



Brussels, **XXX**
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[...] (2023) **XXX** draft

COMMISSION IMPLEMENTING DECISION (EU) .../...

of **XXX**

not approving silver copper zeolite as an existing 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)

COMMISSION IMPLEMENTING DECISION (EU) .../...

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(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 89(1), third subparagraph, thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014² establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes silver copper zeolite (CAS No: 130328-19-7) for product-type 4.
- (2) Sweden was designated as the rapporteur Member State. Silver copper zeolite has been evaluated by the competent authority of Sweden ('the evaluating competent authority') for use in biocidal products of product-type 4, food and feed area disinfectants, as referred to in Annex V to Regulation (EU) No 528/2012.
- (3) On 12 June 2017, the evaluating competent authority submitted the assessment report on the application together with the conclusions of its evaluation to the European Chemicals Agency ('ECHA'). ECHA 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 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 on 3 March 2021³, having regard to the conclusions of the evaluating competent authority.

¹ OJ L 167, 27.6.2012, p. 1.

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).

³ Biocidal Products Committee Opinion on the application for approval of the active substance: silver copper zeolite, Product type: 4, ECHA/BPC/277/2021, adopted on 3 March 2021.

- (5) In its opinion, ECHA concludes that sufficient efficacy has not been demonstrated for the use consisting in the incorporation of the representative biocidal product into food contact materials. Therefore, biocidal products of product-type 4 containing silver copper zeolite are not expected to meet the criterion set out in Article 19(1), point (b)(i) of Regulation (EU) No 528/2012.
- (6) ECHA also concludes that unacceptable risks for human health have been identified from the consumption of food which has been in contact with treated polymers, and no adequate risk mitigation measure could be identified to mitigate those risks. Therefore, biocidal products of product-type 4 containing silver copper zeolite are not expected to meet the criterion set out in Article 19(1), point (b)(iii) of Regulation (EU) No 528/2012.
- (7) Taking into account the opinion of ECHA, it is appropriate not to approve silver copper zeolite as an active substance for use in biocidal products of product-type 4.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

Silver copper zeolite (CAS No: 130328-19-7) is not approved as an active substance for use in biocidal products of product-type 4.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN