COMMISSION IMPLEMENTING DECISION (EU) 2023/470

of 2 March 2023

not approving d-Allethrin as an existing active substance for use in biocidal products of product-type 18 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 (RS)-3-Allyl-2-methyl-4-oxocyclopent-2- enyl-(1R,3R;1R,3S)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate (mixture of 4 isomers 1R trans, 1R: 1R trans, 1S: 1R cis, 1R: 1R cis, 1S 4:4:1:1) ('d-Allethrin') (CAS No: 231937-89-6).

(2) D-Allethrin has been evaluated for use in biocidal products of product-type 18, (insecticides, acaricides and products to control other arthropods), as described in Annex V to Regulation (EU) No 528/2012.

(3) Germany was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the European Chemicals Agency ('the Agency') on 11 January 2017. After the submission of the assessment report, discussions took place in technical meetings organised by the Agency.

(4) 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 12 October 2021 ([3]), having regard to the conclusions of the evaluating competent authority.

(5) According to the opinion of the Agency, biocidal products of product-type 18 containing d-Allethrin cannot be expected to meet the criteria laid down in Article 19(1), points (b)(iii), and (iv), of Regulation (EU) No 528/2012.

(6) In its opinion, the Agency noted that the proposed reference specifications, established on the basis of data provided by one of the applicants, are not in line with the composition of the material that was used for testing to generate the toxicological data provided by the applicants. As a result, on the basis of the data provided in the applications, it could not be established whether the representative biocidal products could fulfil the criteria referred to in Article 19(1), point (b) of Regulation (EU) No 528/2012.

(7) According to the opinion of the Agency, based on the available toxicological data, an unacceptable risk has been identified for the general public due to secondary exposure to genotoxic photometabolites formed after the application of the representative products.

([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]) Biocidal Products Committee Opinion on the application for approval of the active substance: d-Allethrin, Product type: 18, ECHA/BPC/293/2021, adopted on 12 October 2021.

(8) In addition, according to the opinion of the Agency, an unacceptable risk to the environment has been identified for the aquatic compartment (surface water and sediment) and for soil.

(9) In conclusion, no safe use could be identified when considering the risks to human health and the environment for each of the representative biocidal products submitted in the applications.

(10) The conditions for approval of d-Allethrin laid down in Article 4(1) of Regulation (EU) No 528/2012 are therefore not met.

(11) Taking into account the opinion of the Agency, it is not appropriate to approve d-Allethrin for use in biocidal products of product-type 18.

(12) 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

D-Allethrin (CAS No: 231937-89-6) is not approved as an active substance for use in biocidal products of product-type 18.

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, 2 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2023/458

of 1 March 2023

on the non-approval of certain active substances for use in biocidal products 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 in its Annex II a list of active substance/product-type combinations included in the review programme of existing active substances in biocidal products.

(2) For a number of active substance/product-type combinations included in that list, all the participants have withdrawn or are considered to have withdrawn their support in a timely manner.

(3) In accordance with Article 14(1) of Delegated Regulation (EU) No 1062/2014, the European Chemicals Agency published an open invitation to take over the role of participant for those active substance/product-type combinations for which the role of participant had not previously been taken over. For those combinations no notification has been submitted to the European Chemicals Agency within the time limit provided for by Article 14(2) of Delegated Regulation (EU) No 1062/2014. Therefore, those active substance/product-type combinations, in accordance with Article 20, first paragraph, point (b), of Delegated Regulation (EU) No 1062/2014, should not be approved for use in biocidal products.

(4) 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

The active substances listed in the Annex are not approved for the product-types indicated therein.

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*.

([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).

Done at Brussels, 1 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Active substance/product-type combinations not approved:

Entry Number in Annex II to Regulation (EU) No 1062/2014	Substance name	Rapporteur Member State	EC number	CAS number	Product-type(s)
1022	Dialuminium chloride pentahydroxide	NL	234-933-1	12042-91-0	2
691	Sodium N-(hydroxymethyl) glycinate	AT	274-357-8	70161-44-3	6
459	Reaction mass of titanium dioxide and silver chloride	SE	Not available	Not available	1, 2, 6, 7, 9, 10, 11
531	(benzyloxy)methanol	AT	238-588-8	14548-60-8	13
1016	Silver chloride	SE	232-033-3	7783-90-6	1
444	7a-ethyldihydro-1H,3H,5H-oxazolo[3,4-c]oxazole (EDHO)	PL	231-810-4	7747-35-5	6, 13
797	cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (cis CTAC)	PL	426-020-3	51229-78-8	6, 13
368	Methenamine 3-chloroallylochloride (CTAC)	PL	223-805-0	4080-31-3	6, 12, 13

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 ([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 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 ([3]), 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 ([4]), 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

([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: 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