Commission Implementing Regulation (EU) 2017/2002 of 8 November 2017 approving L(+) lactic acid as an existing active substance for use in biocidal products of product-types 2, 3 and 4 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2002

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approving L(+) lactic acid as an existing active substance for use in biocidal products of product-types 2, 3 and 4

(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 the third subparagraph of Article 89(1) 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 products of product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, product-type 3, veterinary hygiene, and product type 4, food and feed area, as described in Annex V to Regulation (EU) No 528/2012.

(3) Germany was designated as evaluating competent authority and submitted the assessment reports together with its recommendations on 3 May 2016.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 27 April 2017 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products of product-types 2, 3 and 4 and containing L(+) lactic acid may be expected to satisfy the criteria of Article 19(1)(b) of Regulation (EU) No 528/2012, provided that certain specifications and conditions concerning their use are complied with.

(6) It is therefore appropriate to approve L(+) lactic acid for use in biocidal products of product-types 2, 3 and 4, subject to compliance with certain specifications and conditions.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/2002. (See end of Document for details)*

(7) 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.

(8) 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-types 2, 3 and 4, subject to the specifications and 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, 8 November 2017.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/2002. (See end of Document for details)*

ANNEX

Common Name	IUPAC NameIdentification Numbers	Minimum degree of purity of the active substance[a]	Date of approval	Expiry date of approval	Product type	Specific conditions
L(+) lactic acid	IUPAC Name: (S)-2-Hydroxypropanoic acid EC No: 201-196-2 CAS No: 79-33-4	≥ 955 g/kg (dry weight)	1 May 2019	30 April 2029	2	The authorisations of biocidal products are subject to the following condition: The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.
					3	The authorisations of biocidal products are subject to the

a 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.

						following conditions: 1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance. 2. In view of the risks identified for the uses assessed,

a 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.