COMMISSION IMPLEMENTING REGULATION (EU) 2023/2089

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-types 2 and 4 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) 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 for use in biocidal products of product-type 2, private area and public health area disinfectants and other biocidal products, and product-type 4, food and feed area disinfectants, as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which correspond to product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, and product-type 4, food and feed area disinfectants, as described in Annex V to Regulation (EU) No 528/2012.

(3) Italy was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment reports together with its conclusions to the Commission on 27 July 2010. After the submission of the assessment reports, discussions took place in technical meetings organised by the Commission and, after 1 September 2013, by the European Chemicals Agency (the 'Agency').

(4) It follows from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 are to be assessed under the evaluation criteria of Directive 98/8/EC.

(5) During the examination of didecylmethylpoly(oxyethyl)ammonium propionate, the identity of this active substance has been redefined in accordance with Article 13 of Delegated Regulation (EU) No 1062/2014 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 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).

(6) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinions of the Agency ECHA/BPC/363/2022 ([4]) and ECHA/BPC/364/2022 ([5]) on 22 November 2022, having regard to the conclusions of the evaluating competent authority.

(7) According to those opinions, biocidal products of product-types 2 and 4 containing DMPAP may be expected to satisfy the requirements corresponding to those laid down in Article 5(1), points (b), (c) and (d), of Directive 98/8/EC, provided that certain requirements concerning their use are complied with.

(8) Taking into account the opinions of the Agency, it is appropriate to approve DMPAP as an active substance for use in biocidal products of product-types 2 and 4 subject to compliance with certain conditions.

(9) 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.

(10) 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-types 2 and 4 subject to the 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, 28 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

([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.

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 February 2025	31 January 2035	2	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) professional users; (ii) environment: groundwater.
					4	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) professional users; (ii) environment: groundwater. (c) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels (MRLs) need to be set or the existing MRLs need to be amended 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]), and any appropriate risk mitigation measures shall be taken to ensure that such MRLs are not exceeded; (d) products containing DMPAP are not incorporated in materials and articles intended to come into contact with food that falls within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council ([4]), unless the Commission has established specific limits on the migration of DMPAP 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 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.

(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).

(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).