Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Silver sodium hydrogen zirconium phosphate

Product type: 4

ECHA/BPC/278/2021

Adopted

3 March 2021

Opinion of the Biocidal Products Committee

on the application for approval of the active substance silver sodium hydrogen zirconium phosphate for product type 4

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 4 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 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 BPC (BPC 27 and BPC 38) 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 4 was adopted on 3 March 2021.

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 (PT 4) 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 4.

Silver sodium hydrogen zirconium 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 max level of 53 mg/kg.

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).

In 2004, EFSA published a scientific opinion on the safety evaluation of amongst others the substance silver sodium hydrogen zirconium phoshate for use in food contact materials (EFSA, 2004[1]). In 2016, EFSA published its opinion regarding the re-evaluation of the safety of silver (E 174) when used as a food additive[2]. Requested by the Commission at BPC-27, a joint document[3] was prepared in the framework of the Memorandum of Understanding between ECHA and EFSA. This joint document is entitled: “Comparison of the evaluations performed on silver compounds used as biocidal active substances in food contact materials (FCM) by EFSA and ECHA”. The conclusions of this document are: i) in line with their respective legislations and guidance on data requirements, EFSA and ECHA performed two evaluations with different objectives and methodologies, noting however that the scenario to estimate the exposure on a daily basis is harmonised; and ii) as a result there are some differences (the scope of the assessment, the toxicological assessment based on a different dataset, the exposure assessment) between the opinions from EFSA and ECHA. However, the assessments are consistent within their respective regulatory framework.

[1] The EFSA Journal (2004)65, 1-17: Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to a 4th list of substances for food contact materials (https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2004.109).
[2] EFSA Journal 2016;14(1):4364 http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4364/epdf
[3] The joint document is published on the ECHA webpage at: https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

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	H410 (very toxic to aquatic life with long lasting effects)
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.

Treated polymers or coatings can be used to make or coat consumer items where an antimicrobial effect is desirable in a food/feed situation, for example: packaging, gaskets, food containers, trays and covers, plastic film, food wrap, tubing, appliances, food processing equipment and utensils, and for the treatment of granular activated carbon.

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 for at least one example use, respectively, for the claims made.

A fungistatic and bacteriostatic claim has been made. The example uses given were i) kitchen utensils and ii) conveyer belt. The function described was to reduce cross-contamination[4] with pathogens. To achieve reduction of bacterial and/or fungal cross contamination, a rather fast cidal effect in a rather dry surrounding would have to be demonstrated. Such tests have not been provided. For example application ii), where a slower effect might be sufficient, no acceptable studies have been submitted either, only a compilation of different information relevant for food contact materials. The documentation shows, however, that the presence of organic material, which is a common condition in food contact, hampers the effects of silver sodium hydrogen zirconium phosphate.

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

[4] Cross-contamination occurs when bacteria and viruses are transferred from a contaminated food or surface such as a chopping board to other food.

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 the 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 pigmentation of tissues and organs is also the key effect considered for the derivation of the chronic reference value.

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 Committee (RAC) has concluded that data on silver zinc zeolite does not fulfil the criteria for classification, the intrinsic properties of silver sodium hydrogen zirconium phosphate are consequently not expected to fulfil the criteria for classification either.

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 the criteria for classification.

There is no robust information available to assess the neurotoxic or immunotoxic potential of silver sodium hydrogen zirconium phosphate or of 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 personal protective equipment and by using either respiratory protection or protective gloves show unacceptable risks. However, the risk is acceptable for industrial professionals when appropriate PPE and RPE is worn.

Consumer use of biocidal products or solid treated articles[5] as food contact material

Scenario	Age group	Risk acceptable
Migration from polymers into food	Adult	no
	Child	no
	Toddler	no
	Infant	no

Consumption of food having been in contact with treated food contact materials shows unacceptable risk.

Environment

Silver sodium hydrogen zirconium phosphate under the use envisaged releases silver ions (Ag^+), which is the active component of the substance. Silver sodium hydrogen zirconium 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 crystalline zirconium hydrogen 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 treatment plants for the intended uses.

The standard concept of assessing the 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 sodium hydrogen zirconium phosphate, including use in other product types.

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

Polymer formulation – industrial use

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

Solid biocidal products or solid treated articles[6] – service life

Scenario	Aquatic	Terrestrial	Risk acceptable
Treated articles, service life (release from treated kitchen utensils or conveyer belts during use)	yes	yes	yes

The risk from polymer formulation is acceptable. Use of treated articles during service life shows acceptable risk.

Overall conclusion

Silver sodium hydrogen zirconium phosphate is supported in several product types (PT 2, 4, 7, and 9), hence it was assumed that a consumer can be exposed within the same time period to foods which have been in contact with food contact materials and to several other treated articles, which fall under other PTs than PT 4. Accordingly, a cumulative exposure assessment should have been performed. However, it was considered not manageable to take into account all possible exposure situations, noting the variety of use situations described in the dossiers and the variety of treated items. In order to compensate for possible simultaneous uses of different articles, the Technical Meeting IV 2013 agreed for silver zinc zeolite to compare the acute exposure with the long-term reference value as a pragmatic approach ("multiple exposure scenario"). The same approach was taken for the silver sodium hydrogen zirconium phosphate assessment for all supported PTs.

The following uses have shown unacceptable risks:

- Industrial use: mixing and loading without PPE and RPE;
- Consumption of food which has been in contact with treated polymers.

Due to risks for human health, no acceptable uses have been identified. For the consumption of food which has been in contact with treated polymers risks cannot be mitigated by introducing risk management measures. Sufficient efficacy has not been demonstrated. Thus, approval cannot be suggested.

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

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>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></td><td>Mutagenicity (M)</td><td>No classification required</td></tr>
<tr><td></td><td>Toxic for reproduction (R)</td><td>No classification required</td></tr>
<tr><td>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 (EU) No 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></td><td>Bioaccumulative (B) or very Bioaccumulative (vB)</td><td>Silver sodium hydrogen zirconium phosphate is not B or vB.</td></tr>
<tr><td></td><td>Toxic (T)</td><td>Silver sodium hydrogen zirconium phosphate is T.</td></tr>
<tr><td rowspan="4">Endocrine disrupting properties</td><td colspan="2">Section A of Regulation (EU) 2017/2100: ED properties with respect to humans</td><td rowspan="4">An assessment of the endocrine disrupting properties according to Regulation (EU) 2017/2100 was not conducted as non-approval is proposed. Consequently, no conclusion can be drawn whether silver sodium hydrogen zirconium phosphate fulfils criterion (d) of Article 5(1) with respect to humans or criterion (e) of Article 10(1) with respect to non-target organisms.</td></tr>
<tr><td colspan="2">Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms</td></tr>
<tr><td colspan="2">Article 57(f) and 59(1) of REACH</td></tr>
<tr><td colspan="2">Intended mode of action that consists of controlling target organisms via their endocrine system(s).</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 other than those related to endocrine disrupting properties</td><td colspan="3">Silver sodium hydrogen zirconium phosphate does not fulfil criterion (e) of Article 10(1).</td></tr>
</table>

Proportion of non-active isomers or impurities	Silver sodium hydrogen zirconium phosphate does not fulfil criterion (f) of Article 10(1).

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"[7], "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[8] and "Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment[9]" agreed at the 54th, 58th and 77th 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).

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 endocrine disruption properties have not been assessed as defined in Regulation (EU) No 2017/2100 and it is therefore not possible to finally conclude on the exclusion criteria related to Article 5(1)(d) and 10(1)(a), and on whether silver sodium hydrogen zirconium phosphate shall be considered a candidate for substitution related to Article 10(1)(e). This is in line with paragraph 16 of the document "Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment"[9].

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 4

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 points (b)(i) and (b)(iii) 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 sodium hydrogen zirconium phosphate gives rise to concern for the environment, i.e. it is classified as Aquatic acute 1.

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[7] 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).

[8] 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.

[9] See document: Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment (https://circabc.europa.eu/sd/a/48320db7-fc33-4a91-beec-3d93044190cc/CA-March18-Doc.7.3a-final-%20EDs-%20active%20substances%20under%20assessment.docx).