Official Journal
of the European Union

EN
L series

2025/1257

27.6.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1257

of 26 June 2025

approving 2-methyl-2H-isothiazol-3-one (MIT) as an existing active substance for use in biocidal products of product-type 6 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 2-methyl-2H-isothiazol-3-one (MIT) (EC No: 220-239-6; CAS No: 2682-20-4) for product-type 6.

(2) MIT has been evaluated for use in biocidal products of product-type 6 (preservatives for products during storage), as described in Annex V to Regulation (EU) No 528/2012.

(3) Slovenia 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 8 March 2020. The Agency discussed the assessment report and the conclusions in technical meetings.

(4) 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 26 November 2024 ([3]), having regard to the conclusions of the evaluating competent authority.

(5) In the opinion, the Agency concluded that biocidal products of product-type 6 containing MIT may be expected to satisfy the criteria laid down in Article 19(1), point (b), of Regulation (EU) No 528/2012, provided that certain conditions concerning their use are complied with.

(6) Taking into account the opinion of the Agency, it is appropriate to approve MIT as an active substance for use in biocidal products of product-type 6 subject to compliance with certain conditions, including certain conditions for placing on the market of treated articles treated with or incorporating MIT.

(7) A reasonable period should elapse before the date of approval of the active substance in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

([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]) Biocidal Products Committee Opinion on the application for approval of the active substance 2-methyl-2H-isothiazol-3-one (MIT); Product-type: 6; ECHA/BPC/449/2024, adopted on 26 November 2024.

HAS ADOPTED THIS REGULATION:

Article 1

2-methyl-2H-isothiazol-3-one (MIT) is approved as an active substance for use in biocidal products of product-type 6, 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, 26 June 2025.

For the Commission
The President
Ursula VON DER LEYEN

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
MIT	IUPAC name: 2-methyl-2H-isothiazol-3-one EC No: 220-239-6 CAS No: 2682-20-4	> 950 g/kg	1 February 2027	31 January 2037	6	(1) The authorisation of biocidal products containing 2-methyl-2H-isothiazol-3-one (MIT) as an active substance 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 assessment of the active substance; (b) the product assessment pays particular attention to: (i) industrial and professional users; (ii) non-professional users: by exposure to the active substance via treated articles; (iii) soil compartment; (c) Member States' competent authorities or, in the case of a Union authorisation the Commission, specify in the summary of the biocidal product characteristics 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. (2) The placing on the market of treated articles is subject to the following conditions: (a) the person responsible for the placing on the market of a treated article treated with or incorporating MIT ensures that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012;

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
						(b) mixtures (other than paints) treated with or incorporating MIT and placed on the market for use by non-professional users do not contain MIT at a concentration triggering classification of the mixture as skin sensitiser category 1 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([2]), unless exposure can be avoided by other means than the wearing of personal protective equipment; (c) the person responsible for the placing on the market for use by non-professionals of a paint treated with or incorporating MIT at a concentration triggering classification of the mixture as skin sensitiser category 1 in accordance with Regulation (EC) No 1272/2008 ensures that: (i) the paint is supplied with appropriate protective gloves in compliance with European Standard EN 374 or equivalent; (ii) the label indicates that protective gloves must be worn during use.

([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 may be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

([2]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).