EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving 2-methylisothiazol-3(2H)-one as an existing active substance for use in biocidal products of product-type 12

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

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

(2) 2-methylisothiazol-3(2H)-one has been evaluated for use in products of product-type 12, slimicides, 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 2 March 2017 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 12 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 12, 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

[1] OJ L 167, 27.6.2012, p. 1.

[2] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

[3] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives

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 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,

For the Commission
The President
Jean-Claude JUNCKER

67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).