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COMMISSION

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**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**of **XXX****

**approving Amines, N-C10–C16-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)

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**approving Amines, N-C10–C16-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<sup>1</sup>, and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014<sup>2</sup> establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes Amines, N-C10–C16-alkyltrimethylenedi-, reaction products with chloroacetic acid.
- (2) Amines, N-C10–C16-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<sup>3</sup> 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-C10–C16-alkyltrimethylenedi-, reaction products with

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<sup>1</sup> OJ L 167, 27.6.2012, p. 1.

<sup>2</sup> 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).

<sup>3</sup> 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).

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-C10–C16-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-C10–C16-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<sup>4</sup>. 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-C10–C16-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,

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*

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<sup>4</sup> 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).