COMMISSION IMPLEMENTING REGULATION (EU) 2015/1981

of 4 November 2015

approving Formaldehyde released from N,N-Methylenebismorpholine as an existing active substance for use in biocidal products for product-types 6 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.

(2) That list includes N,N-Methylenebismorpholine, to be renamed formaldehyde released from N,N-Methylenebismorpholine (hereafter referred to as 'MBM'), as the result of its evaluation.

(3) MBM 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 6, in-can preservatives, and product-type 13, metalworking-fluid preservatives, as defined in Annex V to that Directive, which correspond respectively to product-types 6 and 13 as defined in Annex V to Regulation (EU) No 528/2012.

(4) Austria was designated as evaluating competent authority and submitted the assessment reports, together with its recommendations, to the Commission on 25 July 2013 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 ([4]).

(5) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 3 October 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(6) According to those opinions, biocidal products used for product-types 6 and 13 and containing MBM may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC provided that certain conditions concerning its use are complied with.

(7) It is therefore appropriate to approve MBM for use in biocidal products for product-types 6 and 13 subject to compliance with the specific conditions in the Annex.

(8) The opinions conclude that MBM meets the criteria for classification as carcinogenic category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([5]).

([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 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).

(9) Since pursuant to Article 90(2) of Regulation (EU) No 528/2012, substances for which the Member States' evaluation has been completed by 1 September 2013 should be approved in accordance with Directive 98/8/EC, the period of approval should be 5 years in accordance with the practice established under that Directive.

(10) For the purposes of Article 23 of Regulation (EU) No 528/2012 however, MBM meets the conditions of Article 10(1)(a) of that Regulation and should therefore be considered a candidate for substitution.

(11) Furthermore, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the competent authorities should also evaluate whether the conditions of Article 5(2) can be satisfied to decide if a biocidal product containing MBM can be authorised or not.

(12) Since MBM meets the criteria for classification as carcinogenic category 1B, and as skin sensitiser category 1 as defined in Annex I to Regulation (EC) No 1272/2008, treated articles treated with or incorporating MBM should be appropriately labelled when placed on the market.

(13) 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.

(14) 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

Formaldehyde released from N,N-Methylenebismorpholine is approved as an active substance for use in biocidal products for product-types 6 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, 4 November 2015.

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
Formaldehyde released from N,N-Methylenebismorpholine (hereafter referred to as 'MBM')	IUPAC Name: N,N-Methylenebismorpholine EC No: 227-062-3 CAS No: 5625-90-1	92,1 % w/w	1 April 2017	31 March 2022	6	MBM is considered a candidate for substitution in accordance with Article 10(1)(a) of Regulation (EU) No 528/2012. 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. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. The authorisations of biocidal products are subject to the following conditions: (1) Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met. (2) 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. (3) In view of the risks to professional users, mixing and loading of products to formulation vessels shall be automated, unless it can be demonstrated that potential exposure of skin, eye and respiratory tracts to MBM 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 MBM 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.

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
					13	MBM is considered a candidate for substitution in accordance with Article 10(1)(a) of Regulation (EU) No 528/2012. 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. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. The authorisations of biocidal products are subject to the following conditions: (1) Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met. (2) 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. (3) In view of the risks to professional users, mixing and loading of products to formulation vessels shall be automated, unless it can be demonstrated that potential exposure of skin, eye and respiratory tracts to MBM 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 MBM 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.