

## **Biocidal Products Committee (BPC)**

Opinion on the Union authorisation of the biocidal product family:

### **SALVECO SALVESAFE PRODUCTS**

ECHA/BPC/346/2022

Adopted

15 June 2022



## Opinion of the Biocidal Products Committee

### on the Union authorisation of SALVECO SALVESAFE PRODUCTS

In accordance with Article 44(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the Union authorisation of:

<b>Name of the biocidal product:</b>	<b>SALVECO SALVESAFE PRODUCTS</b>
<b>Authorisation holder:</b>	<b>SALVECO S.A.S.</b>
<b>Active substance common name:</b>	<b>L-(+)-lactic acid (CAS number 79-33-4)</b>
<b>Product types:</b>	<b>PT 2, 3 and 4</b>

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

### Process for the adoption of BPC opinions

Following the submission of an application on the 26 April 2019, recorded in R4BP3 under case number BC-HC051278-51, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 7 January 2022. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-43) and its Working Groups (WG I 2022). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

## **Adoption of the BPC opinion**

### **Rapporteur: France**

The BPC opinion on the Union authorisation of the biocidal product family was reached on 15 June 2022.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority position are published on the ECHA website.

## Detailed BPC opinion and background

### 1. Overall conclusion

The overall conclusion of the BPC is that the biocidal product family is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(1)(s).

The biocidal product family meets the conditions laid down in Article 19(6) of Regulation (EU) No 528/2012 and therefore may be authorised. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of SALVECO SALVESAFE PRODUCTS referred to in Article 22(2) of Regulation (EU) No 528/2012.

### 2. BPC Opinion

#### 2.1 BPC 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%

Meta SPC	Uses	User category		Technical AS concentration
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 SPCs 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°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) in clean conditions (without mechanical action):

- Mandatory target organisms:
  - Bacteria and yeasts: 0.299% w/w L-(+)-lactic acid, 30 min, 10°C

Claimed 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 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

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 (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 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°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) 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% 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°C

Claimed 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 SPCs could claim products with less in-use surfactants than the representative products tested in the efficacy studies (see confidential part of the PAR) and for which no information on the impact on efficacy were provided. Therefore, it is considered that a general instruction for use should be added in the SPC for these Meta SPCs (Meta SPC 1, Meta SPC 2, Meta SPC 3 and Meta SPC 4) indicating that "Minimum in-use concentration of surfactants should be 0.29%."

### **Human health**

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

<b>Classification of product family (meta SPC 8 &amp; 9)</b>	
Hazard category	N.A.
Hazard statement	N.A.

#### 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 could 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, indeed Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. The environment is exposed to Lactic acid via the excretion of faeces and urine by humans, as well as the direct disposal of excreta by other animals (and their subsequent release from the STPs). Therefore, the risks for PT03 uses (in veterinary area) are considered acceptable and no RMM is needed.

Considering the outdoor uses in PT 2-4, 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 for spraying, spreading, wiping, foaming, brush treatment, and mopping application methods, the following RMM should be applied: "For outdoor uses, do not apply the product in case rain is expected within 24 hours". For spraying applications, the following RMM should be applied as well "For outdoor uses, avoid transfer to other areas by wind (drift)".

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

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 not considered a candidate 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 Regulation (EU) No 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 and outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping  Non-professional and professional	Acceptable with RMM*	
		Yeast				
		Enveloped virus				
	4	Bacteria				
		Yeast				
2	2	Bacteria	0.299% to 1.496% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor and outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping  Non-professional and professional	Acceptable with RMM*	
		Yeast				
		Enveloped virus				
	4	Bacteria				
		Yeast				
3	2	Bacteria	0.299% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor and outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping  Professional	Acceptable with RMM*	
		Yeast				
		Enveloped virus				
	4	Bacteria				
		Yeast				
4	2	Bacteria	0.299% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor and outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping  Professional	Acceptable with RMM*	
		Yeast				
		Enveloped virus				
	4	Bacteria				
		Yeast				
5	2	Bacteria	0.4485% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor and 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 and outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping without mechanical action	Acceptable with RMM*
			Yeast			
			Enveloped virus			

Meta-SPC	PT	Target organism	Application rates	Use condition	Conclusion	
	4	Bacteria	0.4485% to 0.598% w/w L-(+)-lactic acid, 5 min, 20°C	Professional	Minimum application rate not acceptable for milk industries: efficacy not demonstrated.	
				Indoor and outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping Professional		
		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 and outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping Professional	Acceptable with RMM*	
		Yeast				
		3	Bacteria	0.299% w/w L-(+)-lactic acid, 30 min, 10°C		Acceptable with RMM*
Yeast						
6	2	Bacteria	0.4485% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor and 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 and outdoor Application by Spraying, spreading, wiping, foam application, brushing, dipping, mopping without mechanical action Professional	Acceptable with RMM*
			Yeast			
		Enveloped virus				
7	2	Bacteria	0.299% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor and outdoor Application by wiping, mopping or brushing, spraying, soaking or dipping	Acceptable with RMM*	
		Yeast				

Meta-SPC	PT	Target organism	Application rates	Use condition	Conclusion
		Enveloped virus		(immersion) without mechanical action Professional	
	4	Bacteria	0.299% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor and outdoor Application by wiping, mopping or brushing, spraying, soaking or dipping (immersion)	Acceptable with RMM*
		Yeast			
		Enveloped virus		Professional and industrial	
	3	Bacteria	0.748% w/w L-(+)-lactic acid, 5 min, 10°C	indoor and outdoor Application by Wiping, mopping or brushing, spraying, soaking or dipping (immersion)	Not acceptable: Efficacy not demonstrated with contact time of 5 min.
		Yeast		Professional	
		Bacteria	0.748% w/w L-(+)-lactic acid, 30 min, 10°C	Indoor and outdoor Application by Wiping, mopping or brushing, spraying, soaking or dipping (immersion)	Acceptable with RMM*
		Yeast		Professional	
8	2	Bacteria	0.598 % to 1.496% L-(+)-lactic acid, 5 min, 20°C	Indoor and outdoor	Acceptable with RMM*
		Yeast		Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping	
		Enveloped virus		Non-professional and professional	
	4	Bacteria			
		Yeast			
9	2	Bacteria	0.598% w/w L-(+)-lactic acid, 5 min, 20°C	Indoor and outdoor	Acceptable with RMM*
		Yeast		Application by Spraying, spreading, wiping, foam application, brushing, dipping, immersion, mopping	
		Enveloped virus		Non-professional and professional	
	4	Bacteria			
		Yeast			

\*RMMs are detailed in the SPC and PAR.

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/biocidal product family have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance 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 is sufficiently effective;
2. the biocidal product family 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.

## **2.2 BPC opinion on the Union authorisation of the biocidal product family**

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

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<sup>1</sup> 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.