



2024/836

13.3.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/836

of 12 March 2024

approving the basic substance magnesium hydroxide E528 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending 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) On 12 January 2021, the Commission received an application from Roullier for the approval of magnesium hydroxide E528 as a basic substance to be used in plant protection as a fungicide on grapevines, olives, banana, oat, rye, triticale, wheat, tomatoes, aubergine, sweet pepper, chili, *Physalis* sp. and pepino, potatoes, rosebush, ornamental plants, peach, apricot, cherry, plum, nectarine, mirabelle and rice crops.
- (2) After the admissibility checks, revised applications were received in May 2021, April 2022 and in January 2023. The application, as revised in January 2023, was accompanied by the information required under Article 23(3), second subparagraph, of Regulation (EC) No 1107/2009.
- (3) The Commission asked the European Food Safety Authority ('the Authority') for scientific assistance pursuant to Article 23(4) of Regulation (EC) No 1107/2009. The Authority provided the Commission with a technical report on magnesium hydroxide E528 on 6 March 2023 ⁽²⁾.
- (4) The Commission presented the review report ⁽³⁾ and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed, on 12 October 2023 and 11 December 2023, respectively.
- (5) The information provided by the applicant shows that magnesium hydroxide E528 is used as food and feed additive, as an osmotic laxative and antacid for the stomach in medicine, as body deodorant in cosmetics, as fertiliser in agriculture and in several industrial uses. Moreover, it is not predominantly used for plant protection purposes, but the substance is useful in plant protection in a product consisting of the substance. Based on the information provided in the application and the Technical Report from the Authority, it can also be concluded that is not a substance of concern; it does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects; and it is not placed on the market as a plant protection product. Consequently, magnesium hydroxide E528 meets the conditions set out in Article 23(1) of Regulation (EC) No 1107/2009.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>.

⁽²⁾ EFSA (European Food Safety Authority), 2023. Outcome of the consultation with Member States and EFSA on the basic substance application for approval of magnesium hydroxide E 528 to be used in plant protection as a fungicide on grapevines, olives, banana, oat, rye, triticale, wheat, tomatoes, aubergine, sweet pepper, chili, *Physalis* sp. and pepino, potatoes, rosebush, ornamental plants, peach, apricot, cherry, plum, nectarine, mirabelle and rice crops. EFSA supporting publication 2023:EN-7902. 106 pp. doi:10.2903/sp.efsa.2023.EN-7902.

⁽³⁾ Final Review report for the basic substance magnesium hydroxide finalised by the Standing Committee on Plants, Animals, Food and Feed on 31 January 2024 in view of the approval of magnesium hydroxide as basic substance in accordance with Regulation (EC) No 1107/2009.

- (6) A Commission Regulation laying down specifications for magnesium hydroxide E528 as an approved food additive ⁽⁴⁾ was available. This information has been taken into account by the Authority as well as by the Commission in the framework of Article 23(2) of Regulation (EC) No 1107/2009.
- (7) The Commission invited the applicant to submit its comments on the Technical Report of the Authority and on the Commission's draft review report. The applicant submitted its comments, which have been carefully examined.
- (8) After examination of the application and all related documents, it may be expected that magnesium hydroxide E528 satisfies, 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 magnesium hydroxide E528 as a basic substance.
- (9) 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.
- (10) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁵⁾ should be amended accordingly.
- (11) 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 magnesium hydroxide E528 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

The Annex to 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*.

⁽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, ELI: <http://data.europa.eu/eli/reg/2012/231/oj>).

⁽⁵⁾ 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, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

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

Done at Brussels, 12 March 2024.

For the Commission
The President
Ursula VON DER LEYEN

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ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Specific provisions
magnesium hydroxide E528 CAS No: 1309-42-8 CIPAC No: Not available	magnesium dihydroxide	95 % Relevant impurities: Lead < 2 mg/kg Arsenic < 3 mg/kg	2 April 2024	Magnesium hydroxide shall be used in accordance with the specific conditions included in the conclusions of the review report on magnesium hydroxide (PLAN/2023/2331 RR Rev2) and in particular Appendices I and II thereof.

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

ANNEX II

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

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Specific provisions
'25	magnesium hydroxide E528 CAS No: 1309-42-8 CIPAC No: Not available	magnesium dihydroxide	95 % Relevant impurities: Lead < 2 mg/kg Arsenic < mg/kg	2 April 2024	Magnesium hydroxide shall be used in accordance with the specific conditions included in the conclusions of the review report on magnesium hydroxide (PLAN/2023/2331 RR Rev2) 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.