COMMISSION IMPLEMENTING REGULATION (EU) 2017/1277

of 14 July 2017

approving 2-octyl-isothiazol-3(2H)-one as an active substance for use in biocidal products of product-type 8

(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) The United Kingdom received on 27 April 2010 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-octyl-isothiazol-3(2H)-one in Annex I to that Directive for use in products of product-type 8, wood preservatives, as described in Annex V to that Directive, which corresponds to product-type 8 as described in Annex V to Regulation (EU) No 528/2012.

(2) The United Kingdom submitted the assessment report together with its recommendations on 4 February 2016 in accordance with Article 90(2) of Regulation (EU) No 528/2012.

(3) 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.

(4) According to that opinion, biocidal products of product-type 8 and containing 2-octyl-isothiazol-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-octyl-isothiazol-3(2H)-one for use in biocidal products of product-type 8, subject to compliance with certain specifications and conditions.

(6) Since 2-octyl-isothiazol-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 incorporating 2-octyl-isothiazol-3(2H)-one should be appropriately labelled 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-octyl-isothiazol-3(2H)-one is approved as an active substance for use in biocidal products of product-type 8, 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 July 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-octyl-isothiazol-3(2H)-one	IUPAC Name: 2-octyl-isothiazol-3(2H)-one EC No: 247-761-7 CAS No: 26530-20-1	960 g/kg w/w	1 January 2018	31 December 2027	8	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 industrial and professional users. (3) In view of the risks identified for the surface water, sediment and soil, labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil sewer or water, and that any losses shall be collected for reuse or disposal. 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-octyl-isothiazol-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.