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)

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(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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/1938. (See end of Document for details)*

(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,

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