Commission Implementing Regulation (EU) 2016/1083 of 5 July 2016 approving amines, N-C10–16-alkyltrimethylenedi-, reaction products with chloroacetic acid as an existing active substance for use in biocidal products of product-types 2, 3 and 4 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/1083

of 5 July 2016

approving amines, N-$C_{10–16}$-alkyltrimethylenedi-, reaction products with chloroacetic acid as an existing active substance for use in biocidal products of product-types 2, 3 and 4

(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 amines, N-$C_{10–16}$-alkyltrimethylenedi-, reaction products with chloroacetic acid.

(2) Amines, N-$C_{10–16}$-alkyltrimethylenedi-, reaction products with chloroacetic acid 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 products of product-type 2, private area and public health area disinfectants and other biocidal products, of product-type 3, veterinary hygiene biocidal products, and of product-type 4, food and feed area disinfectants, as described in Annex V to that Directive, which correspond respectively to product-types 2, 3 and 4 as described in Annex V to Regulation (EU) No 528/2012.

(3) Ireland was designated as evaluating competent authority and submitted the assessment reports together with its recommendations on 30 August 2013.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 15 April 2015 for use in products of product-type 3 and on 8 December 2015 for use in products of product-types 2 and 4 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products of product-types 2, 3 and 4 and containing amines, N-$C_{10–16}$-alkyltrimethylenedi-, reaction products with chloroacetic acid may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC,

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provided that certain specifications and conditions concerning their use are complied with.

(6) It is therefore appropriate to approve amines, N-$C_{10–16}$-alkyltrimethylenedi-, reaction products with chloroacetic acid for use in biocidal products of product-types 2, 3 and 4, subject to compliance with certain specifications and conditions.

(7) For use in products of product-type 4, the evaluation did not address the incorporation of biocidal products containing amines, N-$C_{10–16}$-alkyltrimethylenedi-, reaction products with chloroacetic acid in materials and articles intended to come into contact directly or indirectly with food referred to in Article 1(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council[4]. The approval should therefore not cover such use, unless the Commission has established specific limits on the migration into food, as referred to in Article 5(1)(e) of that Regulation, or has established that such limits are not necessary.

(8) 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.

(9) 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

Amines, N-$C_{10–16}$-alkyltrimethylenedi-, reaction products with chloroacetic acid is approved as an active substance for use in biocidal products of product-types 2, 3 and 4, 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, 5 July 2016.

For the Commission

The President

Jean-Claude JUNCKER

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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
Amines, N-$C_{10–16}$-alkyltrimethylenedi-, reaction products with chloroacetic acid	IUPAC Name: Amines, N-$C_{10–16}$-alkyltrimethylenedi-, reaction products with chloroacetic acid EC No: N/A CAS No: 139734-65-9	The theoretical calculated dry weight specification: 1 000 g/kg (100,0 %, by wt). The active substance as manufactured is an aqueous solution of 160-220 g/kg of amines, N-$C_{10–16}$-alkyltrimethylenedi-, reaction products with chloroacetic acid (16-22 %, by wt).	1 January 2018	31 December 2027	2	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

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							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) children for products used in institutional areas; (c) surface water and sediment for products used in industrial or institutional areas; (d) soil for products used in industrial areas.
					3		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