Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

L(+) lactic acid

Product type: 6

ECHA/BPC/280/2021

Adopted

15 June 2021

Opinion of the Biocidal Products Committee

on the application for approval of the active substance L(+) lactic acid for product type 6

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 6 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 the BPC opinion

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 the Agency on 3 September 2020. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-39) and its Working Groups (WG I 2021). 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 application for approval of the active substance L(+) lactic acid in product type 6 was adopted on 15 June 2021.

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 L(+) lactic acid in product type 6 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 6. The active substance is a carboxylic acid. L(+) lactic acid together with D(-) lactic acid are the two optical isomers of the chiral substance lactic acid. Specifications for the reference source are established.

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 environmental 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 water 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 was re-evaluated as food additive by EFSA in 2020[1] and is used as cosmetics ingredient and as veterinary medicinal product. Furthermore, it has already been approved as biocidal active substance for PT 1, 2, 3 and 4.

A harmonised classification is available (15th ATP[2]). The classification and labelling for L(+) lactic acid according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

[1] EFSA Scientific Opinion on the "Re-evaluation of acetic acid, lactic acid, citric acid, tartaric acid, mono- and diacetyltartaric acid, mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids (E 472a-f) as food additives", adopted on 9 January 2020, EFSA Journal 2020;18(3):6032, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2020.6032

[2] Commission Delegated Regulation (EU) 2020/1182 of 19 May 2020 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R1182

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Skin Corr. 1C; H314 Eye Dam. 1, H318
Labelling	
Pictogram codes	GHS05
Signal Word	Danger
Hazard Statement Codes	H314; Causes severe skin burns and eye damage EUH071; Corrosive to the respiratory tract
Specific Concentration limits, M-Factors	-

b) Intended use, target species and effectiveness

L(+) lactic acid is used as an in-can preservative for liquid detergents. The intended and evaluated use is preservation of detergents, such as fabric conditioners and manual dishwashing liquids. These end-products are treated articles. The biocidal product is used only by professional/industrial users, while the treated articles are used both by professional and non-professional users.

L(+) lactic acid causes inhibition of microorganisms by various mechanisms after entering the microbial cell in its protonated state. These include inhibition of glycolysis and uncoupling of oxidative phosphorylation.

The data on L(+) lactic acid demonstrated basic innate efficacy of the representative biocidal product. Acquired resistance mechanisms against L(+) lactic acid are not known and the risk of resistance development is deemed low.

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) 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 skin corrosive and eye damaging.

L(+) lactic acid does not meet the CMR criteria and is not considered to have endocrine disrupting properties. Due to the very low systemic toxicity of L(+) lactic acid, derivation of any systemic toxicological reference doses as well as ADI and ARfD values was regarded unnecessary. This is in line with the evaluation of the active substance in other regulatory 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 is used as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMEA 2008).

Exposure was compared to endogenous production[3] and dietary exposure, because of the very low systemic toxicity of L(+) lactic acid.

A dermal NOAEC for acute, medium-term and long-term exposure of 10 % L(+) lactic acid was derived. However, the 10 % dermal NOAEC value should not be considered as a general reference value and its applicability should be assessed before being used in the risk characterisation of L(+) lactic acid products.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure[4] and description of scenario**	**Exposed group**	**Conclusion**
Scenario 1 - Formulation of end-products containing L(+) lactic acid (in-can preservative)	Use of 88% a.s. in industrial scale: Primary dermal exposure during connecting transfer line to an automated system (semi-automated transfer system)	Industrial user	Acceptable with protective gloves and eye protection, with semi-automated transfer system
Scenario 2 - Filling preserved end-products (fabric conditioner or washing-up liquids)	Use of preserved end-products with 5% a.s. in a filling plant: Primary dermal exposure during filling tasks (automated, semi closed process)	Industrial user	Acceptable with protective gloves, protective coverall, eye protection, for automated, semi closed process.
Scenario 3 - Application of fabric conditioner	Use of liquid detergent with 5% a.s.: Primary dermal exposure during hand washing laundry	Professional user	Acceptable with protective gloves, eye protection
Scenario 4 - Application of washing up liquids	Use of hand wash-up liquids with 5% a.s.: Primary dermal exposure during hand dishwashing	Professional user	Acceptable with protective gloves, eye protection

[3] At product authorization there is no need to compare levels of endogenous L(+)-lactic acid with systemic exposure levels as the calculations in this evaluation shows that exposure from biocidal use is well below the endogenous production in humans.

[4] See document: Terminology primary and secondary exposure (available from https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/80f71044-fce2-43b3-a73c-e156effc9fcb/Terminology%20primary%20and%20secondary%20exposure.pdf

Scenario 5 - Application of preserved end-products: washing-up liquid	Use of preserved washing-up liquids with 5% of a.s.: Primary dermal and inhalation exposure during mixing and loading and application.	Non-professional user	Undiluted use: acceptable with RMM preventing direct skin (and eye) contact (e.g. adequate packaging, see below) Diluted use: acceptable
Scenario 6 - Application of preserved end-products: fabric conditioners	Use of preserved fabric conditioners with 5 % of a.s.: Primary dermal and inhalation exposure during loading/direct pouring.	Non-professional user	Undiluted use: acceptable with RMM preventing direct skin (and eye) contact (e.g. adequate packaging, see below) Diluted use: acceptable
Scenario 7 - Application of preserved end-products: household cleaners	Use of preserved household cleaners with 5% of a.s.: Primary dermal and inhalation exposure during mixing and loading and application.	Non-professional user	Undiluted use: acceptable with RMM preventing direct skin (and eye) contact (e.g. adequate packaging, see below) Diluted use: acceptable
Secondary exposure	Secondary dermal or oral exposure by contact with cleaned dishes, cleaned laundry, cleaned floors or wash water containing washing-up liquid / household cleaner	General public	acceptable

Professional User:

Systemic effects after handling and use of the active substance L(+) lactic acid are not expected for professionals based on a comparison of exposure estimates with endogenous production of L(+) lactic acid.

Due to its acidity, corrosive reactions of skin and respiratory tract as well as eye damage can arise from either dermal or inhalation exposure to L(+) lactic acid.

Concerning corrosive properties in the respiratory tract of L(+) lactic acid, the inhalation exposure is assessed to be negligible so that no adverse effects are expected.

With respect to the dermal corrosive properties of L(+) lactic acid, dermal exposure to a concentration of 88% and 5% L(+) lactic acid might result in skin corrosion and eye damage, respectively and thus should be minimized with protection measures (protective gloves and eye protection in all scenarios, additionally protective coverall in scenario 2).

Non-professional user / general public:

Primary exposure of non-professionals to the biocidal product (in-can preservative) is not expected since the addition of in-can preservatives to formulations is performed by professional users.

Primary exposure to L(+) lactic acid is expected by application of preserved washing-up liquids, fabric conditioners and household cleaners containing the active substance. Information about possible treated articles was submitted by the applicant. Additionally, information about liquid cleaning products such as wet wipes, cleaners for bathroom, toilet, floor and kitchen was presented. The new information was not considered for exposure assessment but was gathered with the aim of proposing possible risk mitigation measures (RMMs) that may be considered at product authorisation.

The systemic exposure (assessed for washing-up liquids, fabric conditioners and household cleaners) is considered low compared to endogenous production (0.02% at maximum) or to the minimum daily food intake (1.8 %). Even if it is assumed that a subject is exposed simultaneously to all three kinds of treated articles containing the active substance as in-can preservative, exposure is fairly low. Thus, it is concluded that exposure to L(+) lactic acid in these scenarios does not pose a risk to human health.

Treated articles containing the active substance with a concentration of 3-5 %[5] may require classification respectively labelling (in accordance with the additivity approach of Regulation (EC) No. 1272/2008) as Skin Corr. 1/Skin Irrit. 2 (H314/H315) and Eye Dam. 1 (H318) as well as EUH071, as long as no other data (e.g. in-vitro- or in-vivo-studies with a representative formulation) overrule this approach.

For treated articles classified for local effects like skin corrosive/skin irritating or eye damaging, a possible contact to skin (and eyes) has to be excluded. Hence, such treated articles that can be used manually and with direct skin (and eye) contact are not acceptable for the non-professional user. Additionally, exposure to corrosive/irritating treated articles via inhalation used as spray is not acceptable. If skin and eye contact can be excluded by other means, the use may be acceptable. The use of diluted treated articles that show no corrosive or irritating effects is considered acceptable for the non-professional user.

Therefore, at product authorisation stage, it has to be evaluated carefully whether treated formulations can be safely used by non-professional users and whether secondary exposure for the general public is acceptable. If necessary, risk mitigation measures have to be specified. Biocidal products should not be authorised for use in cleaning liquids used for manual work or cleaners with direct skin (and possible eye) contact or used in sprays if these cleaning products are classified for corrosive/irritating effects unless RMMs avoiding skin respectively eye contact can be put in place, e.g.:

- gel-kind formulation avoiding splashes;
- packaging with dosing aid that prevents contact with the concentrate during use;
- packaging with a self-dissolving shell (“pod”).

[5] For treated articles, efficacy was demonstrated for 3 % active substance concentration, whereas 5 % were assessed as worst case concentration for the human health and environmental risk assessment.

A collection of possible RMM relevant for different kinds of treated articles not assessed for active substance approval is part of the assessment report.

Residues in food and feed are not expected from the intended uses of L(+) lactic acid in PT 6 biocidal products.

Environment

L(+) lactic acid was shown to be ready biodegradable but failing the 10 d-window criterion. L(+) lactic acid possesses only one hydrolysable group, the acid group. For hydrolysis of the acid group, the dissociation constant (pK) of 3.8 should be taken into account. The vapour pressure of L(+) lactic acid is 0.4 Pa at 20 °C and the Henry's law constant is 3.6 x 10^{-5} Pa m^3 mol^{-1} indicating that direct evaporation and volatility from water are expected to be insignificant. In general, emissions of L(+) lactic acid to the atmosphere are unlikely to occur. The estimated BCF values in aquatic compartment (BCF_{fish} = 0.048 L/kg) and terrestrial compartment ($BCF_{earthworm}$ = 6.78 L/kg) indicate a low bioaccumulation potential of the a.s. in the environment, and thus the risk of secondary poisoning is considered to be low. L(+) lactic acid is not classified as toxic ($NOEC_{algea}$ = 1.1 g a.s./L) and is not considered to have endocrine disrupting properties.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Formulation of preserved end-product	Formulation of the in-can preserved end-product containing 5 % w/w at an industrial site (indoors). Indirect releases occur via STP to the aquatic compartment (surface water and sediment) as well as due to sludge application on agricultural soil to the terrestrial compartment (soil and groundwater).	acceptable
Application of preserved end-product	The ready-to-use solution (end-product) is used as detergent for dish washing (50 g a.s./kg, consumption per capita of 3 g/d) as well as for fabric softener (50 g a.s./kg, dosage of fabric softener per washing 0.04 L) (both for private use, indoors). Indirect releases occur via STP to the aquatic compartment (surface water and sediment) as well as due to 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 scenarios.

With respect to the groundwater assessment of lactic acid it can be stated that modelling of groundwater concentrations leads to values exceeding the trigger value. As lactate is

metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge is not taken into account in the methods currently used for the assessment. Therefore, modelling of groundwater exposure in case of lactic acid largely overestimates concentrations and is considered unrealistic.

In addition, no potential for bioaccumulation and consequently no concerns for secondary poisoning were identified. Moreover, L(+) lactic acid is not a PBT candidate.

Hence, it can be concluded that the formulation of the preserved end-product as well as the use of the end-products for both evaluated purposes (washing-up liquid and fabric conditioner) does not result in unacceptable risks to the environment.

Overall conclusion

The use of the biocidal product by industrial users formulating preserved end-products poses acceptable risks to the environment and human health when using personal protective equipment (PPE). For the use of the treated articles, acceptable risks for human health and the environment are identified for professional users when using PPE. For treated articles classified for skin corrossion/irritancy and/or eye damage/irritancy, a safe use by non-professional users is possible when risk mitigation measures are established avoiding skin and eye contact to the treated articles. Furthermore, safe application of these treated articles is identified for non-professional users if the in-use active substance concentration is diluted to an appropriate concentration without having contact to the concentrated form.

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	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No	L(+) lactic acid does not fulfil Article 5(1)(e) or Article 10(1)(e)
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s)	No	
Respiratory sensitisation properties	No classification required. L(+) lactic acid does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects other than those related to endocrine disrupting properties	None. L(+) lactic acid does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Not relevant. 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"[6], "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[7] and "Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment[8]" agreed at the 54th, 58th and 77th 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).

[6] 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)

[7] 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

2.2.2. POP criteria

As L(+) lactic acid is neither P nor B nor T, and as it does not have the potential for long range transport, 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 6

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 (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. industrial and professional users;
        ii. non-professional users.
    c. The person placing treated articles on the market containing the active substance at concentrations leading to classification for local effects shall ensure that exposure to the general public is minimized by appropriate mitigation measures.

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) No 528/2012 as L(+) lactic acid is classified as Skin Corr 1C (H314).

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. If an unacceptable risk is identified for industrial and/or 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.

[8] See document: Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment (available from https://circabc.europa.eu/sd/a/48320db7-fc33-4a91-beec-3d93044190cc/CA-March18-Doc.7.3a-final-%20EDs-%20active%20substances%20under%20assessment.docx).

b. An unacceptable risk for non-professional users using treated articles containing the active substance at concentrations leading to classification for local effectsis identified. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, the use of the biocidal product in these treated articles should not be authorised.

c. At product authorization stage, the applicability of the dermal NOAEC should be assessed before being used in the risk characterisation of L(+) lactic acid products, considering the differences in the formulation tested and the formulation of the product.

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