COMMISSION IMPLEMENTING REGULATION (EU) 2022/2048

of 24 October 2022

approving L-(+)-lactic acid as an existing active substance for use in biocidal products of product-type 6 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 89(1), third subparagraph, thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes L-(+)-lactic acid.

(2) L-(+)-lactic acid has been evaluated for use in biocidal products of product-type 6, preservatives for products during storage, as described in Annex V to Regulation (EU) No 528/2012.

(3) Germany was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the European Chemicals Agency ('the Agency') on 3 September 2020.

(4) In accordance with Article 75(1), point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinion of the Agency ([3]) on 15 June 2021, having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, the biocidal products of product-type 6 containing L-(+)-lactic acid may be expected to satisfy the criteria laid down in Article 19(1), point (b), of Regulation (EU) No 528/2012, provided that conditions concerning their use are complied with.

(6) Taking into account the opinion of the Agency, it is appropriate to approve L-(+)-lactic acid for use in biocidal products of product-type 6 subject to compliance with certain conditions.

(7) In particular, since L-(+)-lactic acid is classified for skin corrosion/irritation, sub-category 1C, and eye damage and irritation, Category 1, as specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([4]), the person responsible for placing on the market of substances or mixtures treated with or incorporating the active substance at concentrations leading to classification for skin corrosion/irritation or eye damage/eye irritation should ensure that exposure to the general public is minimised by appropriate risk mitigation measures.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([3]) Biocidal Products Committee Opinion on the application for approval of the active substance: L-(+)-lactic acid, Product type: 6; ECHA/BPC/280/2021, adopted on 15 June 2021.

([4]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(8) Since L-(+)-lactic acid meets the criteria for classification as corrosive to the respiratory tract as specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, the person responsible for placing on the market of substances or mixtures treated with or incorporating the active substance at a concentration leading to classification for corrosion of the respiratory tract should ensure that exposure to the general public is minimised by appropriate risk mitigation measures.

(9) In order to guarantee a safe use of biocidal products containing L-(+)-lactic acid in treated articles and enable users of treated articles to make informed choices, the person responsible for the placing on the market of a treated article treated with or incorporating L-(+)-lactic acid should ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012. Furthermore, Member States competent authorities or, in the case of a Union authorisation, the Commission should specify in the summary of the biocidal product characteristics of a biocidal product containing L-(+)-lactic acid the relevant instructions for use and precautions to be included on the label of the treated articles under Article 58(3), point (e), of Regulation (EU) No 528/2012.

(10) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

L-(+)-lactic acid is approved as an active substance for use in biocidal products of product-type 6, subject to the conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 October 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Date of approval	Expiry date of approval	Product type	Specific conditions
L-(+)-lactic acid	IUPAC Name: (2S)-2-Hydroxypropanoic acid EC No: 201-196-2 CAS No: 79-33-4	≥ 955 g/kg (dry weight)	1 November 2023	31 October 2033	6	The authorisation of biocidal products is subject to the following conditions: 1. 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 ([2]) of the active substance. 2. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: (a) industrial and professional users; (b) non-professional users. The placing on the market of treated articles is subject to the following conditions: 1) The person responsible for the placing on the market of a substance or mixture treated with or incorporating L-(+)-lactic acid at concentrations in the substance or mixture leading to classification for: (a) local effects concerning skin corrosion/irritation or eye damage/eye irritation, in accordance with Regulation (EC) No 1272/2008, shall ensure that exposure to the general public is minimised by appropriate risk mitigation measures. Those measures may include using a gel-like formulation, a packaging with dosing aid or a packaging with a self-dissolving shell; (b) acute toxicity regarding corrosivity to the respiratory tract, in accordance with Regulation (EC) No 1272/2008, shall ensure that airborne exposure to the general public is minimised by appropriate risk mitigation measures. Those measures may include a label to indicate: no entry in the treated area until dry, or no application in the presence of the/in proximity to general public.

						2) The person responsible for the placing on the market of a treated article treated with or incorporating L-(+)-lactic acid shall ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012. 3) Member States competent authorities or, in the case of a Union authorisation, the Commission shall specify in the summary of the biocidal product characteristics of a biocidal product containing L-(+)-lactic acid the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), point (e), of Regulation (EU) No 528/2012.

(1) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

(2) Biocidal Products Committee Opinion on the application for approval of the active substance: L-(+)-lactic acid, Product type: 6; ECHA/BPC/280/2021, adopted on 15 June 2021.