

Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance

pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated

Product type: 18

ECHA/BPC/122/2016

Adopted

11 October 2016

Opinion of the Biocidal Products Committee

on the application for approval of the active substance pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated for product type 18

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 18 of the following active substance:

Common name¹:	pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated
Chemical name:	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica
EC No.:	272-697-1
CAS No.:	68909-20-6
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 Evonik Degussa AG, on 3 May 2006, the evaluating Competent Authority France submitted an assessment report and the conclusions of its evaluation to the Agency (ECHA) on 18 December 2015. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-17) and its Working Groups (WG III 2016) and the Commission via the Biocides Technical Meetings (TM II 2011). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

¹ In Regulation (EU) No 1062/2014 the active substance is referred to as "Silicon dioxide (as a nanomaterial formed by aggregates and agglomerates)" (Entry number 1019 in Annex II, Part 1). For the approval the substance is renamed into pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated.

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the approval of the active substance pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated in product type 18 was adopted on 11 October 2016.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority position(s) 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 pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated in product type 18 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 pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated in product-type 18. Specifications for the reference source are established.

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

Analytical methods are available for the active substance as manufactured and for the relevant and significant impurities. However, information is missing to fully validate these methods (please refer to the section 2.5). Validated analytical method is required for the determination of active substance in formulated product.

There is no harmonised classification and labelling for pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated according to Regulation (EC) No 1272/2008 (CLP Regulation). The proposed classification and labelling by the evaluating Competent Authority is shown below.

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	STOT-RE 2 H373
Labelling	
Pictogram codes	GHS08
Signal Word	Warning
Hazard Statement Codes	H373: May cause damage to organs (lungs) through prolonged or repeated exposure EUH 066: Repeated exposure may cause skin dryness or cracking
Specific Concentration limits, M-Factors	
	-

b) Intended use, target species and effectiveness

Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated based products are used indoor by professional operators by spraying for the control of poultry red mite (*Dermanyssus gallinae*) to protect domestic animals (fowl) in places such as chicken-breeding farms or egg-producing farms. The representative product is an aqueous dispersion which, when it is dried, forms a thick film on the treated surfaces, and does not generate free dust.

Although the mechanism of biocidal action is currently not clear, pyrogenic, synthetic

amorphous silicon dioxide, nano, surface treated seems to act through absorption of the lipid layer covering insects chitin protection, which then leads to desiccation and death of the target organism. By destroying the natural water barrier, the waxy layer of the cuticle and hence disrupting the functioning of the water preservation mechanism, silica interferes with physiological processes of the targeted organisms. Several laboratory studies were submitted with the active substance and the representative product. Results demonstrated sufficient efficacy against the target species and the likely concentration of use of the active substance would be from 10 to 20 g a.s/m². The frequency of application of the product can vary from 1 to 17 applications per year, considering that each application is efficient up to 3 weeks.

Resistance development has not been observed for surface-treated amorphous silica.

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

Human health

Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated is not classified with regards to acute effects, carcinogenicity, teratogenicity and toxicity on the reproduction. Pyrogenic, synthetic amorphous silicon dioxide is neither skin nor eye irritant.

Regarding prolonged exposure, local effects are observed in respiratory tract leading to the proposed classification H373: May cause damage to organs (lungs) through prolonged or repeated exposure. Due to the mode of action of the active substance, the labelling EUH 066: Repeated exposure may cause skin dryness or cracking should be applied.

No systemic effect has been identified and only a risk assessment for local effects is performed.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	Primary or secondary exposure and description of scenario	Exposed group	Conclusion
Surface spray application indoors	Primary exposure during loading and cleaning of the equipment and application of the product	Professional	Acceptable with RPE (APF20)
Surface spray application indoors	Secondary exposure of professional entering the room post application	Professional	Acceptable
Surface spray application indoors	Secondary exposure of professional in charge of litter/manure removal and cleaning via wet process, after depopulation	Professional	Acceptable with RPE (APF20)

With regards to the risk for human health, no risks can be expected from direct or indirect dermal exposure since no hazards (local effects) have been detected in oral studies and in irritation/sensitisation studies. However, the wearing of gloves by operators is recommended to prevent discomfort due to the dusty nature of the active substance.

In the case of respiratory exposure, there is no unacceptable risk to use the representative product when considering the wearing of a half mask with P3 filter for daily exposed professional operators.

For professionals working in the poultry houses and indirectly exposed to the representative product during high airborne dust concentration activities (routine house work, repopulating/depopulating of hens from battery laying and laying litter), the exposure is considered to be negligible. During very high airborne dust concentration activities (litter/manure removal and cleaning after depopulation), the professionals working in the poultry house, exposed to the representative product, have to wear a half mask with P3 filter and use wet process cleaning.

Treated areas are not accessible to the public, thus, no indirect exposure is expected for general public.

Environment

The absence of toxicity observed in the aquatic tests well above the solubility of the active substance, and the overall chemical and toxicological profile of this substance indicate that no hazard is identified for aquatic organisms.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	Description of scenario including environmental compartments	Conclusion
Surface spray application indoors by professional	Exposure to terrestrial and aquatic compartments	Acceptable

Concerning the exposure of the environment, there are no primary emissions of pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated to surface water, sediment and soil.

Acceptable risks for the environment are identified for surface water and sediment after the run-off from agricultural soil and at the outlet of the sewage treatment plant, for agricultural soil and groundwater after the application of contaminated slurry/manure and STP sludge.

Overall conclusion

Overall, a safe use has been identified for both human health and the environment when a product containing pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated is applied indoors in poultry houses as an aqueous dispersion by spraying provided PPE is used.

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	Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	No classification required	
	Toxic for reproduction (R)	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Not relevant for inorganic substance	Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated 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)	Not relevant for inorganic substance	
	Toxic (T)	Not relevant for inorganic substance	
Endocrine disrupting properties	Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated is not considered to have endocrine disrupting properties. Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated does not fulfil criterion (d) of Article 5(1).		
Respiratory sensitisation properties	No classification required. Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects	Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Not relevant as the minimum purity of pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated is 99.8% w/w. Given this, pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated silicon dioxide does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated 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"² and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"³ 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).

² 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>)

³ 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](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

Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated does not meet the criteria for being a persistent organic pollutant.

2.3.BPC opinion on the application for approval of the active substance pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated in product type 18

In view of the conclusions of the evaluation, it is proposed that pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated 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: 998 g/kg (purity of core measured after ignition). Relevant impurity : crystalline silica <0.1%. Reference structural characteristics:
 - Carbon content : 3.0-4.0%;
 - Primary particle size: 6.9-8.6 nm;
 - Specific surface area: 217-225 m²/g;
 - Size of stable aggregated particles: > 70 nm.
2. The active substance is a nanomaterial according to the definition set out in Article 3(1)(z) of Regulation (EU) No 528/2014.
3. The authorisations of biocidal products are subject to the following condition(s):
 - 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. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:
 - i. professional users.
 - c. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/20092 or Regulation (EC) No 396/20053 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

The active substance does not fulfill the criteria according to Article 28(1) to enable inclusion in Annex I of Regulation (EU) No 528/2012 as it is proposed to be classified as STOT-RE 2 (H373).

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 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. Although all forms of synthetic amorphous silica may be surface treated, only the surface treated silica with Pyrogenic Silica (CAS Number 112945-52-5) as a starting material is evaluated for the approval.
- c. According to Article 3(1)(z) of Regulation (EU) No 528/2012, the active substance is a nanomaterial and it cannot be ruled out that there will be no exposure to nano-forms during and after the intended biocidal application considered in this evaluation. It has to be highlighted that the risk assessment performed for the active substance follows current guidelines applicable for non-nanomaterials and was finalised before the reception of the additional information related to nanoform criteria. However, there is no guidance available currently on how to assess the risks of nanomaterials used as a biocide. Therefore, the hazard and risk related to the nano-form of silicon dioxide are not evaluated in this dossier. This assessment will have to be updated according to the evolution of the knowledge and specific regulations about nanomaterials if appropriate.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated. However, further data shall be required as detailed below.

The following data must be provided to the evaluating Competent Authority (France) as soon as possible but not later than six months before the date of approval of the active substance:

- The applied analytical method for determination of the active substance in the technical material needs to be completed with specific parameters.