Commission Implementing Regulation (EU) 2015/1726 of 28 September 2015 approving 2-methylisothiazol-3(2H)-one as an existing active substance for use in biocidal products for product-type 13 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1726

of 28 September 2015

approving 2-methylisothiazol-3(2H)-one as an existing active substance for use in biocidal products for product-type 13

(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 or inclusion into Annex I to Regulation (EU) No 528/2012.

(2) That list includes 2-methylisothiazol-3(2H)-one.

(3) 2-methylisothiazol-3(2H)-one has been evaluated in accordance Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council[(3)] for use in product-type 13, metalworking-fluid preservatives, as defined in Annex V to that Directive, which corresponds to product-type 13, as defined in Annex V to Regulation (EU) No 528/2012.

(4) Slovenia was designated as evaluating competent authority and submitted the assessment report, together with its recommendations, to the Commission on 11 April 2012 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007[(4)].

(5) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 2 October 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(6) According to that opinion, biocidal products used for product-type 13 and containing 2-methylisothiazol-3(2H)-one may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC 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) 2015/1726. (See end of Document for details)*

(7) It is therefore appropriate to approve 2-methylisothiazol-3(2H)-one for use in biocidal products for product-type 13 subject to compliance with the specific conditions in the Annex.

(8) Since 2-methylisothiazol-3(2H)-one meets the criteria for classification as skin sensitiser sub-category 1A as defined in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(5)], treated articles treated with or incorporating 2-methylisothiazol-3(2H)-one should be appropriately labelled when placed on the market.

(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

2-methylisothiazol-3(2H)-one is approved as an active substance for use in biocidal products for product-type 13, 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, 28 September 2015.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/1726. (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 Name: 2-methylisothiazol-3(2H)-one EC No: 220-239-6 CAS No: 2682-20-4	95 % w/w	1 October 2016	30 September 2026	13	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) For professional users, safe operational procedures and

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 16(2) of Directive 98/8/EC. 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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							appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.
						(2)	In view of the risks to the professional users, loading of the products into metalworking fluids shall be semi-automated or automated unless

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 16(2) of Directive 98/8/EC. 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.