



Basic Substance
clayed charcoal
SANTE/11267/2016– rev. 3.0
25 January 2021¹

FINAL Review report for the basic substance clayed charcoal
finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on 24 January 2017 and amended on 25 January 2021
in view of the approval of clayed charcoal as basic substance
in accordance with Regulation (EC) No 1107/2009²

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of clayed charcoal made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009³ concerning the placing of plant protection products on the market, with a view to the possible approval of this substance as basic substance.

In accordance with the provisions of Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 18 May 2015 an application from Ets Christian Callegari, hereafter referred to as the applicant, for the approval of the substance clayed charcoal as basic substance.

The application and attached information were distributed to the Member States and European Food Safety Authority (EFSA) for comments. The applicant was also allowed to address collated comments and provide further information to complete the application, which was finalised in the new version of April 2016.

In 2018, the Commission also received from ETS Callegari an application for the extension of use of clayed charcoal consisting of a formulation as a wettable powder for spray application (whereas the original application covered formulation as granules to be applied in soil).

For both the original request and the request for extension, in accordance with the provisions of Article 23(4) of Regulation (EC) No 1107/2009 the Commission requested scientific assistance on the evaluation of the application to EFSA, who delivered its views on the specific points raised in the commenting phase.

¹ The Standing Committee on Plants, Animals, Food and Feed took note of revision 3 of the review report on 25 January 2021. The review report was amended to include the conclusion on the non-approval of the extension of use of clayed charcoal consisting of a formulation as a wettable powder for spray application (see chapter 5 and Appendix II).

² Review Report established in accordance with Art. 13 of Regulation (EU) No 1107/2009; it does not necessarily represent the views of the European Commission.

³ OJ L 309, 24.11.2009, p. 1-50.

EFSA submitted to the Commission the results of its work in the form of a technical report for clayed charcoal on 6 July 2016⁴ and - for the extension of use - on 28 November 2019⁵.

For both applications, the Commission examined the application, the comments by Member States and EFSA and the EFSA Technical report on the substance together with the additional information and comments provided on it by the applicant, before finalising the current draft review report, which was referred to the Standing Committee on Plants, Animals, Food and Feed for examination. The draft review report was finalised in the meeting of the Standing Committee of 24 January 2017 and amended on 25 January 2021.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the EFSA technical report(s), and the comments and clarifications submitted (background document C), all these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed in support of the **Commission Implementing Regulation (EU) 2017/428**⁶, concerning the approval of clayed charcoal as basic substance under Regulation (EC) No 1107/2009.

The review report has been made available for public consultation by any interested parties.

Without prejudice to the provisions of Regulation (EC) No 178/2002⁷, in particular with respect to the responsibility of operators, following the approval of clayed charcoal as basic substance, operators are responsible for using it for plant protection purposes in conformity with the legal provisions of Regulation (EC) No 1107/2009 and with the conditions established in the sections 4, 5 and Appendixes I and II of this review report.

EFSA will make available to the public all background documents and the final Technical Report of EFSA, as well as the application without the Appendixes and excluding any information for which confidential treatment is justified in accordance with the provisions of Article 63 of Regulation (EC) No 1107/2009.

Products containing exclusively one or more basic substances do not require authorisation in line with derogation set under Article 28 of Regulation (EC) No 1107/2009. As a consequence,

⁴ EFSA (European Food Safety Authority), 2016. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for clayed charcoal for use in plant protection as a protectant in grapevines. EFSA supporting publication 2016:13(7):EN-1061. 28 pp.

⁵ EFSA (European Food Safety Authority), 2019. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for approval of clayed charcoal for the extension of use in plant protection as a protectant against grapevine trunk diseases. EFSA supporting publication 2019:EN-1752. 57 pp.

⁶ OJ L 66, 11.3.2017, p. 1–3.

⁷ OJ L 31, 1.2.2002 p. 1-24 - Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

no further assessment will be carried out on such products. However, the Commission may review the approval of a basic substance at any time in conformity with the provisions of Article 23(6) of Regulation (EC) No 1107/2009.

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

The overall conclusion based on the original application, including the results of the evaluation carried out with the scientific assistance of EFSA, is that there are clear indications that it may be expected that clayed charcoal fulfils the criteria of Article 23.

Clayed charcoal is a mixture of charcoal, meeting the criteria of the food additive E 153 (vegetable carbon), and bentonite, meeting the criteria of feed additive E 558, in the form of granules.

Considering the EFSA conclusions on the original basic substance application for clayed charcoal, the rate of application and the conditions of use which are described in detail in Appendix I and II, it is concluded that the use of clayed charcoal would in principle not lead to concerns for human health.

Clayed charcoal does not have an inherent capacity to cause endocrine disrupting (according to the interim criteria in Regulation 1107/2009), neurotoxic or immunotoxic effects and is not predominantly used for plant protection purposes but nevertheless is useful in plant protection. Finally, it is not placed on the market as a plant protection product.

It can be concluded that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment when used in accordance with the supported uses as described in Appendix II.

In fact, these indications were reached within the framework of the uses which were supported by the applicant in the original application and mentioned in the list of uses supported by available data (attached as Appendix II to this review report) and therefore, they are also subject to compliance with the particular conditions and restrictions in sections 4 and 5 of this report.

Extension of the use pattern beyond those described above will require an evaluation at Community level in order to establish whether the proposed extensions of use can still satisfy the requirements of Article 23 of Regulation (EC) No 1107/2009.

Considering the EFSA technical report from 2019 on the application for extension of the use of the basic substance clayed charcoal for use in the form of wettable powder in spray application, the risk for consumers, the environment and non-target organisms is concluded as acceptable. However, the Technical Report of EFSA identified a concern related to the presence of crystalline silica in a component of clayed charcoal – bentonite. According to EFSA, crystalline silica shall be considered as carcinogenic to humans by inhalation and the concentration of crystalline silica fine (respirable) fraction with particle size $\leq 10 \mu\text{m}$ needs to remain below 0.1% in bentonite. In view of the proposed use as a wettable powder in spray application and potential for exposure via inhalation, bentonite shall be considered as a substance of concern if it contains $\geq 0.1\%$ of crystalline silica with diameter below $10\mu\text{m}$. The Technical Report of EFSA indicates that information available in the application was not sufficient to demonstrate

that the clayed charcoal under evaluation meets the requirement that the level of respirable crystalline silica in bentonite does not exceed 0.1%. This condition is considered necessary to conclude that the ingredient of clayed charcoal, bentonite, is not a substance of concern and that the non-dietary (inhalation) risk from the use of clayed charcoal presented in the application for extension of use is acceptable.

Furthermore, based on the information included in the application it was not possible to identify (a) predominant use(s) of clayed charcoal formulated as wettable powder compliant with the specification set by the approval as a basic substance, and its availability on the market, for purpose(s) other than plant protection. The details on preparation of the clayed charcoal formulated as a wettable powder from the individual ingredients were also not available.

Therefore, the available information does not allow to conclude that clayed charcoal intended for use as wettable powder in spray applications fulfils the conditions set on in Article 23 (1) (a) and (c), namely that it is not a substance of concern and is predominantly used for purposes other than plant protection.

4. Identity and biological properties

The main properties of clayed charcoal are given in Appendix I.

The active substance must comply with Commission Regulation (EU) No 231/2012⁸ for charcoal and Commission Regulation (EU) No 1060/2013⁹ for bentonite.

It has been established that for clayed charcoal as notified by the applicant, no relevant impurities are considered, on the basis of information currently available, of toxicological, ecotoxicological or environmental concern.

5. Particular conditions to be taken into account in relation to the uses as basic substance of clayed charcoal

Clayed charcoal must be identified by the specifications given in Appendix I and must be used in compliance with conditions of supported uses as reported in Appendixes I and II.

The following conditions for use deriving from assessment of the application have to be respected by users:

- Only uses as basic substance being a protectant are approved;
- Granules should be essentially non-dusty according to method CIPAC MT 171.1.

⁸ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁹ Commission Implementing Regulation (EU) No 1060/2013 of 29 October 2013 concerning the authorisation of bentonite as a feed additive for all animal species (OJ L 289, 31.10.2013, p. 33–37).

Use of clayed charcoal must be in compliance with conditions specified in the Appendixes I and II of this review report.

On the basis of the proposed and supported uses (as listed in Appendix II), no particular issues have been identified.

6. List of studies to be generated

No further studies were identified which were at this stage considered necessary.

7. Updating of this review report

The information in this report may require to be updated from time to time 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 23 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, as appropriate, in connection with any amendment of the approval conditions for clayed charcoal in Part C of Annex of the Regulation (EC) No 540/2011.

8. Recommended disclosure of this review report

Considering the importance of the respect of the approved conditions of use and the fact that a basic substance will be not placed on the market as plant protection product, hence, no further assessment will have to be carried out on it, it is very important to inform not only applicants but also potential users on the existence of this review report.

It is therefore recommended that the competent authorities of Member States will make available such report to the general public and operators by means of their national relevant websites and by any other appropriate form of communication to ensure that the information reaches potential users.

APPENDIX I Identity and biological properties

CLAYED CHARCOAL

Common name	Clayed charcoal
Chemical name (IUPAC)	Not available.
Chemical Name. (CA)	Not available.
CAS No	7440-44-0 activated charcoal 1333-86-4 carbon black 1302-78-9 bentonite
CIPAC No and EEC No	231-153-3 (EINECS) activated charcoal 215-609-9 (EINECS) carbon black 215-108-5 (EINECS) bentonite
FAO SPECIFICATION	Not available.
Purity	Charcoal: as in Commission Regulation (EU) No 231/2012 ¹⁰ Bentonite: as in Commission Regulation (EU) No 1060/2013 ¹¹
Molecular formula	Not applicable.
Relevant impurities	None
Molecular mass and structural formula	$\begin{array}{c} \text{C} \\ (\text{Na, Ca})_{0,3}(\text{Al, Mg})_2\text{Si}_4\text{O}_{10}(\text{OH})_2.n\text{H}_2\text{O} \text{ or} \\ (\text{Na,Ca})(\text{Al,Mg})_6(\text{Si}_4\text{O}_{10})_3(\text{OH})_6.n\text{H}_2\text{O} \text{ or} \\ \text{Si}_4(\text{Al}_{(2-x)}\text{R}_x)(\text{O}_{10}, \text{H}_2\text{O})(\text{Ce}_x n\text{H}_2\text{O}) \text{ or} \\ \text{Si}_4(\text{Al}_{(2-x)}\text{R}_x)(\text{H}_2\text{O})_n \end{array}$ <p>where: R = Mg, Fe, Mn, Zn, Ni Ce (cations exchangable) = Ca, Na, Mg</p>
Mode of Use	Soil burying
Preparation to be used	Granule (GR)
Function of plant protection	Protectant

¹⁰ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

¹¹ Commission Implementing Regulation (EU) No 1060/2013 of 29 October 2013 concerning the authorisation of bentonite as a feed additive for all animal species (OJ L 289, 31.10.2013, p. 33–37).

APPENDIX II
CLAYED CHARCOAL

Crop and/ or situation (a)	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate			PHI (days)	Remarks
			Type (d-f)	Conc. of a.i. g/L (i)	Method kind (f-h)	Growth stage & season (j)	No. of application min/max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	Total rate each application kg a.i./ha min max (kg/ha)		
Grapevine Vitis vinifera	F	ESCA (Black Measles) Caused by a complex of fungi that includes several species of <i>Phaeoacremonium</i> primarily by <i>Phaeoacremonium</i> <i>aleophilium</i> , (Pal) (currently known by the name of its sexual stage, <i>Togninia</i> <i>minima</i>), and by <i>Phaeomoniella</i> <i>chlamydospora</i> (Pch)	GR*		Soil burying		1**	**	-	-	500	-	

* Granules should be essentially non-dusty according to method CIPAC MT 171.1

** Every 3 years

(a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)	(i) g/kg or g/L. Normally the rate should be given for the substance (according to ISO)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)	(j) Growth stage at 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
(c) e.g. pests as biting and sucking insects, soil born insects, foliar fungi, weeds or plant elicitor	(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..	(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)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989	(m) PHI - minimum pre-harvest interval
(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	

