

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1448**of 3 September 2021****renewing the approval of the low-risk active substance calcium carbonate 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 20(1) in conjunction with Article 22(1) thereof,

Whereas:

- (1) Commission Directive 2008/127/EC ⁽²⁾ included calcium carbonate as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾.
- (3) The approval of the active substance calcium carbonate, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 August 2022.
- (4) An application for the renewal of the approval of the active substance calcium carbonate was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ⁽⁵⁾ within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.
- (6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 23 October 2019. The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft renewal assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.
- (7) On 9 February 2021, the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether calcium carbonate can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances (OJ L 344, 20.12.2008, p. 89).

⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽⁴⁾ 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).

⁽⁵⁾ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

⁽⁶⁾ EFSA Journal 2021;19(4):6500 Available online: www.efsa.europa.eu

- (8) The Commission presented a renewal report and a draft Regulation regarding calcium carbonate to the Standing Committee on Plants, Animals, Food and Feed on 19 May 2021.
- (9) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined.
- (10) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance calcium carbonate that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (11) The risk assessment for the renewal of the approval of the active substance calcium carbonate is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing calcium carbonate may be authorised. It is therefore appropriate not to maintain the restriction to use as a repellent.
- (12) The Commission further considers that calcium carbonate is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Calcium carbonate is not a substance of concern and fulfils the conditions set in point 5.1 of Annex II to Regulation (EC) No 1107/2009. It is therefore appropriate to renew the approval of calcium carbonate as a low-risk substance.
- (13) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (14) Commission Implementing Regulation (EU) 2021/745 ⁽⁷⁾ extended the approval period of calcium carbonate until 31 August 2022 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of the expiry of that extended approval period, this Regulation should start to apply earlier than that date.
- (15) 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

Renewal of the approval of the active substance

The approval of the active substance calcium carbonate, as specified in Annex I, as low risk substance is renewed.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

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

⁽⁷⁾ Commission Implementing Regulation (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, beflubutamid, benthialdicarb, bifentazate, boscalid, calcium carbonate, captan, carbon dioxide, cymoxanil, dimethomorph, ethephon, extract from tea tree, famoxadone, fat distillation residues, fatty acids C7 to C20, flumioxazine, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxyloglucan, hydrolysed proteins, iron sulphate, metazachlor, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, plant oils/rape seed oil, potassium hydrogen carbonate, propamocarb, prothioconazole, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, tebuconazole and urea (OJ L 160, 7.5.2021, p. 89).

*Article 3***Entry into force and date of application**

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

It shall apply from 1 November 2021.

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

Done at Brussels, 3 September 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Calcium carbonate CAS No 471-34-1 CIPAC No 843	IUPAC name: Calcium carbonate	950 g/kg	1 November 2021	31 October 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on calcium carbonate, and in particular Appendices I and II thereto, shall be taken into account.

⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the renewal report.

ANNEX II

The Annex to Commission Implementing Regulation (EU) No 540/2011 is amended as follows:

- (1) in Part A, entry 224 on calcium carbonate is deleted;
- (2) in Part D, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
'31	Calcium carbonate CAS No 471-34-1 CIPAC No 843	IUPAC name: Calcium carbonate	950 g/kg	1 November 2021	31 October 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on calcium carbonate, and in particular Appendices I and II thereto, shall be taken into account.'