Commission Implementing Regulation (EU) 2016/131 of 1 February 2016 approving C(M)IT/MIT (3:1) as an existing active substance for use in biocidal products for product-types 2, 4, 6, 11, 12 and 13 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/131

of 1 February 2016

approving C(M)IT/MIT (3:1) as an existing active substance for use in biocidal products for product-types 2, 4, 6, 11, 12 and 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. That list includes C(M)IT/MIT (3:1).

(2) C(M)IT/MIT (3:1) has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council[(3)] for use in product-type 2, private area and public health area disinfectants and other biocidal products, product-type 4, food and feed area disinfectants, product-type 6, in-can preservatives, product-type 11, preservatives for liquid-cooling and processing systems, product-type 12, slimicides, and product-type 13, metalworking-fluid preservatives, as defined in Annex V to that Directive, which correspond respectively to product-types 2, 4, 6, 11, 12 and 13 as defined in Annex V to Regulation (EU) No 528/2012.

(3) France was designated as evaluating competent authority and submitted the assessment reports, together with its recommendations, to the Commission on 19 October 2011, 27 November 2012 and 22 April 2013 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007[(4)].

(4) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 5 February 2015, 14 April 2015 and 17 June 2015 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products used for product-types 2, 4, 6, 11, 12 and 13 and containing C(M)IT/MIT (3:1) may be expected to satisfy the requirements of 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) 2016/131. (See end of Document for details)*

(6) It is therefore appropriate to approve C(M)IT/MIT (3:1) for use in biocidal products for product-types 2, 4, 6, 11, 12 and 13 subject to compliance with certain specifications and conditions.

(7) For the use in product-type 4, the evaluation did not address the incorporation of biocidal products containing C(M)IT/MIT (3:1) in materials and articles intended to come into contact directly or indirectly with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council[(5)]. Such materials may require the establishment of specific limits on the migration into food, as referred to in Article 5(1)(e) of that Regulation. The approval should therefore not cover such use unless the Commission has established such limits or it has been established pursuant to that Regulation that such limits are not necessary.

(8) Since C(M)IT/MIT (3:1) meets the criteria for classification as skin sensitiser category 1 as defined in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(6)], treated articles treated with or incorporating C(M)IT/MIT (3:1) 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

C(M)IT/MIT (3:1) is approved as an active substance for use in biocidal products for product-types 2, 4, 6, 11, 12 and 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, 1 February 2016.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/131. (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**
C(M)IT/ MIT (3:1)	IUPAC Name: Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) EC No: n/a CAS No: 55965-84-9	579 g/kg (theoretical calculated dry weight). The active substance is manufactured as a technical concentrate (TK) with different solvents and stabilisers.	1 July 2017	30 June 2027	2	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 condition: For professional users, safe operational procedures and 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. 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 C(M)IT/ MIT (3:1) shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation

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						(EU) No 528/2012.
					4	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 appropriate organisational measures shall be established. Products shall