

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2017/428

of 10 March 2017

approving the basic substance clayed charcoal in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ⁽¹⁾, and in particular Article 23(5) in conjunction with Article 13(2) thereof,

Whereas:

- (1) In accordance with Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 18 May 2015 an application from Ets Christian Callegari for the approval of clayed charcoal as a basic substance. That application was accompanied by the information required by the second subparagraph of Article 23(3).
- (2) The Commission asked the European Food Safety Authority (hereinafter 'the Authority') for scientific assistance. The Authority presented to the Commission a Technical Report on 6 July 2016 ⁽²⁾. The Commission presented the review report ⁽³⁾ and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 7 October 2016 and finalised them for the meeting of that Committee on 24 January 2017.
- (3) The documentation provided by the applicant shows that clayed charcoal does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects, nor is it a substance of concern. Moreover, it is not placed on the market as a plant protection product, nor is it predominantly used for plant protection purposes but nevertheless is useful in plant protection in a product consisting of the substance and water. Consequently, it is to be considered as a basic substance. Clayed charcoal is a mixture of charcoal, as defined in Commission Regulation (EU) No 231/2012 ⁽⁴⁾, and bentonite, as specified in Commission Implementing Regulation (EU) No 1060/2013 ⁽⁵⁾, in the form of granules.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ EFSA (European Food Safety Authority), 2016. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for clayed charcoal for use in plant protection as a protectant in grapevines. EFSA supporting publication 2016:13(7):EN-1061. 28 pp.

⁽³⁾ <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN>

⁽⁴⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁽⁵⁾ 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).

- (4) It has appeared from the examinations made that clayed charcoal may be expected to satisfy, in general, the requirements laid down in Article 23 of Regulation (EC) No 1107/2009, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve clayed charcoal as a basic substance.
- (5) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions for the approval which are detailed in Annex I to this Regulation.
- (6) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽¹⁾ should be amended accordingly.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of a basic substance

The substance clayed charcoal as specified in Annex I is approved as a basic substance subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 March 2017.

For the Commission
The President
Jean-Claude JUNCKER

⁽¹⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Specific provisions
Clayed charcoal CAS No 7440-44-0 231-153-3 (Einecs) (activated charcoal) CAS No 1333-86-4 215-609-9 (Einecs) (carbon black) CAS No 1302-78-9 215-108-5 (Einecs) (bentonite)	Not available.	Charcoal: Purity required by Regulation (EU) No 231/2012 Bentonite: Purity required by Implement- ing Regulation (EU) No 1060/2013	31 March 2017	Clayed charcoal shall be used in accordance with the specific conditions included in the conclusions of the review report on clayed charcoal (SANTE/11267/2016) and in particular Appendices I and II thereof.

⁽¹⁾ Further details on identity, specification and manner of use of basic substance are provided in the review report.

ANNEX II

In Part C of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

'13	Clayed charcoal CAS No 7440-44-0 231-153-3 (Einecs) (activated charcoal) CAS No 1333-86-4 215-609-9 (Einecs) (carbon black) CAS No 1302-78-9 215-108-5 (Einecs) (bentonite)	Not available.	Charcoal: Purity required by Regulation (EU) No 231/2012 (*) Bentonite: Purity required by Implement- ing Regulation (EU) No 1060/2013 (**)	31 March 2017	Clayed charcoal shall be used in accordance with the specific conditions included in the conclusions of the review report on clayed charcoal (SANTE/11267/2016) and in particular Appendices I and II thereof.
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(*) Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

(**) 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).'