

**COMMISSION IMPLEMENTING DECISION (EU) 2022/2005****of 21 October 2022****not approving methylene dithiocyanate as an existing active substance for use in biocidal products of product-type 12 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 <sup>(1)</sup>, and in particular Article 89(1), third subparagraph, thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 <sup>(2)</sup> establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes methylene dithiocyanate (EC No: 228-652-3; CAS No: 6317-18-6).
- (2) Methylene dithiocyanate has been evaluated for use in biocidal products of product-type 12, slimicides, as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council <sup>(3)</sup>, which correspond to product-type 12 as described in Annex V to Regulation (EU) No 528/2012.
- (3) France was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the Commission on 7 August 2013. 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) of Regulation (EU) 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), 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 opinion of the Agency on 8 March 2022 <sup>(4)</sup>, having regard to the conclusions of the evaluating competent authority.
- (6) According to the opinion of the Agency, biocidal products of product-type 12 containing methylene dithiocyanate cannot be expected to meet the criteria laid down in Article 5(1), points (b) (iii) and (iv), and (c), read in conjunction with Article 10(1) of Directive 98/8/EC. The applicant did not submit data of sufficient quality to meet the data requirements set out in point 2.7 (specification of purity of the active substance in g/kg or g/l, as appropriate), point 2.8 (identity of impurities and additives together with the structural formula and the possible range expressed as g/kg or g/l, as appropriate), and point 4.1 (analytical methods for the determination of pure active substance and, where

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

<sup>(4)</sup> Biocidal Products Committee Opinion on the application for approval of the active substance: methylene dithiocyanate, Product type: 12, ECHA/BPC/322/2022, adopted on 8 March 2022.

appropriate, for relevant degradation products, isomers and impurities of the active substance and additives) of Title II of Annex IIA to Directive 98/8/EC. As a result, it was impossible to confirm the minimum purity of the active substance and to set a reference specification for methylene dithiocyanate. Moreover, it was not possible to confirm that the material used to conduct (eco)toxicological studies cover the presented specifications and to conclude on the relevance of the impurities due to the lack of (eco)toxicological data. Lastly, the environmental risk assessment identified unacceptable risks, and no suitable risk mitigation measure could be identified.

- (7) Taking into account the opinion of the Agency, it is not appropriate to approve methylene dithiocyanate for use in biocidal products of product-type 12.
- (8) 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*

Methylene dithiocyanate (EC No: 228-652-3; CAS No: 6317-18-6) is not approved as an active substance for use in biocidal products of product-type 12.

*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, 21 October 2022.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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