Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Silver zeolite

Product type: 2

ECHA/BPC/209/2018

Adopted

17 October 2018

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance Silver 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 non-approval in product type 2 of the following active substance:

Common name:	**Silver zeolite**
Chemical name:	**Silver zeolite (zeolite, LTA framework type[1], ion-exchanged with silver and ammonium ions)**
EC No.:	**not assigned**
CAS No.:	**130328-18-6[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 European Silver Task Force on 17 December 2007, the evaluating Competent Authority Sweden submitted an assessment report and the conclusions of its evaluation to ECHA on 12 June 2017. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-27) and its Working Groups (WG V 2017). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

[1] The framework type is a crucial part of the identity. A silver 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 non-approval of the active substance silver zeolite in product type 2 was adopted on 17 October 2018.

The BPC opinion was adopted by consensus. The opinion is 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 silver zeolite in product type 2 may not 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 zeolite in product type 2.

Silver zeolite (zeolite, LTA framework type, ion-exchanged with silver 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. A specification for the reference source is established. Arsenic (As) is regarded as a relevant impurity with a maximum level of 26 ppm.

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).

A harmonised classification is not available for silver zeolite. The Swedish Chemicals Agency has submitted a proposal for harmonised classification and labelling on 3 July 2017.

The proposed classification and labelling for silver zeolite according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Proposed Classification according to the CLP Regulation	
Hazard Class and Category Codes	Repr. 2 Aquatic acute 1 Aquatic chronic 1
Labelling	
Pictogram codes	GHS08 GHS09
Signal Word	warning
Hazard Statement Codes	H361d H400 H410
Specific Concentration limits, M-Factors	M = 100 for acute and chronic

Justification for the proposal
There is no substance-specific information with respect to fertility effects of silver zeolite. In the absence of substance-specific information, a robust classification proposal cannot be presented. However, due to the structural similarity with silver zinc zeolite and the similarity of effects observed with other silver salts that do not contain zinc, it is reasonable to assume that silver zeolite meets the criteria for classification Repr. 2; H361d (Suspected of damaging the unborn child), as concluded for silver zinc zeolite in the RAC opinion.

b) Intended use, target species and effectiveness

Silver 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 described in detail to be able to demonstrate efficacy. Efficacy has to be demonstrated towards one example use, respectively, for the claims made.

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

For the example use i), fast bacteriocidal 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. It would need to be shown with an appropriatetest simulating practical conditions of use that the required performance standards can be met by a biocidal product containing silver zeolite incorporated into the parts of an air-conditioning system. Such tests have not been provided. In conclusion, efficacy for this example use is not sufficiently demonstrated.

Efficacy for example use i) or ii) has not been sufficiently demonstrated to recommend approval.

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.

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

Human health

For several of the human health endpoints no substance-specific data is available. However, silver zeolite is expected to dissociate during the acidic conditions of the stomach and the constituents of the substance are assumed to be absorbed individually. Therefore, the hazard assessment of silver zeolite is based on data available for each constituent of the substance, i.e. silver and the zeolite backbone.

The assessment of the silver ion is based on studies in which it is indirectly tested, i.e. studies performed with the read-acros substances silver zinc zeolite, silver copper zeolite, silver sodium hydrogen zirconium phosphate, silver chloride and silver acetate. Based on information on silver ion content and silver ion release for the different silver substances, the dose of silver zeolite needed to achieve the equivalent silver ion exposure as present at the NOAELs set for these substances can be calculated.

Animal studies indicate low acute toxicity via oral, dermal and inhalation routes. The substance causes eye irritation but the severity of effects do not fulfil criteria for classification. Based on weight of evidence of the data available silver zeolite is not considered to have a skin sensitisation potential.

The substance is expected to dissociate in the gastrointestinal tract and it is assumed, based on data for silver nitrate, that 5% of the active substance as well as of silver ions released from silver zeolite are orally absorbed. Similarly, the dermal absorption is expected to be 5% based on data for silver nitrate. Effects following subchronic exposure include an increased level of the alkaline phosphatase and pigmentation, effects commonly seen in repeated dose toxicity studies with different silver substances.

Results obtained with other silver zeolites, i.e. silver zinc- and silver copper zeolite, indicate a weak clastogenic potential in vitro but the negative result in an in vivo comet assay with silver zinc zeolite indicates that silver zinc zeolite and by read-across silver zeolite, are not expected to have genotoxic properties in vivo.

There is no substance-specific information on the chronic toxicity and carcinogenic potential of silver zeolite but it is not expected to fulfil criteria for classification since on the data on the read across substance silver zinc zeolite it was concluded by Risk Assessment Committtee (RAC) not to fulfil the criteria (see section 2.1.a on the classification).

There is no substance-specific data available for reproductive toxicity. Due to the structural similarity with silver zinc zeolite and taking into account developmental effects observed with other silver salts that do not contain zinc, it is reasonable to assume that silver zeolite also fulfils criteria for classification Repr. 2; H361d (suspected of damaging the unborn child), as concluded for silver zinc zeolite.

No robust information is available to assess the neurotoxic or immunotoxic potential of silver zeolite or the read across substances. However, the available data did not show clear indications of such properties.

An assessment of the endocrine disruptor (ED) properties was conducted. However, this ED assessment could not be finalised as the data are considered insufficient for an assessment against the criteria laid down in Regulation (EU) No 2017/2100.

The table below summarises the exposure scenarios assessed.

Industrial use

Scenario	Primary exposure and description of scenarios	Risk acceptable
Mixing and loading	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 PPE and by using either respiratory protection or protective gloves show unacceptable risks. However, the risk is acceptable for industrial professionals when appropriate personal protection equipments (respiratory protection, 95%, and protective gloves, 95%) are worn.

Use in 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 and non-professionals, with PPE	no
Joint sealant application	professionals and non-professionals, without PPE	yes

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. However, the risk from primary exposure during joint sealant application is acceptable.

Consumer use of biocidal product or solid treated articles[3]

Non-textile polymers, secondary exposure

Scenario	Exposure category[4]	Risk acceptable
Articles intended for dermal contact	small-scale, all age-groups	yes
	medium-scale, infants and toddlers	no
	medium-scale, children and adults	yes
	large-scale, all age-groups	no
	hand-to-mouth contact infant and toddler	yes
Articles intended for oral contact	small-scale adults, children and toddlers	yes
	Large-scale, all age-groups	yes

Large-scale use of non-textile polymers with direct skin contact shows unacceptable risks for all age-groups. Medium-scale use shows unacceptable risks for infants and toddlers. However, the risk from medium-scale use is acceptable for children and adults. Small-scale use is acceptable for all age-groups. Hand-to-mouth contact from treated articles is acceptable for infants and toddlers. Articles intended for oral contact are acceptable for all age groups.

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

[4] Large scale, medium scale and small scale exposure categories refer to the duration of dermal exposure and exposed body surface.

Textile polymers, secondary exposure

Scenario	Exposure category	Risk acceptable
Oral exposure to treated textile	Taking into mouth by infants	yes
	Taking into mouth by toddlers	no
Textiles intended for direct contact with skin	Use in clothing not intended according to the applicant.	
Textiles	Textile handling	no

The mouthing of treated textiles by infants is acceptable. However, the mouthing of treated textiles by toddlers and handling of textiles (no clothing) show unacceptable risks.

Environment

Silver zeolite releases silver ions (Ag^+) under the use envisaged, which is the active component of silver zeolite. Owing to its use in treated articles, silver zeolite does not enter water bodies in its original composition (i.e. silver adsorbed to zeolite). It will dissociate and, thus, the different components silver and zeolite will have different environmental fates. Silver is released from the treated polymers through ion 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.

No unacceptable risks were identified for sewage treatement plants 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.

Unacceptable risks for groundwater are not expected for the intended uses.

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

The table below summarises the exposure scenarios assessed.

Polymer formulation – industrial use

Scenario	Aquatic	Terrestrial	Risk acceptable
Polymer formulation (handling, compounding and conversion of polymers from which articles (non-textile polymers and textile polymers) are shaped)	yes	yes	yes

Biocidal products or solid treated articles[5] - service life

Scenario	Examples	Aquatic	Terrestrial	Risk acceptable
Non-textile polymers, indoor use	laminated work surface, walls, floors and air conditioning components	yes	yes	yes

Textile polymers, service life

Scenario	Examples	Aquatic	Terrestrial	Risk acceptable
Release to the environment via laundry	clothing	Use in clothing not intended according to the applicant.		

Paints, coatings and sealants, application

Scenario	Aquatic	Terrestrial	Risk acceptable
Sealants indoor	yes	yes	yes

Paints, coatings and sealants, service life

Scenario	Aquatic	Terrestrial	Risk acceptable
Sealants indoor	yes	yes	yes

The risk from polymer formulation is acceptable. Use of paint, coatings and sealants indoors and use of treated articles indoors is acceptable.

Overall conclusion

Sufficient efficacy has not been demonstrated. Thus, approval cannot be suggested.

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 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	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Silver zeolite as inorganic metal is excluded from the P assessment taking into account Annex XIII of the REACH Regulation (EU) No 1272/2008.	Silver zeolite does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of

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

			Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	Silver zeolite is not B or vB.	
	Toxic (T)	Silver zeolite is T.	
Endocrine disrupting properties	The data available is considered insufficient to assess the endocrine properties of silver zeolite. Consequently, no conclusion can be drawn whether silver zeolite fulfils criterion (d) of Article 5(1) or criterion (e) of Article 10(1).		
Respiratory sensitisation properties	Silver zeolite does not fulfil criterion (b) of Article 10(1). No classification is required.		
Concerns linked to critical effects	Silver zeolite does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Silver zeolite does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

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

Silver zeolite does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

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"[6] and in line with "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR"[7] 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). However, the exclusion criteria were not assessed in line with the criteria laid down in the Annex of Regulation (EU) No 2017/2100, which apply as of 7 June 2018.

[6] 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)

[7] 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)

2.2.2. POP criteria

POP criteria are not applicable for silver 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 zeolite in product type 2

In view of the conclusions of the evaluation, it is proposed that silver zeolite shall not be approved. The criteria laid down in point (b)(i) of Article 19(1) of Regulation (EU) 528/2012 are not met.

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 zeolite gives rise to concern for human health and the environment, i.e. it is classified as Repr. 2 and as Aquatic acute 1.

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