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COMMISSION IMPLEMENTING REGULATION (EU) 2025/929

of 21 May 2025

approving 1,2-Benzisothiazol-3(2H)-one (BIT) as an existing active substance for use in biocidal products of product-types 6 and 13 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 1,2-Benzisothiazol-3(2H)-one ('BIT') (EC No: 220-120-9; CAS No: 2634-33-5) for product-types 6 and 13.

(2) BIT has been evaluated for use in biocidal products of product-types 6 (in-can preservatives) and 13 (metalworking-fluid preservatives), as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which correspond to product-types 6 (preservatives for products during storage) and 13 (working or cutting fluid preservatives), as described in Annex V to Regulation (EU) No 528/2012.

(3) Spain was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the Commission on 18 April 2012. 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), first subparagraph, of Regulation (EU) No 528/2012 that applications for which the Member States' evaluation has been completed by 1 September 2013 are to be evaluated in accordance with the substantive conditions for approval laid down in Directive 98/8/EC.

(5) 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 opinions of the Agency on 5 October 2021 ([4]) ([5]), having regard to the conclusions of the evaluating competent authority.

(6) In its opinions, the Agency concluded that BIT may be approved as an active substance for use in biocidal products of product-types 6 and 13.

([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]) 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, ELI: http://data.europa.eu/eli/dir/1998/8/oj).

([4]) Biocidal Products Committee Opinion on the application for approval of the active substance 1,2-Benzisothiazol-3(2H)-one (BIT); Product-type: 6; ECHA/BPC/286/2021, adopted on 5 October 2021.

([5]) Biocidal Products Committee Opinion on the application for approval of the active substance 1,2-Benzisothiazol-3(2H)-one (BIT); Product-type: 13; ECHA/BPC/287/2021, adopted on 5 October 2021.

(7) On 18 July 2023, pursuant to Article 75(1), point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency ([6]) to revise its opinions as the efficacy of the representative biocidal products had not been appropriately assessed according to the applicable guidance document on efficacy ([7]), and this had not been adequately identified by the evaluating competent authority during the evaluation nor during the peer review by the Agency. Tier 2 data representing real-life conditions should have been requested and assessed.

(8) The Biocidal Products Committee adopted the revised opinions of the Agency for product-types 6 and 13 on 18 September 2024 ([8]) ([9]). In those opinions, the Agency concluded that biocidal products of product-types 6 and 13 containing BIT may be expected to satisfy the requirements laid down in Article 5(1), points (b), (c) and (d), of Directive 98/8/EC, provided that certain requirements concerning their use are complied with.

(9) Taking into account the opinions of the Agency, it is appropriate to approve BIT as an active substance for use in biocidal products of product-types 6 and 13 subject to compliance with certain conditions, including certain conditions for placing on the market of treated articles treated with or incorporating BIT in accordance with Article 10 of Directive 98/8/EC read in conjunction with Article 58 of Regulation (EU) No 528/2012.

(10) 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 mixture (other than paints) treated with or incorporating BIT should ensure that the mixture does not contain BIT at a concentration triggering classification of the mixture as skin sensitiser category 1A, unless exposure can be avoided by other means than the wearing of personal protective equipment.

(11) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

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

HAS ADOPTED THIS REGULATION:

Article 1

1,2-Benzisothiazol-3(2H)-one (BIT) is approved as an active substance for use in biocidal products of product-types 6 and 13, 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*.

([6]) Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR – 'Examination of efficacy tier 2 data on specific active substances acting as preservatives (product-types 6-13)'.

([7]) Technical notes for guidance in support of Annex VI of Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocidal products on the market; Common principles and practical procedures for the authorization and registration of products; short title: TNsG on Product Evaluation; February 2008.

([8]) Biocidal Products Committee Opinion on the application for approval of the active substance 1,2-Benzisothiazol-3(2H)-one (BIT); Product-type: 6; ECHA/BPC/442/2024, adopted on 18 September 2024.

([9]) Biocidal Products Committee Opinion on the application for approval of the active substance 1,2-Benzisothiazol-3(2H)-one (BIT); Product-type: 13; ECHA/BPC/443/2024, adopted on 18 September 2024.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 May 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
BIT (Benzisothiazolinone)	IUPAC name: 1,2-Benzisothiazol-3(2H)-one EC No: 220-120-9 CAS No: 2634-33-5	965 g/kg (theoretical calculated dry weight)	1 October 2026	30 September 2036	6	1. The authorisation of biocidal products containing 1,2-Benzisothiazol-3(2H)-one ('BIT') 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, and non-professional users by exposure to BIT via treated articles; (ii) sewage treatment plant and surface water for the uses 'Preservation of additives used in paper production', 'Preservation of additives used in textile production' and 'Preservation of additives used in leather production'; (iii) surface water and groundwater due to direct releases from the uses 'Preservation of paints and coatings in outdoor use' and 'Preservation of polymer emulsions used for paints and coatings in outdoor use'; (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 BIT 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.

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. 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 BIT ensures that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012; (b) the person responsible for the placing on the market for use by non-professionals of a mixture (other than paints) treated with or incorporating BIT ensures that the mixture does not contain BIT at a concentration triggering classification of the mixture as skin sensitiser category 1A, 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 BIT at a concentration triggering classification of the mixture as skin sensitiser category 1A, 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.
					13	1. The authorisation of biocidal products containing 1,2-Benzisothiazol-3(2H)-one (BIT) 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;

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) the product assessment pays particular attention to: (i) industrial or professional users; (ii) surface water, the sewage treatment plant, and sediment; (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 BIT 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 condition: the person responsible for the placing on the market of a treated article treated with or incorporating BIT ensures that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012.

([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.

ELI: http://data.europa.eu/eli/reg_impl/2025/929/oj