

APPROVED: 5 July 2016

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

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context, EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the basic substance application for clayed charcoal are presented. The context of the evaluation was that required by the European Commission in accordance with Article 23 of Regulation (EC) No 1107/2009 following the submission of an application for approval of clayed charcoal as a basic substance for use in plant protection as a protectant in grapevines. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

© European Food Safety Authority, 2016

Keywords: clayed charcoal, basic substance, application, consultation, plant protection, pesticide

Requestor: European Commission

Question number: EFSA-Q-2016-00289

Correspondence: pesticides.peerreview@efsa.europa.eu

Suggested citation: 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:EN-1061. 28 pp.

© European Food Safety Authority, 2016

Reproduction is authorised provided the source is acknowledged.

Summary

Clayed charcoal is an active substance for which, in accordance with Article 23(3) of Regulation (EC) No 1107/2009, the European Commission received an application from Callegari Distribution-SARL for approval as a 'basic substance'. Regulation (EC) No 1107/2009 introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest in applying for approval may be limited. Article 23 of Regulation (EC) No 1107/2009 lays down specific provisions for consideration of applications for approval of basic substances.

In March 2013, the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission on 15 April 2016, EFSA was asked to organise a consultation on the basic substance application for clayed charcoal, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table within three months of acceptance of the specific request.

A consultation on the basic substance application for clayed charcoal, organised by EFSA, was conducted with Member States via a written procedure in January – March 2016. Subsequently, EFSA also provided comments and the applicant was invited to address all the comments received in the format of a reporting table and to provide an application update as appropriate, within a period of 30 days.

The current report summarises the outcome of the consultation process organised by EFSA on the basic substance application for clayed charcoal and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

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.

Clayed charcoal is intended to be used as protectant in grapevines against ESCA (Black Measles).

Regarding the impact on human health, vegetable carbon (E 153) may contain residual carcinogenic and genotoxic polycyclic aromatic hydrocarbons (PAH), the given specification does not give rise to specific concern as it meets the required specification, with the respective levels remaining below 0.1 µg/kg (expressed as benzo[a]pyrene). Given the essentially non-dusty nature of the granules, no concern is concluded with regards to long-term occupational exposures to bentonite dust by inhalation.

Taking into account the method of application (soil treatment) and the non-systemic properties of the components (charcoal, bentonite), residues are not expected to be present on grapes and therefore, consumers are not expected to be exposed to clayed charcoal residues.

The available data were not sufficient to quantify the risk to non-target organisms. However, considering the representative uses, the dietary exposure of terrestrial vertebrates and bees may be considered low. Moreover, clayed charcoal is a granule formulation containing charcoal, meeting the criteria of the food additive E 153 and bentonite, meeting the criteria of feed additive E 558. Considering the available data and the nature of the basic substance, a low risk could be concluded for birds and mammals, aquatic organisms, bees and other non-target arthropods, soil organisms (macro- and microorganisms) and organisms involved in the methods of sewage treatment.

Table of contents

Abstract.....	1
Summary.....	3
1. Introduction.....	5
1.1. Background and Terms of Reference as provided by the requestor	5
1.2. Interpretation of the Terms of Reference.....	5
2. Assessment	6
Documentation provided to EFSA	6
References.....	6
Abbreviations	7
Appendix A – Collation of comments from Member States and EFSA on the basic substance application for clayed charcoal and the conclusions drawn by EFSA on the specific points raised	8
Appendix B – Identity and biological properties.....	26
Appendix C – List of uses.....	27

1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1107/2009¹ (hereinafter referred to as 'the Regulation') introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of the Regulation lays down specific provisions to identify a substance as a basic substance with a view to ensure that such active substances that do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment can be approved as 'basic' and used for plant protection purposes.

Clayed charcoal is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Callegari Distribution-SARL for approval as a 'basic substance' for use in plant protection as a protectant in grapevines

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for clayed charcoal, which was conducted via a written procedure in January – March 2016. The comments received, including EFSA's comments, were consolidated by EFSA in the format of a reporting table. Subsequently, the applicant was invited to address the comments in column 4 of the reporting table and to provide an application update as appropriate. The comments received and the response of the applicant thereon, together with the application update submitted by the applicant, were considered by EFSA in column 5 of the reporting table.

The current report aims to summarise the outcome of the consultation process organised by EFSA on the basic substance application for clayed charcoal and to present EFSA's scientific views on the individual comments received in the format of a reporting table.

The application and, where relevant, any update thereof submitted by the applicant for approval of clayed charcoal as a 'basic substance' in the context of Article 23 of the Regulation, is a key supporting documentation, therefore it is considered as a background documentation to this report and will also be made publicly available, excluding its appendices (Callegari Distribution-SARL, 2015, 2016).

1.2. Interpretation of the Terms of Reference

On 6 March 2013 the European Commission requested EFSA to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received by EFSA on 15 April 2016, EFSA was asked to organise a consultation on the basic substance application for clayed charcoal, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table.

To this end, a technical report containing the finalised reporting table is being prepared by EFSA. The agreed deadline for providing the finalised report is 15 July 2016.

On the basis of the reporting table, the European Commission may decide to further consult EFSA to conduct a full or focussed peer review and to provide its conclusions on certain specific points.

¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

2. Assessment

The comments received on the basic substance application for clayed charcoal and the conclusions drawn by EFSA are presented in the format of a reporting table.

The comments received are summarised in columns 2 and 3 of the reporting table. The applicant's considerations of the comments, where available, are provided in column 4, while EFSA's scientific views and conclusions are outlined in column 5 of the table.

The finalised reporting table is provided in Appendix A of this report. In addition, an overview table on the identity and biological properties of the substance and the list of intended uses in plant protection (GAP table) are provided in Appendix B and C, respectively.

Documentation provided to EFSA

1. Callegari Distribution-SARL, 2015. Basic substance application on clayed charcoal submitted in the context of Article 23 of Regulation (EC) No 1107/2009. May 2015. Documentation made available to EFSA by the European Commission.
2. Callegari Distribution-SARL, 2016. Basic substance application update on clayed charcoal submitted in the context of Article 23 of Regulation (EC) No 1107/2009. April 2016. Documentation made available to EFSA by the applicant.

References

- EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2012. Scientific Opinion on the re-evaluation of vegetable carbon (E 153) as a food additive. *EFSA Journal* 2012;10(4):2592, 34 pp. doi: 10.2903/j.efsa.2012.2592
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012. Scientific Opinion on the safety and efficacy of bentonite as a technological feed additive for all species. *EFSA Journal* 2012;10(7):2787, 19 pp. doi: 10.2903/j.efsa.2012.2787
- JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2006. Combined Compendium of Food Additive Specifications. Monograph 1. Activated Carbon.

Abbreviations

a.s.	active substance
CAS	Chemical Abstracts Service
CIPAC	Collaborative International Pesticides Analytical Council Limited
FAO	Food and Agricultural Organization on the United Nations
GAP	good agricultural practice
GR	granule
IUPAC	International Union of Pure and Applied Chemistry
LOD	limit of detection
PAH	polycyclic aromatic hydrocarbons
PEC	predicted environmental concentration
PPP	plant protection product

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for clayed charcoal and the conclusions drawn by EFSA on the specific points raised

1. Purpose of the application

General					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(1)		NL: No comments.			Noted.

2. Identity of the substance/product as available on the market and predominant use

2.1. Identity and Physical and chemical properties of the substance and product to be used

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)		NL: No comments.			Noted.
2(2)	2.1.5 Specification of the active substance and product, p.10	EFSA: the charcoal used in the production of the clayed charcoal should meet the specifications defined in COMMISSION DIRECTIVE 2008/128/EC of 22 December 2008, laying down specific purity criteria concerning colours for use in foodstuffs and by JECFA (JECFA, 2006)		The charcoal used in the production of the clayed charcoal meet the specifications defined in COMMISSION DIRECTIVE 2008/128/EC as described in the BSA	Addressed: The charcoal used in the production of the clayed charcoal meets the specifications defined in Commission Directive 2008/128/EC ² .
2(3)	2.1.5 Specification of the active	EFSA: The specification of the bentonite used in the		The bentonite used in the production of the clayed	Addressed: The bentonite used in the

² Commission Directive 2008/128/EC of 22 December 2008 laying down specific purity criteria concerning colours for use in foodstuffs. OJ L 6, 10.1.2009, p. 20-63

2.1. Identity and Physical and chemical properties of the substance and product to be used

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	substance and product, p.10	production of the clayed charcoal should be in compliance with the specific purity criteria for food additive E 558		charcoal is in compliance with the specific purity criteria for food additive E 558 1m558 changed pour E558 in the all Dossier.	production of the clayed charcoal is in compliance with the specific purity criteria for feed additive E 558 defined in Reg. (EU) No 1060/2013 ³ .

2.2. Current Former and in case proposed trade names

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(4)		NL: No comments.			Noted.

2.3. Manufacturer of the substance/products

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(5)		NL: No comments.			Noted.

³ 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

2.4. Type of preparation

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(6)		NL: No comments.			Noted.
2(7)	2.4 Type of preparation, p.12	EFSA: the preparation is a mixture of two basic substances, probably a result of some "formulation" process, as it is claimed to be a granule	A description of the process of manufacturing the granules should be indicated	Clayed charcoal is a mixture, only this mixture is having efficacy on field, as vineyards protection. Granulation process is necessary to obtain easy handled material with no powder.	Addressed: The description of the process of manufacturing the granules was submitted in Callegari Distribution-SARL, 2016

2.5. Description of the recipe for the product to be used

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(8)		NL: No comments.			Noted.

3. Uses of the substance and its product

3.1. Field of use

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)		DE: The active substance is a pure soil improver without direct effect to pathogens. No data were provided which	DE: It is recommended to reject the proposal because the active substance is not directly useful in plant protection. The	Soil conditioner may be an mode of action (MOA) in chapter 3 but GAP table describes a bioaggressor target	Addressed: Additional references were added to support the proposed GAP, however not evaluated,

3.1. Field of use

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		allow a detailed description of the cited GAP.	substance might be useful as soil conditioner in an integrated approach.	so this substance is ruled by regulation 1107/2009 EC. 6 more field trial references added.	summaries not presented.
3(2)		DE: The description of Dead Arm Disease in GAP is incorrect. Dead Arm is caused by <i>Eutypa lata</i> and <i>Phomopsis viticola</i> ; Dead Arm should be substituted by ESCA.		Definitions and separations of BDA and ESCA was ongoing during application. Corrected in GAP.	Addressed: The GAP table was corrected.
3(3)		NL: No comments.			Noted.

3.2. Effects on harmful organisms or on plants

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(4)		DE: The literature cited and submitted does not provide the prediction of sufficient efficacy in the intended uses. The cited literature argues that a stimulation of the soil enhances rhizosphere microorganism effects but does not prove that. In young vineyards this indirect effect might occur but no effect should be expected	DE: Withdraw proposal	More references added. 6 more field trial references added.	Addressed: Additional references were added to support the proposed GAP, however not evaluated, not summarised.

3.2. Effects on harmful organisms or on plants

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>in old vineyards with well established mycorrhiza.</p> <p>Furthermore, there is no real proof that mycorrhiza can affect ESCA: the entrance points of the disease is through wounds after cutting upper plant parts and not through roots.</p> <p>The PPT Presentation demonstrating the efficacy of the active substance can not be accepted as sufficient information on the GAP.</p>		<p>This basic substance does not act as a curative substance or biocide substance as usual fungicides.</p> <p>Preventive effect is the only MOA.</p> <p>6 more field trial report references added.</p>	
3(5)		NL: No comments.			Noted.
3(6)		EFSA: it is not clear how the mode of action of clayed charcoal, acting as non-biocide mixture by catching mould particles is effective against the diseases mentioned in the intended uses		<p>MOA is partially described but not fully demonstrated, although efficacy is proved.</p> <p>Reference on utility of charcoal is added. Clayed charcoal limits sporulation of fungi and traps their toxins.</p>	<p>Addressed:</p> <p>Clayed charcoal limits sporulation of fungi and traps their toxins, however the mode of action is not demonstrated.</p>

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(7)		DE: No specific data were provided		This basic substance does not	Addressed.

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		which allow the exclusion of potential phytotoxic effects. Nevertheless, the probability of negative effects is low.		have biocide properties. Both feed and food components are not phytotoxic.	
3(8)		NL: No comments.			Noted.
3(9)		EFSA: there are no studies or literature cited to prove that the use of the product is effective against ESCA, dead arm or black dead arm	Some studies or literature references should be provided to support the intended use	6 more field trial independent report references added.	Addressed: Additional references were added to support the proposed GAP, however not evaluated, not summarised.

4. Classification and labelling of the substance

Classification and labelling of the substance					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
4(1)		NL: No comments.			Noted.

5. Impact on Human and Animal Health

5.1. Toxicokinetics and metabolism in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)		NL: No comments.			Noted.

5.2. Acute toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(2)		NL: No comments.			Noted.

5.3. Short-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(3)		NL: No comments.			Noted.

5.4. Genotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(4)		NL: No comments.			Noted.

5.5. Long-term toxicity					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(5)		NL: No comments.			Noted.
5(6)		EFSA: The safety of bentonite as feed additive has been assessed by the EFSA panel on Additives and Products or Substances used in Animal Feed (EFSA FEEDAP Panel, 2012). Long-term occupational exposures to bentonite dust by inhalation may cause structural and functional damage to the lungs for which no safe levels of exposure have been identified. This information may be relevant to operator/worker/bystander and residential exposure.		TYPE OF PREPARATION; granule, do not exhibit dust during process and burying. Water is added to the mixture see Patent, no dust. Water is added to mix, up to 10% in the product. Reference added.	Addressed: The granules should be essentially non-dusty according to method CIPAC MT 171.1

5.6. Reproductive toxicity					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(7)		NL: No comments.			Noted.

5.7. Neurotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(8)		NL: No comments.			Noted.

5.8. Toxicity studies on metabolites

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(9)		NL: No comments.			Noted.

5.9. Medical Data: adverse effects reported in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(10)		NL: No comments.			Noted.

5.10. Additional Information related to therapeutic properties or health claims

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(11)		NL: No comments.			Noted.

5.11. Additional information related to use as food

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(12)		NL: No comments.			Noted.

5.12. Acceptable daily intake, acute reference dose, acceptable operator exposure level

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(13)		NL: No comments.			Noted.

5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(14)		NL: No comments.			Noted.
5(15)		EFSA: it is noted that the EFSA panel on Food Additives and Nutrient Sources added to Food (EFSA ANS Panel, 2012) recommended to introduce in the specifications for vegetable carbon (E 153) a requirement for residual carcinogenic and genotoxic polycyclic aromatic hydrocarbons (PAH) expressed	EFSA: The technical specification should include a maximum level of PAHs expressed as benzo[a]pyrene using a validated analytical method of appropriate sensitivity (e.g. LOD of 0.1 µg/kg).	Specifications For Benzo(a)pyrene, analytical results is <0.1 µg/kg. Reference added: SGS, 2016	Addressed: The charcoal should meet the specification under 2(2) and the total polycyclic aromatic hydrocarbon (PAH) content should be <0.1 µg/kg expressed as benzo[a]pyrene

5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		as benzo[a]pyrene using a validated analytical method of appropriate sensitivity (e.g. LOD of 0.1 µg/kg). This requirement should apply as well to E 153 used as a basic substance in PPP.			
5(16)		EFSA: The safety of bentonite as feed additive has been assessed by the EFSA panel on Additives and Products or Substances used in Animal Feed (EFSA FEEDAP Panel, 2012). Bentonite may contain crystalline silica; inhalation of silica is known to be hazardous and is associated with increased risk of lung cancer and the industrial disease, silicosis.	EFSA: The amount of dust in the product should be specified and controlled.	TYPE OF PREPARATION; granule, do not exhibit dust during process and burying. Water is added to the mixture see Patent, no dust. Water is added to mix, up to 10% in the product. Reference added.	Addressed: The granules should be essentially non-dusty according to method CIPAC MT 171.1

6. Residues

Residues

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6(1)		NL: No comments.			Noted

Residues					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6(2)		EFSA: no comments having regard to the nature of the components (charcoal, bentonite) and the mode of application (soil treatment) residues of concern are not expected to be present on grapes at harvest.		No further comment. Substance is a mixture of physical components with no systemic properties.	Addressed. Taking into account the method of application (soil treatment) and the non- systemic properties of the components (charcoal, bentonite), residues are not expected to be present on grapes.

7. Fate and Behaviour in the environment

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)		NL: No comments.			Noted.
7(2)		EFSA: No comments.			Noted.

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(3)		NL: No comments.			Noted.
7(4)		EFSA: No comments.			Noted.

8. Effects on non-target species

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		NL: No comments.			Noted.
8(2)		EFSA: PEC in soil are not available. These will be needed unless the available information is sufficient to conclude no hazard to soil dwelling organisms.		Bentonite is a natural soil component.	When buried in the trench the material buried will be 100% product. Outside the dug trench there will be no exposure. The ability of soil dwelling organisms to tolerate the product or its repellent effect on them is not known. Possible effects on soil dwelling organisms have not been discussed however a low risk was concluded (see comment 8(8))

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(3)		NL: No comments.			Noted.
8(4)		EFSA: No comments.			Noted.

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(5)		DE: No data were submitted for the assessment of the product with regard to risk for bees. Nevertheless, the probability of negative effects is low.		Product is intended to be buried in soil. Bentonite is a soil component.	Addressed. Considering the application method and the type of formulation, the exposure to bees is low
8(6)		DE: No experimental reports were submitted from which information about effects on beneficial organisms can be derived. Nevertheless, the probability of negative effects is low.		Bentonite is a natural soil component.	Addressed. Considering the application method and the type of formulation, the exposure to leaf dwelling arthropods is low. Information was not sufficient to quantify the risk to soil dwelling arthropods. However, based on the available data and considering the nature of the basic substance, low risk is concluded
8(7)		NL: No comments.			Noted.
8(8)		EFSA: No comments.			Noted.

8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(8)		DE: Robust experimental studies carried out with relevant soil macroorganisms (e.g. the		Bentonite is a natural soil component. Charcoal is studied in reference (Biochar Quebec,	Information was not sufficient to quantify the risk to soil macroorganisms. However,

8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		standard test earthworm <i>Eisenia fetida</i>) were not submitted. Nevertheless, the probability of negative effects is low.		2010). Reference added.	based on the available data and considering the nature of the basic substance, low risk is concluded
8(9)		NL: No comments.			Noted.
8(10)		EFSA: No comments.			Noted.

8.5. Effects on soil microorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(11)		DE: No robust experimental reports were submitted from which information about effects on soil micro-organisms can be derived The probability of negative effects is low.		Bentonite is a soil component. Charcoal is used as CROP- SUPPORTING media.	Information was not sufficient to quantify the risk to soil microorganisms. However, based on the available data and considering the nature of the basic substance, low risk is concluded.
8(12)		NL: No comments.			Noted.
8(13)		EFSA: No comments.			Noted.

8.6. Effects on other non-target organisms (flora and fauna)

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(14)		NL: No comments.			Noted.
8(15)		EFSA: No comments.			Noted.

8.7. Effects on biological methods of sewage treatment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(16)		NL: No comments.			Noted.
8(17)		EFSA: No comments.			Noted.

9. Overall conclusions with respect of eligibility of the substance to be approved as basic substance**Overall conclusions with respect of eligibility of the substance to be approved as basic substance**

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9(1)		NL: No comments.			Noted.

10. Other comments

Other comments					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
10(1)		DE: General comment on the efficacy evaluation in the dossier: the idea of the authorization of basic substances is that no product approval takes place after the final decision on the a.s.	DE: Therefore, it should be made clear that neither sufficient efficacy nor side effects are well approved and may occur. Within the central zonal steering committee, it is discussed that the described GAPs are not entirely binding for later use but provide the framework for use in practice: they might be used in different crops but should not exceed the quantitative measures of the intended uses.	More references are added. Experiments were done since 2002.	Addressed: The efficacy is not sufficiently addressed.
10(2)			DE: Overall, this proposal should be rejected.		This is a risk management decision.
10(3)		NL: No comments.			Noted.
10(4)		EFSA: it should be emphasized the need to respect strictly the specifications of the starting materials mixed to obtain the granules to be applied, taking into account the high application rate, which would lead to introduction in the soil of around 20 g/ha heavy metals, around 100 µg/ha		See specifications and rate! Maximum rate 500 kg/ha Regular analyses gave < 1,6g/T (sum mercury, cadmium, lead) So calculation gives < 0.8 g/ha for heavy metals, largely less than 20 g/ha for provided calculation. PAHs < 0.1 µg/ka (SGS,	Addressed: The specifications of the starting materials mixed to obtain the granules to be applied should be strictly respected to avoid the introduction of toxic substances in the soil.

Other comments

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		PAHs and 25-50 g/ha Al		2016) Bentonite is a natural soil component containing Aluminium.	

Appendix B – Identity and biological properties

Common name (ISO)	There is no ISO common name for this substance
Chemical name (IUPAC)	Not relevant, the substance is a complex mixture of charcoal and sodium montmorillonite
Chemical name (CA)	Not relevant, the substance is a complex mixture of charcoal and sodium montmorillonite
Common names	Charcoal, bentonite, clay, clayed charcoal
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
Minimum purity	Not relevant
Relevant impurities	Charcoal: as in Commission Directive 2008/128/EC Bentonite: as in Reg. (EU) No 1060/2013
Molecular mass and structural formula	C $(Na, Ca)_{0,3}(Al, Mg)_2Si_4O_{10}(OH)_2 \cdot nH_2O$ or $(Na, Ca)(Al, Mg)_6(Si_4O_{10})_3(OH)_6 \cdot nH_2O$ or $Si_4(Al_{(2-x)}R_x)(O_{10}, H_2O)(Ce_x nH_2O)$ or $Si_4(Al_{(2-x)}R_x)(H_2O)_n$ where: R = Mg, Fe, Mn, Zn, Ni Ce (cations exchangeable) = Ca, Na, Mg
Mode of Use	Soil burying
Preparation to be used	Granule (GR)
Function of plant protection	Protectant

Appendix C – List of uses

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PH (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha min max (g/ha) (l)			
Grapevine <i>Vitis vinifera</i>	France All Member States	<i>ESK Protect®</i>	F	ESCA (Black Measles) Caused by a complex of fungi that includes several species of <i>Phaeoacremonium</i> primarily by <i>Phaeoacremonium aleophilum</i> , (Pal) (currently known by the name of its sexual stage, <i>Togninia minima</i>), and by <i>Phaeomoniella chlamydospora</i> (Pch)	GR (Granule)	-	Soil burying		1*	-	0	0	500	500	-	

* Every 3 years.

- * For uses where the column „Remarks. As above or other conditions to take into account
- (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)
- (b): Outdoor or field use (F), greenhouse application (G) or indoor application (I)
- (c): e.g. pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor
- (d): e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..
- (e): GCPF Codes – GIFAP Technical Monograph N° 2, 1989
- (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)
- (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
- (k): Indicate the minimum and maximum number of application 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