II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2016/1093

of 6 July 2016

approving didecylmethylpoly(oxyethyl)ammonium propionate as an existing active substance for use in biocidal products of product-type 8

(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 didecylmethylpoly(oxyethyl) ammonium propionate.

(2) Didecylmethylpoly(oxyethyl)ammonium propionate 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 8, wood preservatives, as defined in Annex V to that Directive, which corresponds to product-type 8 as defined in Annex V to Regulation (EU) No 528/2012.

(3) Italy was designated as evaluating competent authority and submitted the assessment reports together with its recommendations on 20 November 2007.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 8 December 2015 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, biocidal products of product-type 8 and containing didecylmethylpoly(oxyethyl) ammonium propionate may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain conditions concerning their use are complied with.

(6) It is therefore appropriate to approve didecylmethylpoly(oxyethyl)ammonium propionate for use in biocidal products of product-type 8, subject to compliance with certain specifications and conditions.

([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).

(7) 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.

(8) 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

Didecylmethylpoly(oxyethyl)ammonium propionate is approved as an active substance for use in biocidal products of product-type 8, 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, 6 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
Didecylmethylpoly (oxyethyl)ammonium propionate	IUPAC Name: Alpha-[2-(didecylmethylammonio)ethyl]-.omega.-hydroxy-poly(oxy-1,2-ethanediyl) propionate EC No: None assigned CAS No: 94667-33-1	86,1 % w/w (dry-weight)	1 January 2018	31 December 2027	8	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) industrial and professional users; (b) groundwater for wood in service that will be exposed to frequent weathering. (3) In view of the risks identified for surface and groundwater, labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

(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.