Commission Implementing Regulation (EU) 2016/672 of 29 April 2016 approving peracetic acid as an existing active substance for use in biocidal products for product-types 1, 2, 3, 4, 5 and 6 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/672

of 29 April 2016

approving peracetic acid as an existing active substance for use in biocidal products for product-types 1, 2, 3, 4, 5 and 6

(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 peracetic acid.

(2) Peracetic 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 product-type 1, human hygiene biocidal products, product-type 2, private area and public health area disinfectants and other biocidal products, product-type 3, veterinary hygiene biocidal products, product-type 4, food and feed area disinfectants, product-type 5, drinking water disinfectants, and product-type 6, in-can preservatives, as defined in Annex V to that Directive, which correspond respectively to product-types 1, 2, 3, 4, 5 and 6 as defined in Annex V to Regulation (EU) No 528/2012.

(3) Finland was designated as evaluating competent authority and submitted the assessment reports together with its recommendations on 16 January 2013.

(4) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 30 September 2015 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products used for product-types 1, 2, 3, 4, 5 and 6 and containing peracetic acid may be expected to satisfy the requirements of Article 19(1)(b) of Regulation (EU) No 528/2012, provided that certain conditions concerning its use are complied with.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/672. (See end of Document for details)*

(6) It is therefore appropriate to approve peracetic acid for use in biocidal products for product-types 1, 2, 3, 4, 5 and 6 subject to compliance with certain specifications and conditions.

(7) For the use in product-type 4, the evaluation did not address the incorporation of biocidal products containing peracetic acid in materials and articles intended to come into contact directly or indirectly with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council[(4)]. Such materials may require the establishment of specific limits on the migration into food, as referred to in Article 5(1)(e) of that Regulation. The approval should therefore not cover such use unless the Commission has established such limits or it has been established pursuant to that Regulation that such limits are not necessary.

(8) Peracetic acid is in an aqueous solution containing acetic acid and hydrogen peroxide. Due to the presence of hydrogen peroxide, which can be used in the production of explosive precursors, Regulation (EU) No 98/2013 of the European Parliament and of the Council[(5)] should continue to apply to hydrogen peroxide.

(9) 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.

(10) 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

Peracetic acid is approved as an active substance for use in biocidal products for product-types 1, 2, 3, 4, 5 and 6, 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, 29 April 2016.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/672. (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
Peracetic acid	IUPAC Name: Peroxyethanoic acid EC No: 201-186-8 CAS No: 79-21-0	The specification is based on the starting materials hydrogen peroxide and acetic acid which are used to manufacture peracetic acid. Peracetic acid in an aqueous solution containing acetic acid and hydrogen peroxide.	1 October 2017	30 September 2027	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 of the active substance. The authorisations of biocidal products are subject to the following conditions: (1) Due to the presence of hydrogen peroxide,

a The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made 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.

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						authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013.
					(2)	For professional users, safe operational procedures and appropriate organisational measures shall be established.
					2	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

a The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made 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.

						assessment of the active substance. The authorisations of biocidal products are subject to the following conditions: (1) Due to the presence of hydrogen peroxide, authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013. (2) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used

a The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made 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.