Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Silver sodium hydrogen zirconium phosphate

Product type: 7

ECHA/BPC/214/2018

Adopted

17 October 2018

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

Opinion of the Biocidal Products Committee

on the application for approval of the active substance
Silver sodium hydrogen zirconium phosphate for product type 7

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 7 of the following active substance:

Common name:	**Silver sodium hydrogen zirconium phosphate**
Chemical name:	**Silver sodium zirconium hydrogenphosphate**
EC No.:	**422-570-3**
CAS No.:	**265647-11-8**

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 31 October 2008, 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 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.

Adoption of the BPC opinion

Rapporteur: Sweden

The BPC opinion on the non-approval of the active substance Silver sodium hydrogen zirconium phosphate in product type 7 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 sodium hydrogen zirconium phosphate in product type 7 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 sodium hydrogen zirconium phosphate in product type 7.

Silver sodium hydrogen zirconium phosphate 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. Chromium (Cr) is regarded as a relevant impurity with a maximum level of 53 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 sodium hydrogen zirconium phosphate.

The Swedish Chemicals Agency has submitted a proposal for harmonised classification and labelling on 3 July 2017.

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

Proposed Classification according to the CLP Regulation	
Hazard Class and Category Codes	Aquatic acute 1 Aquatic chronic 1
Labelling	
Pictogram codes	GHS09
Signal Word	Warning
Hazard Statement Codes	H400 H410
Specific Concentration limits, M-Factors	M = 100 for acute and chronic
Justification for the proposal	

b) Intended use, target species and effectiveness

Silver sodium hydrogen zirconium phosphate 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.

Fungistatic and bacteriostatic claims have been made. The intended use is protection of film against direct or indirect effects from micro-organisms to increase the durability of the film. The example uses are i) laminates, e.g. work surfaces and ii) Paint or powder coat finishes e.g. for walls and floors.

The tests provided could not demonstrate fungistatic efficacy for the example uses. Thus, efficacy is not 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

Animal studies indicate a low acute toxicity via oral, dermal and inhalation routes and no potential for skin and eye irritation or skin sensitisation.

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 sodium hydrogen zirconium phosphate are orally absorbed. Similarly, the dermal absorption is expected to be 5% based on data for silver nitrate.

Effects following subchronic exposure include pigmentation of organs and tissues, renal and hepatic toxicity and increased levels of alkaline phosphatase.

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 there were no indications of genotoxicity in the in vivo studies conducted, thereby overruling the positive in vitro findings.

There is no substance-specific data available to assess the chronic toxicity and the carcinogenic potential of the active substance. As a pragmatic approach to avoid further animal testing, the active substance is assumed to have a similar carcinogenic potential as silver zinc zeolite. A justification for the read-across is presented in section 3.9 of the assessment report. Since the Risk Assessment Committtee (RAC) has concluded that data on silver zinc zeolite does not fulfil criteria for classification the intrinsic properties of silver sodium hydrogen zirconium phosphate are consequently not expected to fulfil criteria for classification.

The results of the developmental study and the two-generation study performed do not indicate an intrinsic ability of the substance to cause reproductive toxic effects fulfilling criteria for classification.

There is no robust information available to assess the neurotoxic or immunotoxic potential of silver sodium hydrogen zirconium phosphate or of any of the other silver containing active 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 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

Non-textile polymers, secondary exposure

Scenario	Exposure category[1]	Risk acceptable
Articles intended for dermal contact	small-scale, all age-groups	yes
	medium-scale, all age-groups	yes
	large-scale, adults	yes
	large-scale, child, toddler, infant	no
	hand-to mouth contact infant and toddler	yes
Articles intended for oral contact	small-scale adults, children and toddlers	yes
	Large-scale for infants and toddlers, children and adults	yes

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

Environment

Silver sodium zirconium hydrogen phosphate releases silver ions (Ag^+) under the use envisaged, which is the active component of the substance. Silver sodium zirconium hydrogen phosphate as a complete substance is not soluble in water and is not expected to reach the environment under the use envisaged. Silver is released from the treated polymers through ion exchange and migration in the presence of aquatic media, whereas the phosphate part is expected to mainly remain in the polymer matrix. Zirconium does not contribute significantly to the environmental toxicity of the active substance.

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 sodium hydrogen zirconium phosphate, including use in other product types.

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

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

Solid treated articles, service life

Scenario	Example	Aquatic	Terrestrial	Risk acceptable
Non-textile polymers, indoor use	laminated work surface	yes	yes	yes
Non-textile polymers[2], used outdoors	garden chair	not applicable	yes	yes

Paints, coatings and sealants, application

Scenario	Aquatic	Terrestrial	Risk acceptable[3]
Paints on façade Paints on windows and doorframes	Outdoor use not intended according to the applicant. Therefore, no outdoor scenarios were calculated.		
Sealants outdoor	no	Non-professional: no Professional: yes	no
Sealants indoor	yes	yes	yes
Bridge over pond, Paint on house Paint on noise-barrier Paint on fence post	Outdoor use not intended according to the applicant. Therefore, no outdoor scenarios were calculated.		

Paints, coatings and sealants, service life

Scenario	Aquatic	Terrestrial	Risk acceptable
Paints on façade Paints on windows and doorframes	Outdoor use not intended according to applicant. Therefore, no outdoor scenarios were calculated.		
Sealants outdoor	yes	yes	yes
Sealants indoor	yes	yes	yes
Bridge over pond[4]	no	not applicable	no
Coating on house[2]	not applicable	no	no
Coating on noise-barrier[2]	not applicable	yes	yes
Coating on fence post[2]	not applicable	yes	yes

The risk from polymer formulation is acceptable. Use of non-textile polymers indoor and outdoor is acceptable. Use of paints and coatings on outdoor infrastructure shows unacceptable risks, wheras the use of sealants on outdoor infrastructure is acceptable. Use on smaller infrastructure such as noise barriers or fence posts is acceptable. Use of paints, coaitngs and sealants on indoor infrastructure is acceptable. Use on solid polymer articles for outdoor and indoor use is acceptable.

[2] In solid polymer articles, silver can either be applied in a coating (PT 7), or it can be incorporated into the polymer (PT 9).
[3] For application of paints and coating a distinction is made between professional and non-professional users. Only if the outcome of the risk assessment for professional and non-professional users is different this is indicated.
[4] The applicant did not apply for the use of paints on outdoor infrastructures. Only sealants were mentioned in the application, but not specified whether used indoor or outdoor. However, protective finishes applied to walls, moulded parts and sealants with anti-bacterial or anti-fungal claim (without further specification whether used outdoor or indoor) are intended uses. Potentially, such pre-finished surfaces could be applied on outdoor infrastructure, for example as wall panels. The (*)-marked scenarios are used to simulate such outdoor use of finished surfaces on different kinds of structures.

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:

<table>
<tr><th colspan="2">Property</th><th colspan="2">Conclusions</th></tr>
<tr><td rowspan="3">CMR properties</td><td>Carcinogenicity (C)</td><td>no classification required</td><td rowspan="3">Silver sodium hydrogen zirconium phosphate does not fulfil criterion (a), (b) and (c) of Article 5(1)]</td></tr>
<tr><td>Mutagenicity (M)</td><td>no classification required</td></tr>
<tr><td>Toxic for reproduction (R)</td><td>no classification required</td></tr>
<tr><td rowspan="3">PBT and vPvB properties</td><td>Persistent (P) or very Persistent (vP)</td><td>Silver sodium hydrogen zirconium phosphate as inorganic metal is excluded from the P assessment taking into account Annex XIII of the REACH Regulation 1272/2008.</td><td rowspan="3">Silver sodium hydrogen zirconium phosphate does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)</td></tr>
<tr><td>Bioaccumulative (B) or very Bioaccumulative (vB)</td><td>Silver sodium hydrogen zirconium phosphate is not B or vB.</td></tr>
<tr><td>Toxic (T)</td><td>Silver sodium hydrogen zirconium phosphate is T.</td></tr>
<tr><td>Endocrine disrupting properties</td><td colspan="3">The data available is considered insufficient to assess the endocrine properties of silver sodium hydrogen zirconium phosphate. Consequently, no conclusion can be drawn whether silver sodium hydrogen zirconium phosphate fulfils criterion (d) of Article 5(1) or criterion (e) of Article 10(1).</td></tr>
<tr><td>Respiratory sensitisation properties</td><td colspan="3">Silver sodium hydrogen zirconium phosphate does not fulfil criterion (b) of Article 10(1). No classification is required.</td></tr>
<tr><td>Concerns linked to critical effects</td><td colspan="3">Silver sodium hydrogen zirconium phosphate does not fulfil criterion (e) of Article 10(1).</td></tr>
<tr><td>Proportion of non-active isomers or impurities</td><td colspan="3">Silver sodium hydrogen zirconium phosphate does not fulfil criterion (f) of Article 10(1).</td></tr>
</table>

Consequently, the following is concluded:

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

Silver sodium hydrogen zirconium phosphate 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"[5] and in line with "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR"[6] 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.

2.2.2. POP criteria

POP criteria are not applicable for Silver sodium hydrogen zirconium phosphate, 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 non-approval of the active substance silver sodium hydrogen zirconium phosphate in product type 7

In view of the conclusions of the evaluation, it is proposed that silver sodium hydrogen zirconium phosphate 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 socium hydrogen zirconium phosphate gives rise to concern for the environment, i.e. it is classified as Aquatic acute 1.

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[5] 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)

[6] 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)