EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Pesticides and biocides

Kieselgur (Diatomaceous earth)
SANTE/10898/2020 Rev 4
23 October 2020

Final Renewal report for the active substance Kieselgur (diatomaceous earth)

finalised by the Standing Committee on Plants, Animals, Food and Feed on 23 October 2020 in view of the renewal of the approval of kieselgur (diatomaceous earth) as an active substance in accordance with Regulation (EC) No 1107/2009[1]

1. Procedure followed for the re-evaluation process

This renewal report has been established as a result of the evaluation of kieselgur (diatomaceous earth), in accordance with Regulation (EC) No 1107/2009[2] and Commission Implementing Regulation (EU) No 844/2012[3] following the submission of an application to renew the approval of this active substance expiring in August 2021.

Kieselgur (diatomaceous earth) is a substance that was included in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, by Commission Directive 2008/127/EC [4]. Kieselgur (diatomaceous earth) is deemed to have been approved under Regulation (EC) No 1107/2009 and is listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[5].

An application for renewal of the approval of kieselgur (diatomaceous earth) was submitted by Biofa AG in accordance with Article 1 of Regulation (EU) No 844/2012.

In addition, Biofa AG submitted an application to include the substance into Annex IV of Regulation (EC) No 396/2005[6].

The approval period of kieselgur (diatomaceous earth), originally expiring on 31 August 2019, has been extended twice in accordance with Article 17 of Regulation (EC) No 1107/2009:

- Commission Implementing Regulation 2017/195[7] extended until 31 August 2020 the period of approval of kieselgur (diatomaceous earth) as part of the organisation of the renewal programme.

1 Renewal Report established in accordance with Art. 14 of Regulation (EU) No 844/2012; does not necessarily represent the views of the European Commission.
2 OJ L 309, 24.11.2009, p. 1.
3 OJ L 252, 19.9.2012, p. 26.
4 OJ L 344, 20.12.2008, p. 89.
5 OJ L 153, 11.6.2011, p. 1.
6 OJ L 70, 16.03.2005, p. 1.
7 OJ L 31, 4.2.2017, p. 21.

- Commission Implementing Regulation 2020/1160[8] extended until 31 August 2021 the period of approval of kieselgur (diatomaceous earth) to enable the completion of its review.

Commission Implementing Regulation (EU) No 686/2012[9] allocates the rapporteur Member States and the co-rapporteur Member States, which had to submit the relevant renewal assessment reports and recommendations to the European Food Safety Authority (EFSA).

For kieselgur (diatomaceous earth) the rapporteur Member State was Austria and the co-rapporteur Member State was Greece.

Austria finalised in February 2019 its examination, in the form of a renewal assessment report. This report was sent to the Commission and the European Food Safety Authority on 22 February 2019 and included a recommendation concerning the decision to be taken with regard to the renewal of the approval of kieselgur (diatomaceous earth) for the supported uses.

In accordance with Article 13 of Implementing Regulation (EU) No 844/2012, the EFSA organised an intensive consultation of technical experts from Member States, to review the renewal assessment report and the comments received thereon (peer review). EFSA also launched a public consultation on the RAR.

EFSA sent to the Commission its conclusion on the risk assessment (Conclusions regarding the peer review of the pesticide risk assessment of the active substance)[10] on 27 February 2020. This conclusion refers to several background documents: the renewal assessment report including its revisions and the peer review report.

According to the provisions of Article 14 of Implementing Regulation (EU) No 844/2012, the Commission referred a draft renewal report on the renewal of approval to the Standing Committee on Plants, Animals, Food and Feed, for examination on 18 May 2020. The draft renewal report was finalised by Standing Committee on 23 October 2020.

The present renewal report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and its background documents, these documents are also considered to be part of this renewal report.

2. Purposes of this renewal report

This renewal report, including the background documents and appendices hereto, has been developed and finalised in support of **Commission Implementing Regulation (EU) 2020/2101** [11] concerning the renewal of approval of kieselgur (diatomaceous earth) as an active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing kieselgur (diatomaceous earth) they have to take in accordance with

8 (OJ L 257, 6.8.2020, p. 29).
9 OJ L 200, 27.7.2012, p. 5.
10 EFSA (European Food Safety Authority), 2020. Conclusion on the peer review of the pesticide risk assessment of the active substance kieselgur (diatomaceous earth) EFSA Journal 2020;18(3):6054, 14 pp. https://doi.org/10.2903/j.efsa.2020.6054.
11 OJ L 425, 16.12.2020, p. 79.

the provisions of that Regulation, and in particular the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011[12].

This renewal report provides also for the evaluation required under part I, Section A.2(b) of the above-mentioned uniform principles, as well as under several specific sections of chapter B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the requirements of Regulation (EU) No 283/2013[13], submitted for the purpose of (renewal of) approval of the active substances, as well as the result of the evaluation of those data.

This renewal report will be made available to the public.

The information in this renewal report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009. It is therefore recommended that this renewal report would not be accepted to support any registration outside the context of that Regulation, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this renewal report is based.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion from the evaluation is that it may be expected that plant protection products containing kieselgur (diatomaceous earth) will still fulfil the safety requirements laid down in Article 4(1) to (3) of Regulation (EC) No 1107/2009. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, for each kieselgur (diatomaceous earth) containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses, which were proposed and supported by the applicant and mentioned in the list of uses supported by available data (attached as Appendix II to this renewal report).

No critical areas of concern and no issues that could not be finalised have been identified by EFSA (2020).

Toxicological reference values related to oral exposure were not considered necessary, i.e. Acceptable Daily Intake (ADI), Acute Reference Dose (ARfD) or (Acute) Acceptable Operator Exposure Level (AAOEL/AOEL) were therefore not established.

No acute AOEC was established as it was not considered necessary.

However, considering the toxicity profile of the substance by inhalation, an Acceptable Operator Exposure Concentration (AOEC) is needed to perform a non-dietary risk assessment related to

[12] OJ L 155, 11.6.2011, p. 127.

[13] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance (OJ L 93, 3.4.2013, p. 1)

inhalation exposure. These conclusions on reference values required are in agreement with the previous conclusion of the peer review (EFSA, 2012). Two AOEC values were derived during the peer review; 0.01 mg/m^3 (taking into account the safety margin of 100 as laid down in point 3.6.1 of Annex II to Regulation (EC) No 1107/2009)[14] and 0.06 mg/m^3 (refined value taking into account specificities of kieselgur).

Since sound scientific rationale underpins the setting of the refined value, the AOEC for use in risk assessments for plant protection products containing kieselgur is established as 0.06 mg/m^3.

Kieselgur (diatomaceous earth) occurs naturally and toxicologically is considered not relevant for the consumer since the setting of reference values (ADI, ARfD) were not necessary; a consumer risk via dietary intake is not expected. EFSA recommends the inclusion of kieselgur (diatomaceous earth) in the Annex IV of Regulation (EC) No 396/2005 and confirmed that no MRLs are necessary.

The review has identified acceptable exposure scenarios for operators, workers, residents, bystanders and groundwater which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

As regards the criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605[15] which became applicable on 10 November 2018, EFSA concluded that although no (eco)toxicological data are available to assess the endocrine disrupting properties of kieselgur (diatomaceous earth) for humans and non-target organisms, this does not appear scientifically necessary considering the nature of the substance, being insoluble and inert. Therefore, it was considered scientifically justified to waive the assessment of endocrine disrupting properties of this substance both for humans and non-target organisms and it can be concluded that kieselgur (diatomaceous earth) does not meet the criteria for endocrine disruption.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4(3)(e) of Regulation (EC) No 1107/2009, provided that certain conditions are taken into account as detailed in section 6 of this report.

However, as data were only available for the representative use detailed in Appendix II (indoor use, storage pests), any extension of the use pattern beyond those described above, in particular any use differing from indoor use against storage pests, will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011.

4. Identity and Physical/chemical properties

The main identity of kieselgur (diatomaceous earth) is given in Appendix I.

[14] This conclusion is in agreement with the conclusion reached under the confirmatory data procedure (EFSA, 2016:DOI: 10.2903/sp.efsa.2016.EN-1064).

[15] Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. (OJ L 101, 20.4.2018, p. 33).

The active substance shall have a minimum purity of 1000 g/kg with a minimum content of amorphous silica of 800 g/kg.

The manufacturing impurities listed below are of toxicological, ecotoxicological and/or environmental concern.

The following maximum limits shall apply to those impurities in the active substance as manufactured:

- crystalline silicia with particle size below 10 µm: maximum of 1 g/kg.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of the EFSA.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing kieselgur (diatomaceous earth)

On the basis of the proposed and supported uses (as listed in Appendix II), no particular issues have been identified as requiring particular and short term attention from the Member States.

Member States shall assess any extension of the use pattern beyond use in closed environment against storage pests, in order to establish whether the proposed extensions of use fulfil the requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011.

Member States shall pay particular attention to:

- the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment, in particular respiratory protective equipment.

Conditions of use shall include risk mitigation measures, where appropriate.

7. List of studies to be generated

No further information was identified which is at this stage considered necessary in relation to the approval of kieselgur (diatomaceous earth) under the current approval conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions.

8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the applicant has claimed data protection and which during the re-evaluation process were considered as essential with a view to approval under Regulation (EC) No 1107/2009. This information is only given to facilitate the operation of the provisions of Article 62 of Regulation (EC) No 1107/2009 in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 62 of Regulation (EC) No 1107/2009 and neither does it commit the Commission.

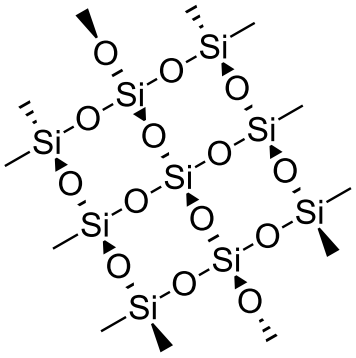
9. Updating of this renewal report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 13, 21, 38, 44, 56 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection with any amendment of the approval conditions for kieselgur (diatomaceous earth)**.**

APPENDIX I

Main identity

KIESELGUR (DIATOMACEOUS EARTH)

Common name (ISO)	Kieselgur (not ISO) *Other synonyms:* Diatomaceous earth Diatomite
Chemical name (IUPAC)	n.a. (consists mainly of silicon dioxide)
Chemical name (CA)	n.a. (consists mainly of silicon dioxide)
CIPAC No	647
CAS No	61790-53-2
EC No (EINECS or ELINCS)	Diatomite is not listed under a separate entry in the EINECS list of existing substances. Diatomite is a natural substance dried with heat and mechanically grinded. Therefore, it may be covered under the heading "Naturally occurring substances" with the EC-number: 310-127-6.
FAO SPECIFICATION	none
Minimum purity	1000 g/kg minimum content of amorphous silica of 800 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	crystalline silica with particle size below 10 μm maximum 1 g/kg
Molecular formula	n.a.
Molecular mass	n.a.
Structural formula	

APPENDIX II

List of uses supported by available data

KIESELGUR (diatomaceous earth)

Crop and/or situation (a)	**Member State or Country**	**Product Name**	**F, G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)** (l)	**Remarks:** (m)
					type (d-f)	**conc. of as** (i)	**method kind** (f-h)	**growth stage & season** (j)	**number min-max** (k)	**interval between appl. (min)**	**g as/hL min-max**	**water L/ha min-max**	**g as/ha min-max**		
Stored cereals YCEST	EU	SilicoSec	I	Insects and mites as storage pests 1INSEC, 1ACARO	CP	1000	Mixing with the grains	During putting into storage	1	-	-	-	1 kg/t	-	Application at danger of infestation
Stored cereals YCEST	EU	SilicoSec	I	Insects and mites as storage pests 1INSEC, 1ACARO	CP	1000	Mixing with the grains	During putting into storage	1	-	-	-	2 kg/t	-	Application at infestation

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) Contact Powder (CP)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval