Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

L(+) Lactic acid

Product type: 1

ECHA/BPC/084/2015

Adopted

10 December 2015

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance L(+) Lactic acid for product type 1

In accordance with Article 90(2) 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 1 of the following active substance:

Common name:	**L(+) Lactic acid**
Chemical name(s):	**(S)-2-Hydroxypropanoic acid**
EC No.:	**201-196-2**
CAS No.:	**79-33-4**

Existing active substance submitted under Article 11 of the Biocidal Products Directive 98/8/EC

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 29 August 2013, the evaluating Competent Authority Germany submitted an assessment report and the conclusions of its evaluation to the Agency on 5 February 2015. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and its Working Groups. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: BPC member for Germany

The BPC opinion on the approval of the active substance L(+) Lactic acid in product type 1 was adopted on 10 December 2015.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the L(+) Lactic acid in product type 1 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 1. 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.

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.

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 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.

The proposed classification and labelling for L(+) Lactic acid according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Eye Dam. 1, H318 Skin Irrit. 2; H315
Labelling	
Pictograms	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

L(+) Lactic acid is intended to be used as a ready to use product directly on the hands as a disinfecting hand soap by professionals and non-professionals.

L(+) Lactic acid shows a basic bactericidal activity according to EN 1276 at a concentration of 3% if combined with 2.5% sodium laureth-2 sulphate (SLeS) after a contact time of 5 minutes in a suspension test. Additionally, it was shown that 2.5% SLeS is not effective if used alone. Therefore, a basic bactericidal activity of 3% L(+) Lactic acid can be concluded.

Sufficient efficacy against the target species for active substance approval has been demonstrated.

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

Human health

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 gastrointestinal microorganisms and uptake via food. L(+) Lactic acid is of generally low toxicity. Due to its acidity it is, however, considered to be a skin irritant and severe eye irritant. Derivation of any systemic toxicological reference dose as well as ADI and ARfD was regarded unnecessary for L(+) lactic acid. This is in line with the evaluation of the active substance in other frameworks. 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). In addition, it has been approved as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMEA 2008).

Exposure was compared to endogenous production and dietary exposure.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**acceptable/ non-acceptable**
Hand disinfection	Primary exposure: Application: hand wash using liquid soap containing 3% L(+) Lactic acid in hospitals and medical practice; 10 events daily, 1 minute per event, followed by rinse with water	Professional users	Acceptable No risk reduction measures were derived. Under normal use conditions as hand soap, eye contact is not expected
Hand washing	Primary: application of hand-washing liquid soap in residential bathrooms	Non-professionals	Non-acceptable due to severe irritation to the eyes
Hand washing	Secondary: inhalation of persons present during hand-washing	Bystanders	Acceptable

According to the risk characterisation the assessed exposure scenario hand disinfection in hospitals with a liquid hand soap for the active substance L (+) lactic acid does not lead to concern for professionals under normal use conditions as hand soap, eye contact is not

expected. It is essential to indicate, that the conclusion only applies to the active substance in the dummy biocidal product and not to other ingredients.

Considering systemic toxicity, no risk to the non-professional has been identified. However, with regard to local effects, no safe use could be demonstrated for primary exposure of the non-professional as washing of the face and potential contact of the eye with the product classified as eye damaging cannot be excluded. Due to the content of L(+) Lactic acid, the dummy product is classified with Eye Dam. 1, H318. Biocidal products classified with Eye Dam. 1, H318 are not considered safe for the non-professional user unless the likelihood of eye exposure can be effectively minimised by product-integrated risk mitigation measures. Classification of the biocidal product can be avoided if appropriate data is provided for the actual biocidal product, or by other means.

Relevant residues in food of plant and animal origin arising from the intended use are not expected. Moreover, because of the natural background and the use as an additive "quantum satis" in foods of the active substance, exposure via food of residues of the active substance is not expected to be a concern.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Professional use; Disinfecting hand soap (i.e. human health care or hospitals)	For professional use a daily frequency of 10 applications was assumed (ready to use product containing 3% a.s., corresponding to 0.03 g a.s. per application). Indirect releases via STP to the aquatic compartment (surface water and sediment) as well as due to sewage sludge application to the terrestrial compartment (soil and groundwater).
Non-professional use; Disinfecting hand soap (Personal or domestic use)	For non-professional use a daily frequency of 5 applications was assumed (ready to use product containing 3% a.s., corresponding to 0.03 g a.s. per application). Indirect releases via STP to the aquatic compartment (surface water and sediment) as well as due to sewage sludge application to the terrestrial compartment (soil and groundwater).

Due to the intended uses, direct exposure of the L(+) lactic acid containing product to the environment is not expected. In fact, exposure of the aquatic compartment (surface water and sediment) will primarily occur via the effluent release from the sewage treatment plant (STP), whereas indirect exposure of the terrestrial compartment (soil and groundwater) is due to application of sewage sludge to agriculturally used areas. Both emission pathways have been evaluated during the environmental risk assessment for L(+) lactic acid.

No unacceptable risks for soil, surface water, sediment and the STP were identified in connection with the evaluated intended uses. Maximum permissible concentration of 0.1 µg/L a.s. in groundwater (according to Groundwater Directive 2006/118/EC and Drinking Water Directive 98/83/EC) were exceeded in a first-tier assessment. The indicated risk for the groundwater compartment could, however, be eliminated by refining the groundwater assessment using the FOCUS PEARL model.
Consequently, no unacceptable risks for the environment were identified in conjunction with the use of L(+) Lactic acid in disinfecting hand soaps.

Overall conclusion:
A safe use for human health and environment is identified for professional use of the hand soap.

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	
Respiratory sensitisation properties	no classification required. L(+) lactic acid does not fulfil criterion (b) of Article 10(1)		
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	Not considered to have endocrine disrupting properties L(+) Lactic acid does not fulfil criterion (d) of Article 5(1).		
Proportion of non-active isomers or impurities	L(+) Lactic acid does not fulfil criterion (f) of Article 10(1).		
Concerns linked to critical effects	L(+) Lactic acid does not fulfil criterion (e) 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"[1] and in line with "Further

[1] 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)

guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[2] 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 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 1

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:

        i. non-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) 528/2012.

2.4. Elements to be taken into account when authorising products

1. 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. For professional users an acceptable use was identified. However, according to Regulation No. 1272/2008 (Annex I, tables 3.3.3 and 3.3.5), safety goggles have to be recommended (precautionary statement P280) based on the classification H318. For product authorisation of hand wash soaps, it is recommended that the composition of these soaps avoids classification as Eye Dam. 1 (H318) as incidental eye contact might occur.

    b. An unacceptable risk for the non-professional use was identified based on the need to wear PPE following the classification of the product as eye-damaging. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised. It is recommended that the composition of hand wash soaps avoids classification as Eye Dam. 1 (H318).

2 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)

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.

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