



2023/2620

27.11.2023

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/2620**

**of 24 November 2023**

**approving sulfur dioxide generated from sulfur by combustion as an active substance for use in biocidal products of product-type 4 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 <sup>(1)</sup>, and in particular Article 89(1), third subparagraph, thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 <sup>(2)</sup> establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes sulfur dioxide generated from sulfur by combustion for product-type 4.
- (2) Sulfur dioxide generated from sulfur by combustion has been evaluated for use in biocidal products of product-type 4, food and feed area disinfectants, 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 of its evaluation to the European Chemicals Agency ('ECHA'). Discussions took place in technical meetings organised by ECHA.
- (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 ECHA 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 ECHA <sup>(3)</sup> on 26 September 2022, having regard to the conclusions of the evaluating competent authority.
- (5) According to that opinion, biocidal products of product-type 4 containing sulfur dioxide generated from sulfur by combustion 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 ECHA, it is appropriate to approve sulfur dioxide generated from sulfur by combustion as an active substance for use in biocidal products of product-type 4 subject to compliance with certain conditions.
- (7) A reasonable period should be allowed to elapse before an existing active substance is approved 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,

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> Biocidal Products Committee Opinion on the application for approval of the active substance *Sulfur dioxide generated from sulfur by combustion*; Product-type 4; ECHA/BPC/354/2022.

HAS ADOPTED THIS REGULATION:

*Article 1*

Sulfur dioxide generated from sulfur by combustion is approved as an active substance for use in biocidal products of product-type 4 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, 24 November 2023.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance <sup>(1)</sup>	Date of approval	Expiry date of approval	Product-type	Specific conditions
sulfur dioxide generated from sulfur by combustion	precursor: sulfur  active substance: sulfur dioxide  EC No: precursor: 231-722-6  EC No: active substance: 231-195-2  CAS No: precursor: 7704-34-9  CAS No: active substance: 7446-09-5	99,5 % w/w	1 October 2024	30 September 2034	4	The authorisation of biocidal products using sulfur dioxide generated from sulfur by combustion 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 risk assessment of the active substance; (b) the product assessment pays particular attention to: (i) professional users; (ii) general public following secondary exposure; (c) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels ('MRLs') need to be set or the existing MRLs need to be amended in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council <sup>(2)</sup> or Regulation (EC) No 396/2005 of the European Parliament and of the Council <sup>(3)</sup> , and any appropriate risk mitigation measures shall be taken to ensure that such MRLs are not exceeded.

<sup>(1)</sup> 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.

<sup>(2)</sup> Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

<sup>(3)</sup> Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).