COMMISSION IMPLEMENTING REGULATION (EU) 2023/2088

of 28 September 2023

approving reaction mass of N,N-didecyl-N-(2-hydroxyethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-hydroxyethoxy)ethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-(2-hydroxyethoxy)ethoxy)ethyl)-N-methylammonium propionate as an active substance for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 Article 89(1), third subparagraph, thereof,

Whereas:

(1) Didecylmethylpoly(oxyethyl)ammonium propionate was approved as an existing active substance for use in biocidal products of product-type 8 by Commission Implementing Regulation (EU) 2016/1093 ([2]).

(2) Didecylmethylpoly(oxyethyl)ammonium propionate is also included in the list of existing active substances of Annex II to Commission Delegated Regulation (EU) No 1062/2014 ([3]) for product-types 2, 4 and 10, referred to with its chemical name 'poly(oxy-1,2- ethanediyl),.alpha.-[2-(didecylmethylammonio)ethyl]-.omega.-hydroxy-, propanoate (salt) ('Bardap 26').

(3) On 22 November 2022, the Biocidal Products Committee of the European Chemicals Agency (the 'Agency') adopted the opinions on the applications for approval of the active substance for use in biocidal products of product-types 2 ([4]) and 4 ([5]), and submitted them to the Commission in accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014.

(4) In those opinions, the Agency concluded that the substance composition and reference specification was consistent with the active substance assessed and approved under product-type 8, but that the name of the substance in the list of Annex II to Delegated Regulation (EU) No 1062/2014 and, consequently, in Implementing Regulation (EU) 2016/1093 was not appropriate. Therefore, pursuant to Article 13 of Delegated Regulation (EU) No 1062/2014, the identity of the active substance didecylmethylpoly(oxyethyl)ammonium propionate was redefined to reaction mass of N,N-didecyl-N-(2-hydroxyethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-hydroxyethoxy)ethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-(2-hydroxyethoxy)ethoxy) ethyl)-N-methylammonium propionate ('DMPAP').

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) 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 (OJ L 182, 7.7.2016, p. 1).

([3]) 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).

([4]) Biocidal Products Committee Opinion on the application for approval of the active substance reaction mass of N,N-didecyl-N-(2-hydroxyethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-hydroxyethoxy)ethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-(2-hydroxyethoxy)ethoxy)ethyl)-N-methylammonium propionate; product-type 2; ECHA/BPC/363/2022.

([5]) Biocidal Products Committee Opinion on the application for approval of the active substance reaction mass of N,N-didecyl-N-(2-hydroxyethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-hydroxyethoxy)ethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-(2-hydroxyethoxy)ethoxy)ethyl)-N-methylammonium propionate; product-type 4; ECHA/BPC/364/2022.

(5) Consequently, the identity of the active substance also needs to be changed in Implementing Regulation (EU) 2016/1093. As a number of changes related to the redefinition of the substance need to be made in Implementing Regulation (EU) 2016/1093, in the interests of clarity, that Regulation should be replaced.

(6) 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

Reaction mass of N,N-didecyl-N-(2-hydroxyethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-hydroxyethoxy)ethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-(2-hydroxyethoxy)ethoxy)ethyl)-N-methylammonium propionate is approved as an active substance for use in biocidal products of product-type 8, subject to the conditions set out in the Annex.

Article 2

Implementing Regulation (EU) 2016/1093 is repealed.

Article 3

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, 28 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

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
reaction mass of N,N-didecyl-N-(2-hydroxyethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-hydroxyethoxy) ethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-(2-hydroxyethoxy) ethoxy)ethyl)-N-methylammonium propionate ('DMPAP')	reaction mass of N,N-didecyl-N-(2-hydroxyethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-hydroxyethoxy) ethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-(2-hydroxyethoxy) ethoxy)ethyl)-N-methylammonium propionate EC No: - CAS No: -	86,1 % w/w dry weight	1 January 2018	31 December 2027	8	The authorisation of biocidal products is subject to the following conditions: (a) the product assessment pays 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; (b) the product assessment pays particular attention to: (i) industrial and professional users; (ii) groundwater for wood in service that will be exposed to frequent weathering; (c) labels and, where provided, safety data sheets of products authorised indicate that industrial or professional application is conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber is 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 are collected for reuse or disposal.

([1]) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.