Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

L(+) lactic acid

Product type: 4

ECHA/BPC/149/2017

Adopted

27 April 2017

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

Opinion of the Biocidal Products Committee

on the application for approval of the active substance L(+) lactic acid for product type 4

In accordance with Article 89(1) 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 (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 4 of the following active substance:

Common name:	**L(+) lactic acid**
Chemical name:	**(S)-2-Hydroxypropanoic acid**
EC No.:	**201-196-2**
CAS No.:	**79-33-4**
Existing active substance	

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by Purac Biochem on 17 July 2007, the evaluating Competent Authority Germany submitted an assessment report and the conclusions of its evaluation to ECHA on 3 May 2016. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-20) and its Working Groups (WG V 2016). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Germany

The BPC opinion on the approval of the active substance L(+) lactic acid in product type 4 was adopted on 27 April 2017.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the L(+) lactic acid in product type 4 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of L(+) lactic acid in product type 4.

Specifications for the reference source are established.

The active substance L(+) lactic acid is a carboxylic acid. L(+) lactic acid and D(-) lactic acid are the two optical isomers of the chiral substance lactic acid. The chemical name of the active substance L(+) lactic acid is (S)-2-Hydroxypropanoic acid. The minimum purity of the active substance as manufactured is ≥ 95.5% w/w. Pure lactic acid is a crystalline solid. The active substance is marketed as an aqueous solution (88% / 93% L(+) lactic acid), which appears as a colourless to yellow light brown liquid with a characteristic odour.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Validated analytical methods are available for the active substance as manufactured.

Relevant residues in food of plant and animal origin and in the environment compartments arising from the application of L(+) lactic acid are not expected. Therefore, residue analytical methods of 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.
L(+) lactic acid has been approved in the EU as a food additive, as a cosmetics ingredient, and as veterinary medicinal product.

Currently, a harmonised classification according to Regulation (EC) No 1272/2008 (CLP Regulation) is not available. A CLH dossier was submitted to ECHA and a RAC opinion is foreseen to be adopted by the end of 2017. The proposed classification and labelling for L(+) lactic acid according to Regulation (EC) No 1272/2008 (CLP Regulation) used for the risk assessment[1] is:

[1] In addition, STOT SE 3; H335 "May cause respiratory irritation" was proposed in the CLH dossier submitted to ECHA, but this was not considered during the evaluation of the biocide dossier.

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Eye Dam.1; H318 Skin Irrit. 2; H315
Labelling	
Pictogram codes	GHS05
Signal Word	Danger
Hazard Statement Codes	H315; Causes skin irritation H318; Causes serious eye damage
Specific Concentration limits, M-Factors	-

b) Intended use, target species and effectiveness

The intended use of the biocidal product in PT 4 is the disinfection of tanks against bacteria in the brewery industry by professional users.

In solution, 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 cells membrane. At a relatively low pH, the uncharged acid enters the cell. Inside the cell, the 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 is observed.

The bactericidal activity of L(+) lactic acid was investigated by studies performed with the in-use concentration of the biocidal product containing 3% lactic acid and 2.5% sodium laureth-2 sulfate (SLeS).

The performed tests provide reliable results for basic efficacy assessment. The following results could be derived from the studies: the dummy product with the in-use concentration of 3% L(+) lactic acid and 2.5% SLeS shows an innate bactericidal activity after a contact time of 5 minutes. Additionally it was shown that 2.5% SLeS is not effective if used alone. Therefore, an innate bactericidal activity of 3% L(+) lactic acid can be concluded. The studies performed are sufficient at the approval stage.

The information provided is only sufficient to show a innate efficacy of L(+) lactic acid. This is accepted in the frame of the approval. Within the frame of product authorisation, essentially more information has to be provided: To support the claim bactericidal further laboratory tests would be necessary. Additionally, further tests in the field of use have to be provided, also tests showing an activity against further organisms, inter alia fungi relevant for the specific field of use.

Development of resistance is considered unlikely due to the non-specific mode of action.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

L(+) lactic acid is an endogenous alpha-hydroxy acid of generally low toxicity. Due to its acidity it is, however, considered to be a skin irritant and causing serious eye damage.

Due to 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. Likewise, 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).

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Disinfection of brewery vessles	Primary inhalation and dermal exposure during pouring of the b.p. (93% a.s.) into the brewery vessel. Afterwards no further contact due to the fully automatic cleaning process. PPE: gloves and eye protection	Professional user	Acceptable with PPE
Disinfection of brewery vessels	Primary and secondary exposure of non-professional users and the general public is not expected.	Non-professional users and the general public	Acceptable

Professional user

According to the generally low toxicity of L(+) lactic acid, systemic effects after the handling and use of the active substance L(+) lactic acid are not expected for professionals.

Considering the disinfection of brewery vessels the only professional exposure takes place during the mixing and loading phase of the biocidal product to the vessel. Application and post-application phases are fully automatic and no further contact by professionals to the disinfectant is expected. Exposure to the biocidal product might result in skin irritation due to skin contact and eye damage due to splashes.

Therefore exposure to the biocidal product during the mixing and loading phase should be minimized with protection measures (gloves and eye protection). If the proposed safety protection measures are implemented, handling and use of the active substance L(+) lactic acid does not lead to unacceptable risks for professionals. It is essential to indicate, that the conclusion only applies to the active substance in the biocidal product (and not to other ingredients).

General public

Primary and secondary exposure of non-professional users and the general public is not expected. Residues in food from the intended PT 4 use are expected to be low compared to naturally occurring levels in food. Therefore the intended use does not significantly contribute to consumer exposure to lactic acid.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Disinfection of tanks in brewery industry – professional use	Indirect release occurs via STP to the aquatic compartment (surface water and sediment) as well as due to sewage sludge application on agricultural soil to the terrestrial compartment (soil and groundwater).	Acceptable

No unacceptable risks for soil, surface water, sediment and the STP were identified in connection with the evaluated intended uses. However, the concentration in groundwater exceeds the quality standard for pesticides of 0.1 µg/L. The refinement of the groundwater assessment with the FOCUS PEARL model revealed that for one arable land scenario (Sevilla) and for seven grassland scenarios the average concentration of L(+) lactic acid closest to the 80th percentile is below the trigger value of 0.1 µg/L. According to the conclusion of the 47th CA meeting in July 2012 the risk for the groundwater compartment is acceptable if there is at least one safe scenario for each of both areas. Hence, it can be concluded that the use of the biocidal dummy product, which is identical to the a.s. L(+) lactic acid, does not result in unacceptable risks for the environment. While sufficient for active substance approval, concentrations below 0.1 µg/L for all nine FOCUS PEARL scenarios will be required for union authorisations and for the representative PEARL scenario(s) for national product authorisation. Consequently, additional data to refine the current risk assessment may be required for product authorisation.

The current assessment of the biodegradation behaviour in soil of lactic acid is most likely too conservative: based on the information submitted in the application a default degradation half-live of 90 days was estimated. Additional information obtained via a literature search shows that in reality the degradation half-life may be lower. For product authorisation the results from this literature search together with the information on the biocidal product and the actual use shall be used to assess the risk for the groundwater compartment.

Overall conclusion

A safe use for human health and the environment is identified for professional use of the product.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	No classification required	L(+) lactic acid does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	No classification required	
	Toxic for reproduction (R)	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	not P or vP	L(+) lactic acid does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B or vB	
	Toxic (T)	not T	
Endocrine disrupting properties	L(+) lactic acid is not considered to have endocrine disrupting properties and does not fulfil criterion (d) of Article 5(1).		
Respiratory sensitisation properties	No classification required. L(+) lactic acid does ot fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects	L(+) lactic acid does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	L(+) lactic acid does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

L(+) lactic acid does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

L(+) lactic acid does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution. The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[2] and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[3] agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of

[2] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)
[3] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

substitution criteria is based on Article 10(1)(a, b, d, e and f).

2.2.2. POP criteria

As L(+) lactic acid is not P, B or vB, it does not meet the criteria for being a persistent organic pollutant.

2.3. BPC opinion on the application for approval of the active substance L(+) lactic acid in product type 4

In view of the conclusions of the evaluation, it is proposed that L(+) lactic acid shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: ≥ 95.5 % w/w (dry weight).

2. The authorisations of biocidal products are subject to the following condition(s):

    a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

    b. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.

The active substance L(+) lactic acid gives no rise to concern according to Article 28 (2) and does therefore fulfil the requirements for inclusion in Annex I of Regulation (EU) No 528/2012. However, it is noted that the classification as STOT SE 3 proposed in the CLH dossier submitted to ECHA would prevent inclusion on Annex I.

2.4. Elements to be taken into account when authorising products

The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product.

a. If an unacceptable risk is identified for professional users, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of L(+) lactic acid**.**

o0o