

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

CVAS Biocidal Product Family based on L(+) Lactic Acid

ECHA/BPC/345/2022

Adopted

15 June 2022

Opinion of the Biocidal Products Committee

on the Union authorisation of CVAS Biocidal Product Family based on L(+) Lactic Acid

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:

Name of the biocidal product family:	CVAS Biocidal Product Family based on L(+) Lactic Acid
Authorisation holder:	CVAS Development GmbH
Active substances common name:	L(+) lactic acid (CAS No 79-33-4)
Product types:	3 and 4

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 24 April 2019, recorded in R4BP3 under case number BC-XR051157-11, 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: Slovenia

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

The BPC opinion was adopted by consensus.

The opinion is 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 CVAS Biocidal Product Family based on L(+) Lactic Acid 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 CVAS Biocidal Product Family based on L(+) Lactic Acid 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 CVAS Biocidal Product Family based on L(+) Lactic Acid consists of 8 meta SPCs and 21 products containing active substance L(+) lactic acid in the concentration range from 1.92 to 17.60%. The structure of the biocidal product family into meta SPCs is based on product type, active substance concentration, classification, and application method.

Biocidal products are used for non-medical teat disinfection after milking in veterinary hygiene (PT3, meta SPCs 1-6) and for hard surface disinfection in food and feed areas (PT4, meta SPCs 7-8) by professional users.

Products in meta SPCs 1-6 are applied by manual or automated dipping or spraying and products in meta SPCs 7-8 by manual or automated foaming or by automated spraying in closed system (CIP) without precleaning.

The non-active substances identified as substances of concern are phosphoric acid, sulphuric acid, methanesulphonic acid and isononanoic acid.

Following intended uses in 8 meta SPCs have been assessed:

Meta SPC/Use No.	Use
Meta SPC 1/ Use # 1	PT3: Teat-disinfection post-milking by manual or automated dipping
Meta SPC 2/ Use # 2	PT3: Teat-disinfection post-milking by manual or automated dipping
Meta SPC 3/ Use # 3	PT3: Teat-disinfection post-milking by manual or automated dipping or spraying
Meta SPC 4/ Use #	PT3: Teat-disinfection post-milking by manual or automated dipping

Meta SPC/Use No.	Use
4	or spraying
Meta SPC 5/ Use # 5	PT3: Teat-disinfection post-milking by manual or automated dipping or spraying
Meta SPC 6/ Use # 6	PT3: Teat-disinfection post-milking by manual or automated dipping or spraying
Meta SPC 7/ Use # 7	PT4: Hard surface disinfection by manual or automated foaming
Meta SPC 8/ Use # 8	PT4: Hard surface disinfection by automated spraying in closed system (CIP)

Physico-chemical properties

The physico-chemical properties of the CVAS Biocidal Product Family based on L(+) Lactic Acid have been adequately characterised. The stability data for the biocidal product family indicate a shelf life of 2 years at ambient temperature. The following storage conditions have been defined:

- Do not store at temperatures above 40°C (meta SPCs 1-8),
- Keep away from heat and direct sunlight (meta SPCs 1-8),
- Protect from frost (meta SPCs 1-8),
- Keep container tightly closed (meta SPCs 1-8),
- Ensure good ventilation/exhaustion (meta SPCs 7-8),
- Do not store together with alkalis (caustic solutions) (meta SPCs 7-8).

The products of the meta SPCs 1-6 do not present any physical hazard. The products of meta SPCs 7 and 8 are classified corrosive to metal, H290, Met Corr. 1.

The analytical method for the determination of the active substance L(+) lactic acid in the biocidal product family is fully validated.

Efficacy

L(+) lactic acid-based teat post-milking (PT3) and surface (PT4) disinfectants in biocidal product family have been demonstrated as sufficiently effective against bacteria and yeasts for all intended uses.

Teat disinfectants post-milking in meta SPCs 1-6 are liquid ready-to-use (RTU) products. Products of meta SPCs 1, 3 and 5 contain 1.92-1.96% and products of meta SPCs 2, 4 and 6 contain 6.80% of L(+) lactic acid. Teats have to be fully covered with disinfectant for at least 5 min contact time.

Hard surface disinfectants in meta SPCs 7-8 are soluble concentrates and contain 16.00-17.60% of L(+) lactic acid. In meta SPC 7, 5% product dilution rate is used against all target organisms, corresponding to 0.80-0.88% of L(+) lactic acid. In meta SPC 8, 2.5% product dilution rate for bacteria and 2% product dilution rate for yeasts is used, corresponding to 0.40-0.44% and 0.32-0.35% L(+) lactic acid, respectively. Cleaning before disinfection is not necessary and minimum contact time is 5 min for bacteria and 15 min for yeasts.

Efficacy of L(+) lactic acid is limited by pH and lower pH is more favourable for efficacy of L(+) lactic acid.

Mode of action of L(+) lactic acid is non-selective and hence the occurrence of resistance against L(+) lactic acid is unlikely. No reduction in efficacy has been reported to the producers of L(+) lactic acid or manufacturers of L(+) lactic acid-based biocidal products indicating that no development of resistant microorganisms has occurred up to date.

Human health

The biocidal products of meta SPCs of the biocidal product family are classified and labelled as follows:

meta SPCs 1 and 3	meta SPCs 2, 4, and 6	meta SPC 5	meta SPCs 7 and 8
/	Skin irritation 2, H315 Eye Damage 1, H318	Skin irritation 2, H315 Eye irritation 2, H319	Skin corrosion 1, H314 Eye Damage 1, H318 Corrosive to the respiratory tract, EUH071

The four co-formulants methanesulphonic acid, phosphoric acid, sulphuric acid and isononanoic acid are considered as substances of concern as they contribute to the low pH and thus to the classification of the biocidal products in mSPC 7 and mSPC 8. Methanesulphonic acid is relevant for mSPC 7 and mSPC 8, whereas phosphoric acid, sulphuric acid and isononanoic acid are relevant for mSPC 8 only. Therefore, a qualitative exposure and risk assessment to determine whether the labelling associated to classification is sufficient or whether other RMM should be applied has been performed.

For the products of CVAS Biocidal Product Family based on L(+) Lactic Acid the risk during teat-disinfection post-milking and hard surface disinfection is acceptable for professional user considering the application in accordance with the labelling instructions and risk mitigation measures as stated in the SPC.

Dietary risk assessment

Based on the risk assessment a dietary exposure of consumers via PT3 and PT4 uses is considered negligible. It is unlikely that the intended uses cause any unacceptable risk for the consumers via residues in food, if the directions for use, as specified in the SPC, are followed.

Risk assessment for animal health

A risk assessment for animal health has been carried out for all the intended uses in PT3 (meta SPCs 1-6). It is unlikely that the intended uses cause any unacceptable risk for livestock animals, if the directions for use, as specified in the SPC, are followed.

Environment

CVAS Biocidal Product Family based on L(+) Lactic Acid biocidal product family is not classified hazardous for the environment.

The environmental risk assessment was only performed for the active substance. Acceptable levels of risk to all environmental compartments (air, STP, surface water, sediment, soil, groundwater) have been demonstrated for the proposed uses of the biocidal products.

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

The description of the biocidal product and of the structure of the family is available in the SPC.

The hazard and precautionary statements of the biocidal 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

An overview of the uses to be authorised is presented below.

Meta SPCs/Uses (Product type)	User	Target organisms	Use conditions	Risk mitigations measures (RMM)
Meta SPC 1 / Use # 1: Teat-disinfection post-milking by manual or automated dipping (PT 3)	Professional	Bacteria, yeasts	ready-to-use products (RTU, 1.92-1.96% L(+) lactic acid) 5 min contact time	/
Meta SPC 2 / Use # 2: Teat-disinfection post-milking by manual or automated dipping (PT 3)	Professional	Bacteria, yeasts	ready-to-use products (RTU, 6.80% L(+) lactic acid) 5 min contact time	- Wear gloves, eye protection and coverall when handling the RTU product.
Meta SPC 3 / Uses # 3:	Professional	Bacteria,	ready-to-use products (RTU,	/

Meta SPCs/Uses (Product type)	User	Target organisms	Use conditions	Risk mitigations measures (RMM)
Teat-disinfection post-milking by manual or automated dipping or spraying (PT 3)		yeasts	1.92-1.96% L(+) lactic acid) 5 min contact time	
Meta SPCs 4 and 6/ Uses # 4 and 6: Teat-disinfection post-milking by manual or automated dipping or spraying (PT 3)	Professional	Bacteria, yeasts	ready-to-use products (RTU, 6.80% L(+) lactic acid) 5 min contact time	- Wear gloves, eye protection and coverall when handling the RTU product.
Meta SPC 5/ Uses # 5: Teat-disinfection post-milking by manual or automated dipping or spraying (PT 3)	Professional	Bacteria, yeasts	ready-to-use products (RTU, 1.92-1.96% L(+) lactic acid) 5 min contact time	- Wear gloves, eye protection and coverall when handling the RTU product.
Meta SPC 7/ Use # 7: Hard surface disinfection by manual or automated foaming (PT	Professional	Bacteria, yeasts	soluble concentrates (16.00-17.60% of L(+) lactic acid) 5% product dilution (0.80-0.88% of L(+)	- Wear gloves, goggles, respiratory protection and protective clothing when handling the concentrated product. - Avoid standing in areas with aerosol formation.

Meta SPCs/Uses (Product type)	User	Target organisms	Use conditions	Risk mitigations measures (RMM)
4)			lactic acid) Bacteria: 5 min contact time Yeast: 15 min contact time	
Meta SPC 8/ Use # 8: Hard surface disinfection by automated spraying in closed system (CIP) (PT 4)	Professional	Bacteria, yeasts	soluble concentrates (16.00-17.60% of L(+) lactic acid) Bacteria: 2.5% product dilution (0.40-0.44% of L(+) lactic acid) for 5 min contact time Yeast: 2% product dilution (0.32-0.35% of L(+) lactic acid) for 15 min contact time	- Wear gloves, goggles, respiratory protection and protective clothing when handling the concentrated product.

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended uses of the 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 products.

For the proposed authorised uses, 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 uses 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 the biocidal product family shall be authorised¹, for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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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.