



2024/2964

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COMMISSION IMPLEMENTING REGULATION (EU) 2024/2964

of 29 November 2024

**approving reaction products of boric acid with didecylamine and ethylene oxide (polymeric betaine)
as an existing 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) 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 N-Didecyl-N-dipolyethoxyammonium borate/Didecylpolyoxethylammonium borate (Polymeric betaine) (CAS No: 214710-34-6) for product-type 8.
- (2) N-Didecyl-N-dipolyethoxyammonium borate/Didecylpolyoxethylammonium borate (Polymeric betaine) has been evaluated for use in biocidal products of product-type 8 (wood preservatives), as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ⁽³⁾, which corresponds to product-type 8 as described in Annex V to Regulation (EU) No 528/2012.
- (3) Greece was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the Commission on 25 February 2011. After the submission of the assessment report, discussions took place in technical meetings organised by the European Chemicals Agency ('the Agency').
- (4) It follows from Article 90(2), first subparagraph, of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 are to be evaluated in accordance with the substantive conditions for approval laid down in Directive 98/8/EC.
- (5) During the examination of N-Didecyl-N-dipolyethoxyammonium borate/Didecylpolyoxethylammonium borate (Polymeric betaine), the name of that active substance has been renamed by the Agency to reaction products of boric acid with didecylamine and ethylene oxide (polymeric betaine).
- (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 read in conjunction with Article 75(1) and (4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinion of the Agency on 29 May 2024 ⁽⁴⁾, having regard to the conclusions of the evaluating competent authority.
- (7) In its opinion, the Agency concluded that biocidal products of product-type 8 containing reaction products of boric acid with didecylamine and ethylene oxide (polymeric betaine) may be expected to satisfy the requirements 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.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>.

⁽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, ELI: http://data.europa.eu/eli/reg_del/2014/1062/oj).

⁽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, ELI: <http://data.europa.eu/eli/dir/1998/8/oj>).

⁽⁴⁾ Biocidal Products Committee Opinion on the application for approval of the active substance reaction products of boric acid with didecylamine and ethylene oxide (Polymeric betaine); Product-type: 8; ECHA/BPC/424/2024, adopted on 29 May 2024.

- (8) Taking into account the opinion of the Agency, it is appropriate to approve reaction products of boric acid with didecylamine and ethylene oxide (polymeric betaine) as an active substance for use in biocidal products of product-type 8 subject to compliance with certain conditions, including certain conditions for placing on the market of treated articles treated with or incorporating reaction products of boric acid with didecylamine and ethylene oxide (polymeric betaine).
- (9) In its opinion, the Agency also concludes that reaction products of boric acid with didecylamine and ethylene oxide (polymeric betaine) meets the criteria for being a very persistent and toxic substance in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽³⁾. Reaction products of boric acid with didecylamine and ethylene oxide (polymeric betaine) therefore meets the condition laid down in Article 10(1), point (d), of Regulation (EU) No 528/2012 and should be considered a candidate for substitution.
- (10) In accordance with Article 23(1) of Regulation (EU) No 528/2012 the competent authorities of the Member States are to perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing an active substance that is a candidate for substitution.
- (11) Since it can be derived 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 should be approved under the substantive conditions for approval laid down in Directive 98/8/EC, the period of approval should be 10 years, in accordance with the practice established under that Directive.
- (12) 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.
- (13) 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 products of boric acid with didecylamine and ethylene oxide (polymeric betaine) 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

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, 29 November 2024.

For the Commission
The President
Ursula VON DER LEYEN

⁽³⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>).

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (%)	Date of approval	Expiry date of approval	Product type	Specific conditions
Polymeric betaine	IUPAC name: reaction products of boric acid with didecylamine and ethylene oxide EC No: not available CAS No: 214710-34-6	100 % weight per weight. Polymeric betaine is an unknown or variable composition, complex reaction products or of biological materials (UVCB) substance.	1 June 2026	31 May 2036	8	<p>(1) Reaction products of boric acid with didecylamine and ethylene oxide ('polymeric betaine') is considered a candidate for substitution in accordance with Article 10(1), point (d), of Regulation (EU) No 528/2012.</p> <p>(2) The authorisation of biocidal products containing polymeric betaine as an active substance is subject to the following conditions:</p> <p>(a) the product assessment shall pay 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;</p> <p>(b) the product assessment shall pay particular attention to:</p> <p>(i) industrial and professional users;</p> <p>(ii) sewage treatment plant, surface water, sediment, soil and groundwater for Use Class (?) 1 (situation in which the wood or wood-based product is inside a construction, not exposed to the weather and wetting) and Use Class 2 (situation in which the wood or wood-based product is under cover and not exposed to the weather, particularly rain and driven rain, but where occasional, but not persistent, wetting can occur);</p> <p>(c) in view of the risks identified for surface water, sediment, soil and groundwater during industrial impregnation and storage of wood intended for Use Class 1 and Use Class 2, labels and, where provided, safety data sheets of products authorised shall indicate the following:</p> <p>(i) all industrial application processes shall be conducted within a contained area situated on impermeable hard standing with bunding to prevent run-off, and a recovery system shall be in place (e.g. sump);</p>

						<p>(ii) measures are in place to prevent any release of cleaning water (after cleaning of floors, tanks, containers) to the environment (sewer, soil, water) during the application phase;</p> <p>(iii) freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses from the application of the product, including any contaminated water / soil, shall be collected for reuse or disposal;</p> <p>(d) Member States' competent authorities or, in the case of a Union authorisation, the Commission shall specify in the summary of the biocidal product characteristics of a biocidal product containing polymeric betaine the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), second subparagraph, point (e), of Regulation (EU) No 528/2012;</p> <p>(e) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels or maximum residue limits need to be set or the existing maximum residue levels or maximum residue limits need to be amended in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council ⁽³⁾ or Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽⁴⁾, and any appropriate risk mitigation measures shall be taken to ensure that such maximum residue levels or maximum residue limits are not exceeded.</p>
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						(3) The placing on the market of treated articles is subject to the following condition: the person responsible for the placing on the market of a treated article treated with or incorporating polymeric betaine shall ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012.
<p>(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.</p> <p>(²) The use classes described in EN 335:2013 are defined in terms of service conditions, with reference to the generalised moisture content and the prevailing biological agents of deterioration (ECHA Guidance on the Biocidal Products Regulation, Volume II: Efficacy, Parts B + C: Assessment and Evaluation, Version 5.0, November 2022).</p> <p>(³) 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, ELI: http://data.europa.eu/eli/reg/2009/470/oj).</p> <p>(⁴) 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, ELI: http://data.europa.eu/eli/reg/2005/396/oj).</p>						