

COMMISSION IMPLEMENTING DECISION (EU) 2022/986**of 23 June 2022****not approving N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 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 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-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (EC No: 219-145-8; CAS No: 2372-82-9).
- (2) N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 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) Portugal was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the Commission on 9 November 2005. After the submission of the assessment report, discussions took place in technical meetings organised by the Commission and, after 1 September 2013, by the European Chemicals Agency ('the Agency').
- (4) 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 evaluated in accordance with the provisions of Directive 98/8/EC.
- (5) In accordance with Article 75(1) 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 opinion of the Agency on 2 December 2020 ⁽⁴⁾, having regard to the conclusions of the evaluating competent authority.
- (6) It can be derived from that opinion that biocidal products of product-type 8 containing N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine may not be expected to meet the criteria laid down in Article 5(1), point (b) of Directive 98/8/EC which correspond to the criteria laid down in provisions Article 19(1), point (b), of Regulation (EU) No 528/2012 as unacceptable risks for human health have been identified, and no suitable risk mitigation measure could be identified.

⁽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).

⁽⁴⁾ Biocidal Products Committee Opinion on the application for approval of the active substance: N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine, Product type: 8, ECHA/BPC/270/2020, adopted on 2 December 2020.

- (7) In the discussions with the representatives of the Member States within the Standing Committee on Biocidal Products, it was considered that the evaluation was made according to realistic worst case conditions, and that limiting the number of cycles of treatment of wood to two per day per operator would not be a suitable risk mitigation measure to reduce the identified risks to human health to an acceptable level, due to difficulties of enforcement and control.
- (8) Taking into account the opinion of the Agency and the discussions in the Standing Committee on Biocidal Products, it is not appropriate to approve N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine for use in biocidal products of product-type 8.
- (9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (EC No: 219-145-8; CAS No: 2372-82-9) is not approved as an active substance for use in biocidal products of product-type 8.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 23 June 2022.

For the Commission
The President
Ursula VON DER LEYEN
