Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

L(+) lactic acid

Product type: 3

ECHA/BPC/148/2017

Adopted

27 April 2017

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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 3

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 3 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 3 was adopted on 27 April 2017.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority position including its grounds are 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 3 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 3.

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 (EU) 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

L(+) lactic acid is intended to be used by professional users for dipping of cow teats after milking (only non-medicinal teat disinfection).

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 representative biocidal product containing 8% of lactic acid.

The performed tests provide reliable results for innate efficacy assessment.

L (+) lactic acid shows an innate bactericidal activity on samples of the target organisms (amongst others: *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus uberis*, *Streptococcus dysgalactiae*, *Escherichia coli*) after a contact time of 10-30 minutes at concentrations of 6.1-6.8%.

The studies performed are sufficient at the approval stage. However, efficacy shall be reviewed in accordance with the relevant guidance documents in the framework of active substance renewal and relevant data shall be provided in the scope of product authorisation.

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. However, the representative biocidal product is not eye damaging.

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**
Teat disinfection - dipping	Primary inhalation and dermal exposure during pouring of a ready-to-use product (8% a.s.) into a dipping cup, dipping of teats of 100 cows, cleaning of equipment	Professional user	Acceptable
Teat disinfection - dipping	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 handling and use of the active substance L(+) lactic acid are not expected for professionals.
Concerning the skin irritating properties of L(+) lactic acid, handling and use of the active substance L(+) lactic acid does not lead to concern for professionals since the concentration of the ready-to-use dummy product (8% a.s.) is below the dermal AEC of 10%. In summary, a safe use for the professional user is identified without taking into account personal protective equipment (PPE) or further risk mitigation measures (e.g. local exhaust ventilation).

General public

Primary and secondary exposure of non-professional users and the general public is not expected. Residues in food from the intended PT 3 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 cows teats in a milking parlour – professional use	The biocidal product contains 84.8 g a.s. per L. The fraction of active substance emitted to waste water is assumed to be 0.5 (the other part of 0.5 remains on the teats). Indirect releases occur 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
Disinfection of cow teats in animal housings – professional use	The biocidal product contains 84.8 g a.s. per L. The fraction of a.s. released to manure is assumed to be 0.5 (the other part of 0.5 remains on the teats). Direct release to soil (via manure application) occurs as well as indirect releases to groundwater, surface water and sediment.	Not acceptable Unacceptable risks for groundwater.

Application in milking parlour (sewage sludge application):
No unacceptable risks for soil, surface water, sediment and the STP were identified in connection with the intended use of the biocidal product (containing 8% (w/w) of L(+) lactic acid) in a milking parlour (connected to STP). However, the exposure assessment for the application of sewage sludge to agricultural areas resulted in groundwater concentrations above the maximum permissible concentration of 0.1 µg/L. The refinement of the $PEC_{groundwater}$ with the FOCUS PEARL model revealed a concentration below the trigger value of 0.1 µg/L and thus, safe application of sewage sludge to agricultural areas could be demonstrated for disinfection of cow teats in a milking parlour. Hence, it can be concluded that the use of the biocidal product does not result in unacceptable risks for the environment.

Application in animal housings (manure application):
No unacceptable risks for soil, surface water and sediment were identified in connection with the intended use of the biocidal product (containing 8% (w/w) of L(+) lactic acid) in animal housings (not connected to STP). However, the exposure assessment for the application of manure to agricultural areas resulted in groundwater concentrations above the maximum permissible concentration of 0.1 µg/L. Even, the refinement of the $PEC_{groundwater}$ with the FOCUS PEARL model did not reveal a concentration below the trigger value of 0.1 µg/L and thus, no safe application of manure to agricultural areas could be demonstrated for disinfection of cow teats in animal housing.

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 and it was assumed that no (anaerobic) degradation takes places in manure. Additional information obtained via a literature search shows that in reality the degradation half-life may be lower in soil and that anaerobic degradation does occur. 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 disinfection of cow teats in a milking parlour by professional users. Unacceptable risks are identified for the groundwater compartment for disinfection of cow teats in animal housing not connected to a STP.

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:

<table>
<tr><th colspan="2">Property</th><th colspan="2">Conclusions</th></tr>
<tr><td>CMR properties</td><td>Carcinogenicity (C)</td><td>No classification required</td><td rowspan="3">L(+) lactic acid does not fulfil criterion (a), (b) and (c) of Article 5(1)</td></tr>
<tr><td></td><td>Mutagenicity (M)</td><td>No classification required</td></tr>
<tr><td></td><td>Toxic for reproduction (R)</td><td>No classification required</td></tr>
<tr><td>PBT and vPvB properties</td><td>Persistent (P) or very Persistent (vP)</td><td>not P or vP</td><td rowspan="3">L(+) lactic acid does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)</td></tr>
<tr><td></td><td>Bioaccumulative (B) or very Bioaccumulative (vB)</td><td>not B or vB</td></tr>
<tr><td></td><td>Toxic (T)</td><td>not T</td></tr>
<tr><td>Endocrine disrupting properties</td><td colspan="3">L(+) lactic acid is not considered to have endocrine disrupting properties and does not fulfil criterion (d) of Article 5(1).</td></tr>
<tr><td>Respiratory sensitisation properties</td><td colspan="3">No classification required. L(+) lactic acid does not fulfil criterion (b) of Article 10(1).</td></tr>
<tr><td>Concerns linked to critical effects</td><td colspan="3">L(+) lactic acid does not fulfil criterion (e) of Article 10(1).</td></tr>
<tr><td>Proportion of non-active isomers or impurities</td><td colspan="3">L(+) lactic acid does not fulfil criterion (f) of Article 10(1).</td></tr>
</table>

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 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 3

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: ≥ 955 g/kg (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 groundwater for products used in animal housings with release to manure.

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:

[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)

a. An unacceptable risk for groundwater is identified for uses in animal housings following manure application on agricultural soil. 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.

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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