

Brussels, XXX SANTE/10566/2019 (POOL/E4/2019/10566/10566-EN.doc) [...](2019) XXX draft

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

of XXX

not approving silver zeolite as an existing active substance for use in biocidal products of product-types 2 and 7

(Text with EEA relevance)

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not approving silver zeolite as an existing active substance for use in biocidal products of product-types 2 and 7

(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 the third subparagraph of Article 89(1) 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 zeolite (EC No: n.a., CAS No: 130328-18-6).
- (2) Silver zeolite has been evaluated for use in products of product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, and of product-type 7, film preservatives, as described in Annex V to Regulation (EU) No 528/2012.
- (3) Sweden was designated as a rapporteur Member State and its competent authority submitted the assessment reports together with its conclusions to the European Chemicals Agency on 12 June 2017.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency³ were adopted on 17 October 2018 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) According to those opinions, biocidal products of product-types 2 and 7 containing silver zeolite may not be expected to meet the criteria laid down in Article 19(1)(b) of Regulation (EU) No 528/2012 as sufficient efficacy has not been demonstrated.
- (6) Taking into account the opinions of the European Chemicals Agency, it is not appropriate to approve silver zeolite for use in biocidal products of product-types 2

OJ L 167, 27.6.2012, p. 1.

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).

Biocidal Products Committee (BPC) opinion on the application for approval of the active substance Silver zeolite, Product type: 2, ECHA/BPC/209/2018, adopted on 17 October 2018; Biocidal Products Committee (BPC) opinion on the application for approval of the active substance Silver zeolite, Product type: 7, ECHA/BPC/212/2018, adopted on 17 October 2018.

- and 7, as the conditions laid down in Article 4(1) of Regulation (EU) No 528/2012 are not satisfied.
- (7) 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 zeolite (EC No: n.a., CAS No: 130328-18-6) is not approved as an active substance for use in biocidal products of product-types 2 and 7.

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
Jean-Claude JUNCKER