Commission Implementing Regulation (EU) 2017/1278 of 14 July 2017 approving 2-methylisothiazol-3(2H)-one as an existing active substance for use in biocidal products of product-type 11 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1278

of 14 July 2017

approving 2-methylisothiazol-3(2H)-one as an existing active substance for use in biocidal products of product-type 11

(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 2-methylisothiazol-3(2H)-one.

(2) 2-methylisothiazol-3(2H)-one has been evaluated for use in products of product-type 11, preservatives for liquid-cooling and processing systems, as described in Annex V to Regulation (EU) No 528/2012.

(3) Slovenia was designated as evaluating competent authority and submitted the assessment report together with its recommendations on 7 April 2016.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 15 December 2016 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, biocidal products of product-type 11 containing 2-methylisothiazol-3(2H)-one 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 2-methylisothiazol-3(2H)-one for use in biocidal products of product-type 11, subject to compliance with certain specifications and conditions.

(7) Since 2-methylisothiazol-3(2H)-one meets the criteria for classification as skin sensitiser sub-category 1A as specified in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(3)], treated articles treated with or

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incorporating 2-methylisothiazol-3(2H)-one should be appropriately labelled when placed on the market.

(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

2-methylisothiazol-3(2H)-one is approved as an active substance for use in biocidal products of product-type 11, 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, 14 July 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) 2017/1278. (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
2-methylisothiazol-3(2H)-one	IUPAC Name2-methylisothiazol-3(2H)-one EC No: 220-239-6 CAS No: 2682-20-4	950 g/kg	1 January 2019	31 December 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. 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.