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.

(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.

([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]) 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).
([4]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).
([5]) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

(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 [1], 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

[1] 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).

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
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 (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 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 identified for professional users, biocidal products shall only be loaded by automated systems, unless it can be demonstrated that risks can be reduced to an acceptable level by other means.

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
						(3) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (2) or Regulation (EC) No 396/2005 of the European Parliament and of the Council (3) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. (4) Products shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of C(M)IT/MIT (3:1) into food or it has been established pursuant to that Regulation that such limits are not necessary. 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 (EU) No 528/2012.
					6	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 industrial or 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. (2) In view of the risks to the environment, biocidal products shall not be used to preserve pulp and paper processing fluids, unless it can be demonstrated that risks can be reduced to an acceptable level.

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
						The placing on the market of treated articles is subject to the following conditions: (1) In view of the risks identified for human health, mixtures treated with or incorporating C(M)IT/MIT (3:1) and placed on the market for use by the general public shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless exposure can be avoided by other means than the wearing of personal protective equipment. (2) In view of the risks identified for human health, liquid detergents treated with or incorporating C(M)IT/MIT (3:1) and placed on the market for use by professional users shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless exposure can be avoided by other means than the wearing of personal protective equipment. (3) In view of the risks identified for human health, mixtures treated with or incorporating C(M)IT/MIT (3:1), other than liquid detergents, and placed on the market for use by professional users shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless exposure can be avoided, including by the wearing of personal protective equipment. (4) 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 (EU) No 528/2012.
					11	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 be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

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) In view of the risks identified for the environment, products shall not be authorised for the preservation of photographic processing liquid, preservation of wood treatment solution and for the use in large open recirculating cooling systems unless it can be demonstrated that risks can be reduced to an acceptable level. (3) In view of risks identified for the environment, and unless it can be demonstrated that risks can be reduced to an acceptable level, labels and, where provided, safety data sheet of products shall indicate that: (a) For uses in small open recirculating cooling systems, risk mitigation measures shall be in place to reduce the direct contamination of terrestrial compartment via air deposition. (b) For uses other than those specified under condition (2), release of waste water from the facilities shall be directed to a sewage treatment plant. 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 (EU) No 528/2012.
					12	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 be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

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) In view of the risks identified for the environment, products shall not be authorised for use in off-shore installations, unless it can be demonstrated that risks can be reduced to an acceptable level. (3) In view of the risks identified for human health, labels or safety data sheets of products authorised for off-shore installations shall indicate that drilling mud shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless safe operational procedures and appropriate organisational measures can be established for workers. (4) In view of the risks identified for the environment, labels or safety data sheets of products authorised for use in paper mills shall indicate the need for an appropriate dilution of the industrial release from the facilities into the watercourse after mechanical/chemical treatment or after treatment in a sewage treatment plant, unless it can be demonstrated that risks can 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 (EU) No 528/2012.
					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 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 identified for professional users, loading of the products into metalworking fluids shall be semi-automated or automated, unless it can be demonstrated that risks can be reduced to an acceptable level by other means.

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
						(3) In view of the risks identified for professional users, labels and, where provided, safety data sheets shall indicate that the products shall not be used in metal working fluids at a concentration triggering classification as skin sensitiser, unless it can be demonstrated that risks can 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 (EU) No 528/2012.

(1) 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.

(2) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

(3) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).