



2025/1282

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COMMISSION IMPLEMENTING REGULATION (EU) 2025/1282

of 2 July 2025

approving 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride as an 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 9(1), point (a), thereof,

Whereas:

- (1) On 25 April 2019, the European Chemicals Agency ('the Agency') received an application, in accordance with Article 7(1) of Regulation (EU) No 528/2012, for the approval of 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride as an active substance 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. That application was evaluated by the competent authority of Slovenia ('the evaluating competent authority').
- (2) On 7 March 2024, the evaluating competent authority submitted the assessment report on the application together with the conclusions of its evaluation to the Agency.
- (3) 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 8(4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinion of the Agency on 26 November 2024 ⁽²⁾, having regard to the conclusions of the evaluating competent authority.
- (4) In its opinion, the Agency concluded that biocidal products of product-type 6 containing 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride 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.
- (5) Taking into account the opinion of the Agency, it is appropriate to approve 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride 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 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride.
- (6) Furthermore, to ensure a high level of safety for human health, the person responsible for the placing on the market for use by non-professionals of a paint treated with or incorporating 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride at a concentration triggering classification of the mixture as skin sensitiser category 1A, should ensure that the paint is supplied with appropriate protective gloves in compliance with European Standard EN 374 or equivalent and that the label indicates that protective gloves must be worn during use.
- (7) 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⁾ Biocidal Products Committee Opinion on the application for approval of the active substance 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride; Product-type 6; ECHA/BPC/450/2024, adopted on 26 November 2024.

HAS ADOPTED THIS REGULATION:

Article 1

2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride 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, 2 July 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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
2-methyl-2,3-di- hydro-1,2-thiazol- 3-one hydrochloride	IUPAC name: 2-methyl-2,3-dihy- dro-1,2-thiazol-3-one hydrochloride EC No: 247-499-3 CAS No: 26172-54-3	> 990 g/kg	1 August 2025	31 July 2035	6	<p>(1) The authorisation of biocidal products containing 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride as an active substance is subject to the following conditions:</p> <p>(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;</p> <p>(b) the product assessment pays particular attention to industrial and professional users;</p> <p>(c) Member States' competent authorities or, in the case of a Union authorisation, the Commission, specify in the summary of the biocidal product characteristics of a biocidal product containing 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride 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>(2) The placing on the market of treated articles is subject to the following conditions:</p> <p>(a) the person responsible for the placing on the market of a treated article treated with or incorporating 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride ensures that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012;</p>

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
						<p>(b) mixtures other than paints treated with or incorporating 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride and placed on the market for use by non-professional users do not contain 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride 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;</p> <p>(c) the person responsible for the placing on the market for use by non-professionals of a paint treated with or incorporating 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride at a concentration triggering classification of the mixture as skin sensitiser category 1A, ensures that:</p> <p>(i) the paint is supplied with appropriate protective gloves in compliance with European Standard EN 374 or equivalent;</p> <p>(ii) the label indicates that protective gloves must be worn during use.</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.

⁽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>).