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, 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.

([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]) 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) 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

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
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 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 product assessment shall pay particular attention to: (a) professional users; (b) surface water and sediment for products used for: (i) the disinfection of animal housing; (ii) the disinfection of vehicles used for animal transport; (iii) the disinfection of footwear and animals' hooves;

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						(c) soil for products used for the disinfection of vehicles used for animal transport; (d) micro-organisms of the sewage treatment plant for products used for the disinfection of footwear and animals' hooves. (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	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: (a) professional users; (b) surface water and sediment for products used in: (i) food, drink and milk industry sites; (ii) milking parlours; (iii) slaughterhouses and butcheries and (iv) large-scale catering kitchens and canteens; (c) soil for products used in: (i) food, drink and milk industry sites; (ii) slaughterhouses and butcheries; and (iii) large-scale catering kitchens and canteens.

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						(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 or Regulation (EC) No 396/2005 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 amines, N-$C_{10–16}$-alkyltrimethylenedi-, reaction products with chloroacetic acid into food or it has been established pursuant to that Regulation that such limits are not necessary.

(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 89(1) of Regulation (EU) No 528/2012. 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).