactic acid consists of 9 META-SPC and is intended for uses in Product Type (PT) 2, 3 and 4 for the following applications:

Product Type 2:

- #1 - Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in domestic, institutional and industrial areas) for META-SPC 1, META-SPC 2, META-SPC 7, META-SPC 8 and META-SPC 9.
- #2 - Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in institutional and industrial areas) for META-SPC 3 and META-SPC 4
- #3 - Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in institutional, medical, and industrial areas) for META-SPC 5.
- #4 - Disinfectants not intended for direct application to humans or animals (disinfectants for all washable hard surfaces in medical areas) for META-SPC 6.

Product Type 3:

- #1 - Disinfectants used to disinfect the materials and surfaces associated with the housing of animals (disinfectants for all washable hard non porous surfaces in veterinary area) for META-SPC 5 and META-SPC 7.

Product Type 4:

- #1 - Food and feed area disinfectants (disinfectant for all washable hard surfaces in domestic, institutional and food industry areas (general disinfection) - for META-SPC 1, META-SPC 2, META-SPC 7, META-SPC 8 and META-SPC 9.
- #2 - Food and feed area disinfectants (disinfectant for all washable hard surfaces in institutional and industrial areas) (general disinfection) - for META-SPC 3 and META-SPC 4.
- #3 - Food and feed area disinfectants (disinfectant for all washable hard surfaces in institutional and industrial areas) (general disinfection, meat and milk industries) for META-SPC 5.

All uses are claimed without mechanical action except for disinfection of hard surfaces PT2 for medical areas (META SPC 5 and 6) and institutional areas (META SPC 7) which are claimed with and without mechanical action.

The products are for non-professional, professional or industrial users.

2.12.5.2 Organisms to be controlled and products, organisms or objects to be protected

The biocidal products are intended to be used to control bacteria, yeasts and enveloped viruses. The product family is used for the purpose of the protection of human and animal health.

2.12.5.3 Effects on target organisms, including unacceptable suffering

The products are intended to produce a reduction in the number of viable bacterial cells (bactericidal activity), yeasts cells (yeasticidal activity) and of infectious enveloped virus particles (virucidal activity) of relevant test organisms under defined conditions.

2.12.5.4 Mode of action, including time delay

According to the Assessment Report of the active substance L-(+)-lactic acid PT2, 3 and 4 (2017), in solution, L(+) lactic acid exists in a pH-dependent equilibrium between the undissociated and dissociated form. Only in its undissociated state, the acid is able to pass the cell membrane. At a relatively low pH, the uncharged acid enters the cell. Inside the cell, the L(+) lactic acid dissociates due to the higher pH. The molecules remain inside the cell, because the resulting ions cannot pass the membrane. The pH inside the cell is lowered and metabolic reactions are inhibited. Further effects are also reported. Decrease of the membrane permeability for amino acids, organic acids, phosphates resulting in uncoupling of both substrate transport and oxidative phosphorylation from the electron transport system. Furthermore, an inhibition of the glycolysis by the lactate ion is observed.

2.12.5.5 Efficacy data

➤ **Efficacy requirements:**

The biocidal product family SALVECO SALVESAFE PRODUCTS consists of products containing the active substance L-(+)-lactic acid in the range of 0.627 to 31.33 % w/w (technical).

Laboratory studies were conducted with reference formulations in accordance with the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C). The results are summarized in Section 6.7 of the IUCLID file and the main efficacy data are summarized in the tables below.

According to the Efficacy Guidance Volume II part B/C:

- **for PT2:**

- For disinfection of hard surfaces in domestic areas by spraying, spreading, wiping, foam application, brush treatment, soaking, dipping, immersion and mopping: phase 2 step 1 and phase 2 step 2 tests on bacteria are basic requirements; yeasts, fungal spores and enveloped viruses are optional organisms for which phase 2 step 1 and phase 2 step 2 tests are needed, except for virus as no P2S2 test is available at the submission of the dossier.
- For disinfection of hard surfaces in healthcare, industrial and institutional areas by spraying, spreading, wiping, foam application, brush treatment, soaking, dipping, and mopping: phase 2 step 1 and phase 2 step 2 tests on bacteria and yeasts are basic requirements; fungal spores and enveloped viruses are optional organisms for which phase 2 step 1 and phase 2 step 2 tests are needed, except for virus as no P2S2 test is available at the submission of the dossier.

- For disinfection of hard surfaces (instruments) in healthcare by immersion: phase 2 step 1 and phase 2 step 2 tests on bacteria, yeasts, fungi and viruses are basic requirements (except for virus as no P2S2 test is available at the submission of the dossier).
- **for PT3:**
 - For disinfection of hard surfaces by spraying, spreading, wiping, foam application, brush treatment, mopping, soaking, dipping and immersion: phase 2 step 1 and phase 2 step 2 tests on bacteria and yeasts are basic requirements; fungal spores and enveloped viruses are optional organisms for which phase 2 step 1 and phase 2 step 2 tests are needed, except for virus as no P2S2 test is available at the submission of the dossier.
- **for PT4:**
 - For disinfection of hard surfaces by spraying, spreading, wiping, foam application, brush treatment, mopping, soaking, dipping and immersion: phase 2 step 1 and phase 2 step 2 tests on bacteria and yeasts are basic requirements; fungal spores and enveloped viruses are optional organisms for which phase 2 step 1 and phase 2 step 2 tests are needed, except for virus as no P2S2 test is available at the submission of the dossier.

➤ **Representative products tested - Effects of coformulants**

All the efficacy tests provided to support the efficacy for hard surfaces disinfectants (PT2, 3 and 4) were performed with the products SalveSafe Food = SalveSafe_FAM3_1 (29.9% w/w L-(+)-lactic acid, META SPC 5) and SalveSafe 15 = Sure Cleaner Disinfectant (29.9% w/w L-(+)-lactic acid, META SPC 7).

According to the applicant, for the biocidal product family SALVECO SALVESAFE PRODUCTS, the final recommended use level of the product is based on the L-(+)-lactic acid concentration. Each product label should provide clear guidelines on how to achieve a required L-(+)-lactic acid level by dilution depending on the % of active substance in the product.

The efficacy of the biocidal product family has been assessed by testing products covering the minimum in use-concentration of active substance of each meta-SPC (see confidential part of the PAR for more details).

Furthermore, surfactants claimed in the composition are expected to increase disinfection efficacy of products in soiled conditions. Nevertheless, surfactants might, in rare cases, also have a negative impact on efficacy. Then, the applicant has provided two additional phase 2 step 1 tests with products containing the minimum active substance (0.299%) and the maximum surfactants claimed (see confidential part of the PAR for the table of experimental data on these studies).

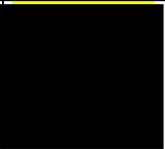
These studies demonstrate that higher content of surfactants (compared to efficacy data in same conditions with minimum surfactants) do not have a negative impact on the minimum effective concentration. Therefore, eCA consider that the approach proposed by the applicant as acceptable.

However, based on the composition of the family, some Meta SPC could claim products with less in use surfactants than the representative products tested in the efficacy studies

(see confidential part of the PAR) and therefore for which no information on the impact on efficacy has been provided.

Therefore, eCA consider that a general instruction for use should be added in the SPC for these Meta SPC (Meta SPC 1, Meta SPC 2, Meta SPC 3 and Meta SPC 4) indicated that "Minimum in use concentration of surfactants should be 0.29%."

➤ **Experimental data - PT2/PT4**

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Bactericide	Disinfection of hard surfaces in medical and food industry area. (Dairy and Meat)	Meta SPC 5 product: SalveSafe Food = SalveSafe_FAM3_1 (29.9% w/w L-(+)-lactic acid)	Bacteria <i>Staphylococcus aureus</i> ATCC 6538, <i>Enterococcus hirae</i> ATCC10541, <i>Pseudomonas aeruginosa</i> ATCC 15442, <i>Escherichia coli.</i> ATTC 10536	EN 1276	Phase 2 step 1 test (suspension test) Concentration tested:0.01%, 0.1%, 1.0%, 1.5% Contact time: 5 minutes Temperature: 20°C Conditions tested: - 10 g/L skimmed milk - Medical dirty conditions: (3 g/L albumin + 3 mL/L sheep erythrocytes (according to EN 13727)) Criteria: at least a 5 log reduction	Bactericidal activity demonstrated at: - 1.5% v/v (10 g/L skimmed milk) - 1.0% v/v (under medical dirty conditions (3 g/L albumin + 3 mL/L sheep erythrocytes)	 Report no- A18257-I, vs2,  (IUCLID report 1) R.I.: 2

<p>Bactericide</p>	<p>Disinfection of hard surfaces in medical area.</p>	<p>Meta SPC 5 product: SalveSafe Food = SalveSafe_FAM3_1 (29.9% w/w L-(+)-lactic acid)</p>	<p>Bacteria <i>Staphylococcus aureus</i> ATCC 6538, <i>Enterococcus hirae</i> ATCC10541, <i>Pseudomonas aeruginosa</i> ATCC 15442, <i>Escherichia coli.</i> ATCC 10536</p>	<p>EN13697</p>	<p>Phase 2 step 2 (surface test) Concentration tested: 0.1%, 1.5%, 2% Contact time: 5 minutes Temperature: 20°C Medical dirty conditions: 3 g/L albumin + 3 mL/L sheep erythrocytes (according to EN 13727) Criteria: at least a 4 log reduction</p>	<p>Bactericidal activity demonstrated at 1.5% v/v.</p>	<p>[REDACTED] [REDACTED] [REDACTED] [REDACTED] Report 190299.V2, [REDACTED] [REDACTED] (IUCLID report 2) R.I.: 2</p>
<p>Bactericide</p>	<p>Disinfection of hard surfaces in industrial (food industry - Dairy) area.</p>	<p>Meta SPC 5 product: SalveSafe Food 10 = SalveSafe_FAM3_1 (29.9% w/w L-(+)-lactic acid)</p>	<p>Bacteria <i>Enterococcus hirae</i> CIP 58.55</p>	<p>EN13697</p>	<p>Phase 2 step 2 (surface test) Concentration tested: 0.1%, 2%, 2.5%, 3% Contact time: 5 minutes Temperature: 20°C 10 g/L skimmed milk</p>	<p>Activity against <i>Enterococcus hirae</i> (limiting test organism in EN1276 in the same conditions) demonstrated at 2% v/v.</p>	<p>[REDACTED] [REDACTED] Report N°RE-1071/0219, [REDACTED] [REDACTED] (IUCLID report 4) R.I.: 1 (most challenging test organism for bacteria under</p>

					Criteria: at least a 4 log reduction		general dirty conditions and P2S1 tests with skimmed milk)
Bactericide	Disinfection of hard surfaces medical area.	Meta SPC 5 product: SalveSafe Food 10 = SalveSafe_FAM3_1 (29.9% w/w L-(+)-lactic acid)	Bacteria <i>Staphylococcus aureus</i> DSM 799 <i>Enterococcus hirae</i> CIP 58.55 <i>Pseudomonas aeruginosa</i> DSM939	EN13727: 2015	Phase 2 step 1 (suspension test) Concentration tested: 0.1%, 1.0%, 2% Contact time: 5 minutes Temperature: 20°C Medical dirty conditions: 3 g/L albumin + 3 mL/L sheep erythrocytes Criteria: at least a 5 log reduction	Bactericidal activity demonstrated efficacy at 1% v/v.	[REDACTED] Report RE-1072/0219, [REDACTED] (IUCLID report 3) R.I.: 1
Bactericide	Disinfection of hard surfaces in domestic, institutional and industrial (food industry) area.	Meta SPC 7 product: SalveSafe 15 (29.9% w/w L-(+)-lactic acid) Batch: 6780052018	Bacteria <i>Staphylococcus aureus</i> ATCC 6538, <i>Enterococcus hirae</i> ATCC10541,	EN1276	Phase 2 step 1 test (suspension test) Concentration tested: 0.1%, 0.8%, 1.0% Contact time: 5 minutes	Bactericidal activity demonstrated at 1% v/v.	[REDACTED] [REDACTED] [REDACTED] [REDACTED] Report 190112.VI, [REDACTED] [REDACTED]

			<i>Pseudomonas aeruginosa</i> ATCC 15442, <i>Escherichia coli</i> ATCC 10536		Temperature: 20°C Dirty conditions: 3 g/L albumin Criteria: at least a 5 log reduction		(IUCLID report 6) R.I.: 1
Bactericide	Disinfection of hard surfaces in domestic, institutional and industrial (food industry) area.	Meta SPC 7 product: SalveSafe 15 (29.9% w/w L-(+)-lactic acid)	Bacteria <i>Staphylococcus aureus</i> ATCC 15442 <i>Escherichia coli</i> ATCC 10536 <i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Enterococcus hirae</i> ATCC 10541	EN13697	Phase 2 step 2 (surface test) Concentration tested: 0.1%, 0.8%, 1.0%, 1.5% Contact time: 5 minutes Temperature: 20°C Dirty conditions: 3 g/L albumin Criteria: at least a 5 log reduction	Bactericidal activity demonstrated at 1% v/v.	[REDACTED] [REDACTED] [REDACTED] [REDACTED] Report 190420.V1, [REDACTED] (IUCLID report 5) R.I.: 1
Bactericide	Disinfection of hard surfaces medical area.	Meta SPC 5 product: SalveSafe Food 10 = SalveSafe_FAM3_1 (29.9% w/w L-(+)-lactic acid)	Bacteria <i>Enterococcus hirae</i>	EN16615:2 015	Phase 2 step 2 test (surface test) Concentration tested: 1.5% Contact time: 5 minutes Temperature: 20°C	Activity against <i>Enterococcus hirae</i> demonstrated at 1.5% v/v.	[REDACTED] [REDACTED] Report RE20-1083-2 (IUCLID report 18)

		(29.9% w/w L-(+)-lactic acid)			<p>Concentration tested: 0.1%, 1.0%, 2.0%</p> <p>Contact time: 5 minutes</p> <p>Temperature: 20°C</p> <p>Medical dirty conditions: 3 g/L albumin + 3 mL/L sheep erythrocytes</p> <p>Criteria: at least a 4 log reduction</p>	<p>Report 190357.VI, [REDACTED]</p> <p>(IUCLID report 8)</p> <p>R.I.: 1</p>
Yeasticide	Disinfection of hard surfaces in industrial (food industry - Dairy) area.	<p>Meta SPC 5 product:</p> <p>SalveSafe Food 10 = SalveSafe_FAM3_1</p> <p>(29.9% w/w L-(+)-lactic acid)</p>	<p>Yeasts</p> <p><i>Candida albicans</i> DSM 1386</p>	EN13697	<p>Phase 2 step 2 test (surface test)</p> <p>Concentration tested: 0.1%, 2%, 2.5%, 3%</p> <p>Contact time: 5 minutes</p> <p>Temperature: 20°C</p> <p>10 g/L skimmed milk</p> <p>Criteria: at least 3 log reduction</p>	<p>Yeasticidal activity demonstrated at 2% v/v.</p> <p>[REDACTED]</p> <p>Report N°RE-1071/0219, [REDACTED]</p> <p>(IUCLID report 4)</p> <p>R.I.: 1</p>

Yeasticide	Disinfection of hard surfaces in medical and industrial (food industry - Meat) area.	Meta SPC 5 product: SalveSafe Food= SalveSafe_FAM3_1 (29.9% w/w L-(+)-lactic acid)	Yeasts <i>Candida albicans</i> ATCC 10231	EN13697	Phase 2 step 2 test (surface test) Concentration tested: 0.1%, 1.5%, 2% Medical dirty conditions: 3 g/L albumin + 3 mL/L sheep erythrocytes (according to EN 13727) Contact time: 5 minutes Temperature: 20°C Criteria: at least a 3 log reduction	Yeasticidal activity demonstrated at 1.5% v/v.	[REDACTED] [REDACTED] [REDACTED] Report 190299.V2, [REDACTED] [REDACTED] (IUCLID report 2) R.I.: 1
Yeasticide	Disinfection of hard surfaces in domestic, institutional and industrial (food industry) area.	Meta SPC 7 product: Pfechant - Cleaner Disinfectant = SalveSafe 15 (29.9% w/w L-(+)-lactic acid)	Yeasts <i>Candida albicans</i> ATCC 10231	EN1650	Phase 2 step 1 test (suspension test) Dirty conditions (3 g/L BSA) Concentration tested: 0.1%, 0.8%, 1.0% Contact time: 5 minutes Temperature: 20°C	Yeasticidal activity demonstrated at 1% v/v.	[REDACTED] [REDACTED] Report 775.17-1 EN 1650 PB-2, [REDACTED] [REDACTED] (IUCLID report 9) R.I.: 1

					Criteria: at least a 4 log reduction		
Yeasticide	Disinfection of hard surfaces in domestic, institutional and industrial (food industry) area.	Meta SPC 7 product: Salve Safe 15 (29.9% w/w L-(+)-lactic acid)	Yeasts <i>Candida albicans</i> ATCC 10231	EN 13697 (2015)	Phase 2 step 2 test (surface test) Dirty conditions (3 g/L BSA) Concentration tested: 0.1%, 0.8%, 1.0% Contact time: 5 minutes Temperature: 20°C Criteria: at least a 3 log reduction	Yeasticidal activity demonstrated at 0.8% v/v.	<p>██████████</p> <p>██████████</p> <p>██████████</p> <p>██████████</p> <p>Report A18264,</p> <p>██████████</p> <p>(IUCLID report 10)</p> <p>R.I.: 2</p>
Yeasticide	Disinfection of hard surfaces medical area and meat industry.	Meta SPC 5 product: SalveSafe Food 10 = SalveSafe_FAM3_1 (29.9% w/w L-(+)-lactic acid) Batch: 15860052020	Yeasts <i>Candida albicans</i>	EN16615:2 015	Phase 2 step 2 test (surface test) Concentration tested: 1.5% Contact time: 5 minutes Temperature: 20°C Dirty conditions (3 g/L BSA + 3 mL/L sheep erythrocytes)	Yeasticidal activity demonstrated at 1.5%	<p>██████████</p> <p>██████████ Report RE20-1083-2</p> <p>(IUCLID report 18)</p> <p>R.I.: 1</p>

					Criteria: at least a 4 log reduction		
Virucide	Disinfection of hard surfaces in domestic, institutional, medical, and industrial (food industry) area.	Meta SPC 7 product: SalveSafe 15 (29.9% w/w L-(+)-lactic acid)	Virus modified vaccinia virus Ankara	EN 14476:2013 +A1:2015/p rA2:2016	Phase 2 step 1 test (suspension test) Dirty conditions (3 g/L BSA + 3 mL/L sheep erythrocytes Concentration tested: 0.1%, 1.0%, 2.0% Contact time: 5 minutes Temperature 20°C Criteria: at least a 4 log reduction	Activity against enveloped virus demonstrated at 1% v/v.	<div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> Report LI-019-044, <div style="background-color: black; width: 100px; height: 15px; display: inline-block;"></div> (IUCLID report 11) R.I.: 1

In these efficacy tests with fresh samples of the representative products at 29.9% w/w L-(+)-lactic acid:

➤ **Medical dirty conditions:**

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276, EN13727 and EN 13697), at 20°C, with a contact time of 5 minutes with medical dirty conditions (3 g/L albumin + 3 mL/L sheep erythrocytes). In these conditions, bactericidal activity is shown at the in-use concentration of 1.5% v/v.
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650, EN 13624, EN 13697 and EN16615), at 20°C, with a contact time of 5 minutes with medical dirty conditions (3 g/L albumin + 3 mL/L sheep erythrocytes). In these conditions, yeasticidal activity is shown at the in-use concentration of 1.5% v/v.
- virucidal activity (enveloped viruses) is demonstrated according to phase 2, step 1 test (EN 14476), at 20°C, with a contact time of 5 minutes with medical dirty conditions (3 g/L albumin + 3 mL/L sheep erythrocytes). In these conditions, virucidal activity is shown at the in-use concentration of 1% v/v.

Only efficacy data against *E. hirae* was provided according to P2S2 test (EN 16615) and no tests with the other mandatory strains were provided. Therefore, efficacy against bacteria with mechanical action is not considered to be supported based on the efficacy data provided and only efficacy without mechanical action is validated.

➤ **General dirty conditions:**

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (3 g/L albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 1% v/v.
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (3 g/L albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 1% v/v.

No specific efficacy test with dirty conditions (3 g/L albumin) has been provided against virus. However, we consider that the efficacy data provided against virus (EN14476) with medical dirty conditions (worst case, 3 g/L albumin + 3 mL/L sheep erythrocytes) are also acceptable to support efficacy against virus for general disinfection.

➤ **Dirty conditions (milk industries):**

- bactericidal activity is demonstrated both in phase 2, step 1 (EN 1276) and phase 2 step 2 tests (EN 13697, only against *E. hirae*) at 20°C, with a contact time of 5 minutes with dirty conditions (10 g/L skimmed milk). In these conditions, bactericidal activity is shown at the in-use concentration of 2% v/v.

Please note that *E. hirae* is the most challenging test organisms for bacteria under general dirty conditions (3 g/L albumin) in the P2S1 and P2S2 tests and also in the P2S1 tests with skimmed milk. Therefore, we agree to consider as acceptable the P2S2 test to support the efficacy for milk industries even though only this strain was tested. Moreover this approach is in line with the requirement in the efficacy guidance Volume II Part B/C section 5.4.4.2.2.

- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (10 g/L skimmed milk). In these conditions, yeasticidal activity is shown at the in-use concentration of 2% v/v.

➤ **Experimental data – PT3**

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Bactericide	Disinfection of hardsurfaces in veterinary area.	Meta SPC 5 product: SalveSafe Food 10= SalveSafe_FAM3_1 (29.9% w/w L-(+)-lactic acid) Batch: 9810052019	Bacteria <i>Enterococcus hirae</i> DSM 3320 <i>Proteus vulgaris</i> DSM 30118 <i>Pseudomonas aeruginosa</i> DSM 939 <i>Staphylococcus aureus</i> DSM 799	EN1656:2010	Phase 2 step 1 test (suspension test) Concentration tested: 0.1%, 0.8%, 1% Contact time: 30 minutes Low soiling conditions (3 g/L BSA) Temperature: 10°C Criteria: at least a 5 log reduction	Bactericidal activity demonstrated efficacy at 1% v/v.	 Report n° RE19-126-1 (IUCLID report 12) R.I.: 1
Bactericide	Disinfection of hard surfaces in veterinary area.	Meta SPC 5 product: SalveSafe Food 10= SalveSafe_FAM3_1 (29.9% w/w L-(+)-lactic acid)	Bacteria <i>Enterococcus hirae</i> DSM 3320 <i>Proteus vulgaris</i> DSM 30118	EN14349:2012	Phase 2 step 2 test (non porous surface test) Concentration tested: 0.1%, 0.8%, 1% Contact time: 30 minutes	Bactericidal activity demonstrated efficacy at 1% v/v.	 Report n° RE19-128-2 (IUCLID report 13) R.I.: 1

		Batch: 9810052019	<i>Pseudomonas aeruginosa</i> DSM 939 <i>Staphylococcus aureus</i> DSM 799		Low soiling conditions (3 g/L BSA) Temperature: 10°C Criteria: at least a 4 log reduction		
Yeasticide	Disinfection of hardsurfaces in veterinary area.	Meta SPC 5 product: SalveSafe Food 10= SalveSafe_FAM3_1 (29.9% w/w L-(+)-lactic acid) Batch: 9810052019	Yeasts <i>Candida albicans</i> DSM 1386	EN1657	Phase 2 step 1 test (suspension test) Concentration tested: 0.1%, 0.8%, 1% Contact time:30 minutes Low soiling conditions (3 g/L BSA) Temperature: 10°C Criteria: at least a 4 log reduction	Yeasticidal activity demonstrated at 1% v/v.	 Report n° RE19-127-1 (IUCLID report 14) R.I.: 1
Yeasticide	Disinfection of hardsurfaces in veterinary area.	Meta SPC 5 product: SalveSafe Food 10= SalveSafe_FAM3_1	Yeasts <i>Candida albicans</i> DSM 1386	EN16438:2 014	Phase 2 step 2 test (non porous surface test) Concentration tested: 0.1%, 0.8%, 1%	Yeasticidal activity demonstrated at 1% v/v.	 Report n° RE19-129-3

		(29.9% w/w L- (+)-lactic acid) Batch: 9810052019			Contact time: 30 minutes Low soiling conditions (3 g/L BSA) Temperature: 10°C Criteria: at least a 3 log reduction		(IUCLID report 15) R.I.: 1
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In these efficacy tests with fresh samples of the representative product at 29.9% w/w L-(+)-lactic acid:

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1656 and EN 14349), at 10°C, with a contact time of 30 minutes with low soiling conditions (3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 1% v/v.
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1657 and EN 16438), at 10°C, with a contact time of 30 minutes with low soiling conditions (3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 1% v/v.

➤ **Experimental data : META SPC 7 – PT2 and PT4**

The following reports are limited to meta-SPC7 and the use of the product SalveSafe 15 (identical to DIVERSEY product Sure Cleaner Disinfectant). But please note that the studies carried out with the meta SPC7 product presented above are also taken into account for the conclusions of the meta SPC7.

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Bactericide	Disinfection of hard surfaces in domestic, institutional	Meta SPC 7 product:	Bacteria <i>Pseudomonas aeruginosa</i>	EN 1276:2010	Phase 2 step 1 test (suspension test)	Bactericidal activity demonstrated efficacy at 1%	

	and industrial (food industry) area.	Sure Cleaner Disinfectant (= SalveSafe 15)= 29.9% L-(+)-lactic acid Batch: MUL17-11-15 36140	<i>Escherichia coli</i> <i>Staphylococcus aureus</i> <i>Enterococcus hirae</i>		Concentration tested: 1.0%, 1.3%, 1.5% and 2% Clean conditions: 0.3 g/L bovine albumin Contact time: 30 s and 60 s Temperature: 20°C Criteria: at least a 5 log reduction	v/v (with 30 and 60 seconds contact time).	Report SN 23695 (IUCLID report DIV 03) R.I.: 2 (no inactive concentration)
Bactericide	Disinfection of hard surfaces in domestic, institutional and industrial (food industry) area.	Meta SPC 7 product: Sure Cleaner Disinfectant (= SalveSafe 15) =29.9% L-(+)-lactic acid Batch: MUL17-11-15 36140	Bacteria <i>Pseudomonas aeruginosa</i> <i>Escherichia coli</i> <i>Staphylococcus aureus</i> <i>Enterococcus hirae</i>	EN13697:2 015	Phase 2 step 2 test (surface test) Concentration tested: 0.5%, 1.0%, 1.5%, 2% and 3% Clean conditions (0.3 g/L bovine albumin and 8.5 g/L skimmed milk for <i>P. aeruginosa</i>) and dirty conditions (3 g/L bovine albumin) Contact time: 5 min Temperature: 20-22°C Criteria: at least a 4 log reduction	Bactericidal activity demonstrated efficacy at 0.5% v/v (clean conditions) and 1.5 % v/v (dirty conditions).	 Report: SN 20491 (IUCLID report DIV 04) R.I.: 2 (no inactive concentration for clean conditons)

<p>Ds le rapportBac tericide</p>	<p>Disinfection of hard surfaces in domestic, institutional and industrial (food industry) area.</p>	<p>Meta SPC 7 product: Sure Cleaner Disinfectant (= SalveSafe 15) =29.9% L-(+)-lactic acid Batch: MUL 462447</p>	<p>Bacteria <i>Enterococcus hirae</i></p>	<p>EN16615:2 015</p>	<p>Phase 2 step 2 test (surface test) Concentrations tested: 0.5%, 1.0% and 1.5% Contact time: 1 and 5 min Temperature: 22°C Clean conditions (0.3 g/L BSA) Criteria: at least a 5 log reduction</p>	<p>Activity against <i>E. hirae</i> demonstrated at 1.5% v/v (5 min contact time). Efficacy criteria not achieved within 1 min.</p>	<p>[REDACTED] [REDACTED] Report AAC81276 (IUCLID report DIV 05) R.I.: 3 (tests on other mandatory species missing)</p>
<p>Yeasticide</p>	<p>Disinfection of hard surfaces in domestic, institutional and industrial (food industry) area.</p>	<p>Meta SPC 7 product: Sure Cleaner Disinfectant (= SalveSafe 15)= 29.9 % L-(+)-lactic acid Batch: 462727</p>	<p>Yeasts <i>Candida albicans</i></p>	<p>EN1650:20 13</p>	<p>Phase 2 step 1 test (suspension test) Concentration tested: 0.25% 0.5%, 1.0%, 1.5% and 2% Clean condition: 0.3 g/L bovine albumin Contact time: 5 min Temperature: 20°C Criteria: at least a 4 log reduction</p>	<p>Yeasticidal activity demonstrated at 1% v/v.</p>	<p>[REDACTED] [REDACTED] (IUCLID report DIV 07) R.I.: 1</p>
<p>Yeasticide</p>	<p>Disinfection of hard surfaces in domestic,</p>	<p>Meta SPC 7 product:</p>	<p>Yeast</p>	<p>EN13697:2 015</p>	<p>Phase 2 step 2 test (surface test)</p>	<p>Yeasticidal activity demonstrated</p>	<p>[REDACTED] [REDACTED] [REDACTED]</p>

	institutional and industrial (food industry) area.	Sure Cleaner Disinfectant (= SalveSafe 15)= 29.9% L-(+)-lactic acid Batch: MUL 462427	<i>Candida albicans</i>		Concentration tested: 0.5%, 1.0% and 1.5% Contact time: 1 and 5 min Clean condition: 0.3 g/L bovine albumin Temperature: 18-25°C Criteria: at least a 3 log reduction	efficacy at 1% v/v (5 min contact time). Efficacy criteria not achieved within 1 min.	Report: AAC98931, [REDACTED] Number: STULV19AA150 0-1, Version: 1 (IUCLID report DIV 10) R.I.: 1
Yeasticide	Disinfection of hard surfaces in domestic, institutional and industrial (food industry) area.	Meta SPC 7 product: Sure Cleaner Disinfectant (= SalveSafe 15)= 29% L-(+)-lactic acid Batch: MUL 462447	Yeasts <i>Candida albicans</i>	EN16615:2 015	Phase 2 step 2 test (surface test) Concentrations tested: 1%, 1.5% and 2% Contact time: 1 and 5 min Clean conditions (0.3 g/L BSA) Temperature: 22°C Criteria: at least a 4 log reduction	Yeasticidal activity demonstrated at 1% v/v (CT: 1 min and 5 min).	[REDACTED] Report AAC81335 (IUCLID report DIV 08) R.I.: 2 (no inactive concentration)
Yeasticide	Disinfection of hard surfaces in domestic, institutional and industrial	Meta SPC 7 product: Sure Cleaner Disinfectant	Yeasts <i>Candida albicans</i>	EN16615:2 015	Phase 2 step 2 test (surface test) Concentrations tested: 1.0%, 1.5% and 2%	Yeasticidal activity demonstrated at 1% v/v (CT: 5 min) and 1.5%	[REDACTED] Report AAC81299

	(food industry) area.	(= SalveSafe 15)= 29% L-(+)-lactic acid Batch: MUL 462447			Contact time: 1 and 5 min Dirty conditions: 3 g/L albumin + 3 mL/L sheep erythrocytes Temperature: 22°C Criteria: at least a 4 log reduction	v/v (CT: 1 min and 5 min).	(IUCLID report DIV 09) R.I.: 1 (supportive data)
Virucide	Disinfection of hard surfaces in domestic, institutional, medical, and industrial (food industry) area.	Meta SPC 7 product: Sure Cleaner Disinfectant (= SalveSafe 15)= 29.9% L-(+)-lactic acid Batch: MUL 462427	Virus modified vaccinia virus Ankara	EN14476:2 015	Phase 2 step 1 test (suspension test) Clean condions (0.3 g/L BSA) Concentration tested: 0.02%, 0.2%, 0.5%, 1.0% and 1.5% Contact time: 1 and 30 min. Temperature: 20°C Criteria: at least a 4 log reduction	Activity against enveloped virus demonstrated at 0.5% v/v (CT: 1 min) and 0.2 % (CT: 30 min).	[REDACTED] Report: L19-0184MV-2 (IUCLID report DIV 02) R.I.: 1
Virucide	Disinfection of hard surfaces in domestic, institutional, medical, and industrial	Meta SPC 7 product: Sure Cleaner Disinfectant (= SalveSafe	Virus modified vaccinia virus Ankara	EN14476:2 015	Phase 2 step 1 test (suspension test) Dirty conditions (3 g/L BSA)	Activity against enveloped virus demonstrated efficacy at 0.5% v/v.	[REDACTED] Report: L19-0184MV-3

	(food industry) area.	15)= 29.9% L-(+)-lactic acid Batch: MUL 462427			Concentration tested: 0.02%, 0.2%, 0.5%, 1.0% and 1.5% Contact time: 1 min. Temperature: 20°C Criteria: at least a 4 log reduction		(IUCLID report DIV 02b) R.I.: 1
Virucide	Disinfection of hard surfaces in domestic, institutional, medical, and industrial (food industry) area.	Meta SPC 7 product: Sure Cleaner Disinfectant (= SalveSafe 15) =29.9% L-(+)-lactic acid	Virus modified vaccinia virus Ankara	EN16777:2 018	Phase 2 step 2 test (surface test) Dirty conditions (3 g/L BSA) Concentrations tested: 0.1% to 2% Contact time: 2 and 5 min Temperature: 20°C Criteria: at least a 4 log reduction	Activity against enveloped virus demonstrated at 1% (CT: 5 min) and 2% (CT: 2 min).	 Report L20/0498MV.1 (IUCLID report DIV_01) R.I.: 1

In these efficacy tests with fresh samples of the representative product at 29.9% w/w L-(+)-lactic acid:

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 5 minutes with clean conditions (0.3 g/L bovine albumin). In these conditions, bactericidal activity is shown at the in-use concentration of 1% v/v.
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650, EN 13697 and EN16615), at 20°C, with a contact time of 5 minutes with clean conditions (0.3 g/L bovine albumin). In these conditions, yeasticidal activity is shown at the in-use concentration of 1% v/v.

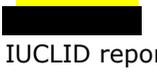
- virucidal activity (enveloped viruses) is demonstrated according to phase 2, step 1 and step 2 tests (EN 14476 and EN16777), at 20°C, with respectively a contact time of 1 and 5 minutes with dirty conditions (3 g/L bovine albumin). In these conditions, virucidal activity is shown at the in-use concentration of 1% v/v (CT: 5 min).
- virucidal activity (enveloped viruses) is demonstrated according to phase 2, step 1 test (EN 14476), at 20°C, with a contact time of 1 minute with clean conditions (0.3 g/L bovine albumin). In these conditions, virucidal activity is shown at the in-use concentration of 0.5% v/v.

Only efficacy data against *E. hirae* was provided according to P2S2 test (EN 16615) and no tests with the other mandatory strains were provided. Therefore, efficacy against bacteria with mechanical action is not considered to be supported based on the efficacy data provided and only efficacy without mechanical action is validated.

• **Experimental data: META SPC 7 – PT3**

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Bactericide	Disinfection of hard surfaces in veterinary area.	Meta SPC 7 product: Sure Cleaner Disinfectant (= SalveSafe 15)= 29.9% L-(+)-lactic acid Batch: MUL 462427	Bacteria <i>Pseudomonas aeruginosa</i> <i>Proteus vulgaris</i> <i>Staphylococcus aureus</i> <i>Enterococcus hirae</i>	EN1656:2010	Phase 2 step 1 test (suspension test) Low soiling conditions (3 g/L BSA) Concentration tested: 0.5%, 1.0% and 1.5% Contact time: 1 and 5 min Temperature: 20°C Criteria: at least a 5 log reduction	Bactericidal activity demonstrated efficacy at 1.5% v/v (CT: 1 min) and at 1% (CT: 5 min).	[REDACTED] Analytical Report: AAD02986, [REDACTED] Number: STULV19AA149 6-1, Version: 1 (IUCLID report DIV 11) R.I.: 1
Bactericide	Disinfection of hard surfaces	Meta SPC 7 product:	Bacteria	EN1656:2010	Phase 2 step 1 test (suspension test)	Bactericidal activity	[REDACTED]

	in veterinary area.	Sure Cleaner Disinfectant (= SalveSafe 15)= 29.9% L-(+)-lactic acid Batch: MUL 462427	<i>Pseudomonas aeruginosa</i> <i>Proteus vulgaris</i> <i>Staphylococcus aureus</i> <i>Enterococcus hirae</i>		Low soiling conditions (3 g/L BSA) Concentration tested: 0.5%, 1.0% and 1.5% Contact time: 30 min Temperature: 10°C Criteria: at least a 5 log reduction	demonstrated efficacy at 1% v/v.	Analytical Report: AAD02873, [REDACTED] Number: STULV19AA149 5-1, Version: 1 (IUCLID report DIV 12) R.I.: 1
Bactericide	Disinfection of hard surfaces in veterinary area.	Meta SPC 7 product: Sure Cleaner Disinfectant (= SalveSafe 15)= 29.9% L-(+)-lactic acid Batch: MUL 462427	Bacteria <i>Pseudomonas aeruginosa</i> <i>Proteus vulgaris</i> <i>Staphylococcus aureus</i> <i>Enterococcus hirae</i>	EN14349:2 012	Phase 2 step 2 test (non porous surface test) Low soiling conditions (3 g/L BSA) Concentrations tested: 1.0%, 1.5%, 2% and 2.5% Contact time: 1 and 5 min Temperature: 20°C Criteria: at least a 4 log reduction	Bactericidal activity demonstrated efficacy at 2.5% v/v (CT: 5 min). Efficacy criteria not achieved within 1 min.	[REDACTED] Report AAD03170 (IUCLID report DIV 13) R.I.: 1
Bactericide	Disinfection of hard surfaces in veterinary area.	Meta SPC 7 product: Sure Cleaner Disinfectant (= SalveSafe	Bacteria <i>Pseudomonas aeruginosa</i> <i>Proteus vulqaris</i>	EN14349:2 012	Phase 2 step 2 test (non porous surface test) Low soiling conditions (3 g/L BSA)	Not fulfilled the norm (methodological deviations).	[REDACTED] [REDACTED] [REDACTED]

		15)=29.9% L-(+)-lactic acid Batch: 18.03.2020	<i>Staphylococcus aureus</i> <i>Enterococcus hirae</i>		Concentrations tested: 2.5%, 3 and 3.5% Contact time: 30 min Temperature: 10°C Criteria: at least a 4 log reduction	(but similar acceptable study available on the dossier, see efficacy report n° RE19-128-2 (IUCLID report 13))	 (IUCLID report DIV 13b) R.I.: 3
Bactericide	Disinfection of hard surfaces in domestic, institutional and industrial (food industry) area.	Meta SPC 7 product: Sure Cleaner Disinfectant (= SalveSafe 15) = 29% L-(+)-lactic acid Batch: MUL 18-03-20 481347	Bacteria <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Enterococcus hirae</i> <i>Proteus hauseri (vulgaris)</i> Yeasts <i>Candida albicans</i>	EN16615:2015 modified (stainless steel)	Phase 2 step 2 test (surface test) Concentrations tested: 2.5%, 3.0% and 3.5% Contact time: 30 min Temperature: 10°C Dirty conditions (3 g/L BSA) Criteria: at least a 5 log (bacteria) or 4 log (yeasts) reduction	Not fulfilled the norm (methodological deviation: surface tested (stainless steel) is not in accordance to the EN 16615)	   Test report NR DZ/29/10/20  IUCLID report DIV 06) R.I.: 3
Yeasticide	Disinfection of hard surfaces in veterinary area.	Meta SPC 7 product: Sure Cleaner Disinfectant (= SalveSafe 15)= 29.9% L-(+)-lactic acid	Yeasts <i>Candida albicans</i>	EN1657:2005	Phase 2 step 1 test (suspension test) Low soiling conditions (3 g/L BSA) Concentrations tested: 0.5%, 1.0%, 1.5%, 2.0% and 2.5%	Yeasticidal activity demonstrated at 1.5% v/v (CT: 30 min).	 Analytical Report: AAD03181,  Number:

		Batch: MUL 462427			Contact time: 30 min Temperature: 10°C Criteria: at least a 4 log reduction		STULV19AA150 1-1, Version: 1 (IUCLID report DIV 14) R.I.: 1
Yeasticide	Disinfection of hard surfaces in veterinary area.	Meta SPC 7 product: Sure Cleaner Disinfectant (= SalveSafe 15) =29.9% L-(+)-lactic acid Batch: MUL 462427	Yeasts <i>Candida albicans</i>	EN16438:2 014	Phase 2 step 2 test (non porous surface test) Low soiling conditions (3 g/L BSA) Concentrations tested: 1.0%, 1.5%, 2.0% and 2.5% Contact time: 30 min Temperature: 10°C Criteria: at least a 3 log reduction	Yeasticidal activity demonstrated at 2.5% (CT: 30 min).	 Report AAD03254 (IUCLID report DIV 15) R.I.: 2 (yeasticidal activity validated at 2% in the report but control (Nts<14) is not valid at this concentration)

In these efficacy tests with fresh samples of the representative product at 29.9% w/w L-(+)-lactic acid:

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1656 and EN 14349), at 20°C, with a contact time of 5 minutes with low soiling conditions (3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 2.5 % v/v.
- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1656 and EN 14349 (SALVECO study, n° RE19-128-2 (IUCRID report 13))), at 10°C, with a contact time of 30 minutes with low soiling conditions (3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 1% v/v.
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1657 and EN 16438), at 10°C, with a contact time of 30 minutes with low soiling conditions (3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 2.5% v/v.

Please note that no acceptable efficacy tests against bacteria and yeast to support mechanical action have been provided and therefore only efficacy without mechanical action is validated.

Conclusion on the efficacy of the product

The products of the family SALVECO SALVESAFE PRODUCTS have shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 for the following uses:

META-SPC 1

- Use 1: Disinfectants for all washable hard surfaces (PT 02) with dirty conditions (without mechanical action)

Household area:

- Mandatory target organisms:
 - Bacteria: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
- Other target organisms:
 - Enveloped viruses and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

Institutions and industry areas:

- Mandatory target organisms:
 - Bacteria, yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
- Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

Claimed application rate of 0.299% to 1.496% w/w L-(+)-lactic acid is then validated.

- Use 2: Disinfectants for all washable hard surfaces in domestic, institutional and industrial areas in contact with food (PT 04) with dirty conditions (without mechanical action) – for general disinfection:

- Mandatory target organisms:
 - Bacteria, yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

Claimed application rate of 0.299% to 1.496% w/w L-(+)-lactic acid is then validated.

META-SPC 2

- Use 1: Disinfectants for all washable hard surfaces (PT 02) with dirty conditions (without mechanical action)

Household area:

- Mandatory target organisms:
 - Bacteria: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
- Other target organisms:
 - Enveloped viruses and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

Institutions and industry areas:

- Mandatory target organisms:
 - Bacteria, yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

- Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°CClaimed application rate of 0.299% to 1.496% w/w L-(+)-lactic acid is then validated.

- Use 2: Disinfectants for all washable hard surfaces in domestic, institutional and industrial areas in contact with food (PT 04) with dirty conditions (without mechanical action) – for general disinfection:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°CClaimed application rate of 0.299% to 1.496% w/w L-(+)-lactic acid is then validated.

META-SPC 3

- Use 1: Disinfectants for all washable hard surfaces in institutional and industrial areas (PT 02) with dirty conditions (without mechanical action) – for general disinfection:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
- Use 2: Disinfectants for all washable hard surfaces in institutional and industrial areas in contact with food (PT 04) with dirty conditions (without mechanical action) – for general disinfection:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

META-SPC 4

- Use 1: Disinfectants for all washable hard surfaces in institutional and industrial areas (PT 02) with dirty conditions (without mechanical action) – for general disinfection:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
- Use 2: Disinfectants for all washable hard surfaces in institutional and industrial areas in contact with food (PT 04) with dirty conditions (without mechanical action) – for general disinfection:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

META-SPC 5

- Use 1: Disinfectants for all washable hard surfaces (PT 02) with dirty conditions (without mechanical action):

Institutions and industry areas:

- Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
- Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20 °C

Claimed application rate of 0.4485% w/w L-(+)-lactic acid is then validated.

Medical areas:

- Mandatory target organisms:
 - Bacteria, yeasts: 0.4485% w/w L-(+)-lactic acid, 5 min, 20°C
- Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

Claimed application rate of 0.4485% w/w L-(+)-lactic acid is then validated.

As no efficacy data have been provided to support the use by immersion in medical areas against fungi and viruses (mandatory target organisms), the application by immersion in medical area is not demonstrated.

Moreover, as only efficacy data against *E. hirae* was provided according to P2S2 test (EN 16615) and no tests with the other mandatory strains were provided, efficacy with mechanical action is not considered to be supported based on the efficacy data provided and only efficacy without mechanical action is validated.

- Use 2: Disinfectants for all washable hard surfaces in institutional and industrial areas in contact with food (PT 04) with dirty conditions (without mechanical action):

General disinfection and meat industries (except slaughterhouses):

- Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

Claimed application rate of 0.4485% to 0.598% w/w L-(+)-lactic acid is then validated.

Milk industries:

- Mandatory target organisms:
 - Bacteria and yeasts: 0.598% w/w L-(+)-lactic acid, 5 min, 20°C

The claimed application rate for this use are 0.4485% to 0.598% w/w L-(+)-lactic acid. Therefore, only the maximum application rate of 0.598% w/w L-(+)-lactic acid is validated for milk industries and the application rate of 0.4485% w/w L-(+)-lactic acid is not demonstrated.

- Use 3: Disinfectants for all washable non-porous hard surfaces in veterinary areas (PT 03) with clean conditions (without mechanical action):
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 30 min, 10 °CClaimed application rate of 0.299% w/w L-(+)-lactic acid is then validated.

META-SPC 6

- Use 1: Disinfectants for all washable hard surfaces in medical areas (PT 02) with dirty conditions (without mechanical action):
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.4485% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses: 0.4485% w/w L-(+)-lactic acid, 5 min, 20°C

As no efficacy data have been provided to support the use by immersion in medical areas against fungi and viruses (mandatory target organisms), the application by immersion in medical area is not demonstrated.

Moreover, as only efficacy data against *E. hirae* was provided according to P2S2 test (EN 16615) and no tests with the other mandatory strains were provided, efficacy with mechanical action is not considered to be supported based on the efficacy data provided and only efficacy without mechanical action is validated.

META-SPC 7

- Use 1: Disinfectants for all washable hard surfaces (PT 02) with clean and dirty conditions (without mechanical action)
 - Household area:*
 - Mandatory target organisms:
 - Bacteria: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Institutions and industry areas:*
 - Mandatory target organisms:
 - Bacteria, yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

- Other target organisms:

- Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

As only efficacy data against *E. hirae* was provided according to P2S2 test (EN 16615) and no tests with the other mandatory strains were provided efficacy with mechanical action (claimed for institutional area) is not considered to be supported based on the efficacy data provided and only efficacy without mechanical action is validated.

- Use 2: Disinfectants for all washable hard surfaces in domestic, institutional and industrial areas in contact with food (PT 04) with clean and dirty conditions (without mechanical action) – for general disinfection:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
- Use 3: Disinfectants for all washable hard non-porous surfaces in veterinary areas (PT 03) with clean conditions (without mechanical action):
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.748% w/w L-(+)-lactic acid, 30 min, 10°C

As no efficacy data has been provided against yeasts (mandatory target organism) with a contact time of 5 minutes, the efficacy for this contact time is not validated.

META-SPC 8

- Use 1: Disinfectants for all washable hard surfaces (PT 02) with dirty conditions (without mechanical action)
 - Household area:*
 - Mandatory target organisms:
 - Bacteria: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Institutions and industry areas:*
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C

Claimed application rate of 0.598% or 1.496% w/w L-(+)-lactic acid (RTU products) is then validated.

- Use 2: Disinfectants for all washable hard surfaces in domestic, institutional and industrial areas in contact with food (PT 04) with dirty conditions (without mechanical action) – general disinfection:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°CClaimed application rate of 0.598% or 1.496% w/w L-(+)-lactic acid (RTU products) is then validated.

META-SPC 9

- Use 1: Disinfectants for all washable hard surfaces (PT 02) with dirty conditions (without mechanical action)
Household area:
 - Mandatory target organisms:
 - Bacteria: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C*Institutions and industry areas:*
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20°C
 - Other target organisms:
 - Enveloped viruses: 0.299% w/w L-(+)-lactic acid, 5 min, 20°CClaimed application rate of 0.598% w/w L-(+)-actic acid (RTU products) is then validated.
- Use 2: Disinfectants for all washable hard surfaces in domestic, institutional and industrial areas in contact with food (PT 04) with dirty conditions (without mechanical action) – general disinfection:
 - Mandatory target organisms:
 - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 5 min, 20 °CClaimed application rate of 0.598% w/w L-(+)-lactic acid (RTU products) is then validated.

Please note that based on the composition of the family, some Meta SPC could claim products with less in use surfactants than the representative products tested in the efficacy studies (see confidential part of the PAR) and therefore for which no information on the impact on efficacy were provided.

Therefore, eCA consider that a general instructions for use should be added in the SPC for these Meta SPC (Meta SPC 1, Meta SPC 2, Meta SPC 3 and Meta SPC 4) indicated that "Minimum in use concentration of surfactants should be 0.29%."

2.12.5.6 Occurrence of resistance and resistance management

Development of resistance is considered unlikely due to the non-specific mode of action (L-(+)-lactic acid, Assessment Report PT2, 3, 4 (2017).

2.12.5.7 Known limitations

None.

2.12.5.8 Evaluation of the label claims

The uses assessed in this dossier belong to the Product Type 2, 3 and the Product Type 4.

The products are used by professional and non-professional users.

Please refer to conclusion on efficacy regarding the accordance of the label claimed with the submitted efficacy data and uses claimed.

2.12.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

Not relevant.

2.12.6 Risk assessment for human health

The SALVECO SALVESAFE PRODUCTS biocidal products family (BPF) is composed of 9 meta SPC containing several products with a concentration of active substance L-(+)-lactic acid ranging from 0.627% to 31.33% (technical active substance).

Products of the family are concentrated products intended to be used diluted (Meta SPC 1 to 7) or ready-to-use products (Meta SPC 8 and 9). Products of all meta SPC are intended to be used by professional users but only products of the Meta SPC 1, 2, 8 and 9 are also intended to non-professional users.

The pH of the products of the Meta SPC 1 to 7 are between 1.49 and 1.55. The pH of the products of the Meta SPC 8 and 9 are, respectively, at 2.27 and 2.7.

2.12.6.1 Assessment of effects on Human Health

No acute oral and dermal toxicity study, nor skin and eye irritation studies neither skin sensitisation study have been performed on any product of the biocidal product family SALVECO SALVESAFE PRODUCTS.

However, the applicant has provided three *in vivo* toxicological studies carried out with similar products for skin corrosion/irritation (two studies covering all Meta SPCs of the family) and for eye irritation (covering Meta SPC 8 and 9 only).

A comparison between the composition of the tested products and the worst-case formulation of the compared Meta SPC has been performed (Refer to the Confidential annex).

Overall, the composition, the classification by calculation and the pH of the tested products are similar and close to those of the products of the compared Meta SPC (or worst case for the tested product). Thus, the read-across is accepted.

A classification by calculation according to the CLP Regulation n°1272/2008 rules is performed for the end-point with no submitted studies. The harmonised classification (when available) and classification proposed in the provided MSDS have been used for active substances and coformulants.

No human data is available.

Skin corrosion and irritation**Meta SPC 1 to 7 (concentrated products)**

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 <i>Average score (24, 48, 72h)/animal; reversibility; other adverse local</i>	Remarks <i>(e.g. major deviations)</i>	Reference
Acute Dermal Irritation, OECD 404, GLP, Reliability 1	Rabbit, Albino New Zealand, Males, Three	DESINFECTI ON (undiluted) (formulation containing 28.2% L-(+)-lactic acid pure), 0.5 mL test item per animal, Exposure period of 4h	<p>Slight to well defined erythrema, slight oedema was noted in all animals 1h after patch removal. Superficial tissue destruction (restricted to the epidermis) was noted in two animals 1h after patch removal. Then, a scab was noted from day 1 and was totally reversible between days 9-10. Dryness was noted in one animal from day 3 and was totally reversible on day 10.</p> <p>Average scores (24, 48, 72h) for each animal after 4h of exposure:</p> <p>Erythrema/eschar: 2, 2, 2 Oedema: 1.3, 2, 2.</p> <p>All the observed effects was reversible on day 7.</p> <p>The test item is therefore classified for skin irritation (H315).</p>	None	IC-OECD-PH-11/0117, [REDACTED]

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Skin irritation
Justification for the value/conclusion	<p>When looking at the scores, the average score for erythema/eschar and oedema and the reversibility of the observed effects, the criteria (1) and (2) of the table 3.2.2 (3.2.2.7.1) of the Annex I of the CLP Regulation are not fulfilled.</p> <p>However, several relevant effects such as erythema and oedema, superficial tissues destruction, scab and dryness are observed from 1h after patch removal and during several days (up to 10 days post treatment). Since the tested product as well as the products of the Meta SPCs 1 to 7, have an extreme pH (<2) and are classified for skin corrosion by calculation (according to the CLP criteria), these observations reflect the chemical exposure to the product.</p> <p>In these conditions, even if the criteria (1) and (2) of the table 3.2.2 of Annex I of the CLP Regulation are not fulfilled, these observed effects cannot be ignored. Following a conservative approach, it was chosen to conclude for a skin irritant (H315) classification.</p> <p>Based on a read-across with an <i>in vivo</i> (Acute Skin Irritation (rabbit) OECD 404) study and according to the classification rules laid down in the CLP Regulation</p>
Classification of the product according to CLP	Skin Irrit. 2 – H315 (Meta SPC 1,2,3,4,5,6 and 7)

Meta SPC 8 and 9 (ready-to-use products)

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	Remarks	Reference
Acute Dermal Irritation, OECD 404, GLP, Reliability 1	Rabbit, Albino New Zealand, Males, Three	BASE 34 VERSION 7.6c M (undiluted) (formulation containing 3.52% L-(+)-lactic acid pure),	<p>Average score (24, 48, 72h)/animal; reversibility; other adverse local</p> <p>No effect was observed after 1h of exposure.</p> <p>Average scores (24, 48, 72h) for each animal after 4h of exposure :</p> <p>Erythrema: 0.7, 1, 0.3 Oedema: 0, 0, 0.</p>	None	Tn 268 / 07-1698, P. 

		0.5 mL test item per animal, Exposure period of 4h	All the observed effects were reversible on day 3. The test item is therefore not classified for skin irritation.		
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Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritant for skin
Justification for the value/conclusion	Based on a read-across with an <i>in vivo</i> (Acute Skin Irritation (rabbit) OECD 404) study and according to the classification rules laid down in the CLP Regulation
Classification of the product according to CLP	No classification (Meta SPC 8 and 9)

Eye irritation

Meta SPC 1 to 7 (concentrated products)

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Serious eye damaging
Justification for the value/conclusion	No study has been submitted. Based on the extreme pH (<2) of the products of the Meta SPC 1 to 7 and according to the classification rules laid down in the CLP Regulation, a classification Serious eye damage Category 1 (H318) is required for all products of these Meta SPC.
Classification of the product according to CLP	Eye Dam. 1 – H318 (Meta SPC 1,2,3,4,5,6 and7)

Meta SPC 8 and 9 (ready-to-use products)

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 <i>Average score (24, 48, 72h)/ observations and time point of onset, reversibility</i>	Remarks <i>(e.g. major deviations)</i>	Reference
Acute Eye Irritation, OECD 405, GLP, Reliability 1	Rabbit, Albino New Zealand, Female, Three	Solution désinfectante (formulation containing 2.38% L-(+)-lactic acid pure), 0.1 mL test item per animal	Average scores (24, 48, 72h) for each animal after treatment: Conjunctivae: Chemosis: 1, 0.3, 0.3 Redness: 2, 1, 1 Iris Lesion: 0.7, 0, 0.3 Corneal opacity : 1, 0.3, 0.3	None	IO-OCDE-PH-17/0206, F. [REDACTED]

			<p>All the observed effects were reversible on day 3 for two of three rabbits and on day 7 for the third.</p> <p>The test item is therefore not classified for eye irritation.</p>		
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Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritant for eyes
Justification for the value/conclusion	Based on a read-across with an <i>in vivo</i> (Acute Eye Irritation (rabbit) OECD 405) study and according to the classification rules laid down in the CLP Regulation
Classification of the product according to CLP	No classification (Meta SPC 8 and 9)

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	<p>Based on available data on the composition of the products and according to the classification rules laid down in the CLP Regulation, no classification for the respiratory tract irritation is required for any products of the family SALVECO SALVESAFE PRODUCTS.</p> <p>In addition, since the products of the family are neither classified for skin corrosion (only skin irritation) nor for acute toxicity by inhalation, the labelling EUH071 is not required even for the product for which an exposure to aerosols is expected.</p>
Classification of the product according to CLP	No classification (All Meta SPC)

Data waiving	
Information requirement	-
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory tract irritation. The assessment is based on the available data on the composition of the products of the BPF and according to the classification rules laid down in the CLP Regulation.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitizer
Justification for the value/conclusion	<p>Based on available data on the composition of the products and according to the classification rules laid down in the CLP Regulation, no classification for the skin sensitisation are required for any product of the family SALVECO SALVESAFE PRODUCTS.</p> <p>However, several ingredients contained in the perfumes are classified Skin Sens 1 or 1B and are present at a content equal to or superior to 1/10th of the GCL in some Meta SPC. According to the CLP regulation, a supplemental statement EUH208 "Contains X. May produce an allergic reaction" is required for products containing these ingredients. For details see the confidential annex.</p>
Classification of the product according to CLP	<p>No classification (All Meta SPC)</p> <p>A supplemental statement is required for products of: Meta SPC 2 and 4:</p> <ul style="list-style-type: none"> - For fragrance Cool Mint: EUH208 – Contains Eucalyptol, Carvone and Limonene. May produce an allergic reaction - For fragrance Pure: EUH 208 – Contains Methyl salicylate and Eugenol. May produce an allergic reaction - For fragrance Eucalyptus Leaves: EUH208 – Contains Eucalyptol. May produce an allergic reaction. <p>Meta SPC 6: EUH208 - "Contains Eucalyptol and Carvone. May produce an allergic reaction".</p>

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitizer for the respiratory tract
Justification for the value/conclusion	<p>Based on available data on the composition of the products and according to the classification rules laid down in the CLP Regulation, no classification for the respiratory sensitisation is required for any products of the family SALVECO SALVESAFE PRODUCTS.</p>
Classification of the product according to CLP	No classification (All Meta SPC)

Data waiving	
Information requirement	-
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. The assessment is based on the

	available data on the composition of the products of the BPF and according to the classification rules laid down in the CLP Regulation.
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Acute toxicityAcute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not toxic by oral route
Justification for the selected value	Based on available data on the composition of the products and according to the classification rules laid down in the CLP Regulation, no classification is required for the acute toxicity by oral route for any product of the family SALVECO SALVESAFE PRODUCTS.
Classification of the product according to CLP	No classification (All Meta SPC)

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not toxic by inhalation route
Justification for the selected value	Based on available data on the composition of the products and according to the classification rules laid down in the CLP Regulation, no classification is required for acute toxicity by inhalation for any product of the family SALVECO SALVESAFE PRODUCTS.
Classification of the product according to CLP	No classification (All Meta SPC)

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not toxic by dermal route
Justification for the selected value	Based on available data on the composition of the products and according to the classification rules laid down in the CLP Regulation, no classification is required for acute toxicity by dermal route for any product of the family SALVECO SALVESAFE PRODUCTS.
Classification of the product according to CLP	No classification (All Meta SPC)

Information on dermal absorption

No dermal absorption study has been submitted by the applicant. Therefore, according to the EFSA Guidance on dermal absorption (2017), the default dermal absorption value of 50% is chosen for the risk characterisation.

Value used in the Risk Assessment – Dermal absorption	
Substance	L(+)-lactic acid
Value	50% (if necessary)
Justification for the selected value	According to EFSA Guidance 2017, a default value of 50% is chosen (water-based formulation, dilution)

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

In addition to the active substance L(+)-Lactic Acid (classified for skin corrosion), the following substances contribute to the classification of the products:

- "Poly(oxy-1,2-ethanediyl), .alpha.-(carboxymethyl)-.omega.-(octyloxy)-" classified for skin irritation is contained in the products of the Meta SPC 1 to 7 at a content equal or above the limit threshold of classification of 10% for skin irritation.
- "Poly(oxy-1,2-ethanediyl), .alpha.-(carboxymethyl)-.omega.-(octyloxy)-" and "D-glucopyranose, oligomeric, C10-16 (even numbered)-alkyl glycosides" classified for eye damage are contained in the products of Meta SPC 1 to 7 at a content equal or above the limit threshold of classification of 3%.

According to the "Guidance on the BPR, volume III Human Health- Assessment & Evaluation (Parts B+C)" these classified ingredients that led to classification of products of the Meta SPC 1 to 7 of the BPF SALVECO SALVESAFE PRODUCTS should be considered as substance of concern (SoC). For these SoCs, a banding evaluation is done according the scheme described in the "Guidance on the BPR, volume III Human Health- Assessment & Evaluation (Parts B+C)", p356.

None of ingredients of the composition have either an European IOELV, nor are an active substance that acts as a co-formulant (at a C≥0.1%).

For additional information please refer to the confidential annex.

Available toxicological data relating to a mixture

None

Other

None

2.12.6.2 Exposure and risk assessment

Introductory remarks

The SALVECO SALVESAFE PRODUCTS biocidal products family (BPF) is composed of 9 Meta SPC intended to be use for disinfection of hard surfaces containing L(+)-Lactic Acid as active substance. No substance of concern with available TRV has been identified.

Following the WG TOX I - 2021 that took place on March 2021 and in the frame of the discussion of the CAR of Lactic Acid TP6, it has been agreed not to perform the comparison of endogenous L-(+)-lactic acid with systemic exposure levels at product authorization. Consequently, any calculation regarding the estimation of level of exposure of L-(+)-lactic acid does not make sense anymore.

Therefore, since the Meta SPC 1 to 7 of the BPF SALVECO SALVESAFE PRODUCTS are classified Skin Irrit. 2 (H315) and Eye Dam. 1 (H318), only a qualitative local risk assessment has to be performed for the exposure to L-(+)-lactic.

The Meta SPC 8 and 9 of the BPF SALVECO SALVESAFE PRODUCTS are not classified for human health.

Moreover, the most concentrated in-use solutions (dilution of the products of the Meta SPC 1 to 7) claimed by the applicant contain 1.57% of technical active substance i.e. the same concentration that the max of the Meta SPC 8. The maximum content of cofomulants in the in-use solution corresponds also to the maximum of the Meta SPC 8.

Thus, the classification of the in-use solutions (from Meta SPC s 1 to 7) are covered by the Meta SPC 8. These in-use solutions are not classified.

Therefore, no qualitative local risk assessment is necessary neither for the products of the Meta SPC 8 and 9 nor for the in-use solutions (dilutions of the products of the Meta SPC 1 to 7). No specific risk mitigation measure is necessary.

Consequently, no risk assessment and no specific risk mitigation measure is necessary for the secondary exposure (users and general public).

The products of the Meta SPC 1 to 7 are concentrated products that should be diluted before use. The products of the Meta SPC 8 and 9 are ready-to-use.

Products of all Meta SPC are intended to be used by professional users but only products of the Meta SPC 1, 2, 8 and 9 are also intended to non-professional users.

No rinsing is required.

Overall, a risk assessment (qualitative risk assessment for local effects) is needed only when users (professional and non-professional) are exposed to the concentrated product i.e. when mixing and loading the product during dilution.

Identification of main paths of human exposure towards active substance and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	Primary (direct) exposure			Secondary (indirect) exposure			
	Industrial use	Professional use	Non-professional use	Industrial use	Professional use	General public	Via food
Inhalation	n.a.	Yes	Yes	n.a.	No	No	
Dermal	n.a.	Yes	Yes	n.a.	Yes	Yes	
Oral	n.a.	No	No	n.a.	No	Yes	Yes

[Please indicate the main paths of human exposure by stating "yes", "no" or "n.a." (not applicable) for each cell.]

List of scenarios

Summary table: exposure scenarios

Summary table: exposure scenarios		
Scenario and task number	Description of scenario and tasks	Exposed group
Primary exposure		
Scenario [1]	Hard surface disinfection Meta SPC 1 to 7 (concentrated products to be diluted) by Professional users	
Task [1.1]	Mixing & loading <i>Manual preparation of treatment solution: dilution of the concentrate product (covers the automatic M&L)</i>	Professionals
Task [1.2]	Application <i>Application of the diluted product and cleaning of the surfaces with the product by spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping or soaking</i>	Professionals
Task [1.3]	Post application <i>Rubing or brushing if necessary. Or wiping dry or letting air dry</i>	Professionals
Scenario [2]	Hard surface disinfection Meta SPC 1 and 2 (concentrated products to be diluted) by Non-Professional users	
Task [2.1]	Mixing & loading <i>Manual preparation of treatment solution: dilution of the concentrate product (covers the automatic M&L)</i>	Non-Professionals
Task [2.2]	Application <i>Application of the diluted product and cleaning of the surfaces with the product by spraying, spreading, wiping, foam application, brush treatment, dip treatment, immersion, mopping, soaking, .</i>	Non-Professionals
Task [2.3]	Post application <i>Rubing or brushing if necessary. Or wiping dry or letting air dry</i>	Non-Professionals

Industrial exposure

The product is not intended to be used by industrial.

Professional exposure

Scenario [1] - Hard surface disinfection Meta SPC 1 to 7 (concentrated products to be diluted) by Professional users

Local effects

- Qualitative risk assessment

The products from the Meta SPC 1 to 7 of the SALVECO SALVESAFE PRODUCTS family are intended to be diluted by professionals before applying the diluted product on the hard surfaces by fully wetting all surface. The surfaces can then be rubbed or brushed if necessary or wiped dry or let to air dry.

The Meta SPC 1 to 7 are classified as follows:

- Skin Irrit. 2 (H315);
- Eye Dam. 1 (H318);

The dilutions are not classified. Thus, no risk assessment is necessary during application of the product and the post-application (Task [1.2] and [1.3]).

Therefore, according to the Guidance on the Biocidal Products Regulation - Volume III Human health - Assessment and Evaluation (Parts B + C), a qualitative risk characterization for local effects is required when handling the product i.e. during the mixing and loading (Task [1.1]).

The manual mixing and loading represents a worst-case scenario compared to automated (or semi-automated) mixing and loading. No information is provided by the applicant.

Table 1: **Local effects – Qualitative assessment Mixing and loading (dilution) of products of Meta SPC 1 to 7 by professional users**

Hazard		Exposure						Risk
Hazard category	Effects in terms of C&L	Who is exposed	Tasks, uses, processes	Potential exposure routes	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM	Conclusion on risk
High	Eye Dam. 1 (H318)	Professional	Scenario [1] Task [1.1]	Ocular	<u>Frequency:</u> daily <u>Duration:</u> few minutes per day	Practically no exposure expected, except potential splashes and spills	<u>PPE:</u> Chemical goggles <u>Labelling:</u> <ul style="list-style-type: none"> • According to CLP • Instructions for use and Storage • P sentence on the label • “Wash hands after use of the concentrate product” (in order to prevent from possible hand/eye contact) • “Avoid contact with eyes” • “Avoid splashes and spills during mixing and loading (dilution)” 	The risk is considered acceptable with the relevant RMM.

Low	Skin Irrit. (H315)	Professional	Scenario [1] Task [1.1]	Dermal	See above	Skin exposure through potential liquid spills around the opening of the bottle and/or during mixing and loading	<u>PPE:</u> - Substance /task appropriate gloves; - Coverall <u>Labelling:</u> • According to CLP • Instructions for use and Storage • P sentence on the label • "Wash hands after use"	The risk is considered acceptable with the relevant RMM.
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Conclusion - Scenario [1]

For products from the meta SPC 1 to 7 of the SALVECO SALVESAFE PRODUCTS family, **the risk during hard surface disinfection by professionals is acceptable** considering the qualitative risk assessment for local effects with the following risk mitigation measures (RMM):

- Wear protective chemical resistant gloves, chemical goggles and a coverall when handling the concentrate product (during dilution) - PPE material to be specified by the authorisation holder within the product information.
- Wash hands after use of the concentrate product.
- Avoid contact with eyes.
- Avoid splashes and spills during mixing and loading (dilution).

Non-professional exposure

Scenario [2] – Hard surface disinfection Meta SPC 1 and 2 (concentrated products to be diluted) by Non-professional users

Local effects

- Qualitative risk assessment

The products from the Meta SPC 1 and 2 of the SALVECO SALVESAFE PRODUCTS family are intended to be diluted by non-professionals before applying the diluted product on the hard surfaces by fully wetting all surface. The surfaces can then be rubbed or brushed if necessary or wiped dry or let to air dry.

The Meta SPC 1 and 2 are classified as follows:

- Skin Irrit. 2 (H315);
- Eye Dam. 1 (H318);

The dilutions are not classified. Thus, no risk assessment is necessary during application of the product and the post-application (Task [2.2] and [2.3]).

Therefore, according to the Guidance on the Biocidal Products Regulation - Volume III Human health - Assessment and Evaluation (Parts B + C), a qualitative risk characterization for local effects is required when handling the product i.e. during the mixing and loading (Tasks [2.1]).

Table 2: Local effects – Qualitative assessment Mixing and loading (dilution) of products of Meta SPC 1 and 2 by non-professional users

Hazard		Exposure						Risk
Hazard category	Effects in terms of C&L	Who is exposed	Tasks, uses, processes	Potential exposure routes	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM	Conclusion on risk
High	Eye Dam. 1 (H318)	Non-Professional	Scenario [2] Task [2.1]	Ocular	<u>Frequency:</u> not daily (only when the dilution is emptied) <u>Duration:</u> equal to or less than few minutes per day	Practically no exposure expected except potential splashes and spills	<u>No PPE</u> <u>Labelling:</u> <ul style="list-style-type: none"> • According to CLP • Instructions for use and Storage • P sentence on the label • "Wash hands after use of the concentrate product" 	The risk is considered acceptable with the relevant RMM.

							(in order to eliminate the possible hand/eye contact) <ul style="list-style-type: none"> • "Avoid contact with eyes" • "Avoid splashes and spills during mixing and loading (dilution)" <u>Packaging:</u> <ul style="list-style-type: none"> • Child-proof closure 	
Low	Skin Irrit. (H315)	Non-Professional	Scenario [2] Task [2.1]	Dermal	See above	Skin exposure through potential liquid spills around the opening of the bottle and/or during mixing and loading	<u>No PPE</u> <u>Labelling:</u> <ul style="list-style-type: none"> • According to CLP • Instructions for use and Storage • P sentence on the label • "Wash hands after use" 	The risk is considered acceptable with the relevant RMM.

Conclusion - Scenario [2]

For products from the meta SPC 1 and 2 of the SALVECO SALVESAFE PRODUCTS family, **the risk during hard surface disinfection by non-professionals is acceptable** considering the qualitative risk assessment for local effects with the following risk mitigation measures (RMM):

- Wash hands after use of the concentrate product.
- Avoid contact with eyes.
- Avoid splashes and spills during mixing and loading (dilution).
- A child-proof closure is required.

Exposure of the general public

Since RTU products (Meta SPC 8 and 9) and the in-use solutions (dilutions of the products of the Meta SPC 1 to 7) are not classified for human health no risk assessment and no specific risk mitigation measure is necessary for the secondary exposure of the general public.

Monitoring data

None

Dietary exposure

By definition PT 02 is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore, residue in food or feed are not expected for LACTIC ACID BASED PRODUCTS for PT 2 uses.

Regarding the uses on PT 3 and 4, residues in food or feed might be expected.

For L(+) lactic acid, the following evaluation was provided in the Assessment Report, 2007: *"L(+) lactic acid is a naturally occurring alpha-hydroxy acid found in plants, animals and humans. Major sources of L(+) lactic acid in the human organism are endogenous production (e.g. via anaerobic catabolism of glycogen and glucose) production by gastro intestinal microorganisms and uptake via food. The production of L(+) lactic acid as an intermediary metabolite in a 70 kg resting man is estimated to be in the range of 117-230 g/d but can be much higher during exercise. The mean daily per capita intake of L(+) lactic acid and D(-) lactic acid from milk and milk products has been estimated to be approximately 1 g in Switzerland (Walther, 2006). The estimated overall intake via food in the EU and the USA is estimated to be 1.65-2.76 g/person/day.*

L(+) lactic acid has been approved in the EU as a food additive without an ADI or upper limit (quantum satis; Dir. 95/2/EC), as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMEA 2008)."

Moreover, "Because of the very low systemic toxicity of L(+) lactic acid, derivation of any systemic toxicological reference dose was regarded unnecessary. Considering the intended uses, exposure is estimated to be clearly below endogenous production (>100 g/person/day) and dietary exposure (>1 g/person/day). Therefore, neither an ADI nor an ARfD have been set".

As a conclusion, based on the low concentration of L(+) lactic acid, the endogenous production and compared to naturally occurring levels in food, significant indirect exposure via intended uses is not expected for PT 03 and PT 04 uses.

Moreover, two co-formulants included in the SALVECO SALVESAFE PRODUCTS family were identified as substances of concern for human health. Nevertheless, based on the characteristics of these substances, it was not considered necessary to derive toxicological reference values. Therefore, risk for consumer via indirect exposure via food is excluded.

List of scenarios

Not relevant.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use¹	Intended use	Reference value(s)²
1.	Food	Lactic Acid (E 270) – Food additive	Quantum satis (Regulation (EU) 1129/2011)
2.	Veterinary	Lactic Acid - All food producing species	No MRL required (Regulation (EC) No 37/2010)
3.	Cosmetic	Lactic Acid – Used as buffering humectant or skin conditioning	Up to a maximum level of 2.5% and a pH ≥ 5 (SCCBFP, 2000)

¹ e.g. plant protection products, veterinary use, food or feed additives

² e.g. MRLs. Use footnotes for references.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not relevant.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Not relevant.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not relevant.

Risk for consumers via residues in food

By definition, PT 02 biocidal product is not intended for direct application to humans or animals and is not used for direct contact with food or feeding stuffs.

Regarding PT 03 and 04 uses, considering properties of L-(+)-lactic acid, no significant exposure via food is expected. Based on the low concentration of L-(+)-lactic acid, the endogenous production and compared to naturally occurring levels in food, significant indirect exposure in food is not expected.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not relevant

Overall conclusion on risk assessment for human health

Overall conclusion on the risk assessment for human health from local exposure		
Use description	Conclusion	Set of RMMs
Hard surface disinfection by professionals	<i>Acceptable with the following risk mitigation measures</i>	<p><u>Meta SPC 1,2,3,4,5,6,7:</u> "Wear protective chemical resistant gloves, chemical goggles and a coverall when handling the concentrate product (during dilution) - PPE material to be specified by the authorisation holder within the product information. "Wash hands after use of the concentrate product" "Avoid contact with eyes" "Avoid splashes and spills during mixing and loading (dilution)"</p> <p><u>Meta SPC 8&9: None</u></p>
Hard surface disinfection by non-professionals	<i>Acceptable with the following risk mitigation measures</i>	<p><u>Meta SPC 1&2:</u> "Wash hands after use of the concentrate product" "Avoid contact with eyes" "Avoid splashes and spills during mixing and loading (dilution)" "A child-proof closure is required"</p> <p><u>Meta SPC 8&9: None</u></p>

2.12.6 Risk assessment for animal health

The risk for animal health is considered covered by human health assessment.

2.12.7 Risk assessment for the environment

The biocidal product family (BPF) contains several biocidal products (BP) grouped into nine sub-groups (meta-SPC). All BPs contain L-(+)-lactic acid. The data on active substance are provided by the assessment report of L-(+)-lactic acid for PT02, 03, 04⁴. The available ecotoxicological information are used for risk assessment for the environment.

No substance of concern has been defined for the environment.

⁴ Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, Assessment Report L-(+)-lactic acid Product-type 02, 03 and 04, June 2017

2.12.7.1 Effects assessment on the environment

There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture in accordance with rules laid down in Regulation (EC) No 1272/2008 (CLP). Further ecotoxicological studies on the biocidal product itself are not required as no substance of concern has been defined for the environment.

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

Meta-SPC 1 +2	Not classified for environment (for details please refer to the confidential PAR)
Meta-SPC 3+4	
Meta-SPC 5+6	
Meta-SPC 7	
Meta-SPC 8	
Meta-SPC 9	

The effect assessment of the BPs on the environment is based on ecotoxicity and e-fate data from the L-(+)-lactic acid substance assessment report.

The relevant PNECs for the environmental risk characterisation are reported below.

Summary PNEC values for active substance (as reported in assessment report for the active substance L-(+)-lactic acid)

Compartment	Lowest endpoint	AF	PNEC value
Aquatic	ErC50: 3 900 mg/L	1 000	3.9 mg/L
Sediment	-	-	4.8 mg/kg wwt *
STP	NOEC \geq 100 mg/L	10	10 mg/L
Soil	-	-	1.9 mg/kg wwt *

* The PNEC_{soil} and the PNEC_{sediment} are derived using the equilibrium partitioning method (ECHA Guidance on BPR Vol IV, Part B, v2.0, 2017, equations 89 and 91). The Log_{kw} of the active substance being lower than 5.0, no additional assessment factor has been added.

Further Ecotoxicological studies

No new data is available.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No new data is available.

Supervised trials to assess risks to non-target organisms under field conditions

No new data is available.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No new data is available.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

No new data is available.

Foreseeable routes of entry into the environment on the basis of the use envisaged

No new data is available.

Further studies on fate and behaviour in the environment (ADS)

No new data is available.

Leaching behaviour (ADS)

No new data is available.

Testing for distribution and dissipation in soil (ADS)

No new data is available.

Testing for distribution and dissipation in water and sediment (ADS)

No new data is available.

Testing for distribution and dissipation in air (ADS)

No new data is available.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

No new data is available.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

No new data is available.

2.12.7.2 Exposure assessment

All the biocidal products (BPs) of this family are intended to be used for disinfection of hard surfaces in domestic, institutional, industrial and medical areas. Additionally, BPs from Meta-SPC 5 and 7 are also intended to be used in veterinary areas (animal housing

disinfection) and BPs from Meta-SPC 1, 2, 3, 4, 8 and 9 for the disinfection household surfaces (private uses).

All the BPs can be used for indoor or outdoor disinfection.

“Outdoor” disinfection cover the following uses:

- Disinfection of garden furnitures – private use
- Disinfection of outside doors of institutional/industrial buildings
- Local disinfection of industrial food containers/tanks/tankers stored outside (disinfection of openings)

Product types and maximum concentrations of technical active substance in BPs of Meta-SPC 1 to 9 are presented in the table below:

Meta-SPC	Product type	Product description	Use description	Mode of application	Maximum in-use concentration L(+) lactic acid % (w/w)
Meta-SPC 1+2	PT2/PT4	Concentrated disinfectant (Dilutable at 1, 2, 3 or 10%)	Multi-purpose concentrated disinfectant for hard surfaces in domestic, institutional, industrial and food industry areas - Professional and private	Manual application, spraying, spreading, foam application, brush treatment, immersion	1.566%
Meta-SPC 3+4	PT2/PT4	Concentrated disinfectant (Dilutable at 1, 2 or 4%)	Multi-purpose concentrated disinfectant for hard surfaces in institutional, industrial and food industry areas – Professional (private)		0.313%
Meta-SPC 5	PT2/PT3/PT4	Concentrated disinfectant (Dilutable at 1, 1.5 or 2%)	Multi-purpose concentrated disinfectant for hard surfaces in institutional, medical, veterinary and industrial areas including food industry (general, meal and milk industries) - Professional		0.47% (PT2) 0.627% (PT4) 0.313% (PT3)
Meta-SPC 6	PT2	Concentrated disinfectant (Dilutable at 1.5%)	Multi-purpose concentrated disinfectant for hard surfaces in medical area - Professional		0.47%

Meta-SPC 7	PT2/PT3/PT4	Concentrated disinfectant (Dilutable at 1% and 2.5%)	Multi-purpose concentrated disinfectant for hard surfaces in domestic institutional, medical, veterinary and industrial areas including food industry - Professional	0.313% (PT2/PT4) and 0.783% (PT3)
Meta-SPC 8	PT2/PT4	Ready to use disinfectant	Multi-purpose ready-to-use disinfectant for hard surfaces in domestic, institutional and industrial (including food industry) areas - Professional and private	1.566%
Meta-SPC 9	PT2/PT4	Ready to use disinfectant	Multi-purpose ready-to-use disinfectant for hard surfaces in domestic, institutional and industrial (including food industry) areas - Professional and private	0.627%

A worst case representative product with the maximum in-use concentration of L-(+)-lactic acid among all BPs of 1.566% is considered to be relevant for environmental risk assessment for all the BPF claimed uses. This worst case product was assessed with all the emission scenarios listed below in order to cover emissions following uses of BPs of all Meta-SPCs.

General information

Assessed PT	PT 2
Assessed scenarios	<p>INDOOR USES</p> <p>PT02 – Scenario 1: Disinfectants used for sanitary purposes (tonnage)</p> <p>PT02 – Scenario 2: Disinfectants used for sanitary purposes (consumption)</p> <p>PT02 – Scenario 3: Disinfectants used in industrial areas</p> <p>PT02 – Scenario 4: Medical - Room, furniture and objects (tonnage)</p> <p>PT02 – Scenario 5: Medical - Room, furniture and objects (consumption)</p>

	<p>PT02 – Scenario 6: Medical - Disinfection of surfaces or equipment by immersion</p> <p>OUTDOOR USES</p> <p>PT02 – Scenario 1: Disinfection of outdoor surfaces - urban area, STP</p> <p>PT02 – Scenario 2: Disinfection of outdoor surfaces - urban area, separate sewer system</p> <p>PT02 – Scenario 3: Disinfection of outdoor surfaces - Rural areas</p>
ESD(s) used	<p>Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), March 2001</p> <p>Supplement to the ESD for PT 2: Emission scenarios for private and public health area disinfectants and other biocidal products (JRC Scientific and Technical Reports, 2011)</p> <p>Adaptation of the Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses, OECD n°18, 2008</p> <p>Adaptation of the Emission scenario document for biocides used as masonry preservatives, EUBEES, 2002</p> <p>Assessment of direct emission to surface water in urban areas (PT 6.2/6.3 and 7-10), UBA, 2014</p>
Approach	<p>PT02 – Scenario 1: tonnage approach</p> <p>PT02 – Scenario 2: consumption approach</p> <p>PT02 – Scenario 3: consumption approach</p> <p>PT02 – Scenario 4: tonnage approach</p> <p>PT02 – Scenario 5: consumption approach</p> <p>PT02 – Scenario 6: consumption approach</p> <p>Outdoor scenarios 1 to 3: consumption approaches</p>
Distribution in the environment	<p>Calculated based on Guidance for BPR IV Part B+C (2017).</p> <p>Assessment report: L-(+)-Lactic acid Product-type 02, 03 and 04, June 2017</p> <p>Technical Agreements for Biocides February 2021</p>
Groundwater simulation	No
Confidential annex	Yes
Life cycle steps assessed	<p>Production: No</p> <p>Formulation No</p> <p>Use: Yes</p> <p>Service life: No</p>

Remarks	/
Assessed PT	PT 3
Assessed scenarios	<p>INDOOR USES</p> <p>PT03 – Scenario 1: Disinfection of animal housings</p> <p>PT03 – Scenario 2: Disinfectants used for veterinary hygiene by dipping</p> <p>OUTDOOR USES</p> <p>Covered by Outdoor uses PT02 scenarios 1, 2 and 3</p>
ESD(s) used	ESD for PT 3: Emission scenarios for veterinary hygiene biocidal products (JRC Scientific and Technical Reports, 2011)
Approach	Consumption approach
Distribution in the environment	<p>Calculated based on Guidance for BPR IV Part B+C (2017).</p> <p>Assessment report: L-(+)-Lactic acid Product-type 02, 03 and 04, June 2017</p> <p>Technical Agreements for Biocides February 2021</p>
Groundwater simulation	No
Confidential annex	No
Life cycle steps assessed	<p>Production: No</p> <p>Formulation No</p> <p>Use: Yes</p> <p>Service life: No</p>
Remarks	/

Assessed PT	PT 4
Assessed scenarios	<p>INDOOR USES</p> <p>PT04 – Scenario 1: Disinfectants used in milking parlour systems</p> <p>PT04 – Scenario 2: Disinfection in large scale kitchens/canteens and slaughterhouses</p> <p>PT04 – Scenario 3: Disinfection dipping for medium to small-scale applications in PT04</p> <p>OUTDOOR USES</p> <p>Covered by Outdoor uses PT02 scenarios 1, 2 and 3</p>
ESD(s) used	ESD for PT 4: Emission scenarios for Disinfectants used in food and feed areas (JRC Scientific and Technical Reports, 2011)
Approach	Consumption approach

Distribution in the environment	Calculated based on Guidance for BPR IV Part B+C (2017). Assessment report: L-(+)-Lactic acid Product-type 02, 03 and 04, June 2017 Technical Agreements for Biocides February 2021
Groundwater simulation	No
Confidential annex	No
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	/

PT02 Scenarios

Emission estimation – Indoor uses

2.12.7.2.1 PT02 – Scenario 1: Disinfectants used for sanitary purposes (Tonnage approach)

Please refer to the confidential PAR for the assessment of the tonnage approach, which indicates that the consumption based approach is the worst case.

2.12.7.2.2 PT02 – Scenario 2: Disinfectants used for sanitary purposes (Consumption approach)

Local emission due to disinfection of lavatory and surfaces were calculated using ESD for PT2 Disinfection in institutional areas (RIVM, 2011). This scenario covers the PT02 use of multi-purpose disinfectants for hard surfaces in domestic and institutional areas (professional and private).

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario: Disinfectants used for sanitary purposes based on an average consumption			
Number of inhabitants feeding one STP <i>N_{local}</i>	10 000	[-]	Default
In use concentration of technical active substance <i>C_{product%}</i>	1.566	% w/w	S - Maximum value
Fraction released to wastewater <i>F_{water}</i>	1	[-]	Default
Density <i>D</i>	1.109	[-]	S - Maximum value
Active substance in product (maximum in-use concentration of technical active substance) <i>C_{product}</i>	1.737E-02	kg.l ⁻¹	S - Maximum value <i>C_{product%} x D / 100</i>
Consumption per capita <i>Q_{product}</i>	0.007 (General purpose and lavatory)	l.cap ⁻¹ .d ⁻¹	Default
Penetration factor of disinfectant <i>F_{penetr}</i>	0.5	[-]	Default

Calculations for PT02 - Scenario 2

$$E_{\text{local water}} = N_{\text{local}} * Q_{\text{product}} * C_{\text{product}} * F_{\text{penetr}} * F_{\text{water}}$$

Resulting local emission to relevant environmental compartments		
Compartment	Local emission (Elocal) [kg/d]	Remarks
Wastewater	6.08E-01	Applicable to all BPs designed for PT02 domestic and institutional uses

2.12.7.2.3 PT02 – Scenario 3: Disinfectants used in industrial areas

Local emission due to disinfection of industrial areas were calculated using ESD for PT2 Disinfection in industrial premises (RIVM, 2011). This scenario applies to disinfection of a wide range of surfaces: small surfaces such as furniture and bigger surfaces such as rooms, walls or floors. Industrial premises are considered as local emission sources which release their wastewater to a local STP. This scenario covers the PT02 use of multi-purpose disinfectants for hard surfaces in industrial area (professional).

The scenario is based on the concentration of the active substance and volume applied on a surface: an application rate of 0.1 L/m² (based on Technical Agreements for Biocides Environment (ENV) Version 2.1, December 2019, in case of absence of more specific information) was considered for the assessment. A surface area of 1000 m² was assessed as it represents a worst-case according to the ESD (compared to small scale areas).

Input parameters for calculating the local emission				
Input		Value	Unit	Remarks
Scenario: Disinfectants used in industrial areas				
Application rate of biocidal product	<i>Vform</i>	0.1	[l.m ⁻²]	Default values (TAB ^{Erreur ! Signet non défini.} ENV 26, 2018)
In use concentration of technical active substance	<i>Cproduct%</i>	1.566	[% w/w]	S - Maximum value
Density	<i>D</i>	1.109	[-]	S - Maximum value
concentration at which Technical active substance is used	<i>Cform</i>	17.37	[g.l ⁻¹]	S - Maximum value <i>Cproduct%</i> x <i>D</i> x 10
Surface area to be disinfected	<i>AREAsurface</i>	1000	[m ²]	Default (large scale)
Number of applications per day	<i>Nappl</i>	1	d ⁻¹	Default
Fraction of substance disintegrated during or after application (before release to the sewage system)	<i>Fdis</i>	0	[-]	Default
Fraction released to wastewater	<i>Fwater</i>	1	[-]	Default

Calculations for PT02 – Scenario3

$$E_{\text{local water}} = V_{\text{form}} * C_{\text{form}} * A_{\text{REAsurface}} * N_{\text{appl}} * (1 - F_{\text{dis}}) * F_{\text{water}} / 1000$$

Resulting local emission to relevant environmental compartments		
Compartment	Local emission (Elocal) [kg/d]	Remarks
Wastewater	Large scale: 1.74	Applicable to all PT02 BPs designed for professional uses in industrial area

2.12.7.2.4 PT02 – Scenario 4: Medical - Room, furnitures and objects (Tonnage approach)

Please refer to the confidential PAR for the assessment of the tonnage approach, which indicates that the consumption based approach is the worst case.

2.12.7.2.5 PT02 – Scenario 5: Medical - Room, furnitures and objects (Consumption approach)

Local emission due to disinfection surfaces in medical sector was calculated using ESD for PT2 by Van der Poel (2001). This scenario covers the PT02 use of multi-purpose disinfectants for hard surfaces in medical area (professional).

Input parameters for calculating the local emission				
Input		Value	Unit	Remarks
Scenario: Disinfectants used for sanitary purposes in hospitals based on the amount of solution of disinfectant used on a day				
Fractions released to wastewater	<i>Sanitary purposes</i> <i>Fsan,water</i>	0.55	[-]	Default
	<i>Brushes</i> <i>Fobj,water</i>	0.95	[-]	Default
In use concentration of technical active substance	<i>Cproduct%</i>	1.566	[% w/w]	S -Maximum value
Density	<i>D</i>	1.109	[-]	S - Maximum value
Technical concentration at which active substance is used	<i>Sanitary purposes</i> <i>Csan</i>	1.74E-02	[kg.l ⁻¹]	S - Maximum value $C_{product\%} \times D / 100$
	<i>Brushes</i> <i>Cobj</i>	1.74E-02	[kg.l ⁻¹]	S - Maximum value $C_{product\%} \times D / 100$
Amount of water with active substance	<i>Sanitary purposes</i> <i>Qwater_san</i>	25	[l.d ⁻¹]	Default
	<i>Brushes</i> <i>Qwater_obj</i>	25	[l.d ⁻¹]	Default

Calculations for PT02 - Scenario 5

$$E_{local,water} = Q_{water_san} * C_{san} * F_{san,water} + Q_{water_obj} * C_{obj} * F_{obj,water}$$

Resulting local emission to relevant environmental compartments		
Compartment	Local emission (Elocal) [kg/d]	Remarks
Wastewater	6.51E-01	Applicable to all BPs designed for PT02 professional uses in medical area

2.12.7.2.6 PT02 – Scenario 6: Medical – Disinfection of surfaces or equipment by immersion

According to the TAB ENV v2.0, ENV-45, a scenario has been proposed for the disinfection of medical equipment. This scenario has thus been used in the following assessment, using the default values agreed at WG-I-2015. It is assumed that 30 dipping baths per day (default value from the TAB) is a worst-case value. This scenario covers the PT02 use of multi-purpose disinfectants for hard surfaces in medical area (professional) by immersion.

Input parameters for calculating the local emissions			
Scenario: Disinfection of surfaces by immersion			
Input	Value	Unit	Remarks
In use concentration of technical active substance [$C_{product\%}$]	1.566	[% w/w]	S - Maximum value
Density [D]	1.109	-	S - Maximum value
Technical in-use concentration in the product [C_{disinf}]	17.37	g/l	S - Maximum value $C_{product\%} \times D \times 10$
Volume of solution in dipping bath [$Q_{dipping_bath}$]	0.01	m ³	D
Maximum number of dipping bath per day [$N_{dipping_bath}$]	30	d ⁻¹	D
Fraction released to wastewater [F _{water}]	1	-	D

Calculations for Scenario 6

$$\mathbf{E_{localwater}} = C_{disinf} * Q_{dipping_bath} * F_{water} * N_{dipping_bath} * 10$$

Resulting local emission to relevant environmental compartments		
Compartment	Local emission (E _{localSTP}) [kg/d]	Remarks
Local emission (E _{localSTP})	5.21	0

Emission estimation – Outdoor uses

The outdoor disinfection covers the following uses:

- Disinfection of garden furnitures – private use
- Disinfection of outside doors of institutional/industrial buildings
- Local disinfection of industrial food containers/tanks/tankers stored outside

More specifically, outdoor disinfection for general public means disinfection of small surfaces like house's outdoor but also tables, furnitures, restaurant terraces, counters or other surfaces which can be food-contact (PT04) or not (PT02) according to the applicant. For PT03, the outdoor disinfection could be the disinfection of fences, paddocks, open enclosures, troughs, doors etc.

During the application outdoors, emissions can reach the environment through the run-off. Then, the product can be rinsed off with water or rain, and emissions can also occur during this phase.

According to the ESD for PT 10 (2002), two relevant locations can be differentiated:

- In the city (urban area), the product is likely to enter paved ground during application or rinsing phase to the sewer system subsequently reaching the sewage treatment plant (STP, scenario 1) or directly the surface water via direct rainwater discharge (scenario 2). The rinsing phase also covers the leaching by rain if the product is not rinsed.
- In the countryside (rural area), the product directly reaches the soil (scenario 3) after the application and the rinsing phase/rain event.

In ESD PT2, no scenario is currently available for calculating the environmental emissions of a product applied for the disinfection of outdoor surfaces such as terraces or walls. For this use, active substance emissions were calculated by adapting the scenario for outdoor application of insecticides (ESD for PT18, 2008) as well as scenarios for masonry preservatives (ESD for PT10, 2002) to the use of the SALVECO SALVESAFE PRODUCTS according to AHEE-4.

2.12.7.2.7 PT02 - Outdoor Scenario 1 – Disinfection of outdoor surfaces – urban area, STP

In urban area, the emissions are directed to the sewage treatment plant (STP). Calculations were based on certain hypotheses and input values, which are detailed in the following paragraphs.

The application rate of 0.1 L product/m² is applied.

1. Treated surfaces size:

House:

A default use where a user disinfects a house terrace and walls is assessed. For the walls and the terrace, the harmonised parameters from the TAB and ESD are considered. In houses that have a terrace, it is considered that both these surfaces can be treated simultaneously during a disinfection event. In houses that do not have a terrace, only walls treatment is considered.

As a worst-case scenario, the following hypotheses are taken:

- Terrace: As a default value, it is considered that the terrace has a surface of **30 m²** (TAB v2.0, 2018). This corresponds to a 7.5 m x 4 m terrace, adjacent to the small side of the house (see Figure 1). It is assumed that the terrace is paved.
- Walls (x4): As a worst-case value, it is considered that wall disinfection takes place all around the house. This corresponds to a treated area **125 m²**. This surface area corresponds to the area indicated in the ESD for PT18 (2008) for outdoor application of insecticides against crawling insects.

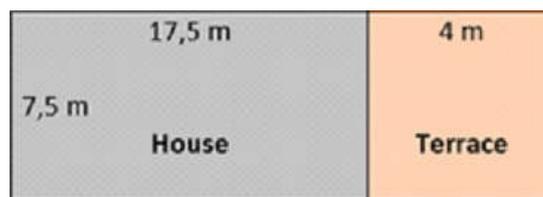


Figure 1: Sizing of the house/terrace

– Total:

For houses with terrace: the emissions from all treated surface will reached the sewer and the sewage treatment plant: $125 + 30 = \mathbf{155\ m^2}$.

For houses without terrace: the product is applied to walls only and emissions are from $\mathbf{125\ m^2}$ of walls.

Large building:

A default use where a professional user disinfects the walls surrounding a larger building is assessed. For this type of building, the terrace is not considered.

- Walls: The TAB v2.0 of 2018 indicates that the default surface for a “large building” is $609\ m^2$ (ENV 140). This corresponds to a $29\ m \times 21\ m$ building. Assuming the outer walls of this building are disinfecting up to $2.5\ m$ (same value than the houses), this corresponds to a treated area of $2 \times (21 \times 2.5 + 29 \times 2.5) = \mathbf{250\ m^2}$.

2. Emission pathways:

As a worst case, it was considered that releases from application and rinsing/rain event arise the same day with 100% emissions at the day of application.

3. Simultaneity factor and number of building treated daily:

Simultaneity factor is a parameter that considers simultaneous emissions from several buildings and houses to a STP. It was calculated based on consumer’s behaviour. In practice, the disinfection of outer surfaces in houses and large buildings will not be performed on a regular basis, but can rather be expected to take place on average only once to twice a year.

$$F_{sim} = 2/365 = 0.00547 \text{ use/building or house/yr}$$

Houses:

Environmental modelling considers a default city of 4000 houses, including 2500 houses having a terrace (TAB v2.0, ENV140, 2018). With a simultaneity factor of 0.00547, this means that $2500 \times 0.00547 = \sim\mathbf{14}$ households owing a terrace can simultaneously use the product in a day. Concerning the rest of houses without a terrace, $(4000-2500) \times 0.00547 = \sim\mathbf{9}$ households walls can be treated simultaneously.

Large buildings:

The TAB (v2.0, ENV140, 2018) indicates that the number of large buildings in a default city is 300. Based on this indication, $300 \times 0.00547 = \sim\mathbf{2}$ large buildings will simultaneously emit product in a day.

As both emissions from houses and large buildings can occur simultaneously, local emissions from both these sources were summed.

Input parameters for calculating the local emissions			
Input	Value	Unit	Remarks
Application rate	0.1	L/m ²	D
Concentration of active substance in the product	17.37	g/L	S - considering a worst case % of 1.566 and a density of 1.109
Quantity of active ingredient applied [Q _{ai}]	1.737E-03	kg/m ²	O
Disinfected surface [AREA]: - house without a terrace (walls) - house with a terrace (walls + terrace) - large building (walls)	125 155 250	m ²	See calculations of parameters above
Number of buildings disinfected daily [N _{local}]: - houses without a terrace - houses with a terrace - large buildings	9 14 2	/d	See calculations of parameters above
Fraction released to water [F _{water}]	1	-	Default value (ESD PT2, 2011)
Fraction of substance disintegrated during or after application, before release to the environment [F _{dis}]	0	-	Default value (ESD PT2, 2011)
Fraction of houses on which an algaecide / disinfectant is applied [F _{house}]	0.5		AHEE-4

Calculations for Scenario 1

Resulting local emissions to relevant environmental compartments		
Compartment	Local emission (E_{local}_{STP}) [kg/d]	Remarks
Houses without terrace: Local emission to STP	9.77E-01	O
Houses with terrace: Local emission to STP	1.88	O
Large buildings: Local emission to STP	4.34E-01	O
Total (Houses without a terrace + Houses with a terrace + Large building) - Local emission to STP	3.30	O

2.12.7.2.8 PT02 - Outdoor Scenario 2 – Disinfection of outdoor surfaces – urban area, separate sewer system

Some cities have a separate sewer system, in which the wastewater and rainwater are collected in distinct canalisations. Wastewater is directed to a STP, while rainwater is emitted directly to surface water.

In such cities, the products that are used outside of houses will be collected by the rainwater sewer system, resulting in their direct emission to surface waters. For the PT2 outdoor surfaces disinfection use of the products of the family, the assessment of the risk to the surface water compartment in case of a separate sewer system is thus relevant.

The emitted quantities will be identical to that calculated for scenario 2 above, but it will be directed to the rainwater system rather than to the STP.

Resulting local emissions to relevant environmental compartments		
Compartment	Local emission ($E_{\text{local surface water}}$) [kg/d]	
Total (Houses without a terrace + Houses with a terrace + Large building) - Local emission to STP	3.30	See scenario 2 calculations

2.12.7.2.9 PT02 - Outdoor Scenario 3 – Disinfection of outdoor surfaces – rural areas

In a rural area, product emissions are directed to the soil compartment.

1. Treated surfaces size:

House:

A default use where a user disinfects a house terrace and/or surrounding walls is assessed. For the walls, it is considered that the user disinfects the whole surface of the walls as it is intended in the SPC. For the terrace, the harmonised parameters from the TAB are considered.

In tier 1, it is considered that both these surfaces can be treated simultaneously during a disinfection event. The worst-case emissions to soil are located around the terrace (at this location, the soil received the product used to treat one wall and the terrace).

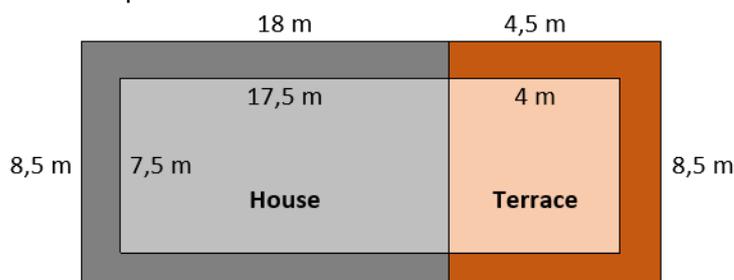


Figure 2: Sizing of the house/terrace and of the soil area receiving the product

- Terrace: As a default value, it is considered that the terrace has a surface of **30 m²** (TAB v2.0, 2018). This corresponds to a 7.5 m x 4 m terrace, adjacent to the small side of the house. It is assumed that the terrace is paved.
- Walls (x1): $7.5 \times 2.5 = \mathbf{18.75 \text{ m}^2}$
- Total: $18.75 + 30 = \mathbf{48.75 \text{ m}^2}$

In tier 2, the surfaces are not treated simultaneously during a disinfection event. Treatments of terrace or walls alone are also considered.

- Terrace: **30m²**
- Walls (x4): $2 \times (7.5 \times 2.5) + 2 \times (17.5 \times 2.5) = \mathbf{125 \text{ m}^2}$

Large building:

It is assumed that only houses are relevant for the rural area (i.e. the assessment of the houses covers large buildings, as the treated surfaces are proportional of the volume of the receiving compartment), therefore emissions of large building are assessed in urban context only.

2. Receiving compartment sizes:

Following the indications in the TAB (v2.0, ENV 153), it is considered that product emissions from the terrace will reach a 0.5 m band of soil surrounding the terrace (3 sides), and up to a 0.5 m soil depth.

Tier 1:

- Soil surrounding a wall + a terrace (around three sides of the terrace): $8.5 \text{ (TAB v2.0, ENV154)} \times 0.5 = \mathbf{4.25 \text{ m}^3}$

Tier 2:

- Soil surrounding a house alone: **13 m³** (ESDTP18, 2008)
- Soil surrounding a terrace = **4.25 m³**

3. Emission pathways:

The drift from façade rinsing or the leaching by rain reaches the volume of soil adjacent to the treated surface. Therefore, as a worst case, it is assumed that after the rinsing step or a rain event, 100% of the product will be emitted to the soil adjacent to the treated surface during a disinfection event. No distinct assessment for application and rinsing was considered considering that rinsing could not be managed by RMM. The assessment of the adjacent is considered as covering the distant soil.

Input parameters for calculating the local emissions			
Input	Value	Unit	Remarks
Application rate	0.1	L/m ²	S
Concentration of substance in the product	17.37	g/L	S - considering a worst case % of 1.566 and a density of 1.109
Quantity of active ingredient applied [Qai]	1.737E-03	kg/m ²	O

Area treated: - Tier 1: [AREA _{wall+terrace}] - Tier 2 o [AREA _{walls}] o [AREA _{terrace}]	48.75 125 30	m ²	TAB v2.0, 2018, ENV154, ESDTP18, 2008 See calculations 1.
Soil volume receiving the product: - Tier 1: [V _{wall+terrace}] - Tier 2 o [V _{walls}] o [V _{terrace}]	4.25 13 4.25	m ³	See calculations 2.
Bulk density of wet soil [RHO _{soil}]	1700	kgww/m ³	Default value (ESD PT18, 2008)

Calculations for Scenario 3

Resulting local emissions to relevant environmental compartments		
Compartment	Local emission (E _{local,soil}) [kg/d]	Remarks
Tier 1		
Local emission to soil surrounding a terrace, when terrace and walls are treated simultaneously [E _{local,soil-walls+terrace}]	8.47E-02	O
Tier 2		
Local emission to soil surrounding a house, when walls are treated alone [E _{local,soil-walls}]	2.17E-01	O
Local emission to soil surrounding a terrace, when a terrace is treated alone [E _{local,soil-terrace}]	5.21E-02	O

PT03 Scenarios

2.12.7.2.10 PT03 – Scenario 1: Disinfection of animal housings

All parameters (area of accommodations, number of animals...) are from ESDTP3, 2011 and ESDTP18 for stables and manure storage systems, 2006. For an easier reading of the PAR, only worst-case situations are presented: "Veal calves" for releases via manure/slurry (grassland as a worst case) and "Turkey in free range – litter floor" for releases via the STP. This scenario covers the PT03 use of multi-purpose disinfectants for hard surfaces in veterinary area (professional).

For information, the calculations were not performed according to the latest agreements made for PT3 assessment. However, the results are considered as a worst-approach and therefore no revision of the calculations was made.

Input parameters for calculating the local emission					
Parameter	Nomenclature	Value		Unit	Origin
INPUTS					
Type of housing/manure storage (for application of the notification)	cat-subcat (i1)	Turkey in free range – litter floor (releases to STP)	Veal calves (release to slurry/manure)	[-]	D
Type of biocide	bioctype (i2)	Disinfectant		[-]	D
Type of application	App _{way} (i3)	Spraying		[-]	D
In use concentration of technical active substance	C _{product%}	1.566		[% w/w]	S - Maximum value
Density	D	1.109		[-]	S - Maximum value
Technical content of active ingredient in applied formulation (after dilution)	F _{bioc}	17.37		[g.L ⁻¹]	S - Maximum value C _{product%} x D x 10
Amount of product prescribed to be used per m ²	V _{prod}	0.1		[L.m ⁻²]	S
Fraction of active ingredient released	F _{slurry/manure}	0.3	0.5	[-]	D
	F _{waste water}	0.2	0	[-]	D
Area of the housing	AREA	8 040	650	[m ²]	D – Total area
Biocide application interval	T _{bioc-int}	182	91	[d]	D/O
Number of disinfectant applications in one year	N _{app-bioc}	2	4	[-]	D
Number of manure applications - grassland	N _{lapp-grass}	4	4	[-]	D
Manure application time interval for grassland	T _{gr-int}	53	53	[d]	D
Number of animals	N _{animal i1}	10 000	80	[-]	D
Amount of nitrogen per animal	Q _{nitrog i1}	0.00482	0.02382	[kg.d ⁻¹]	D
OUTPUTS					
STP					
Emission from one application to sewer (turkey)	E _{local wastewater}	2.79	n.r.	[kg.d ⁻¹]	O
Manure/slurry exposure					
Amount of a.i. in manure after one application (veal calf)	Q _{ai manure/slurry}	n.r. (covered by veal calf)	5.65E-01	[kg]	O

2.12.7.2.11 PT03 – Scenario 2: Disinfectants used for veterinary hygiene by dipping

All parameters (area of accommodations, number of animals...) considered are from the ENV 55 of the Technical agreement for Biocides (TAB ENV February 2021). For the disinfection of equipment in dipping baths, a volume of 100L is considered as indicated in the TAB (2019). Since the fraction of release in the STP ($F_{stp}=1$) is the same for all the types of housing/manure storage, emissions to sewer are identical for all the animal categories. For the exposure via manure/slurry, only veal calves is presented as a worst-case. This scenario covers the PT03 use of multi-purpose disinfectants for hard surfaces in veterinary area (professional) by immersion.

Input parameters for calculating the local emission				
Parameter	Nomenclature	Value	Unit	Origin
INPUTS				
Type of housing/manure storage (for application of the notification)	cat-subcat (i1)	Veal calves for slurry/manure n.r. for STP	[-]	D
Type of biocide	bioctype (i2)	Disinfectant	[-]	D
Type of application	App _{way} (i3)	Bath	[-]	D
In use concentration of technical active substance	C _{product%}	1.566	[% w/w]	S - Maximum value
Density	D	1.109	[-]	S - Maximum value
Technical content of active ingredient in applied formulation (after dilution)	F _{bioc}	17.37	[g.L ⁻¹]	S - Maximum value C _{product%} x D x 10
Volume of the reservoir (tub)	[V _{reserv}]	100	L	D - Dipping bath for small items of equipment (TAB ENV 55, 2019)
Fraction of active ingredient released	F _{slurry/manure}	1	[-]	D
	F _{waste water}	1	[-]	D
Time interval between two applications (tub fillings)	T _{bioc-int}	1	[d]	D
Number of disinfectant applications (tub fillings) in one year	N _{app-bioc}	365	[-]	D
Number of manure applications - grassland	N _{lapp-grass}	4	[-]	D
Manure application time interval for grassland	T _{gr-int}	53	[d]	D
OUTPUTS				
STP				
Local emission after one application in the sewer	E _{local wastewater}	1.74	[kg.d ⁻¹]	0
Manure/slurry exposure				

Amount of a.i. in manure after one application (veal calf)	$Q_{\text{manure/slurry}}$	1.74	[kg]	0
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PT04 Scenarios

2.12.7.2.12 PT04 – Scenario 1: Disinfectants used in milking parlour systems

Local emission due to disinfection of milking parlour systems were calculated using the ESD for PT4 Disinfection of milking parlour systems (SCC, 2011). This scenario covers the PT04 use of multi-purpose disinfectants for hard surfaces in food industry including milk industry (professional).

Input parameters for calculating the local emission				
Input	Symbol	Value	Unit	Remarks
In use concentration of technical active substance	$C_{\text{product}\%}$	1.566	[% w/w]	S - Maximum value
Density	D	1.109	[-]	S - Maximum value
Technical concentration of active substance in biocidal product	C_{form}	17.37	g/L	S - Maximum value $C_{\text{product}\%} \times D \times 10$
Amount of disinfectant used for cleaning of the milking installation	V_{forminst}	130	L/d	D
Amount of disinfectant used for cleaning of the milk storage tank	V_{formtank}	45	L/d	D
Fraction released to wastewater	F_{water}	1	[-]	D
Fraction of substance disintegrated during or after application (before release to the sewage system)	F_{dis}	0	[-]	D
Output				
Quantity of active ingredient used	Q_{ai}	3.04E+03	g/d	$Q_{\text{ai}} = C_{\text{form}} * (V_{\text{forminst}} + V_{\text{formtank}})$
Calculations: $E_{\text{localwater}} = Q_{\text{ai}} * (1 - F_{\text{dis}}) * F_{\text{water}} / 1000$				
Local emission to wastewater	$E_{\text{localwater}}$	3.04	kg/d	0

2.12.7.2.13 PT04 – Scenario 2: Disinfection in large scale kitchens/canteens and slaughterhouses

Local emission due to disinfection of large scale kitchens/canteens and slaughterhouses were calculated using the ESD for PT4 Disinfection of milking parlour systems (SCC, 2011). This scenario covers the PT04 use of multi-purpose disinfectants for hard surfaces in food industry (professional). The local emission is based on the application rate of disinfectant per m² and the area of the treated surface. The main fraction of residues is released to the sewer system. The application of this scenario covers the use in domestic premises (non-professional).

An application rate of 0.1 L/m² (based on Technical Agreements for Biocides Environment (ENV) Version 2.1, December 2019), is considered as a default value.

Therefore, the application rate in active substance is 1.566 g/m².

Input parameters for calculating the local emission				
Input	Unit	Symbol	Value	Remarks
Surface area to be disinfected for slaughterhouses	m ²	AREA _{surface}	10000	Default value
Surfaces area to be disinfected for kitchens and canteens	m ²	AREA _{surface}	2000	Default value
In use concentration of technical active substance	C _{product} %	% w/w	1.566	S - Maximum value
Density	[-]	D	1.109	S - Maximum value
Technical concentration of active substance in the product	g/m ²	Q _{a.i.appl}	1.737	S - Maximum value C _{product} % x D x 10
Number of application per day	d ⁻¹	N _{appl}	1	Default value
Fraction of substance disintegrated during or after application, before release to the sewer system	-	F _{dis}	0	Worst case
Fraction of the substance eliminated due to on-site pre-treatment of the plant waste water	-	F _{elim}	0	Default value
Fraction released to wastewater	-	F _{water}	1	Default value
OUTPUT				
Calculations:				
$E_{local\ water} = Q_{a.i.appl} \cdot AREA_{surface} \cdot N_{appl} \cdot (1 - F_{dis}) \cdot (1 - F_{elim}) \cdot F_{water} / 1000$				
Slaughterhouses				

Emission rate to wastewater (standard STP) for general purposes	kg/d	Elocalwater	1.74E+01	O
Catering kitchens				
Emission rate to wastewater (standard STP) for general purposes	kg/d	Elocalwater	3.47	O

2.12.7.2.14 PT04 – Scenario 3: Disinfection by dipping for medium to small-scale applications in PT04

Local emission due to disinfection by dipping in food and feed areas was calculated using ENV 217 from the Technical agreement for Biocides (TAB ENV). The disinfection of equipment by dipping is mentioned in the section 2.2 of the ESD (Disinfection in large scale kitchens, canteens, slaughterhouses and butcheries) as followed (ESD-TP04 (2011) – tables 7 and 8):

- In slaughterhouses and butcheries, dipping could be applied for cutting boards, depending on size (once per week).
- In large scale catering kitchens and canteens, dipping could be applied for cutting boards and food containers, depending on size (1 – 2 times per day); after contact with critical foods (meat, poultry, fish, eggs); for slicers (1 – 2 times per day and if required).

The scenario proposes to consider that the equipment is disinfected in dipping baths with a capacity of up to 100 liters and that the bath content will be disposed of to drain once per day. This volume of solution is considered not to fit with large scale facilities, but rather to small or medium areas.

According to the ESD for PT04, wastewaters from catering kitchens and canteens are diluted with the wastewater streams from other premises. It can be expected as a realistic typical case scenario that several small to medium scale facilities using baths are connected to the same sewage treatment plant. The scenario therefore proposes to consider that 5 sites at the STP scale use 100 liters on a daily basis.

This scenario covers the PT04 use of multi-purpose disinfectants for hard surfaces in food industry (professional) by immersion.

Calculations were performed considering the worst case value for the in-use concentration covering all the META SPC. The maximum in-use application rate in active substance is 17.37 g/L. Input parameters for calculating the local emission				
Input		Value	Unit	Remarks
In use concentration of technical active substance	$C_{product\%}$	% w/w	1.566	S - Maximum value
Density	D	1.106	[-]	S - Maximum value
Technical concentration of active substance in biocidal product	C_{form}	17.37	g/L	S - Maximum value $C_{product\%} \times D \times 10$

Volume of one dipping bath	V_{bath}	100	L	D
Number of sites connected to the same STP using the disinfection solution	N_{appl}	5	[-]	D
Fraction released to wastewater	F_{water}	1	[-]	D
Fraction of substance disintegrated during or after application (before release to the sewage system)	F_{dis}	0	[-]	D
Fraction of substance eliminated due to onsite pre-treatment of waste water	F_{elim}	0	[-]	D
Output				
Calculation: $E_{\text{localwater}} = C_{\text{form}} * V_{\text{bath}} * N_{\text{appl}} * (1 - F_{\text{dis}}) * (1 - F_{\text{elim}}) * F_{\text{water}}$				
Emission rate to wastewater (standard STP) for general purposes	$E_{\text{localwater}}$	8.68	kg/d	O

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
PT02 Indoor uses	Yes	No	No	No	Yes	No	Yes	yes	No
PT02 Outdoor uses - urban areas, STP (covering PT03 and PT04)	Yes	No	No	No	Yes	No	Yes	Yes	No
PT02 Outdoor uses - urban areas, separate sewer system (covering PT03 and PT04)	Yes	No	No	No	No	No	No	No	No
PT02 Outdoor uses - Rural areas (covering PT03 and PT04)	No	No	No	No	No	No	Yes	Yes	No
PT03 – Scenario 1: Disinfection of animal housings (via STP)	Yes	No	No	No	Yes	No	Yes	Yes	No
PT03- Scenario 2: Disinfectants used for veterinary hygiene by dipping (via manure)	Yes	No	No	No	Yes	No	Yes	Yes	No
PT03- Scenario 2: Disinfectants used for veterinary hygiene by dipping (via STP)	Yes	No	No	No	Yes	No	Yes	Yes	No
PT04 - Indoor uses	Yes	No	No	No	Yes	Yes	Yes	Yes	No

Input parameters (only set values) for calculating the fate and distribution in the environment of L-(+)-Lactic acid			
Input	Value	Unit	Remarks
Molecular weight	90.08	g.mol ⁻¹	Assessment Report L-(+)-lactic acid Product-type 02, 03 and 04, June 2017
Melting point	53	°C	
Boiling point	204.2	°C	
Vapour pressure (at 20°C)	0.4	Pa	
Water solubility (at 12°C)	1.00E+06	mg/l	Completely miscible with water
Log Octanol/water partition coefficient	-0.74	Log 10	Assessment Report L-(+)-lactic acid Product-type 02, 03 and 04, June 2017
Organic carbon/water partition coefficient (Koc)	20	l/kg	

Henry's Law Constant (at 20°C)	3.60E-05	Pa/m ³ /mol	
Biodegradability	Readily biodegradable	-	Failing the 10 days window criterion
Rate constant for STP	0.3	h ⁻¹	Assessment Report L-(+)-lactic acid Product-type 02, 03 and 04, June 2017
ktotal (0.2 m relevant for STP)	2.61E-02	d ⁻¹	Worst case value
DT ₅₀ for degradation in soil (at 12°C)	30	d	30d as refinement for 90d value in AR

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
Air	2.50E-05	Simple treat v4.0
Water	22.5	
Sludge	0.20	
Degraded in STP	77.3	

Calculated PEC values

Summary table on calculated PEC values						
	PEC _{STP}	PEC _{water}	PEC _{sed} (EPM covered by water)	PEC _{soil}	PEC _{GW}	PEC _{air}
	[mg/L]	[mg/l]	[mg/kg _{wwt}]	[mg/kg _{wwt}]	[µg/l]	[mg/m ³]
Indoor uses – PT02						
PT02 – Scenario 1: Disinfectants used for sanitary purposes (tonnage)	Covered by the consumption approach - Refer to confidential Annex					
PT02 – Scenario 2: Disinfectants used for sanitary purposes (consumption)	6.83E-02	6.83E-03	n.r	1.57E-03	1.01	n.r
PT02 – Scenario 3: Disinfectants used in industrial areas – large scale	1.95E-01	1.95E-02	n.r	4.48E-03	2.90	n.r
PT02 – Scenario 4: Medical sector - Room, furnitures and objects (tonnage)	Covered by the consumption approach - Refer to confidential Annex					
PT02 – Scenario 5: Medical sector - Room, furnitures and objects (consumption)	7.32E-02	7.32E-03	n.r	1.68E-03	1.09	n.r

PT02 – Scenario 6: Medical - Disinfection of surfaces or equipment by immersion		5.86E-01	5.86E-02	n.r	1.35E-02	8.69	n.r
Outdoor uses – PT02 (covering PT03 and 04)							
Scenario 1: urban areas, STP		3.71E-01	3.71E-02	n.r	8.51E-03	5.50	n.r
Scenario 2: urban areas, separate sewer system		n.r	5.49E-01	n.r	n.r	n.r	n.r
Scenario 3: Rural areas	Tier 1 (walls+terrace)	n.r	n.r	n.r	1.17E+01	2.49E+04	n.r
	Tier 2 (walls)	n.r	n.r	n.r	9.82	2.09E+04	n.r
	Tier 2 (terrace)	n.r	n.r	n.r	7.21	1.53E+04	n.r
Indoor uses – PT3							
PT03 – Scenario 1: Disinfection of animal housings	Via manure (Veal calves)	n.r	7.88E-02	n.r.	3.71E-01	788	n.r
	Via STP (Turkey)	3.14E-01	3.14E-02	n.r.	7.21E-03	4.66	n.r
PT03- Scenario 2: Disinfectants used for veterinary hygiene by dipping	Via manure (Veal calves)	n.r.	1.29E+01	n.r.	6.06E+01	1.29E+05	n.r.
	Via STP	1.95E-01	1.95E-02	n.r	4.48E-03	2.90	n.r
Indoor uses – PT04							
PT04 – Scenario 1: Disinfectants used in milking parlour systems		3.42E-01	3.42E-02	n.r	7.85E-03	5.07	n.r
PT04 – Scenario 2: Disinfection in large scale kitchens/canteens and slaughterhouses	Kitchens, canteens	3.90E-01	3.90E-02	n.r	8.97E-03	5.79	n.r
	Slaughterhouses	1.95	1.95E-01	n.r	4.48E-02	2.90E+01	n.r
PT04 – Scenario 3: Disinfection dipping for medium to small-scale applications in PT04		9.76E-01	9.76E-02	n.r	2.24E-02	1.45E+01	n.r

The concentration of the active substance L(+) Lactic acid in groundwater exceeds the quality standard for pesticides and biocidal products according to Directive 2006/118/EC for drinking water (0.1 µg/L). A qualitative argumentation for non performing Focus Pearl refinement is developed in the following section "Risk characterization".

Primary and secondary poisoning

Primary poisoning

As the proposed uses of BPs will not result in direct exposures to birds and mammals, the risk for the primary poisoning is considered acceptable.

Secondary poisoning

According to the L-(+)-lactic acid assessment report, the bioaccumulation potential L(+) lactic acid and thus the risk of secondary poisoning is considered to be low as indicated by the BCF_{fish} (0.048 L/kg) and the $BCF_{earthworm}$ (6.78 L/kg).

2.12.7.3 Risk characterisation

Atmosphere

Emissions and PECs in air are considered as negligible. It can be concluded that the use of the products of SALVECO SALVESAFE PRODUCTS will not pose a significant risk to the atmospheric compartment.

Sewage treatment plant (STP), Aquatic compartment, Terrestrial compartment and Groundwater

Summary table on calculated PEC/PNEC values					
	PEC/PNEC _{STP}	PEC/PNEC water	PEC/PNEC sed (EPM covered by water)	PEC/PNEC soil	PEC _{GW} (µg/L)
Indoor uses – PT2					
PT02 – Scenario 1: Disinfectants used for sanitary purposes (tonnage)	Covered by the consumption approach - Refer to confidential Annex				
PT02 – Scenario 2: Disinfectants used for sanitary purposes (consumption)	6.83E-03	1.75E-03	n.r	8.26E-04	1.01
PT02 – Scenario 3: Disinfectants used in industrial areas – large scale	1.95E-02	5.01E-03	n.r	2.36E-03	2.90
PT02 – Scenario 5: Medical sector - Room, furnitures and objects (tonnage)	Covered by the consumption approach - Refer to confidential Annex				
PT02 – Scenario 5: Medical sector - Room, furnitures and objects (consumption)	7.32E-03	1.88E-03	n.r	8.85E-04	1.09

PT02 – Scenario 6: Disinfection of surfaces or equipment by immersion		5.86E-02	1.50E-02	n.r	7.08E-03	8.69
Outdoor uses						
Scenario 1: urban areas, STP		3.71E-02	9.51E-03	n.r	4.48E-03	5.50
Scenario 2: urban areas, separate sewer system		n.r.	1.41E-01	n.r	n.r	n.r
Scenario 3: Rural areas	Tier 1 (walls and terrace)	n.r	n.r	n.r	6.16	2.49E+04
	Tier 2 (walls)	n.r	n.r	n.r	5.17	2.09E+04
	Tier 2 (terrace)	n.r	n.r	n.r	3.79	1.53E+04
Indoor uses – PT3						
PT03 – Scenario 1: Disinfection of animal housings	Via manure (Veal calves)	n.r	2.02E-02	n.r.	1.95E-01	788
	Via STP (Turkey)	3.14E-02	8.06E-03	n.r.	3.80E-03	4.66
PT03- Scenario 2: Disinfectants used for veterinary hygiene by dipping	Via manure (Veal calves)	n.r.	3.30	n.r.	3.19E+01	1.29E+05
	Via STP	1.95E-02	5.01E-03	n.r	2.36E-03	2.90
Indoor uses – PT04						
PT04 – Scenario 1: Disinfectants used in milking parlour systems		3.42E-02	8.76E-03	n.r	4.13E-03	5.07
PT04 – Scenario 2: Disinfection in large scale kitchens/canteens and slaughterhouses	Kitchens, canteens	3.90E-02	1.00E-02	n.r	4.72E-03	5.79
	Slaughterhouses	1.95E-01	5.01E-02	n.r	2.36E-02	2.90E+01
PT04 – Scenario 3: Disinfection dipping for medium to small-scale applications in PT04		9.76E-02	2.50E-02	n.r	1.18E-02	1.45E+01

Conclusions:

Emissions and PECs in air are considered as negligible. It can be concluded that the use of the products of SALVECO SALVESAFE PRODUCTS will not pose a significant risk to the atmospheric compartment.

For the groundwater (at WGII2020) and for soil (WGIII2021), it was stated that Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food

constituent and also a growth regulator intended to increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L-(+)-Lactic acid naturally occurs as a fermentation by-product of anaerobic degradation of organic matter. This substance may covalently bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD⁺ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations (Tier 1). Modelling of groundwater exposure in case of Lactic acid largely overestimates concentrations and is considered unrealistic.

For all these reasons, it can be stated that Lactic acid does not cause unacceptable risks for soil and groundwater, without need for further refined calculations.

Considering the indirect releases to the aquatic and terrestrial compartment via the STP or a separate sewer system, all the uses lead to acceptable risks. These include indoor uses for PT02 and PT04. Therefore the PT02 and 04 multi-purpose disinfectants for hard surfaces in domestic, institutional, medical and industrial areas (general, meal and milk industries) applied by spraying, spreading, foam application, brush treatment and immersion do not pose risks to the environmental compartments.

Nevertheless, for PT03 uses (in veterinary area), risks are considered unacceptable for the aquatic and terrestrial compartments when considering the scenario “Disinfectants used for veterinary hygiene by dipping” via the release of manure/slurry for the veal calves scenario. As veal calves is considered as the worst-case, a refinement is necessary. The exposure calculations are not presented but the risks are also unacceptable for all other types of animal housings for the soil compartment. The following RMM should be applied to consider the risks for the use *Multi-purpose concentrated disinfection for hard surfaces in veterinary areas by immersion* acceptable: **Do not discharge the biocidal product nor the diluted solution of the biocidal product to the manure deposit. Baths containing the product need to be removed to a sewer connected to a sewage treatment plant.** However, according to the WG I 2022, it was stated that a qualitative assessment is sufficient in case of indirect release to surface water. Therefore, the risks for PT03 uses (in veterinary area) are considered acceptable and no RMM is needed.

Considering the outdoor uses, these applications lead to risk ratios higher than 1 for the terrestrial compartment in case of direct release to soil. However, according to the WGIII2021, the risks are considered acceptable based on the argumentation on the natural occurrence of this substance in soil.

Primary and secondary poisoning

Primary poisoning

As the proposed uses of BPs will not result in direct exposures to birds and mammals, the risk for the primary poisoning is considered acceptable.

Secondary poisoning

According to the L-(+)-lactic acid assessment report, the bioaccumulation potential L-(+)-lactic acid and thus the risk of secondary poisoning is considered to be low as indicated by the BCF_{fish} (0.048 L/kg) and the $BCF_{earthworm}$ (6.78 L/kg).

Mixture toxicity

All BPs contain only one active substance. There are no substance of concern with regard to the environment. An assessment of the mixture toxicity is therefore not necessary.

Aggregated exposure (combined for relevant emission sources)

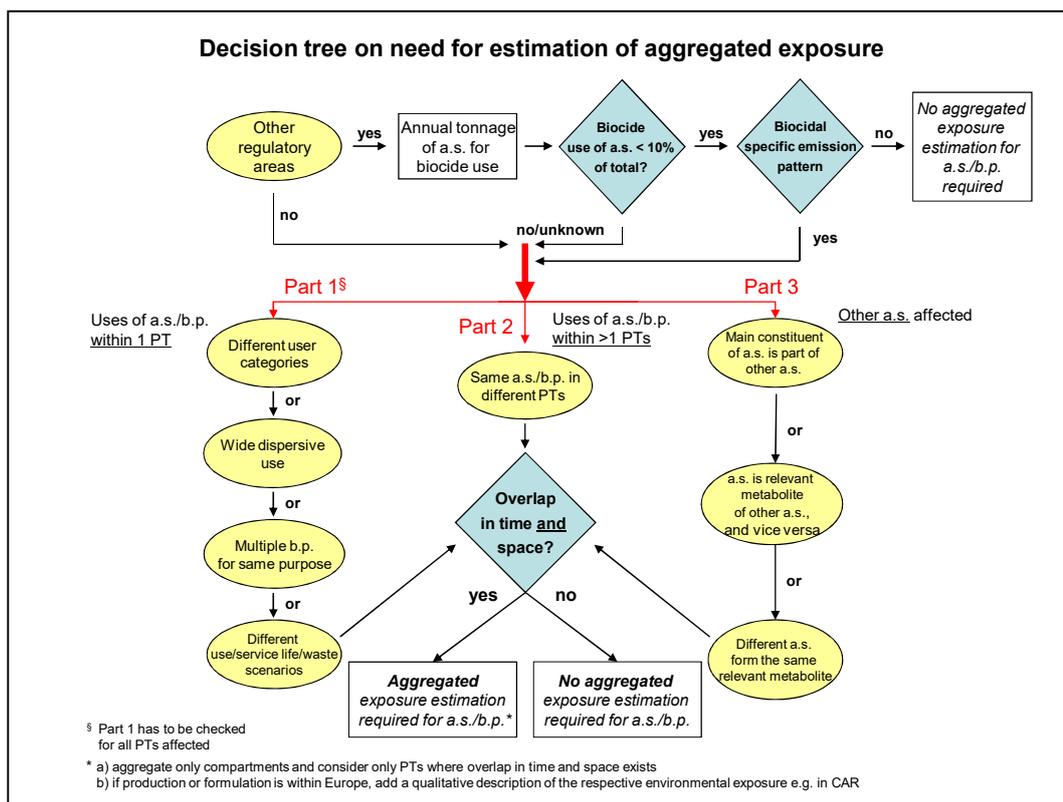


Figure 1: Decision tree on the need for estimation of aggregated exposure

As stated in the L-(+)-lactic acid assessment report, According to the " Decision tree on the need for estimation of aggregated exposure" (BIP6 . 7 Decision Tree Agg Expo) the requirement for aggregated exposure estimations was checked for L-(+)-lactic acid. L-(+)-lactic acid is also regulated in other regulatory areas (e.g. cosmetics regulation, food legislation). The amount of L-(+)-lactic acid that is used annually for biocidal purposes amounts to 5% of the total production and import volume of L-(+)-lactic acid in the EU in 2012. Thus, the biocidal use of L-(+)-lactic acid accounts for less than 10% of the total production and import volume in the EU."

The intended uses of the BPF products are widely dispersive and do not represent a specific emission pattern. Consequently, it has been concluded that no aggregated exposure assessment for a.s. L-(+)-lactic acid has to be performed.

Overall conclusion on the risk assessment for the environment of the product

Considering a worst case representative product with the maximum in-use concentration of L(+) lactic acid, all the indoor uses in PT02 and PT04 are considered acceptable for all the relevant compartments and for all the meta SPC.

Considering the indoor uses in PT03, the multi-purpose disinfectants for hard surfaces in veterinary area by immersion is considered unacceptable for the aquatic and terrestrial compartments *via* the spreading of manure/slurry to the environment. Therefore, the following RMM should be applied to consider this intended use acceptable: ***Do not discharge the biocidal product nor the diluted solution of the biocidal product to the manure deposit. Baths containing the product need to be removed to a sewer connected to a sewage treatment plant.*** However, according to the WG I 2022, it was stated that a qualitative assessment is sufficient in case of indirect release to surface water. Therefore, the risks for PT03 uses (in veterinary area) are considered acceptable and no RMM is needed.

Considering the outdoor uses in PT02 – PT03 and PT04, these applications lead to risk ratios higher than 1 for the terrestrial compartment in case of direct release to soil. However, according to the WGIII2021, the risks are considered acceptable based on the argumentation on the natural occurrence of this substance in soil.

In order to reduce unnecessary releases to the environment and for spraying application, the following RMMs should be applied: "For outdoor uses, do not apply the product in case rain is expected within 24 hrs" and "For outdoor uses, avoid transfer to other areas by wind (drift)".

2.12.8 Measures to protect man, animals and the environment

Please refer to summary of the product assessment and to the relevant sections of the assessment report.

2.12.9 Assessment of a combination of biocidal products

Not relevant

2.12.10 Comparative assessment

Not relevant

3 Annexes⁵

3.1 List of studies for the biocidal product family

Author (s)	Year Report date	Reference No. (<i>Annex III requirement</i>) / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publicati on	Source (where different from company) Study sponsor	GLP (Yes/N o)	Data Protecti on Claimed (Yes/No)
██████████ ████	████	3.1 Appearance (at 20°C and 101.3 kPa)	Appearance (at 20°C and 101.3 kPa) SALVESAFE FAM1_2	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM1_2 Report number: N °2019/039	Study report	SALVECO	No	Yes
██████████ ████	████	3.1 Appearance (at 20°C and 101.3 kPa)	Appearance (at 20°C and 101.3 kPa) SALVESAFE FAM2_3	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM2_3 Report number: N °2019/056	Study report	SALVECO	No	Yes
██████████ ████	████	3.1 Appearance (at 20°C and 101.3 kPa)	Appearance (at 20°C and 101.3 kPa) SALVESAFE FAM3_1	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM3_1 Report number: N °2019/059	Study report	SALVECO	No	Yes
██████████ ████	████	3.1 Appearance (at 20°C and 101.3 kPa)	Appearance (at 20°C and 101.3 kPa) SALVESAFE FAM3_2	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM3_1 Report number: N °2019/060	Study report	SALVECO	No	Yes

⁵ When an annex is not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

██████ ██	██████	3.1 Appearance (at 20°C and 101.3 kPa)	Appearance (at 20°C and 101.3 kPa) SALVESAFE_15	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_15 Report number: N °2019/017	Study report	SALVECO	No	Yes
██████ ██	██████	3.1 Appearance (at 20°C and 101.3 kPa)	Appearance (at 20°C and 101.3 kPa) SALVESAFE_15	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_15 Report number: N °2019/017	Study report	SALVECO	No	Yes
██████ ██	██████	3.1 Appearance (at 20°C and 101.3 kPa)	Appearance (at 20°C and 101.3 kPa) SALVESAFE FAM5_8	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM5_8 Report number: N °2019/068	Study report	SALVECO	No	Yes
██████ ██	██████	3.1 Appearance (at 20°C and 101.3 kPa)	Appearance (at 20°C and 101.3 kPa) SALVESAFE FAM6_2	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM6_2 Report number: N °2019/070	Study report	SALVECO	No	Yes
██████ ██	██████	3.2 Acidity, Alkalinity	Acidity, alkalinity and pH SALVESAFE FAM1_2	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM1_2 Report number: N °2019/039	Study report	SALVECO	No	Yes
██████ ██	██████	3.2 Acidity, Alkalinity	Acidity, alkalinity and pH SALVESAFE FAM2_3	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM2_3 Report number: N °2019/056	Study report	SALVECO	No	Yes

[REDACTED]	[REDACTED]	3.2 Acidity, Alkalinity	Acidity, alkalinity and pH SALVESAFE FAM3_1	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM3_1 Report number: 2019/059	Study report	SALVECO	No	Yes
[REDACTED]	[REDACTED]	3.2 Acidity, Alkalinity	Acidity, alkalinity and pH SALVESAFE FAM3_2	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM3_1 Report number: 2019/060	Study report	SALVECO	No	Yes
[REDACTED]	[REDACTED]	3.2 Acidity, Alkalinity	Acidity, alkalinity and pH SALVESAFE_15	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_15 Report number: N °2019/017	Study report	SALVECO	No	Yes
[REDACTED]	[REDACTED]	3.2 Acidity, Alkalinity	Acidity, alkalinity and pH SALVESAFE_FAM5_8	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM5_8 Report number: N °2019/068	Study report	SALVECO	No	Yes
[REDACTED]	[REDACTED]	3.2 Acidity, Alkalinity	Acidity, alkalinity and pH SALVESAFE_FAM6_2	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM6_2 Report number: N °2019/070	Study report	SALVECO	No	Yes
[REDACTED]	[REDACTED]	3.3 Relative density (liquids) and bulk, tap density (solids)	Relative density SALVESAFE_FAM1_2	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM1_2 Report number: N °2019/039	Study report	SALVECO	No	Yes

		3.3 Relative density (liquids) and bulk, tap density (solids)	Relative density SALVESAFE_FAM2_3	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM2_3 Report number: N°2019/056	Study report	SALVECO	No	Yes
		3.3 Relative density (liquids) and bulk, tap density (solids)	Relative density SALVESAFE_FAM3_1	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM3_1 Report number: N°2019/059	Study report	SALVECO	No	Yes
		3.3 Relative density (liquids) and bulk, tap density (solids)	Relative density SALVESAFE_FAM3_2	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM3_2 Report number: N°2019/060	Study report	SALVECO	No	Yes
		3.3 Relative density (liquids) and bulk, tap density (solids)	Relative density SALVESAFE_15	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_15 Report number: N°2019/017	Study report	SALVECO	No	Yes
		3.3 Relative density (liquids) and bulk, tap density (solids)	Relative density SALVESAFE_FAM5_8	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM5_8 Report number: N°2019/0068	Study report	SALVECO	No	Yes
		3.3 Relative density (liquids) and bulk, tap density (solids)	Relative density SALVESAFE_FAM6_2	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM6_2 Report number: N°2019/070	Study report	SALVECO	No	Yes

[REDACTED]	[REDACTED]	3.4.1 Storage stability tests	Accelerated storage stability, SALVESAFE FAM1_2	Title: ACCELERATED STORAGE STABILITY for 14 days at 54 +/- 2°C - Salvesafe_FAM1_2 Report number: N°2019/073	Study report	SALVECO	No	Yes
[REDACTED]	[REDACTED]	3.4.1 Storage stability tests	Accelerated storage stability, SALVESAFE FAM2_3	Title: ACCELERATED STORAGE STABILITY for 14 days at 54 +/- 2°C - Salvesafe_FAM2_3 Report number: N°2019/090	Study report	SALVECO	No	Yes
[REDACTED]	[REDACTED]	3.4.1 Storage stability tests	Accelerated storage stability, SALVESAFE FAM3_1	Title: ACCELERATED STORAGE STABILITY for 14 days at 54 +/- 2°C - Salvesafe_FAM3_1 Report number: 2019/093	Study report	SALVECO	No	Yes
[REDACTED]	[REDACTED]	3.4.1 Storage stability tests	Accelerated storage stability, SALVESAFE FAM3_2	Title: ACCELERATED STORAGE STABILITY for 14 days at 54 +/- 2°C - Salvesafe_FAM3_2 Report number: N°2019/094	Study report	SALVECO	No	Yes
[REDACTED]	[REDACTED]	3.4.1 Storage stability tests	Accelerated storage stability, SALVESAFE_15	Title: ACCELERATED STORAGE STABILITY for 14 days at 54 +/- 2°C - Salvesafe_15	Study report	SALVECO	No	Yes

				Report number: N° 2019/019				
██████ ██	██████	3.4.1 Storage stability tests	Accelerated storage stability, SALVESAFE FAM5_8	Title: ACCELERATED STORAGE STABILITY for 14 days at 54 +/- 2°C - Salvesafe_FAM5_8 Report number: N° 2019/102	Study report	SALVECO	No	Yes
██████ ██	██████	3.4.1 Storage stability tests	Accelerated storage stability, SALVESAFE FAM6_2	Title: ACCELERATED STORAGE STABILITY for 14 days at 54 +/- 2°C - Salvesafe_FAM6_2 Report number: N° 2019/104	Study report	SALVECO	No	Yes
██████ ██	██████	3.4.1 Storage stability tests	Long term storage stability, SALVESAFE_FAM1	Title: LONG TERM STORAGE STABILITY FOR 2 YEAR AT 23 +/- 4°C - Salvesafe_FAM1_2 Report number: N° 2019/106	Study report	SALVECO	No	Yes
██████ ██	██████	3.4.1 Storage stability tests	Long term storage stability, SALVESAFE_FAM2_3	Title: LONG TERM STORAGE STABILITY FOR 2 YEAR AT 23 +/- 4°C - Salvesafe_FAM2_3 Report number: N° 2019/107	Study report	SALVECO	No	Yes
██████ ██	██████	3.4.1 Storage stability tests	Long term storage stability, SALVESAFE_FAM3_2	Title: LONG TERM STORAGE STABILITY	Study report	SALVECO	No	Yes

				FOR 2 YEAR AT 23 +/- 4°C - Salvesafe_FAM3_2 Report number: N° 2019/108				
██████ ██	██████	3.4.1 Storage stability tests	Long term storage stability, SALVESAFE_15	Title: LONG TERM STORAGE STABILITY FOR 2 YEAR AT 23 +/- 4°C - Salvesafe_15 Report number: N° 2019/018	Study report	SALVECO	No	Yes
██████ ██	██████	3.4.1 Storage stability tests	Long term storage stability, SALVESAFE_FAM5_8	Title: LONG TERM STORAGE STABILITY FOR 2 YEAR AT 23 +/- 4°C - Salvesafe_FAM5_8 Report number: N° 2019/112	Study report	SALVECO	No	Yes
██████ ██	██████	3.4.1 Storage stability tests	Long term storage stability, SALVESAFE_FAM6_2	Title: LONG TERM STORAGE STABILITY FOR 2 YEAR AT 23 +/- 4°C - Salvesafe_FAM6_2 Report number: N° 2019/113	Study report	SALVECO	No	Yes
██████ ██	██████	3.5 Technical characteristics of the biocidal product	Persistent foaming, SALVESAFE_FAM1_2	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM1_2 Report number: N° 2019/039	Study report	SALVECO	No	Yes
██████ ██	██████	3.5 Technical characteristics of the biocidal product	Persistent foaming, SALVESAFE_FAM2_3	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM2_3	Study report	SALVECO	No	Yes

				Report number: N °2019/056				
██████ ██	██████	3.5 Technical characteristics of the biocidal product	Persistent foaming, SALVESAFE_FAM3_1	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM3_1 Report number: 2019/059	Study report	SALVECO	No	Yes
██████ ██	██████	3.5 Technical characteristics of the biocidal product	Persistent foaming, SALVESAFE_FAM3_2	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM3_2 Report number: N °2019/060	Study report	SALVECO	No	Yes
██████ ██	██████	3.5 Technical characteristics of the biocidal product	Persistent foaming, SALVESAFE_15	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_15 Report number: N °2019/017	Study report	SALVECO	No	Yes
██████ ██████ ██	██████	3.5 Technical characteristics of the biocidal product	Particle Size distribution	Title: Formula MMAD beforeaging and after-aging 12 empty bottles + pumps Report number: 15924	Study report	SALVECO	No	Yes
██████ ██████	██████	3.5 Technical characteristics of the biocidal product	Particle Size Distribution Long-term	Title: SALVESAFE FAM5_3 Long term Report number: 17125	Study report	SALVECO	No	Yes
██████ ██	██████	3.8 Surface tension	Surface tension, SALVESAFE FAM1_2	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM1_2 Report number: N °2019/039	Study report	SALVECO	No	Yes

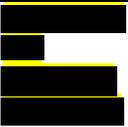
		3.8 Surface Tension	Surface tension, SALVESAFE FAM2_3	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM2_3 Report number: N °2019/056	Study report	SALVECO	No	Yes
		3.8 Surface Tension	Surface tension, SALVESAFE FAM3_1	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM3_1 Report number: N °2019/059	Study report	SALVECO	No	Yes
		3.8 Surface Tension	Surface tension, SALVESAFE FAM3_2	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM3_2 Report number: N °2019/060	Study report	SALVECO	No	Yes
		3.8 Surface Tension	Surface tension, SALVESAFE_15	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_15 Report number: N °2019/017	Study report	SALVECO	No	Yes
		3.8 Surface Tension	Surface tension, SALVESAFE FAM5_8	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM5_8 Report number: N °2019/068	Study report	SALVECO	No	Yes
		3.8 Surface Tension	Surface tension, SALVESAFE FAM6_2	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM6_2 Report number: N °2019/070	Study report	SALVECO	No	Yes

██████ ██	██████	3.9 Viscosity	Viscosity, SALVESAFE FAM1_2	Title: PHYSICOCHEMICAL ANALYSIS Salvesafe_FAM1_2 Report number: N °2019/039	Study report	SALVECO	No	Yes
██████	██████	3.9 Viscosity	Viscosity, SALVESAFE FAM2_3	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM2_3 Report number: N °2019/056	Study report	SALVECO	No	Yes
██████	██████	3.9 Viscosity	Viscosity, SALVESAFE FAM3_1	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM3_1 Report number: N °2019/059	Study report	SALVECO	No	Yes
██████	██████	3.9 Viscosity	Viscosity, SALVESAFE FAM3_2	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM3_2 Report number: N °2019/060	Study report	SALVECO	No	Yes
██████	██████	3.9 Viscosity	Viscosity, SALVESAFE_15	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_15 Report number: N °2019/017	Study report	SALVECO	No	Yes
██████	██████	3.9 Viscosity	Viscosity, SALVESAFE FAM5_8	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM5_8 Report number: N °2019/068	Study report	SALVECO	No	Yes

		3.9 Viscosity	Viscosity, SALVESAFE FAM6_2	Title: PHYSICOCHEMICAL ANALYSIS - Salvesafe_FAM6_2 Report number: N °2019/070	Study report	SALVECO	No	Yes
		4.6 Flammable liquids	Flammable liquids, SALVESAFE FAM1_2	Title: Flash point SALVESAFE FAM1_2 Report number: RNC20-03649.001	Study report	SALVECO	No	Yes
		4.8 Self-reactive substances and mixtures	Self-reactive substances and mixtures	Title: DSC Analysis	Study report	SALVECO	No	Yes
		4.16 Corrosive to metals	Corrosive to metals,2020,Metas 1-7	Title: Metal corrosion test for CLP-directive on product "MAX CONC AMM" Report number: JC_20-235- 1 final 200622	Study report	SALVECO	No	Yes
		4.16 Corrosive to metals	Corrosive to metals,2020,Metas 8-9	Title: Metal corrosion test for CLP-directive on product "MAX PAE AMM" Report number: JC_20-235- 2 final 200622	Study report	SALVECO	No	Yes
		4.16 Corrosive to metals	Corrosive to metals 28 days, Metas 1-7	Title: Metal corrosion test on product Max Conc AMM for 28 days Report number: 21/431-1	Study report	SALVECO	No	Yes

[REDACTED]	[REDACTED]	4.16 Corrosive to metals	Corrosive to metals 28 days, Metas 1-7	Title: Metal corrosion test on product Max PAE AMM for 28 days Report number: 21/431-2	Study report	SALVECO	No	Yes
[REDACTED]	[REDACTED]	4.17.1 Auto-ignition temperature (liquids and gases)	Auto-ignition temperature (liquids and gases)	Title : B35 V23.5 Cool Mint Lot :16540052020 – Température d’auto-inflammation Report number : R/20/20704	Study report	SALVECO	No	Yes
[REDACTED]	[REDACTED]	5 Methods of detection and identification	Methods of detection and identification, 2019	Title: Validation of HPLC method for the quantification of lactic acid	Study report	SALVECO	No	Yes
[REDACTED]	[REDACTED]	5 Methods of detection and identification	Methods of detection and identification, 2020	Title: Validation of LC/MS method for the quantification of substance of concern in samples Report number: 2020/054	Study report	SALVECO	No	Yes
[REDACTED]	[REDACTED]	6.7 Efficacy data to support these claims	1_Bactericide EN1276_EN13727_SalveSafe_FAM3_1_phase2 step1	Title: SalveSafe Food Bactericidal activity EN1276 Report number: A 18257-1	Study report	SALVECO	Yes	Yes
[REDACTED]	[REDACTED]	6.7 Efficacy data to support these claims	2_Bactericide_Yeasticide EN 13697_SalveSafe_FAM3_1_phase2 step2	Title : SalveSafe Food Bactericidal and yeasticidal activity EN 13697 (under EN13727 medical dirty conditions) Report number: 190299.V2	Study report	SALVECO	Yes	Yes

		6.7 Efficacy data to support these claims	3_Bactericide EN13727_SalveSafe_FAM3_1_phase2 step1	Title: RAPPORT D'ESSAI N °1071/0219 Report number: RE-1072/0219	Study report	SALVECO	Yes	Yes
		6.7 Efficacy data to support these claims	4_Bactericide_Yeasticide EN 13697_milk_SalveSafe_FAM3_1_phase2 step2	Title : RAPPORT D'ESSAI N °RE-1071/0219 Report number: RE-1071/0219	Study report	SALVECO	Yes	Yes
		6.7 Efficacy data to support these claims	5_Bactericide_ EN 13697_SalveSafe_15_phase2 step2	Title: SalveSafe 15 Bactericidal activity EN 13697 Report number: 190420.VI	Study report	SALVECO	Yes	Yes
		6.7 Efficacy data to support these claims	6_Bactericide_EN1276_SalveSafe15_phase2 step1	Title: SalveSafe 15 bactericidal activity - EN 1276- Report number: 190112.VI	Study report	SALVECO	Yes	Yes
		6.7 Efficacy data to support these claims	7_Yeasticide EN 1650_EN 13624_SalveSafe_FAM3_1_phase2 step1	Title: SalveSafe Food - Yeasticidal activity EN1650 Report number: A 18257-2	Study report	SALVECO	Yes	Yes
		6.7 Efficacy data to support these claims	8_Yeasticide EN 13624_SalveSafe_FAM3_1_phase2 step1	Title: SalveSafe Food yeasticidal efficacy (EN13624) Report number: 190357.VI	Study report	SALVECO	Yes	Yes
		6.7 Efficacy data to support these claims	9_Yeasticide EN1650_SalveSafe_15_phase2step1	Title: Final report PFechant - Cleaner Disinfectant Report number: 775.17-1 EN 1650 PB 2	Study report	SALVECO	Yes	Yes

		6.7 Efficacy data to support these claims	10_Yeasticide EN 13697_SalveSafe_15_phase2 step2	Title: Salve Safe 15 yeasticidal activity (EN13697) Report number: A 18264	Study report	SALVECO	Yes	Yes
		6.7 Efficacy data to support these claims	11_Antiviral agent EN 14476_SalveSafe_15_phase2 step1	Title: Efficacy of SalveSafe 15 against the modified vaccinia virus Ankara in the virucidal quantitative suspension test for chemical disinfectants and antiseptics Report number : LI-019-044	Study report	SALVECO	Yes	Yes
		6.7 Efficacy data to support these claims	12_Bactericide_EN1656_SalveSafe Food 10	Title : Evaluation of the bactericidal activity according to the NF EN 1656 : 2010 standard. Product:SalveSafe Food 10. Batch: 9810052019 Report number: Test report n° RE19-126-1	Study report	SALVECO	Yes	Yes
		6.7 Efficacy data to support these claims	13_Bactericide_EN14349_SalveSafe Food 10	Title : Evaluation of the bactericidal activity according to the NF EN 14349 : 2012 standard Product : SalveSafe Food 10 Batch : 9810052019 Report number: Test report n° RE19-128-2	Study report	SALVECO	Yes	Yes

██████████ ██████████	██████████	6.7 Efficacy data to support these claims	14_Yeasticide_EN1657_SalveSafe Food 10	Title : Evaluation of the yeasticidal activity according to the NF EN 1657 : 2006 standard Product : SalveSafe Food 10 Batch : 9810052019 Report number: Test report n° RE19-127-1	Study report	SALVECO	Yes	Yes
██████████ ██████████	██████████	6.7 Efficacy data to support these claims	15_Yeasticide_EN16438_SalveSafe Food 10	Title : Evaluation of the yeasticidal activity according to the NF EN 16438 : 2014 standard Product : SalveSafe Food 10 Batch : 9810052019 Report number: Test report n° RE19-129-3	Study report	SALVECO	Yes	Yes
██████████ ██████████ ██████████	██████████	Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_01 Virucide_EN16777_Sure Cleaner Disinfectant	Title: Evaluation of the effectiveness of SURE Disinfectant Cleaner - test report L20/0498MV.1 Report number: L20/0498MV.1	Study report	Diversey Europe BV	Yes	Yes

[REDACTED]	[REDACTED]	Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_02 and 02b Virucide_EN14476_Sure Cleaner Disinfectant	Title: Evaluation of the effectiveness of Sure Cleaner Disinfectant based on EN 14476:2013 + A1: 2015 (clean conditions) Report number: L19/0184MV.2	Study report	Diversey Europe Operations	Yes	Yes
[REDACTED]	[REDACTED]	Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_02 and 02b Virucide_EN14476_Sure Cleaner Disinfectant	Title: Evaluation of the Effectiveness of Sure Cleaner Disinfectant based on EN 14476:2013 +A1:2015 (3.0 g/L BSA, dirty conditions) Report number: L19/0184MV.3	Study report	Diversey Europe Operations BV	Yes	Yes
[REDACTED]	[REDACTED]	Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	DIV_03 Bactericide_EN1276 clean_Sure Cleaner Disinfectant	Title: SURE Cleaner Disinfectant EN 1276. Quantitative suspension test - bactericidal activity (phase 2, step 1) Report number: SN 23695	Study report	Diversey Europe Operations BV	Yes	Yes

		IUCLID Section No. 6.7						
		Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_04 Bactericide_EN13697_phase2 step2	Title: Sure Cleaner Disinfectant EN 13697 - Quantitative non-porous surface test – bactericidal and yeasticidal activity (phase 2, step 2) Report number: SN 20491	Study report	Diversey Europe Operations BV	Yes	Yes
		Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_05 Bactericide_EN16615_clean_phase2 step2	Title: Analytical Report: AAC81276 - Sure Cleaner Disinfectant - Quantitative test for the evaluation of the bactericidal and yeasticidal activity on nonporous surface with mechanical action employing wipes in the medical area (4-field test) - phase 2/ step 2 Report number: AAC81276	Study report	Diversey Europe BV	Yes	Yes

		Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_06 Bactericide_EN16615_dirty_phase2_step2_10°C	Title: Evaluation of activity according to PNEN 16615:2015-06 modified* Report number: DZ/29/10/20	Study report	Diversey Europe BV	Yes	Yes
		6.7 Efficacy data to support these claims	DIV_07 Yeasticide_EN1650 clean_Sure Cleaner Disinfectant	Title: EN1650 (2008) Quantitative suspension test for the evaluation of yeasticidal activity of chemical disinfectants and antiseptic used in food, industrial, domestic and institutional areas	Study report	Diversey Europe Operations BV	Yes	Yes
		Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_08 yeasticide_EN16615_clean_phase2_step2	Title: Analytical Report: AAC81335 - Sure Cleaner Disinfectant - Quantitative test for the evaluation of the bactericidal and yeasticidal activity on nonporous surface with mechanical action employing wipes in the medical area (4-field test) - phase 2/	Study report	Diversey Europe BV	Yes	Yes

				step 2 Report number: AAC81335				
██████████ ██████████	██████████	Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_09 yeasticide_EN16615_dirty_phase2 step2	Title : Analytical Report: AAC81299 - Sure Cleaner Disinfectant - Quantitative test for the evaluation of the bactericidal and yeasticidal activity on nonporous surface with mechanical action employing wipes in the medical area (4-field test) - phase 2/ step 2 Report number: AAC81299	Study report	Diversey Europe BV	Yes	Yes
██████████ ██████████ ██████████	██████████	Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_10 Yeasticide_EN13697_phase2 step2	Title: Analytical Report: AAC98931, Eurofins Number: STULV19AA1500-1, Version: 1 Report number: Analytical Report: AAC98931, Eurofins Number: STULV19AA1500-1, Version: 1	Study report	Diversey Europe BV	Yes	Yes

		Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_11 Bactericide_EN1656_QST_phase2 step1	Title: Analytical Report: AAD02986, Eurofins Number: STULV19AA1496-1, Version: 1 Report number: Analytical Report: AAD02986, Eurofins Number: STULV19AA1496-1, Version: 1	Study report	Diversey Europe BV	Yes	Yes
		Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_12 Bactericide_EN1656_QST_phase2 step1_2contact times	Title: Analytical Report: AAD02873, Eurofins Number: STULV19AA1495-1, Version: 1 Report number: Analytical Report: AAD02873, Eurofins Number: STULV19AA1495-1, Version: 1	Study report	Diversey Europe BV	Yes	Yes
		6.7 Efficacy data to support these claims	DIV_13 Bactericide_EN14349_phase2 step2_2contact times	Title: SURE CLEANER DISINFECTANTS - EN 14349 – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on	Study report	Diversey Europe BV	Yes	Yes

				non-porous surfaces without mechanical action Report number: AAD03170				
██████████ ██████████	██████████	Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_13b Bactericide_EN14349_phase2_step2_10°C	Title: Sure CleanerDisinfectant - FM10672, EN14349 Bactericidal	Study report	Diversey Europe Operations BV	Yes	Yes
██████████ ██████████ ██████████	██████████	Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	IUCLID Document name: 6.7-DIV_14 EN 1657_10°C	Title: Analytical Report: AAD03181, Eurofins Number: STULV19AA1501-1, Version: 1 Report no. Analytical Report: AAD03181, Eurofins Number: STULV19AA1501-1, Version: 1	Type of publication: study report	Company Owner: DIVERSEY EUROPE BV	no	Yes
██████████ ██████████	██████████	Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory	DIV_15 Yeasticide_EN16438_phase2_step2_10°C	Title: Analytical report AAD03254-Sure Cleaner Disinfectant - Quantitative surface test for the evaluation	Study report	Diversey Europe BV	Yes	Yes

		tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7		of fungicidal and yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical act Report number: AAD03254				
██████ ██	██████	6.7 Efficacy data to support these claims	16_Bactericide_EN1276_SalveSafe15_MAX_phase2_step1-copy	Title : Evaluation de l'activité bactéricide selon la norme NF EN 1276 : 2019 Produit : SalveSafe 15 Max Report number: n° RE20-0670-2	Study report	SALVECO	Yes	Yes
██████ ██	██████	6.7 Efficacy data to support these claims	17_Bactericide_EN13727_SalveSafe_Food_Max_phase2_step1	Title: Essai de suspension pour l'évaluation de l'activité bactéricide selon la norme NF EN 13727 : 2015 Produit : SalveSafe Food Max Report number: n° RE20-0669-2	Study report	SALVECO	Yes	Yes
██████ ██	██████	6.7 Efficacy data to support these claims	18_Bactericide & yeasticide_EN16615_dirty_phase2_step2_20°C	Title: Evaluation of the bactericidal and yeasticidal activity according to the NF EN 16615 : 2015 standard Product : SalveSafe food. Partial test against the strains: Candida albicans and	Study report	SALVECO	Yes	Yes

				Enterococcus hirae Report number: RE20-1083-1				
██████████ ██████████	██████████	6.7 Efficacy data to support these claims	19_ Bactericide & yeasticide_EN16615_dirty_phase2 step2_20°C	Title: Evaluation of the bactericidal and yeasticidal activity according to the NF EN 16615 : 2015 Standard Product: SalveSafe Food Report number: RE20-1462-1	Study report	SALVECO	Yes	Yes
██████████ ██████████ ██████████	██████████	6.7 Efficacy data to support these claims	20_Virucide_EN16777_Cleaner disinfectant_phase2 step2	Title : Evaluation of the effectiveness of Cleaner disinfectant - Test report L21/0574MV.1 Report number: L21/0574MV.1	Study report	SALVECO	Yes	Yes
██████████ ██████████ ██████████	██████████	6.7 Efficacy data to support these claims	21_Virucide_EN16777_SalveSafe Food_phase2 step2	Title : Evaluation of the effectiveness of SalveSafe Food - Test report L21/00828MV.1 Report number: L21/00828MV.1	Study report	SALVECO	Yes	Yes
██████████ ██████████	██████████	8.1.1 Skin irritation / corrosion	META-SPC 1, Skin irritation / corrosion, Colas, 2011	Title: Assessment of acute dermal irritation Report number: ICOCDE-PH-11/0117	Study report	SALVECO	Yes	Yes
██████████ ██████████	██████████	8.1.1 Skin irritation / corrosion	META-SPC 2, Skin irritation / corrosion, Colas, 2011	Title: Assessment of acute dermal irritation Report number: ICOCDE-	Study report	SALVECO	Yes	Yes

				PH-11/0117				
██████	██████	8.1.1 Skin irritation / corrosion	META-SPC 3, Skin irritation / corrosion, Colas, 2011	Title: Assessment of acute dermal irritation Report number: ICOCDE-PH-11/0117	Study report	SALVECO	Yes	Yes
██████	██████	8.1.1 Skin irritation / corrosion	META-SPC 4, Skin irritation / corrosion, Colas, 2011	Title: Assessment of acute dermal irritation Report number: ICOCDE-PH-11/0117	Study report	SALVECO	Yes	Yes
██████	██████	8.1.1 Skin irritation / corrosion	META-SPC 5, Skin irritation / corrosion, Colas, 2011	Title: Assessment of acute dermal irritation Report number: ICOCDE-PH-11/0117	Study report	SALVECO	Yes	Yes
██████	██████	8.1.1 Skin irritation / corrosion	META-SPC 6, Skin irritation / corrosion, Colas, 2011	Title: Assessment of acute dermal irritation Report number: ICOCDE-PH-11/0117	Study report	SALVECO	Yes	Yes
██████	██████	8.1.1 Skin irritation / corrosion	META-SPC 6, Skin irritation / corrosion, Colas, 2011	Title: Assessment of acute dermal irritation Report number: ICOCDE-PH-11/0117	Study report	SALVECO	Yes	Yes

██████	██████	8.1.1 Skin irritation / corrosion	META-SPC 7, Skin irritation / corrosion, Colas, 2011	Title: Assessment of acute dermal irritation Report number: ICOCDE-PH-11/0117	Study report	SALVECO	Yes	Yes
██████	██████	8.1.1 Skin irritation / corrosion	META-SPC 8, Skin irritation / corrosion, Gomond, 2007	Title: Evaluation de l'effet irritant/corrosif aigu sur la peau chez le lapin - Elément d'essai: BASE 34 VERSION 7.6c M Report number: Tn 268/07-1698	Study report	SALVECO	Yes	Yes
██████	██████	8.1.1 Skin irritation / corrosion	META-SPC 9, Skin irritation / corrosion, Gomond, 2007	Title: Evaluation de l'effet irritant/corrosif aigu sur la peau chez le lapin - Elément d'essai: BASE 34 VERSION 7.6c M Report number: Tn 268/07-1698	Study report	SALVECO	Yes	Yes
██████	██████	8.1.2 Eye irritation	META-SPC 1, Eye irritation, Waiver	Title: Guidance on the Application of the CLP Criteria - Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures	Guidance		No	No
██████	██████	8.1.2 Eye irritation	META-SPC 2, Eye irritation, Waiver	Title: Guidance on the Application of the CLP Criteria - Guidance to	Guidance		No	No

				Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures				
████	████	8.1.2 Eye irritation	META-SPC 3, Eye irritation, Waiver	Title: Guidance on the Application of the CLP Criteria - Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures	Guidance		No	No
████	████	8.1.2 Eye irritation	META-SPC 4, Eye irritation, Waiver	Title: Guidance on the Application of the CLP Criteria - Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures	Guidance		No	No
████	████	8.1.2 Eye irritation	META-SPC 5, Eye irritation, Waiver	Title: Guidance on the Application of the CLP Criteria - Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and	Guidance		No	No

				mixtures				
████	████	8.1.2 Eye irritation	META-SPC 6, Eye irritation, Waiver	Title: Guidance on the Application of the CLP Criteria - Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures	Guidance		No	No
████	████	8.1.2 Eye irritation	META-SPC 7, Eye irritation, Waiver	Title: Guidance on the Application of the CLP Criteria - Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures	Guidance		No	No
████	████	8.1.2 Eye irritation	META-SPC 8, Eye irritation, Richeux, 2017	Title: Solution désinfectante Assessment of acute eye irritation/ corrosion Report number : IO-OCDE-PH-17/0206	Study report	SALVECO	Yes	Yes
████	████	8.1.2 Eye irritation	META-SPC 9, Eye irritation, Richeux, 2017	Title: Solution désinfectante Assessment of acute eye irritation/ corrosion	Study report	SALVECO	Yes	Yes

				Report number : IO-OCDE-PH-17/0206				
████	████	8.3.1 Skin sensitisation	Family, Skin sensitisation, waiver	Title: Guidance on the Application of the CLP Criteria - Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures	Guidance		No	No
████	████	8.3.2 Respiratory sensitisation	Family, Respiratory sensitisation, waiver	Title: Guidance on the Application of the CLP Criteria - Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures	Guidance		No	No
████	████	8.5.1 Acute toxicity: oral	Family, Acute toxicity: oral, waiver	Title: Guidance on the Application of the CLP Criteria - Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures	Guidance		No	No

[REDACTED]	[REDACTED]	8.5.2 Acute toxicity: inhalation	Family, Acute toxicity: inhalation, waiver	Title: Guidance on the Application of the CLP Criteria - Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures	Guidance		No	No
[REDACTED]	[REDACTED]	8.5.3 Acute toxicity : dermal	Family, Acute toxicity: dermal, waiver	Title: Guidance on the Application of the CLP Criteria - Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures	Guidance		No	No
[REDACTED]	[REDACTED]	8.6 Dermal absorption	Dermal Absorption	Title: Guidance on dermal absorption Report number: EFSA Journal 2017;15(6):4873, 60 pp.	Publication		No	No

[REDACTED]								
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3.2 Output tables from exposure assessment tools

3.3 New information on the active substance

3.4 Residue behaviour

Not Relevant.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)⁶

Author (s)	Year Report date	Reference No. (<i>Annex III requirement</i>) / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publicati on	Source (where different from company) Study sponsor	GLP (Yes/N o)	Data Protecti on Claimed (Yes/No)
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⁶ If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

[REDACTED]	[REDACTED]	6.7 Efficacy data to support these claims	1_Bactericide EN1276_EN13727_SalveSafe_FAM3_1_phase2 step1	Title: SalveSafe Food Bactericidal activity EN1276 Report number: A 18257-1	Study report	SALVECO	Yes	Yes
[REDACTED]	[REDACTED]	6.7 Efficacy data to support these claims	2_Bactericide_Yeasticide EN 13697_SalveSafe_FAM3_1_phase2 step2	Title : SalveSafe Food Bactericidal and yeasticidal activity EN 13697 (under EN13727 medical dirty conditions) Report number: 190299.V2	Study report	SALVECO	Yes	Yes
[REDACTED]	[REDACTED]	6.7 Efficacy data to support these claims	3_Bactericide EN13727_SalveSafe_FAM3_1_phase2 step1	Title: RAPPORT D'ESSAI N °1071/0219 Report number: RE-1072/0219	Study report	SALVECO	Yes	Yes
[REDACTED]	[REDACTED]	6.7 Efficacy data to support these claims	4_Bactericide_Yeasticide EN 13697_milk_SalveSafe_FAM3_1_phase2 step2	Title : RAPPORT D'ESSAI N °RE-1071/0219 Report number: RE-1071/0219	Study report	SALVECO	Yes	Yes
[REDACTED]	[REDACTED]	6.7 Efficacy data to support these claims	5_Bactericide_EN 13697_SalveSafe_15_phase2 step2	Title: SalveSafe 15 Bactericidal activity EN 13697 Report number: 190420.VI	Study report	SALVECO	Yes	Yes
[REDACTED]	[REDACTED]	6.7 Efficacy data to support these claims	6_Bactericide_EN1276_SalveSafe15_phase2 step1	Title: SalveSafe 15 bactericidal activity - EN 1276- Report number: 190112.VI	Study report	SALVECO	Yes	Yes
[REDACTED]	[REDACTED]	6.7 Efficacy data to support these claims	7_Yeasticide EN 1650_EN 13624_SalveSafe_FAM3_1_phase2 step1	Title: SalveSafe Food - Yeasticidal activity EN1650 Report number: A	Study report	SALVECO	Yes	Yes

				18257-2				
████████	████	6.7 Efficacy data to support these claims	8_Yeasticide EN 13624_SalveSafe_FAM3_1_phase2 step1	Title: SalveSafe Food yeasticidal efficacy (EN13624) Report number: 190357.VI	Study report	SALVECO	Yes	Yes
████████	████	6.7 Efficacy data to support these claims	9_Yeasticide EN1650_SalveSafe_15_phase2step1	Title: Final report PFechant - Cleaner Disinfectant Report number: 775.17-1 EN 1650 PB_2	Study report	SALVECO	Yes	Yes
████████ ████ ████████ ████████	████	6.7 Efficacy data to support these claims	10_Yeasticide EN 13697_SalveSafe_15_phase2 step2	Title: Salve Safe 15 yeasticidal activity (EN13697) Report number: A 18264	Study report	SALVECO	Yes	Yes
████████	████	6.7 Efficacy data to support these claims	11_Antiviral agent EN 14476_SalveSafe_15_phase2 step1	Title: Efficacy of SalveSafe 15 against the modified vaccinia virus Ankara in the virucidal quantitative suspension test for chemical disinfectants and antiseptics Report number : LI-019-044	Study report	SALVECO	Yes	Yes
████████ ████	████	6.7 Efficacy data to support these claims	12_Bactericide_EN1656_SalveSafe Food 10	Title : Evaluation of the bactericidal activity according to the NF EN 1656 : 2010 standard. Product:SalveSafe Food 10. Batch:	Study report	SALVECO	Yes	Yes

				9810052019 Report number: Test report n° RE19-126-1				
██████████ ████	██████	6.7 Efficacy data to support these claims	13_Bactericide_EN14349_SalveSafe Food 10	Title : Evaluation of the bactericidal activity according to the NF EN 14349 : 2012 standard Product : SalveSafe Food 10 Batch : 9810052019 Report number: Test report n° RE19-128-2	Study report	SALVECO	Yes	Yes
██████████ ██	██████	6.7 Efficacy data to support these claims	14_Yeasticide_EN1657_SalveSafe Food 10	Title : Evaluation of the yeasticidal activity according to the NF EN 1657 : 2006 standard Product : SalveSafe Food 10 Batch : 9810052019 Report number: Test report n° RE19-127-1	Study report	SALVECO	Yes	Yes
██████████ ██	██████	6.7 Efficacy data to support these claims	15_Yeasticide_EN16438_SalveSafe Food 10	Title : Evaluation of the yeasticidal activity according to the NF EN 16438 : 2014 standard Product : SalveSafe Food 10 Batch : 9810052019 Report number: Test report n° RE19-129-3	Study report	SALVECO	Yes	Yes

		Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_01 Virucide_EN16777_Sure Cleaner Disinfectant	Title: Evaluation of the effectiveness of SURE Disinfectant Cleaner - test report L20/0498MV.1 Report number: L20/0498MV.1	Study report	Diversey Europe BV	Yes	Yes
		Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_02 and 02b Virucide_EN14476_Sure Cleaner Disinfectant	Title: Evaluation of the effectiveness of Sure Cleaner Disinfectant based on EN 14476:2013 + A1: 2015 (clean conditions) Report number: L19/0184MV.2	Study report	Diversey Europe Operations	Yes	Yes
		Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and	DIV_02 and 02b Virucide_EN14476_Sure Cleaner Disinfectant	Title: Evaluation of the Effectiveness of Sure Cleaner Disinfectant based on EN 14476:2013 +A1:2015 (3.0 g/L BSA, dirty conditions) Report number: L19/0184MV.3	Study report	Diversey Europe Operations BV	Yes	Yes

		relevant IUCLID Section No. 6.7						
██████ ██████ ██████	██████	Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_03 Bactericide_EN1276 clean_Sure Cleaner Disinfectant	Title: SURE Cleaner Disinfectant EN 1276. Quantitative suspension test - bactericidal activity (phase 2, step 1) Report number: SN 23695	Study report	Diversey Europe Operations BV	Yes	Yes
██████ ██████ ██████	██████	Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_04 Bactericide_EN13697_phase2 step2	Title: Sure Cleaner Disinfectant EN 13697 - Quantitative non-porous surface test – bactericidal and yeasticidal activity (phase 2, step 2) Report number: SN 20491	Study report	Diversey Europe Operations BV	Yes	Yes
██████ ██████	██████	Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used	DIV_05 Bactericide_EN16615_clean_phase2 step2	Title: Analytical Report: AAC81276 - Sure Cleaner Disinfectant - Quantitative test for the evaluation of the bactericidal	Study report	Diversey Europe BV	Yes	Yes

		including performance standards where appropriate and relevant IUCLID Section No. 6.7		and yeasticidal activity on nonporous surface with mechanical action employing wipes in the medical area (4-field test) - phase 2/ step 2 Report number: AAC81276				
		Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_06 Bactericide_EN16615_dirty_phase2_step2_10°C	Title: Evaluation of activity according to PNEN 16615:2015-06 modified* Report number: DZ/29/10/20	Study report	Diversey Europe BV	Yes	Yes
		6.7 Efficacy data to support these claims	DIV_07 Yeasticide_EN1650 clean_Sure Cleaner Disinfectant	Title: EN1650 (2008) Quantitative suspension test for the evaluation of yeasticidal activity of chemical disinfectants and antiseptic used in food, industrial, domestic and institutional areas	Study report	Diversey Europe Operations BV	Yes	Yes

		<p>Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant</p> <p>IUCLID Section No. 6.7</p>	<p>DIV_08 yeasticide_EN16615_clean_phase2 step2</p>	<p>Title: Analytical Report: AAC81335 - Sure Cleaner Disinfectant - Quantitative test for the evaluation of the bactericidal and yeasticidal activity on nonporous surface with mechanical action employing wipes in the medical area (4-field test) - phase 2/ step 2 Report number: AAC81335</p>	<p>Study report</p>	<p>Diversey Europe BV</p>	<p>Yes</p>	<p>Yes</p>
		<p>Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant</p> <p>IUCLID Section No. 6.7</p>	<p>DIV_09 yeasticide_EN16615_dirty_phase2 step2</p>	<p>Title : Analytical Report: AAC81299 - Sure Cleaner Disinfectant - Quantitative test for the evaluation of the bactericidal and yeasticidal activity on nonporous surface with mechanical action employing wipes in the medical area (4-field test) - phase 2/ step 2 Report number: AAC81299</p>	<p>Study report</p>	<p>Diversey Europe BV</p>	<p>Yes</p>	<p>Yes</p>
		<p>Annex II/III requirement: Efficacy data to support these claims, including any available standard</p>	<p>DIV_10 Yeasticide_EN13697_phase2 step2</p>	<p>Title: Analytical Report: AAC98931, Eurofins Number: STULV19AA1500-1, Version: 1</p>	<p>Study report</p>	<p>Diversey Europe BV</p>	<p>Yes</p>	<p>Yes</p>

		protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7		Report number: Analytical Report: AAC98931, Eurofins Number: STULV19AA1500-1, Version: 1				
		Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_11 Bactericide_EN1656_QST_phase2 step1	Title: Analytical Report: AAD02986, Eurofins Number: STULV19AA1496-1, Version: 1 Report number: Analytical Report: AAD02986, Eurofins Number: STULV19AA1496-1, Version: 1	Study report	Diversey Europe BV	Yes	Yes
		Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_12 Bactericide_EN1656_QST_phase2 step1_2contact times	Title: Analytical Report: AAD02873, Eurofins Number: STULV19AA1495-1, Version: 1 Report number: Analytical Report: AAD02873, Eurofins Number: STULV19AA1495-1, Version: 1	Study report	Diversey Europe BV	Yes	Yes

[REDACTED]	[REDACTED]	6.7 Efficacy data to support these claims	DIV_13 Bactericide_EN14349_phase2 step2_2contact times	Title: SURE CLEANER DISINFECTANTS - EN 14349 – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on non-porous surfaces without mechanical action Report number: AAD03170	Study report	Diversey Europe BV	Yes	Yes
[REDACTED]	[REDACTED]	Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_13b Bactericide_EN14349_phase2 step2_10°C	Title: Sure CleanerDisinfectant - FM10672, EN14349 Bactericidal	Study report	Diversey Europe Operations BV	Yes	Yes
[REDACTED]	[REDACTED]	Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where	IUCLID Document name: 6.7-DIV_14 EN 1657_10°C	Title: Analytical Report: AAD03181, Eurofins Number: STULV19AA1501-1, Version: 1 Report no. Analytical Report: AAD03181, Eurofins Number:	Type of publication: study report	Company Owner: DIVERSEY EUROPE BV	no	Yes

		appropriate and relevant IUCLID Section No. 6.7		STULV19AA1501-1, Version: 1				
██████ ██	██████	Annex II/III requirement: Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant IUCLID Section No. 6.7	DIV_15 Yeasticide_EN16438_phase2_step2_10°C	Title: Analytical report AAD03254- Sure Cleaner Disinfectant - Quantitative surface test for the evaluation of fungicidal and yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical act Report number: AAD03254	Study report	Diversey Europe BV	Yes	Yes
██████ ██	██████	6.7 Efficacy data to support these claims	16_Bactericide_EN1276_SalveSafe15_MAX_phase2_step1-copy	Title : Evaluation de l'activité bactéricide selon la norme NF EN 1276 : 2019 Produit : SalveSafe 15 Max Report number: n° RE20-0670-2	Study report	SALVECO	Yes	Yes
██████ ██	██████	6.7 Efficacy data to support these claims	17_Bactericide_EN13727_SalveSafe_Food_Max_phase2_step1	Title: Essai de suspension pour l'évaluation de l'activité bactéricide selon la norme NF EN 13727 : 2015 Produit : SalveSafe Food Max Report number: n°	Study report	SALVECO	Yes	Yes

				RE20-0669-2				
██████████ ██████████	██████████	6.7 Efficacy data to support these claims	18_ Bactericide & yeasticide_EN16615_dirty_phase2 step2_20°C	Title: Evaluation of the bactericidal and yeasticidal activity according to the NF EN 16615 : 2015 standard Product : SalveSafe food. Partial test against the strains: Candida albicans and Enterococcus hirae Report number: RE20-1083-1	Study report	SALVECO	Yes	Yes
██████████ ██████████	██████████	6.7 Efficacy data to support these claims	19_ Bactericide & yeasticide_EN16615_dirty_phase2 step2_20°C	Title: Evaluation of the bactericidal and yeasticidal activity according to the NF EN 16615 : 2015 Standard Product: SalveSafe Food Report number: RE20-1462-1	Study report	SALVECO	Yes	Yes
██████████ ██████████ ██████████	██████████	6.7 Efficacy data to support these claims	20_Virucide_EN16777_Cleaner disinfectant_phase2 step2	Title : Evaluation of the effectiveness of Cleaner disinfectant - Test report L21/0574MV.1 Report number: L21/0574MV.1	Study report	SALVECO	Yes	Yes
██████████ ██████████ ██████████	██████████	6.7 Efficacy data to support these claims	21_Virucide_EN16777_SalveSafe Food_phase2 step2	Title : Evaluation of the effectiveness of SalveSafe Food - Test report L21/00828MV.1	Study report	SALVECO	Yes	Yes

				Report number: L21/00828MV.1				
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3.6 Confidential annex

See confidential PAR.

3.7 Other