Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Silicon dioxide Kieselguhr

Product type: 18

ECHA/BPC/121/2016

Adopted

11 October 2016

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance silicon dioxide Kieselguhr 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 name[1]:	**silicon dioxide Kieselguhr**
Chemical name(s):	**Not available**
EC No.:	**612-383-7**
CAS No.:	**61790-53-2**
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 initially by Dr. Schaette AG and then by Biofa AG on 15 June 2009, the evaluating Competent Authority France submitted an assessment report and the conclusions of its evaluation to the Agency 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). 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 "Silicium dioxide (Silicium dioxide / Kieselguhr)" (Entry number 831 in Annex II, Part 1). For the approval the substance is renamed into silicon dioxide Kieselguhr. Diatomaceous earth is also used as synonym.

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the approval of the active substance silicon dioxide Kieselguhr in product-type 18 was adopted on 11 October 2016.

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 the silicon dioxide Kieselguhr 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 silicon dioxide Kieselguhr 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 not complete to fully validate these methods (please refer to the section 2.5). and additional information is required to set a limit of quantification (LOQ).

There is no harmonised classification and labelling for silicon dioxide Kieselguhr according to Regulation (EC) No 1272/2008 (CLP Regulation). The proposed classification and labelling by the evaluating Competent Authority is:

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

Silicon dioxide Kieselguhr based products are used indoor:

- by professional operators for the control ofpoultry red mites in poultry pens and for the control of arthropods in food and feed processing industry or storage facilities;

- by non-professionals for the control of arthropods in private households into crack and crevice and in food and feed processing industry or storage facilities.

The representative product containing 100 % of the active substance is a dustable powder which is applied as dry dust with hand operated or electrostatic dusters. Several studies were submitted with the active substance and the representative product. Results demonstrated sufficient efficacy against the target species at the application rate of 50 g/m^2 during 28 days with 3 applications (poultry mite), as dust barrier at a dose of 5 g/m (0.5-2 cm width and app. 2 mm hight) (black ant, silverfish, wood louse) and as surface treatment on carpets at the application rate of 10 g/m^2 (cat flea). No efficacy data were submitted to support the use "crack and crevice". Therefore the efficacy dose for application into crack and crevices against fleas is not validated.

The mechanism of biocidal action is currently not clear, silicon dioxide Kieselguhr 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.

Resistance development has not been observed for silicon dioxide Kieselguhr.

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

Human health

Silicon dioxide Kieselguhr is not classified with regards to acute effects, carcinogenicity, teratogenicity and toxicity on the reproduction. Silicon dioxide Kieselguhr is either skin nor eye irritant andno skin sensitization effect is observed. Regarding prolonged exposure, local effects are observed on lungs leading to the 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**
Indoor surface large-scale dusting in food processing and storage facilities	**Primary exposure** during mixing and loading then application of the product	Professional	Not acceptable with RPE
Indoor surface large-scale dusting in poultry pens or stables	**Primary exposure** during mixting and loading application of the product	Professional	Not acceptable with RPE
Indoor surface dusting into crack and crevice	**Primary exposure** during the dusting in crack and crevice application	Non-professional	Not acceptable
Indoor surface application of dust barriers	**Primary exposure** during pouring of dust barrier application	Non-professional	Acceptable
Indoor surface application of dust barriers	**Secondary exposure** after application of dust barriers	General public	Acceptable
Indoor surface application of dust barriers	**Secondary exposure** via food/feed	General public	Acceptable

Secondary exposure scenarios for which unacceptable risk has been identified during primary exposure have not been assessed.

With regards to the risk for human health:

- for non-professional, acceptable risk can be expected during the dust barrier application from direct or indirect dermal exposure since no hazards (systemic or local effects) have been detected in oral studies and in irritation/sensitisation studies. Regarding the exposure via food, indirect exposure to silicon dioxide kieselguhr via food/feed will be negligible and risk is considered acceptable.

- for professionals dusting at a large scale in storage facilities or in stables, an unacceptable risk for inhalation is identified during the primary exposure to the representative product.

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 the organisms of the environment.

The table below summarises the exposure scenarios assessed:

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Indoor surface large-scale dusting in poultry pens or stables– Release via manure/slurry application to land and via STP	Exposure to terrestrial compartment (not relevant for aquatic compartment)	Acceptable
Indoor surface Large-scale dusting in food processing and storage facilities and in private households by dust barrier - Release via emission to the STP	Exposure to terrestrial compartment (not relevant for aquatic compartment)	Acceptable

With regard to the environment, acceptable risk is identified, as predicted releases to relevant environmental compartment (i.e. soil) should be considered as negligible compared to the background level of natural silica.

Overall conclusion

Overall, a safe use has been identified for environment and for human health only for non-professional use when a product containing silicon dioxide Kieselguhr is applied indoor as pouring of dust barriers in private households.

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	Silicon dioxide Kieselguhr 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	Slicon dioxide Kieselguhr 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	Silicon dioxide Kieselguhr is not considered to have endocrine disrupting properties. Silicon dioxide Kieselguhr does not fulfil criterion (d) of Article 5(1).		
Respiratory sensitisation properties	No classification required. Silicon dioxide Kieselguhr does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects	Silicon dioxide Kieselguhr does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Not relevant as the miniumum purity of silicon dioxide Kieselguhr is 100 % w/w. Given this, silicon dioxide Kieselguhr does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

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

Silicon dioxide Kieselguhr 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

[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)

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).

2.2.2. POP criteria

Silicon dioxide Kieselguhr does not meet the criteria for being a persistent organic pollutant

2.3. BPC opinion on the application for approval of the active substance silicon dioxide Kieselguhr in product-type 18

In view of the conclusions of the evaluation, it is proposed that silicon dioxide Kieselguhr 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: 1000 g/kg by wt (100 %). The active substance is an UVCB containing 70 % or more silicon dioxide. Relevant impurity : crystalline silica <0.1%.

2. The authorisations of biocidal products are subject to the following condition(s):

    a. The product assessment shall pay particular attention to exposures, risks and the efficacy linked to any use 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. professionals users;
        ii. non-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 470/2009 or Regulation (EC) No 396/2005 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:

    i. An unacceptable risk for professionals dusting at a large scale indoor storage facilities or stables is identified. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures like establishing safe operational procedures and appropriate organizational measures or by other means, silicon dioxide Kieselguhr based products used for the control of poultry red mites in poultry pens and for the control of insects in food and feed processing industry facilities should not be authorized.

    ii. An unacceptable risk for non-professional dusting into crack and crevice is identified. If the risk cannot be reduced to an acceptable level by appropriate

risk mitigation measures or by other means, silicon dioxide Kieselguhr based products used for dusting into crack and crevice by non-professionals should not be authorized.

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 diatomaceous earth. However, an X-ray analysis has been provided for the determination of the relevant impurity crystalline silica, in the active substance but no validation data is available in the study. As the method is derived from a NIOSH method, the proposed method is considered acceptable nevertheless validation data are needed for confirmation and to set a limit of quantification (LOQ). The data should be provided to the evaluating Competent Authority (France) as soon as possible but no later than 6 months before the date of approval of the active substance.

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