COMMISSION IMPLEMENTING REGULATION (EU) 2017/2327

of 14 December 2017

approving 2-methyl-1,2-benzisothiazol-3(2H)-one as an active substance for use in biocidal products of product-type 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 Article 90(2) thereof,

Whereas:

(1) Poland received on 26 November 2009 an application, in accordance with Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council ([2]), for the inclusion of the active substance 2-methyl-1,2-benzisothiazol-3(2H)-one in Annex I to that Directive for use in products of product-type 6, in-can preservatives, as described in Annex V to that Directive, which corresponds to product-type 6 as described in Annex V to Regulation (EU) No 528/2012.

(2) Poland submitted the assessment report together with its recommendations on 24 March 2016 in accordance with Article 90(2) of Regulation (EU) No 528/2012.

(3) The opinion of the European Chemicals Agency was formulated on 27 June 2017 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(4) According to that opinion, biocidal products of product-type 6 containing 2-methyl-1,2-benzisothiazol-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.

(5) It is therefore appropriate to approve 2-methyl-1,2-benzisothiazol-3(2H)-one for use in biocidal products of product-type 6, subject to compliance with certain specifications and conditions.

(6) Since 2-methyl-1,2-benzisothiazol-3(2H)-one meets the criteria for classification as a skin sensitiser sub-category 1A (strong sensitiser) as specified in point 3.4.2.2.1.2 of Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([3]), treated articles treated with or incorporating 2-methyl-1,2-benzisothiazol-3(2H)-one should be labelled appropriately when placed on the market.

(7) 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.

(8) 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-methyl-1,2-benzisothiazol-3(2H)-one is approved as an active substance for use in biocidal products of product-type 6, subject to the specifications and conditions set out in the Annex.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, 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 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

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 December 2017.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance [1]	Date of approval	Expiry date of approval	Product type	Specific conditions
2-methyl-1,2-benzisothiazol-3(2H)-one (MBIT)	IUPAC Name: 2-methyl-1,2-benzisothiazol-3(2H)-one EC No: Not available CAS No: 2527-66-4	≥ 997 g/kg	1 July 2018	30 June 2028	6	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 of the active substance; (2) in view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: (a) professional users; (b) surface water and groundwater for the outdoor use of preserved paints and plasters and the use of preserved fluids used in paper, textile or leather production. The placing on the market of treated articles is subject to the following condition: The person responsible for the placing on the market of a treated article treated with or incorporating 2-methyl-1,2-benzisothiazol-3(2H)-one shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

[1] 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.