Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Silver zinc zeolite

Product type: 2

ECHA/BPC/414/2024

Adopted

29 February 2024

Opinion of the Biocidal Products Committee

on the application for approval of the active substance Silver zinc zeolite for product type 2

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 2 of the following active substance:

Common name:	**Silver zinc zeolite**
Chemical name:	**Silver zinc zeolite (zeolite, LTA[1] framework type, surface-modified with silver, zinc and ammonium ions)**
EC No.:	**not assigned**
CAS No.:	**130328-20-0[2]**
Existing active substance	

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by the European Silver Task Force on 17 December 2007 the evaluating Competent Authority Sweden submitted an assessment report and the conclusions of its evaluation to the Commission on 7 May 2012. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the Technical Meeting (TM II/2013 and TM IV/2013), BPC (BPC-27, BPC-28 and BPC-50) and its Working Groups (WG-III-2015, II-2016, III-2016, V-2016, V-2017, IV-2023). Additionally, the ED Expert Group was consulted in April and October 2018. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

[1] 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 would not be considered the same substance.
[2] The CAS-name is zeolites, synthetic, Ag. The entry in the CAS inventory is broader than the specified chemical name.

Adoption of the BPC opinion

Rapporteur: Sweden

The BPC opinion on the approval of the active substance silver zinc zeolite in product type 2 was adopted on 29 February 2024.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority position including their grounds are published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the silver zinc zeolite in product type (PT) 2 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of silver zinc zeolite in PT 2.

Silver zinc zeolite (zeolite, LTA framework type, surface-modified with silver, zinc and ammonium ions) is an inorganic active substance, which cannot be analysed as the complete substance. The specification is thus based on the concentration ranges for major elements as well as maximum levels for elements regarded as impurities. Specifications for the reference sources are established. Chromium (Cr) and arsenic (As) are regarded as relevant impurities with a max level of 40 mg/kg each.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the intended use, storage and transportation of the active substance and biocidal product.

Validated analytical methods are available for the technical material with respect to the major elements as well as the elements regarded as impurities (significant and relevant). Validated analytical monitoring methods for silver are available for the relevant matrices (soil, water and food).

The Scientific Committee on Consumer Safety (SCCS) published an opinion on silver zinc zeolite in December 2023[3].

The following classification and labelling according to Regulation (EC) No 1272/2008 (CLP Regulation) has been agreed by RAC[4] and is included in the 10th ATP:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Repr. 2 Skin Irrit. 2 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1
Labelling	
Pictogram codes	GHS08 GHS05 GHS09
Signal Word	Danger
Hazard Statement Codes	H361d (suspected of damaging the unborn child) H315 (causes skin irritation) H318 (causes serious eye damage) H410 (very toxic to aquatic life with long lasting effects)

[3] Scientific Committee on Consumer Safety (SCCS) OPINION on Silver Zinc Zeolite ((SCCS/1650/23))

[4] Committee for Risk Assessment (RAC): Opinion proposing harmonised classification and labelling at EU level of Silver zinc zeolite (Zeolite, LTA framework type, surface-modified with silver and zinc ions); CLH-O-0000001412-86-90/F, Adopted 4 December 2015.

Specific Concentration limits, M-Factors	M = 100 for acute, chronic

b) Intended use, target species and effectiveness

Silver zinc zeolite is used to treat polymers to achieve an antimicrobial effect. The silver ion is the active species, which is released out of the treated polymer. The silver ion interacts with the cell membrane of microorganisms, interferes with electron transport processes, binds to nucleic acids, inhibits enzymes and catalyses free radical oxygen species.

Generally, the antimicrobial effect of polymer materials containing silver active substances is dependent on how much of the silver is released. A precondition for the release of silver is a solvent, i.e. a liquid which the material comes into contact with. A dry polymer material surface will not release any silver ions and thus will not exert an antimicrobial effect. This is why claims and use-conditions have to be specified to be able to demonstrate efficacy. Efficacy has to be demonstrated towards at least one example use, respectively, for the claims made.

A claim against bacteria and fungi has been made. The example uses given were i) wall or floor covering to reduce cross-contamination[5] and ii) air conditioning components to inhibit microbial growth.

For example use i), rather fast bactericidal effects in a dry surrounding would need to be demonstrated. Such tests were not provided.

For example use ii), bacteriostatic efficacy under wet conditions needs to be demonstrated. However, normally disinfectants for air-conditioning systems are applied by airborne diffusion of an aerosol, a smoke, a vapour or a gas[6]. It would need to be shown with an appropriate test simulating realistic conditions of use that the required performance standards can be met even by a material containing silver zinc zeolite incorporated into the parts of an air-conditioning system.

Efficacy for example application i) has not been demonstrated. For these types of applications, demonstration of rather fast bactericidal effects would be necessary. Neither use-conditions nor the necessary speed for the claimed effects have been shown with the efficacy tests submitted. Thus, bactericidal effects have not been demonstrated.

For example use ii) basic efficacy has been shown. Efficacy in a test simulating realistic conditions of use has not been shown. However, as this application has been evaluated and peer-reviewed before the above mentioned efficacy guidance started to apply, the tests submitted are accepted. Thus bacteriostatic efficacy for a PT 2 example applications is considered demonstrated. Fungistatic efficacy, however, has not been shown.

Resistance

The risk of antibacterial resistance and cross resistance developing from an increased use of silver, in particular new and increasing wide-spread and disperse use in consumer products, cannot be assessed with the currently available information. Therefore, attention should be paid to risks posed by the development of resistance/tolerance to silver and co-resistance to other relevant antimicrobial compounds at the renewal of active substance approval.

[5] Cross contamination is the process by which bacteria or other micro-organisms are unintentionally transferred from one object/person to another.
[6] See Guidance on the Biocidal Products Regulation: Volume II Efficacy, Parts B+C (published on the ECHA web-site).

c) Overall conclusion of the evaluation including need for risk management measures

Human health

The toxicological studies available are performed with different types of silver zinc zeolites. These are not technically equivalent but read-across among the materials is considered justified.

Animal studies indicate a low acute toxicity via oral, dermal or inhalation routes but the substance causes skin and eye irritation as reflected in the harmonised classification Skin Irrit. 2; H315 and Eye Dam. 1; H318, respectively. Silver zinc zeolite did not cause skin sensitisation reactions in guinea pigs. The substance is expected to dissociate in the gastrointestinal tract and in the absence of substance-specific information it is assumed, based on data for silver nitrate, that 5% of the active substance as well as of silver ions released from silver zinc zeolite are orally absorbed. Similarly, the dermal absorption is expected to be 5% based on data for silver nitrate.

Effects noted following subchronic exposure to silver zinc zeolite include a decrease in haemoglobin (in dogs), histopathological changes in kidneys and discoloration of tissues and organs. The mutagenic potential of the substance has been adequately investigated *in vitro* and *in vivo*. While the *in vitro* test in mammalian cells indicated a mutagenic potential of silver zinc zeolite there were no indications of genotoxicity in *the in vivo* studies conducted, thereby overruling the positive *in vitro* findings. Based on information on chronic toxicity and carcinogenicty of silver zinc zeolite, it was concluded by the Risk Assessment Committee (RAC) that classification is not warranted. However, RAC concluded that silver zinc zeolite fulfils criteria for classification Repr. 2; H361d (suspected of damaging the unborn child). No robust information is available to assess the neurotoxic or immunotoxic potential of silver zinc zeolite. However, the available data do not show clear indications of such properties.

Endocrine-disrupting properties were assessed in accordance with the current Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No528/2012 and (EC) No1107/2009 (2018). Based on available information, it can be concluded that silver zinc zeolite does not have endocrine disrupting properties in humans.

The tables below summarises the exposure scenarios assessed.

Industrial use

Scenario	Primary exposure and description of scenarios	Risk acceptable
Mixing and loading (i.e. incorporation of silver zinc zeolite into polymers)	Tier 1	no
	Tier 2 (respiratory protection, 95%)	no
	Tier 2 (protective gloves, 95%)	no
	Tier 2 (respiratory protection, 95% and protective gloves, 95%)	yes

Mixing and loading without personal protective equipment (PPE) showed unacceptable risks. However, the risk is acceptable for industrial professionals when appropriate PPE and RPE is worn.

Use of liquid biocidal products (paints and coatings)

Scenario	Primary exposure and description of scenarios	Risk acceptable
Spray application	by professionals with PPE	no
Brush and roll application	by professionals with PPE and non-professionals,	no

The risks for professionals and non-professionals when applying paints by spraying, brushing or rolling are not acceptable. PPE equipment is not sufficient to mitigate these risks.

Consumer use of solid biocidal products or treated articles[7]

Non-textile polymers

Scenario	Exposure category[8]	Risk acceptable
Articles intended for dermal contact	small-scale, all age-groups	yes
	medium-scale, all age-groups	yes
	large-scale, all age-groups	no
	hand-to mouth contact, infant and toddler	yes
Articles intended for oral contact	all scales, all age-groups	yes

Small- and medium-scale use of non-textile polymers with direct skin contact show acceptable risks in all age-groups, while for large-scale use unacceptable risk was identified which cannot be mitigated. Hand-to-mouth contact from treated articles is acceptable for infants and toddlers. Articles intended for oral contact are acceptable for all age groups.

Textile polymers

Scenario	Exposure category	Risk acceptable
Oral exposure to treated textile	taking into mouth by infants and toddlers	no
Textiles intended for direct contact with skin	small and large -scale, all age-groups	no
Textiles	handling of wet textiles (e.g. laundry)	no

The mouthing of treated textiles by infants and toddlers and wearing textiles intended for direct contact with skin is unacceptable for all age groups. Handling of wet textiles (e.g. laundry) is not acceptable. The risks identified cannot be mitigated.

Environment

Silver zinc zeolite, under the use envisaged, releases silver ions (Ag^+) which are the active component of silver zinc zeolite. Besides silver, also zinc ions are released. Thus, environmental fate has been addressed for silver as well as for zinc, because both are toxic to environmental organisms. Owing to its use in treated articles, silver zinc zeolite does not enter water bodies in its original composition (i.e. silver and zinc adsorbed to zeolite). It will dissociate and, thus, the different components silver, zinc and zeolite will have different environmental fates. Silver and zinc are released from the treated polymers through ion

[7] Depending on the claim, some of the treated articles might be considered biocidal products.
[8] Exposure categories refer to the duration of exposure and exposed body surface.

exchange and migration in the presence of aquatic media, whereas the zeolite part is expected to mainly remain in the polymer matrix.

Emissions to atmosphere are negligible.

Zinc contributes significantly only to the overall toxicity to microbiological processes in sewage treatment plants (STP). Thus, except for the STP, the environmental risk assessment is conducted for silver only. No unacceptable risks were identified for STP for the intended uses.

The standard concept of assessing potential for bioaccumulation is not applicable for metals. Trophic transfer can be an important route of exposure, but evidence of significant biomagnification is lacking. No unacceptable risk for secondary poisoning has been identified.

No concern for groundwater is expected for the intended uses.

No further risks for the environment are identified from aggregated exposure to silver zinc zeolite, including use in other product types.

Endocrine-disrupting properties were assessed in accordance with the current Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No528/2012 and (EC) No1107/2009 (2018). Based on the available information it is not possible to conclude whether silver zinc zeolite fulfils the criteria for endocrine disruption in non-target organisms.

The tables below summarise the exposure scenarios assessed.

Polymer formulation – industrial use

Scenario	Aquatic	Terrestrial	Risk acceptable
Polymer formulation (handling, compounding and conversion of polymers from which solid articles and/or textiles are shaped)	yes	yes	yes

Solid biocidal products or treated articles[9] - service life

Scenario	Aquatic	Terrestrial	Risk acceptable
Non-textile polymers, indoor use	yes	yes	yes

Treated textiles, service life

Scenario	Aquatic	Terrestrial	Risk acceptable
Release to environment via laundry	yes	yes	yes

Paints and coatings, application and service life

Scenario	Aquatic	Terrestrial	Risk acceptable
Indoor	yes	yes	yes

[9] Depending on the claim, some of the treated articles might be considered biocidal products.

The risk from polymer formulation is acceptable. The application of paints or coatings indoors as well as the use of treated articles indoors is acceptable.

Overall conclusion

Silver zinc zeolite is used to treat articles. Examples for such are different moulded polymer articles such as toilet seats, laminated surfaces, flooring and textiles (both non-apparel and apparel), etc. These articles can – depending on the claim – belong to different product types. To tackle the wide variety of different uses, types of articles were grouped into exposure categories stipulating the contact path (oral or dermal), a typical contact surface and a typical contact-time. In this way standardised risk assessments could be carried out for a potentially innumerable amount of different treated articles. Within the categories, a realistic worst-case was assumed.

As a result, some exposure categories show risks which cannot be mitigated, some show risks which can be mitigated by risk mitigation measures, and some exposure categories are safe (for example the use of small-scale treated non-textile polymers intended for dermal or oral contact).

The following uses have shown unacceptable risks:

- Industrial use: mixing and loading without PPE and RPE;
- Spray application and brush and roll application of liquid biocidal products (paints and coatings) by professionals and non-professionals even when using PPE;
- Use of treated non-textile polymers intended for large-scale direct contact to skin;
- Textiles intended for direct contact with skin or which can be mouthed by toddlers and infants;
- Handling of wet textiles (e.g. laundry).

The "Note on the specific conditions to be set in the approval of active substances in relation with treated articles" (CA-Nov14-Doc.6.2 – Final) establishes principles concerning the introduction of possible restrictions in the approval process. In the note it is stated that restrictions shall only be introduced if a major concern is identified. It is concluded that this is the case for the above mentioned exposure categories of treated non-textile polymers and treated textiles, as an unacceptable risk was identified which cannot be mitigated. A major concern is identified due to the wide-spread use pattern involving the general public, including vulnerable groups like children, infants and toddlers.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		**Conclusions**	
CMR properties	Carcinogenicity (C)	no classification required	Silver zinc zeolite does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	no classification required	
	Toxic for reproduction (R)	Repr. Cat. 2	

Property		Conclusions	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Silver zinc zeolite as inorganic substance is excluded from the P assessment taking into account Annex XIII of the REACH Regulation (EU) No 1272/2008.	Silver zinc zeolite does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	Silver zinc zeolite is not B or vB.	
	Toxic (T)	Silver zinc zeolite is T.	
Endocrine disrupting properties	Silver zinc zeolite does not fulfil criterion (d) of Article 5(1). The available information is not sufficient to conclude whether silver zeolite fulfils criterion (e) of Article 10(1).		
Respiratory sensitisation properties	Silver zinc zeolite does not fulfil criterion (b) of Article 10(1). No classification required.		
Concerns linked to critical effects other than those related to endocrine disrupting properties	No other concerns identified.		
Proportion of non-active isomers or impurities	Silver zinc zeolite does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

Silver zinc zeolite does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012

The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR" [10] and in line with "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR" [11] agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

[10] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)

[11] See document: Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

The available information is not sufficient to conclude whether silver zeolite fulfils the substitution criterion (e) of Article 10(1), due to lack of information on non-target organisms other than mammals. However, since the assessment report was submitted before 1 September 2013, further information cannot be requested. Therefore, the criterion for substitution is assessed based on available information required at the time of submission of the assessment report.

2.2.2. POP criteria

POP criteria are not applicable for silver zinc zeolite, as the substance is inorganic. There are no indications (monitoring data or modelling data) of any long-range transport potential of the active substance either.

2.3. BPC opinion on the application for approval of the active substance silver zinc zeolite in product type 2

In view of the conclusions of the evaluation, it is proposed that silver zinc zeolite shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: 990 g/kg dry weight with the following relevant impurities: arsenic and chromium, each with a maximum content of 40 mg/kg dry weight.

2. The authorisations of biocidal products are 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 above 300 cm^2 for adults and children, or 200 cm^2 for toddlers and infants.

    c. Products shall not be authorised for treatment of textiles that, used by themselves or incorporated in other articles, may

        i) come into contact with human skin, including indirect via body fluids,
        ii) be handled under wet conditions, for example rinsed or washed, or
        iii) 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), point (e), of Regulation (EU) No 528/2012.

3. 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 above 300 cm^2 for adults and children, or 200 cm^2 for toddlers and infants, 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, may

i) come into contact with human skin, including indirect via body fluids,
ii) be handled under wet conditions, for example rinsed or washed, or
iii) be mouthed by children under the age of 2 years.

c. The person responsible for the placing on the market of an article treated with or incorporating the active substance silver zinc zeolite shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012. Silver zinc zeolite gives rise to concern for human health and the environment, i.e. it is classified as Repr. 2, and as Aquatic acute 1.

2.4. Elements to be taken into account when authorising products

1. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

    a. If an unacceptable risk is identified for industrial and/or professional users, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

    b. An unacceptable risk is identified for spray- or brush- and roll application by professionals and non-professionals of liquid biocidal products (paints and coatings) containing silver zinc zeolite. If the risk cannot be reduced to an acceptable level by introducing risk mitigation measures or by other means, products should not be authorised for these methods of application.

2.5. Requirement for further information

Sufficient information has been provided to verify the conclusions on the active substance, permitting the proposal for the approval of silver zinc zeolite.

At the renewal of active substance approval, attention should be paid to risks posed by the development of resistance/tolerance to silver and co-resistance to other relevant antimicrobial compounds.

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