COMMISSION IMPLEMENTING REGULATION (EU) 2016/1938

of 4 November 2016

approving citric acid as an existing active substance for use in biocidal products of product-type 2

(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 citric acid.

(2) Citric acid has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council ([3]) for use in products of product-type 1, human hygiene biocidal products, as defined in Annex V to that Directive, which corresponds to product-type 1 as defined in Annex V to Regulation (EU) No 528/2012.

(3) However, the evaluation covered an anti-viral tissue impregnated with citric acid which would be placed on the market with the claim 'kills 99,9 % of cold & flu viruses in the tissue'. In accordance with Article 1 of Commission Implementing Decision (EU) 2015/1985 ([4]), such anti-viral tissue is to be considered as a biocidal product falling within product-type 2 as defined in Annex V to Regulation (EU) No 528/2012. Therefore, this approval of citric acid as an existing active substance should only cover its use in biocidal products of product-type 2, disinfectants and algaecides not intended for direct application to humans or animals.

(4) Belgium was designated as evaluating competent authority and submitted the assessment report together with its recommendations on 23 August 2013.

(5) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 16 February 2016 for use in products of product-type 2 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(6) According to that opinion, biocidal products of product-type 2 containing citric acid may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.

(7) It is therefore appropriate to approve citric acid for use in biocidal products of product-type 2, subject to compliance with certain specifications and conditions.

(8) 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.

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

([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]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).
([4]) Commission Implementing Decision (EU) 2015/1985 of 4 November 2015 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on an anti-viral tissue impregnated with citric acid (OJ L 289, 5.11.2015, p. 26).

HAS ADOPTED THIS REGULATION:

Article 1

Citric acid is approved as an active substance for use in biocidal products of product-type 2, 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, 4 November 2016.

For the Commission
The President
Jean-Claude JUNCKER

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
Citric acid	IUPAC Name: 2-hydroxy-1,2,3-propanetricarboxylic acid EC No: 201-069-1 CAS No: 77-92-9	995 g/kg	1 March 2018	28 February 2028	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.

(1) The purity indicated in this column was the minimum degree of purity of the active substance evaluated in accordance with Article 89(1) of Regulation (EU) No 528/2012. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated active substance.