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COMMISSION IMPLEMENTING REGULATION (EU) 2024/2635

of 3 October 2024

approving silver zinc zeolite as an existing active substance for use in biocidal products of product-types 2, 7 and 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 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 silver zinc zeolite (CAS No: 130328-20-0) for product-types 2, 7 and 9.

(2) Silver zinc zeolite has been evaluated for use in biocidal products of product-types 2 (private area and public health area disinfectants and other biocidal products), 7 (film preservatives) and 9 (fibre, leather, rubber and polymerised materials preservatives), as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which correspond respectively to product-types 2 (disinfectants and algaecides not intended for direct application to humans or animals), 7 (film preservatives) and 9 (fibre, leather, rubber and polymerised materials preservatives), as described in Annex V to Regulation (EU) No 528/2012.

(3) Sweden was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the Commission on 7 May 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 substances 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 29 February 2024 ([4]), ([5]), ([6]), having regard to the conclusions of the evaluating competent authority.

([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 Silver zinc zeolite; Product-type: 2; ECHA/BPC/414/2024, adopted on 29 February 2024.

([5]) Biocidal Products Committee Opinion on the application for approval of the active substance Silver zinc zeolite; Product-type: 7; ECHA/BPC/415/2024, adopted on 29 February 2024.

([6]) Biocidal Products Committee Opinion on the application for approval of the active substance Silver zinc zeolite; Product-type: 9; ECHA/BPC/416/2024, adopted on 29 February 2024.

(6) Taking into account the opinions of the Agency, it can be concluded that biocidal products of product-types 2, 7 and 9 containing silver zinc zeolite may be expected to satisfy the requirements laid down in Article 5(1), points (b), (c) and (d), read in conjunction with Article 10(1) of Directive 98/8/EC, provided that certain requirements concerning their use are complied with. It is therefore appropriate to approve silver zinc zeolite as an active substance for use in biocidal products of product-types 2, 7 and 9 subject to compliance with certain conditions, including certain conditions for placing on the market of treated articles treated with or incorporating silver zinc zeolite.

(7) 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.

(8) 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

Silver zinc zeolite is approved as an active substance for use in biocidal products of product-types 2, 7 and 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, 3 October 2024.

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
Silver zinc zeolite	IUPAC name: Silver zinc zeolite (zeolite, LTA ([2]) framework type, surface-modified with silver, zinc and ammonium ions) EC No: not assigned CAS No: 130328-20-0 ([3])	990 g/kg dry weight with the following relevant impurities: arsenic and chromium, each with a maximum content of 40 mg/kg dry weight.	1 March 2026	29 February 2036	2	(1) The authorisation of biocidal products containing silver zinc zeolite as an active substance is subject to the following conditions: (a) 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; (b) products shall not be authorised for treatment of non-textile polymers that may come into direct contact with skin with contact area of more than 300 cm^2 for adults and children (> 2 years old), and of more than 200 cm^2 for toddlers (1-2 years old) and infants (< 1 year old); (c) products shall not be authorised for treatment of textiles that, used by themselves or incorporated in other articles, satisfy any of the following conditions: (1) may come into contact with human skin, including indirectly via body fluids; (2) may be handled under wet conditions; (3) may be mouthed by children under the age of 2 years. (d) Member States competent authorities or, in the case of a Union authorisation the Commission, shall specify in the summary of the biocidal product characteristics of a biocidal product containing silver zinc zeolite 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) non-textile polymer articles treated with or incorporating silver zinc zeolite that may come into direct contact with skin of more than 300 cm^2 for adults and children (> 2 years old), and of more than 200 cm^2 for toddlers (1-2 years old) and infants (< 1 year old), shall not be placed on the market; (b) textiles treated with or incorporating silver zinc zeolite shall not be placed on the market if they, used by themselves or incorporated in other articles, satisfy any of the following conditions: (1) may come into contact with human skin, including indirectly via body fluids; (2) may be handled under wet conditions; (3) may be mouthed by children under the age of 2 years; (c) the person responsible for the placing on the market of a treated article treated with or incorporating silver zinc zeolite shall ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012.
					7	(1) The authorisation of biocidal products containing silver zinc zeolite as an active substance is subject to the following conditions: (a) 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; (b) products shall not be authorised for treatment of non-textile polymers that may come into direct contact with skin with contact area of more than 300 cm^2 for adults and children (> 2 years old), and of more than 200 cm^2 for toddlers (1-2 years old) and infants (< 1 year old);

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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
						(c) products shall not be authorised for use in paints or coatings which are intended to be used on outdoor infrastructures, such as houses, façades or noise barriers, or structures above water, such as bridges; (d) Member States competent authorities or, in the case of a Union authorisation the Commission, shall specify in the summary of the biocidal product characteristics of a biocidal product containing silver zinc zeolite 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 conditions: (a) non-textile polymer articles treated with or incorporating silver zinc zeolite that may come into direct contact with skin of more than 300 cm^2 for adults and children (> 2 years old), and of more than 200 cm^2 for toddlers (1-2 years old) and infants (< 1 year old), shall not be placed on the market; (b) the person responsible for the placing on the market of a paint or coating treated with or incorporating silver zinc zeolite shall ensure that the label of that paint or coating indicates that it shall not be used on outdoor infrastructures, such as houses, façades or noise barriers, or structures above water, such as bridges; (c) the person responsible for the placing on the market of a treated article treated with or incorporating silver zinc zeolite shall ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, 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
					9	(1) The authorisation of biocidal products containing silver zinc zeolite as an active substance is subject to the following conditions: (a) 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; (b) products shall not be authorised for treatment of non-textile polymers that may come into direct contact with skin with contact area of more than 300 cm^2 for adults and children (> 2 years old), and of more than 200 cm^2 for toddlers (1-2 years old) and infants (< 1 year old); (c) products shall not be authorised for treatment of textiles that, used by themselves or incorporated in other articles, satisfy any of the following conditions: (1) may come into contact with human skin, including indirectly via body fluids; (2) may be handled under wet conditions; (3) may be mouthed by children under the age of 2 years; (4) may be used outdoors; (d) Member States competent authorities or, in the case of a Union authorisation the Commission, shall specify in the summary of the biocidal product characteristics of a biocidal product containing silver zinc zeolite 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.

ELI: http://data.europa.eu/eli/reg_impl/2024/2635/oj

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) non-textile polymer articles treated with or incorporating silver zinc zeolite that may come into direct contact with skin of more than 300 cm^2 for adults and children (> 2 years old), and of more than 200 cm^2 for toddlers (1-2 years old) and infants (< 1 year old), shall not be placed on the market; (b) textiles treated with or incorporating silver zinc zeolite shall not be placed on the market if they, used by themselves or incorporated in other articles, satisfy any of the following conditions: (1) may come into contact with human skin, including indirectly via body fluids; (2) may be handled under wet conditions; (3) may be mouthed by children under the age of 2 years; (4) may be used outdoors; (c) the person responsible for the placing on the market of a treated article treated with or incorporating silver zinc zeolite shall ensure 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 may be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.
([2]) Linde Type A (framework type of the zeolite). The framework type is a crucial part of the identity. A silver zinc zeolite with a different framework-type shall not be considered the same substance.
([3]) The CAS-name is zeolites, synthetic, Ag. The entry in the CAS inventory is broader than the specified chemical name.