



EUROPEAN
COMMISSION

Brussels, **XXX**
PLAN/325/2023
(POOL/E4/2023/325/325-EN.docx)
[...] (2023) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**approving sulfur dioxide released from sodium metabisulfite as an active substance for
use in biocidal products of product-type 9 in accordance with Regulation (EU) No
528/2012 of the European Parliament and of the Council**

(Text with EEA relevance)

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approving sulfur dioxide released from sodium metabisulfite as an active substance for use in biocidal products of product-type 9 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 products¹, and in particular Article 9(1), point (a), thereof,

Whereas:

- (1) On 2 December 2013, 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 sulfur dioxide released from sodium metabisulfite as an active substance for use in biocidal products of product-type 9, fibre, leather, rubber and polymerised materials preservatives, as described in Annex V to Regulation (EU) No 528/2012. That application was evaluated by the competent authority of Germany ('the evaluating competent authority').
- (2) On 22 January 2018, the evaluating competent authority submitted the assessment report on the application together with the conclusions of its evaluation to the Agency. The Agency discussed the assessment report and the conclusions in technical meetings.
- (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 September 2022², having regard to the conclusions of the evaluating competent authority.
- (4) In the opinion, the Agency concludes that biocidal products of product-type 9 using sulfur dioxide released from sodium metabisulfite 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 sulfur dioxide released from sodium metabisulfite as an active substance for use in biocidal products of product-type 9 subject to compliance with certain conditions.

¹ OJ L 167, 27.6.2012, p. 1.

² Biocidal Products Committee Opinion on the application for approval of the active substance sulfur dioxide released from sodium metabisulfite; Product-type 9; ECHA/BPC/355/2022, adopted on 26 September 2022.

- (6) 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

Sulfur dioxide released from sodium metabisulfite is approved as an active substance for use in biocidal products of product-type 9 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,

For the Commission
The President
Ursula VON DER LEYEN



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ANNEX

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to the

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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
sulfur dioxide released from sodium metabisulfite	IUPAC name: disodium disulphite EC No: 231-673-0 CAS No: 7681-57-4	Minimum purity of sodium metabisulfite: 95 % w/w	1 August 2023	31 July 2033	9	The authorisation of biocidal products is subject to the following conditions: (1) The product assessment shall pay 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 risk assessment of the active substance; (2) The product assessment shall pay particular attention to: (a) professional users; (b) toddlers.

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.