TECHNICAL REPORT

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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

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 an extension of use 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 an extension of use in plant protection as a protectant against grapevine trunk diseases. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

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

Requestor: European Commission

Question number: EFSA-Q-2019-00623

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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 ETS Callegari for approval of an extension of use 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.

On 15 April 2016 EFSA received a first request from the European Commission to organize a consultation on the basic substance application submitted by the applicant Callegari Distribution-SARL 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. A Technical Report containing the finalised reporting table was issued by EFSA on 19 July 2016.

Clayed charcoal was approved on 10 March 2017 by Commission Implementing Regulation (EU) 2017/428, in accordance with Article 23 of Regulation (EC) No 1107/2009, for the use as a protectant.

By a further specific request, received from the European Commission on 27 September 2019, EFSA was asked to organise a consultation on the basic substance application for the extension of use of clayed charcoal, consisting of a spray application, 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 the extension of use of clayed charcoal, organised by EFSA, was conducted with Member States via a written procedure in June-August 2019. 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 the extension of use of 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 and wettable powder.

Clayed charcoal is intended to be used as protectant in grapevines against ESCA (Black Measles). The first assessment covered soil application (granules) and the extension of the use includes spray application (wettable powder).

Regarding the impact on human and animal health, as a formulation of a wettable powder, the product may contain dust of crystalline silica that is considered as carcinogenic to humans by inhalation if exceeding 0.1% crystalline silica (in bentonite). The application and related documents are not informative regarding the content of particles ≤ 10 µm that are relevant to carcinogenic effects by inhalation. However, the applicant claims a content below 0.1% (units unclear) in its answers to the comments. This concern is not related to ingestion of the product by the oral route; both compounds clayed charcoal and bentonite being used as food and feed additives.

The extension of use consists of a spray application on the trunk of grapevines at a growth stage when there is no formation of leaves and fruits. Also because of the non-systemic properties of the components (charcoal, bentonite), residues are not expected in leaves and fruits. Based on these considerations, the consumer exposure to clayed charcoal residues can therefore be considered as negligible and a dietary risk is considered as very unlikely.

Substantive issues relating to the application for basic substance approval in the area of fate and behaviour in the environment were not identified.

Issues in the area of ecotoxicology were not identified.

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1. Introduction

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

Regulation (EC) No 1107/2009[1] (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 a first application from Callegari Distribution-SARL for approval as a 'basic substance' to be used in plant protection as a protectant against grapevine trunk diseases.

On 15 April 2016 the European Food Safety Authority (EFSA) was requested by European Commission to organise a consultation on the basic substance application submitted, 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. A Technical Report containing the finalised reporting table was issued by EFSA on 19 July 2016 (EFSA, 2016).

Clayed charcoal was approved on 10 March 2017 by Commission Implementing Regulation (EU) 2017/428, in accordance with Article 23 of Regulation (EC) No 1107/2009, for the use as a protectant.

In February 2018, the European Commission received a further application from ETS Callegari for the extension of use of the basic substance clayed charcoal, consisting of a spray application for the use in plant protection as a protectant against grapevine trunk diseases.

Following a specific mandate received on 27 September 2019, the European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for the extension of use of clayed charcoal, which was conducted via a written procedure in June-August 2019. 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 the extension of use of 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 the extension of use 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 (ETS Callegari; 2019a,b).

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 27 September 2019, EFSA was asked to organise a consultation on the basic substance application for the extension of use of 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.

[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.

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 27 December 2019.

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.

2. Assessment

The comments received on the basic substance application for the extension of use of 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. ETS Callegari, 2019a. Basic substance application on clayed charcoal submitted in the context of Article 23 of Regulation (EC) No 1107/2009. June 2019 . Documentation made available to EFSA by the European Commission.

2. ETS Callegari, 2019b. Basic substance application update on clayed charcoal submitted in the context of Article 23 of Regulation (EC) No 1107/2009. October 2019. Documentation made available to EFSA by the applicant.

References

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.

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
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LOD	limit of detection
MOA	Mode of action
NFU	National Farmers' Union
WP	Wettable Powder

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for Clayed charcoal (extension of use) 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) -			EFSA: Please in very beginning clearly indicate the aim of this application: extension of the use including use of wettable powder as formulation by spray application on grapevine	"Extension of use" clearly written	Addressed Description of the aim of the extension of the use was provided in the Application update (ETS Callegari, 2019b)

1.1 Name and address of applicants

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

No comments.

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

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
2(1)	General	NL: Most supporting data/information is written in French and therefore no full evaluation was possible. However, it seems that sufficient data/information is presented to confirm the identity.		Most of the cited document are in English, and only few documents are in French a legal language in EU. Efficacy results are shown in table easily readable.	Addressed There is enough information to confirm the identity of the basic substance
2(2)	Predominant use	NL. The applicant does not describe the predominant use of the product itself outside agriculture, but the predominant uses outside agriculture of the ingredients of the product (activated charcoal, vegetable charcoal, water and bentonite) Does the product itself have uses		Predominant uses outside agriculture use are fully described. Substance is a qualified fertilizer (NFU Norm). Each ingredient (vegetable charcoal, bentonite, activated charcoal) has been used for many years in animal feed. The patent I have filed is based solely on the percentage of each ingredient, the particle size, the BET (specific surface)	Addressed The vegetable carbon (E153) and bentonite (E558) are used as food and feed additives.

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
		outside of plant protection? It appears that the product can't be mixed from the ingredients by others as the process is protected by a patent, so availability of the ingredients from uses outside of plant protection is not relevant.		of the charcoal and the dosage. Substance is a qualified fertilizer (NFU Norm). Separate ingredients are fully available, patent is only a specific mode of mixture to avoid dust and to produce initial substance as granules. Some other approved basic are supported by patents (bicarbonate, vinegar, beer, onion oil, H_2O_2…)	

2.1. Identity and Physical 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

No comments.

2.1.1. Common name of the substance and product and their synonyms/plant nomenclature

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

No comments.

2.1.2. Chemical name with CAS, EEC and CIPAC numbers

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

No comments.

2.1.3. Molecular and structural formula, molecular mass

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

No comments.

2.1.4. Method or methods of manufacture of the substance and of the product

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

No comments.

2.1.5. Description and specification of purity of the active substance and product

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

No comments.

2.1.6. Identity of inactive isomers, impurities and additives

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

No comments.

2.1.7. Methods of analysis

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

No comments.

2.2. Current, former and in case proposed trade names of substances/ products as put on the market

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

No comments.

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

No comments.

2.4. Type of preparation of the substance/product

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

No comments.

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

No comments.

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

No comments.

3.2. Effects on harmful organisms or on plants (including mode of action)

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)	3.2 Effects on harmful organisms or on plants (including mode of action)	NL: It is claimed that the product has no effect on any harmful organisms, this is at odds with the claims that are made in other sections, i.e in 3.1 it is claimed that the product is used as a protectant against ESCA black arm (BDA).		Protectant does not means biocide. More efficacy results are included in the updated BSA. The purpose of the product is to protect plants against pests (especially against the fungi	Addressed Clayed charcoal is intended to be used as protectant in grapevines against ESCA (Black Measles). The exact mode of action is not known. Some evidences were provided proposing as a potential mode

3.2. Effects on harmful organisms or on plants (including mode of action)

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
		The nature of the effects against ESCA and other claimed pathogens should be described.		that are the cause of vine diseases, BDA) by limiting their sporulation (Vegepolys).	of action inhibition of mycelial growth of three pathogens that are involved in grapevine trunk diseases. Additional field results related with the efficacy were added to the updated Application update (ETS Callegari, 2019b).
3(2)	3.2 EFFECTS ON HARMFUL ORGANISMS OR ON PLANTS (INCLUDING MODE OF ACTION)	DE: It is stated that there is no effect on harmful organisms, as the components are not biocides. This is contradictory to the statement in chapter 3.3 that apparently the mycelial development of *Phaeomoniella chlamydospora* (Pch) and *Phaeoacremonium aleophilum* (Pal) is affected. The presumed mode of action ("clayed charcoal is acting as non-biocide mixture by catching mould particles") is	DE: The mode of action and possible effects on organisms (plants and pathogens) should be clarified.	Growth and migration control in vitro was determined More field results added in the updated BSA Both component are feed therefore no biocidal properties could be linked. Growth and migration control/inhibition does not mean biocidal effect. More field results added in the	See 3(1)

3.2. Effects on harmful organisms or on plants (including mode of action)

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
		very hypothetical and vague. No proof is provided for the statements in this chapter.		updated BSA.	

3.2.1. Effects on harmful 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
3(3)	3.2.1 Effects on harmful organisms	NL: It is claimed that the product has no effect on any harmful organisms, this is at odds with the claims that are made in other sections, i.e in 3.1 it is claimed that the product is used as a protectant against ESCA black arm (BDA).		See above No mechanism or mode of action described does not repeal usefulness. Inhibition of bioagressors is a more	See 3(1)

3.2.1. Effects on harmful 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
		The nature of the effects against ESCA and other claimed pathogens should be described.		convenient name for this type of MOA. More field efficacy results are included in the updated BSA.	

3.2.2. Mode of action

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)	3.2.2 mode of action.	NL: The description for the mode of action should be more detailed. "catching mould	SANCO/10363/2012 rev.9 states:	SANCO/10363/2012 rev.9 states: „should", when available. Other active	See 3(1)

3.2.2. Mode of action

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
		particles" is very imprecise in both its description of fungal morphology and biology and the mechanism by which the product achieves the desired effect.	From Points 3.1. to 3.3. Function on plant protection: Applicant should indicate which is the mechanism of action against pests, weeds and diseases or if it has any eliciting mechanism, etc...Where there is uncertainty, a putative mechanism should be suggested.	substances showed properties which evolved during time (i.e. phosphonates fungicides then now elicitors). The request is based solely for the protection of the vine against wood diseases and in particular the ESCA, BOA. The product (clayey coal) acts on the main strains of the fungi responsible for these diseases.	

3.3. Usefulness in the framework of plant protection

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(5)	3.3 USEFULNESS IN THE FRAMEWORK OF PLANT PROTECTION	DE: Three references have been provided in order to proof the usefulness for plant protection of the extended application. All three references are unpublished, not peer-reviewed reports of experiments. Végépolys 2017a describes the potential of charcoal to absorb certain mycotoxins. It is not clear how this capacity can be useful for plant protection, as the intended use is to spray charcoal on the trunks but the mycotoxins are active in the plant cells. Végépolys 2017b describes the *in vitro* inhibition of mycelial growth of three pathogens that are involved in grapevine trunk diseases. This indicates that mycelial growth inhibition may be a mode of action, but in planta	DE: Unequivocal evidence that clearly demonstrates the usefulness in the framework of plant protection, such as references to published scientific (peer-reviewed) literature, would be helpful.	More efficacy results are included in the updated BSA. Extension uses are with 1/18 to 1/16 of the initial concentration and only on trunks during winter (BBCH 00) = no leaves. Spraying in winter (between the size of the vine and bud burst) from January to the end of March, beginning of April following the location of the vineyards. Mode of action is amplified in the updated BSA.	See 3(1)

3.3. Usefulness in the framework of plant protection

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
		verification would be needed to be sure. Lamarque 2017 describes very briefly (in keywords) a field trial. The number of symptomatic plants was reduced by 81 % in the treated plot when compared to a control plot. However, the plant material in the control originated from another nursery. In conclusion, the usefulness for plant protection is not well documented			

3.3.1. Charcoal

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
No comments.					

3.4. 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(6)	3.4 summary of intended uses.	NL: In the table of intended uses, Under method of kind it is claimed that the product is applied by spray application. Is the product sprayed on the soil, or directly on the trunk? (usually spray application refers to treatment of the entire plant but that would		Extension uses are with 1/18 to 1/16 of the initial concentration and only on trunks during winter (BBCH 00) = no leaves. GAP table modified accordingly. More field assays are included in updated BSA / More efficacy	Addressed Clarification was provided and the GAP table was updated. The intended application is spray on the trunk.

3.4. 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
		seem unlikely here) It would be helpful to describe the method more clearly, especially because in other parts of the dossier, the description is also very vague: (for example, on page 15 under 2017 extension of uses) "*it appears that the STOPESCA is applied on the surface to affect the mycelial development.*"		results are included in the updated BSA. The liquid spray of clay is applied on the trunk in winter (vegetative rest of the vine), only between size and budding, the product does not apply in times of foliage growth. Spraying equipment has recovery panels to prevent product loss.	

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

No comments.

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)	Acute effects	NL: Since the extension of use of this basic substance now concerns a spray application (instead of the existing burying use), for which direct contact with operator or worker occurs, it would be appreciated if some argumentation could be provided why there will be no acute adverse expected after inhalation or dermal exposure as dust mask, gloves and glasses are prescribed (see 5.13).		Formulation in this extension is liquid so no dust possible. Both components are inert material, charcoal from wood (food additive), bentonite (feed additive). PraNaturals Bentonite Clay Mask, 250g - Naturally purifies skin and deep pores - Pure Clay and Calcium Montmorillonite Powder - 100% Organic, Detoxifying, Anti-Aging and Therapeutic Facial Mask. This protective equipment (gloves) is especially recommended to prevent the operator or the user from getting dirty (black colour of	The formulation is a wettable powder that is mixed with water to be sprayed for this application for extension of use. Accordingly, the product may contain dust of crystalline silica that is considered as carcinogenic to humans by inhalation if exceeding 0.1% crystalline silica in bentonite. The application and related documents are not informative regarding the content of particles ≤ 10 µm that are relevant to carcinogenic effects by inhalation. However, the applicant mentions in column 4 (9(2)) that "the dust

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
				the product).	concentration […] is less than 0.1% mg / m3" – units unclear. This concern is not related to ingestion by the oral route; both compounds clayed charcoal and bentonite are used as food and feed additives. See also 5(2, 3, 4) and 9(2)
5(2)	Short-term effects	NL: Since the extension of use of this basic substance now concerns a spray application (instead of the existing burying use), for which direct contact with operator or worker occurs, it would be appreciated if some argumentation could be provided why there will be no adverse expected after		Both components own feed and food status. Extension uses are with 1/18 to 1/16 of the initial concentration.	See 5(1)

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
		inhalation or dermal exposure as dust mask, gloves and glasses are prescribed (see 5.13).		No biocide effect or concern for these food/feed additives. Also used in cosmetics	

5.1.1. Charcoal (E153)

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

No comments.

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

No comments.

5.2.1. Bentonite (Sodium Montmorillonite) (clay) (E558)

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

No comments.

5.3. Short-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA		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

No comments.

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

No comments.

5.4.1. Bentonite (Sodium Montmorillonite) (clay) (E558)

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

No comments.

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

No comments.

5.5.1. Bentonite (Sodium Montmorillonite) (clay) (E558)

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

No comments.

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

No comments.

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
No comments.					

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
No comments.					

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
No comments.					

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

No comments.

5.10.1. Charcoal (E153)

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

No comments.

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

No comments.

5.11.1. Charcoal (E153)

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
No comments.					

5.11.2. Bentonite (Sodium Montmorillonite) (clay) (E558)

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
No comments.					

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
No comments.					

5.12.1. Charcoal (E153)

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
No comments.					

5.12.2. Bentonite (Sodium Montmorillonite) (clay) (E558)

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
No comments.					

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(3)	Risk evaluation	NL: Since the extension of use of this basic substance now		Extension uses are with 11/18 to 1/16 of the initial	See 5(1)

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
		concerns a spray application (instead of the existing burying use), for which direct contact with operator or worker occurs, it would be appreciated if some argumentation could be provided why there will be no risk expected after inhalation or dermal exposure as dust mask, gloves and glasses are prescribed.		concentration. Formulation content in water is 14% so no dust possible. Operator contact with charcoal or bentonite should not be considered of concern. Clay coal is non-toxic to humans, but it is advisable to use a mask, glasses and gloves to handle the product because its colour is messy (black). In case of dust in the eye use ophthalmic wash solution or rinse with water. On skin rinse with water, if inhaled rinse mouth with water.	
5(4)	B.13	EFSA: Since the preparation form has changed from the previous application, from granules essentially non-dusty in nature to wettable powder,		Formulation with water to avoid dust. Bentonite is common soil component. Charcoal own food	See 5(1)

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
		the content of crystalline silica in bentonite needs to be controlled as remaining below 0.1% and not below 1% as reported in this chapter. At the percentage of crystalline silica reported (1%), the product should be considered as potentially carcinogenic to humans by inhalation.		additive status. The bentonite dust used in the composition (clayey coal) contains a percentage of crystalline cilice less than 0.1% mg / m3, cristobalite and tridynite less than 0.05 mg / m3 No toxic effect for humans, the ingredients (vegetable charcoal / clay) are used in cosmetics (mask) to cleanse the skin, vegetable charcoal is also incorporated into the toothpaste, vegetable charcoal is sold in pharmacies for pathologies of food transit.	

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)	6. Residues	NL: Since the extension of use of this basic substance now concerns a spray application (instead of the existing burying use), for which direct contact with the plant occurs, it would be appreciated if some argumentation could be provided why no residues are expected (possibly because application takes place at BBCH00).		Extension uses are with 1/18 to 1/16 of the initial concentration and only on trunks during winter (BBCH 00) = no leaves. GAP table modified accordingly Clayey coal is sprayed at the maximum rate of 30 kg / ha, or 3 g per vine trunk (vine trunk), the down falling portion is beneficial to plant development (Johannes Lehmann and Stephen Joseph 2009).	Addressed The extension of use consists of a spray application on the trunk of grapevines in winter (after the cutting of the vines to before spring on the vegetative rest of the vine), only between size and budding. The product is applied at BBCH growth stage 00 when there is no formation of leaves and fruits. Also because of the non-systemic properties of the components (charcoal, bentonite), residues are not expected on grapes. The consumer exposure to clayed charcoal residues can therefore

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
					be considered as negligible.
6(2)		EFSA: Please clarify the method for the use in the GAP table 3.4 (Basic substance application – May 2019) regarding the spray uses on grapevine (Extension), i.e. whether application is made only on the trunks of the grapevines or on the whole plant or to the soil surrounding the grapevine plants. If a direct contact with the plant cannot be excluded, any argumentation that residues of clayed charcoal and bentonite are not expected in grapes at harvest and that the consumer dietary risk assessment can be considered as negligible		Extension uses are with 1/18 to 1/16 of the initial concentration and only on trunks during winter (BBCH 00) = no leaves. GAP table modified accordingly No residues excepted from BBCH 00 treatments. Spraying is carried out between winter, between pruning and budding of the vine, from December to March, directly on the vine (trunk), no foliage or fruit.	Addressed The GAP table for the spray uses on grapevines has been amended accordingly. See also 6(1)

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
		should be demonstrated. See also section 2 for the toxicological properties of clayed charcoal and bentonite.			

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)	7.1 fate and behaviour in the environment	EFSA: Since the extension of use of this basic substance now concerns a spray application (instead of the existing burying use), for which direct contact with the plant is not excluded, it would be appreciated if it can be clarified if the target of the spray is the ground as written here or the vine trunks / stems or the complete vine plants. Other sections (eg. section 8) indicate that the trunks are sprayed?	It appears that the text in this section needs updating to specify the intended target of the spray. It currently says sprayed into the ground. Probably this needs to be updated to something like spraying the woody plant material of grape vines?	Extension uses are with 1/18 to 1/16 of the initial concentration and only on trunks during winter (BBCH 00) = no leaves. GAP table modified accordingly The spray is not on the ground but on the vine (trunk) and wood after the size, the goal is to avoid the development of spores of mushrooms on the vine.	Section 7.1 of the application document has not been updated. The statement is still made in this section that 'as the product is sprayed into the ground'. The clarification in column 4 has not been made in this section of the application. It seems the information in this section remains inaccurate concerning the mode of application. See also 3(6)

7.1.1. Charcoal

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
No comments.					

7.1.2. Bentonite (Sodium Montmorillonite) (clay) (E558)

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
No comments.					

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
No comments.					

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

No comments.

8.1.1. Birds

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

No comments.

8.1.2. Mammals

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
No comments.					

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
No comments.					

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
No comments.					

8.3.1. Effects on bees

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

No comments.

8.3.2. Effects on other arthropods

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

No comments.

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

No comments.

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

No comments.

8.5.1. Bentonite (Sodium Montmorillonite) (clay) (E558)

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

No comments.

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

No comments.

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

No comments.

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)	Overall conclusion	NL: Please delete the blue sentence at d and include a synthesis of the conclusions of the evaluation.		Supressed	
9(2)	9. Overall conclusions	DE: According to Commission Regulation (EU) 2017/428 clayed charcoal was approved as basic substance on basis of the conditions according to SANTE/11267/2016. Only granules were approved with the condition that these granules should be essentially non-dusty. The reason for this condition was that bentonite contains crystalline silica which is considered as known human carcinogen by WHO (IARC) and German MAK.		According to the EU regulation 2017/458 the granules of (clayey coal) are free of dust because the particles of bentonite and coal are agglomerated. Manufacturing method of mixing (clay coal). The two raw materials are received in bags and mixed in a machine (ribbon mixer). The operator is equipped with gloves, glasses, and a dust mask. A high suction located above the mixer prevents the spread of dust that is recycled	See 5(1)

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
		However, the submitted basic substance application contains additionally to the product formulation "GR (Granule)" also a formulation as "WP (Wettable Powder)". Therefore, inhalation exposure should be excluded or content of crystalline silica should be below 0.1 %/LoD (as for Kieselgur). The possible harmful effects on human health of bentonite powder are also confirmed by the applicant with the requirement that it is compulsory to wear a dust mask, gloves and glasses when the mix is prepared. Therefore, the wettable powder does currently not fulfil the conditions of Regulation (EC) No		in a cyclone. The dust concentration around the unit is in accordance with the regulations, ie cristaline cilice less than 0.1% mg / m3, cristobalite and tridynite less than 0.05 mg / m3 No possible armful effect on humans. Feed additive Food additive Cosmetics Health treatments for charcoal Clay (bentonite) and charcoal are not of concern! No dust No aerial silica possible.	

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
		1107/2009, Article 23, 2. "…that the substance has neither an immediate or delayed harmful effect on human or animal health …".			

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

No comments.

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	Charcoal: as in Commission Directive 2008/128/EC Bentonite: as in Reg. (EU) No 1060/2013
Relevant impurities	Crystalline silica: maximum content of particles ≤ 10 µm: 0.1%
Molecular mass and structural formula	C (Na, Ca)0,3(Al, Mg)2Si4O10(OH)2.nH2O or (Na, Ca)(Al,Mg)6(Si4010)3(OH)6.nH20orSi4(Al(2-x)Rx)(O10, H2O)(CexnH2O) orSi4(Al(2-x)Rx)(H2O)n where: R = Mg, Fe, Mn, Zn, Ni Ce (cations exchangable) = Ca, Na, Mg
Mode of Use	Soil burying and Trunk spray
Preparation to be used	Granule (GR), Wettable powder (WP)
Function of plant protection	Protectant

Appendix C – List of extension 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)	kg a.i./ha min max (g/ha) (l)		
Grapevine *Vitis vinifera*	All Member States	*STOPESCA* ®	F	ESCA (Black Measles) complex of fungi that includes several species of *Phaeoacremonium* spp. primarily by *Phaeoacremonium aleophilium*, (Pal) (currently known by the name of its sexual stage, *Togninia minima*), and by *Phaeomoniella chlamydospora* (Pch)[£]	WP (Wettable powder)		Spray application on trunk	Winter (after the cutting of the vine) to before spring Before stage BBCH 00	1	-	12 to 15	200 to 250	max 30	max 30	n.a.	

£ http://www.ipm.ucdavis.edu/PMG/r302100511.html

* 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