Commission Implementing Regulation (EU) 2016/2290 of 16 December 2016 approving peracetic acid as an existing active substance for use in biocidal products of product-types 11 and 12 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/2290

of 16 December 2016

approving peracetic acid as an existing active substance for use in biocidal products of product-types 11 and 12

(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 for use in products of product-type 11, preservatives for liquid-cooling and processing systems, and of product-type 12, slimicides, as described 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 3 July 2015.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 14 June 2016 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 11 and 12 and containing peracetic 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 peracetic acid for use in biocidal products of product-types 11 and 12, subject to compliance with certain specifications and conditions.

(7) 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 explosives precursors, authorisations of biocidal products containing peracetic acid

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/2290. (See end of Document for details)*

should be without prejudice to Regulation (EU) No 98/2013 of the European Parliament and of the Council[(3)].

(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

Peracetic acid is approved as an active substance for use in biocidal products of product-types 11 and 12, 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, 16 December 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) 2016/2290. (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 July 2018	30 June 2028	11	The authorisations of biocidal products are subject to the 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

a 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 to be technically equivalent to the evaluated active substance.

						of the active substance. 2. Due to the presence of hydrogen peroxide, authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013. 3. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:. a) industrial and professional users; b) marine water for products

a 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 to be technically equivalent to the evaluated active substance.