EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food Safety, Sustainability, and Innovation
Pesticides and Biocides

Basic Substance
magnesium hydroxide E528
PLAN/2023/2331 RR Rev2
31 January 2024

FINAL Review report for the basic substance magnesium hydroxide E528
finalised by the Standing Committee on Plants, Animals, Food and Feed on 31 January 2024
in view of the approval of magnesium hydroxide E528
as basic substance in accordance with Regulation (EC) No 1107/2009[1]

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of magnesium hydroxide E528, made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009[2] concerning the placing of plant protection products on the market, with a view to the possible approval of this substance as basic substance.

In accordance with the provisions of Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 12 January 2021 an application from Staphyt regulatory for the company Roullier, hereafter referred to as the applicant, for the approval of the substance magnesium hydroxide E528 as basic substance. This application was not complete and a revised application has been received in May 2021 and May 2022. The final revision of the application was received in January 2023.

The application and attached information were distributed to the Member States and European Food Safety Authority (EFSA) for comments. The applicant was also allowed to address collated comments and provide further information to complete the application.

In accordance with the provisions of Article 23(4) of Regulation (EC) No 1107/2009 the Commission requested scientific assistance on the evaluation of the application to the EFSA, who delivered its views on the specific points raised in the commenting phase.

EFSA submitted to the Commission the results of its work in the form of a technical report for magnesium hydroxide E528 on 6 March 2023[3].

[1] Review Report established in accordance with Art. 13 of Regulation (EU) No 1107/2009; it does not necessarily represent the views of the European Commission.
[2] OJ L 309, 24.11.2009, p. 1-50.
[3] EFSA (European Food Safety Authority), 2023. Technical report on the 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. 57 pp. doi: 10.2903/sp.efsa.2023.EN-7902.

The Commission examined the application, the comments by Member States and EFSA and the EFSA Technical report on the substance together with the additional information and comments provided by the applicant, before finalising the current review report, which was referred to the Standing Committee on Plants, Animals, Food and Feed for examination. The review report was finalised by the Standing Committee on 31 January 2024.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the EFSA technical report, and the comments and clarifications submitted, all these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed in support of **Commission Implementing Regulation (EU) 2024/836**[4] concerning the approval of magnesium hydroxide E528 as basic substance under Regulation (EC) No 1107/2009.

The review report will be published and made available to any interested party.

Without prejudice to the provisions of Regulation (EC) No 178/2002[5], in particular with respect to the responsibility of operators, following the approval of magnesium hydroxide E528 as basic substance, operators are responsible for using it for plant protection purposes in conformity with the legal provisions of Regulation (EC) No 1107/2009 and the conditions established in sections 4 and 5, and Appendices I and II of this review report.

EFSA has made available to the public all background documents and its final Technical Report as well as the application without the Appendices in accordance with the provisions of Article 63 of Regulation (EC) No 1107/2009.

Products containing exclusively one or more basic substances do not require authorisation in line with the derogation set under Article 28 of Regulation (EC) No 1107/2009. As a consequence, no further assessment will be carried out on such products. However, the Commission may review the approval of a basic substance at any time in conformity with the provisions of Article 23(6) of Regulation (EC) No 1107/2009.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion based on the application, including the results of the evaluation carried out with the scientific assistance of EFSA, and the comments and further additional information provided by the applicant to address the open points identified in the Technical Report from

[4] OJ L, 2024/836, 13.3.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/836/oj.

[5] OJ L 31, 1.2.2002 p. 1-24 - Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

EFSA, is that there are clear indications that it may be expected that magnesium hydroxide E528 fulfils the criteria of Article 23 for the uses specified in Appendix II.

Magnesium hydroxide E528 is used as a food additive (authorised at *quantum satis*[6]) and feed additive, in medicine as an osmotic laxative and antacid for the stomach, in cosmetics as body deodorant, in agriculture as fertiliser and in several industrial uses (e.g. as fire retardant).

The specifications for magnesium hydroxide for approval as basic substance should be set according to the ones for E528 under Commission Regulation (EU) No 231/20121[7], as proposed by EFSA. It is therefore appropriate that the name of this basic substance is magnesium hydroxide E 528.

Even though several adverse effects were notified to ECHA's Classification and Labelling Inventory (like effects to the eyes or to the skin), the vast majority of notifiers did not identify any hazards and no harmonised classification for any hazard has been recommended so far by ECHA[8].

In the Technical Report, EFSA refers to a study submitted under the REACH registration dossier for magnesium hydroxide[9] that identified skin sensitisation. In the dossier, a positive local lymph node assay (LLNA) was reported. However, in the endpoint summary of the dossier, this was considered in a weight of evidence approach as a false positive due to a negative guinea pig maximisation test (GPMT) and no data was reported of skin sensitisation in humans over 20 years. Therefore, the REACH registrants concluded, based on a weight of evidence approach, using both animal testing and human information, that magnesium hydroxide is not regarded and not classified as a skin sensitiser.

EFSA also concluded that Magnesium hydroxide E 528 does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects.

Based on the absence of a harmonised classification and the content of the REACH registration, magnesium hydroxide should not be considered as a substance of concern.

The proposed use as basic substance is as a fungicide applied by field spraying 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.

With regard to residues in food and feed, EFSA indicated that under realistic conditions of use, it is extremely unlikely that the Tolerable Upper Intake Level for magnesium (250 mg/kg bw per day as established for Mg^{2+} by the European Commission Scientific Committee on Food (SCF, 2001)) is exceeded.

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6 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

7 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.

8 https://echa.europa.eu/it/information-on-chemicals/cl-inventory-database/-/discli/details/13362.

9 REACH registration dossier for magnesium hydroxide. EC number: 215-170-3; CAS number: 1309-42-8. https://echa.europa.eu/it/registration-dossier/-/registered-dossier/16073.

The environmental exposure assessment was also considered acceptable by EFSA.

A low risk was concluded by EFSA for birds and mammals, aquatic organisms, earthworms and other soil macro-organisms, soil micro-organisms and biological methods of sewage treatment. No information was available on the actual exposure levels for the relevant exposure routes as well as on the exceedance of the natural background levels following the proposed uses of magnesium hydroxide E 528. However, because the substance is expected to have a low ecotoxicological profile towards non-target arthropods (including bees) and magnesium is naturally occurring in the environment, the proposed use of magnesium hydroxide E528 can be considered to constitute a low risk to bees and non-target arthropods other than bees.

Therefore, considering the EFSA Technical Report and the conditions of use which are described in detail in Appendices I and II, it is concluded that the use of the magnesium hydroxide E 528 would not lead to concerns for human health. Furthermore, no residues or unacceptable effects on the environment are expected for this use.

Magnesium hydroxide E 528 is not predominantly used for plant protection purposes but nevertheless is useful in plant protection in a product consisting of the substance and water. Finally, it is not placed on the market as a plant protection product.

Overall, it can be concluded that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment when used in accordance with the preparation for use in Appendix I and for the uses as described in Appendix II.

These conclusions were reached within the framework of the uses which were supported by the applicant and mentioned in the list of uses supported by available data (attached as Appendix II to this review report) and therefore, they are also subject to compliance with the particular conditions and restrictions in sections 4 and 5 of this report.

Extension of the use pattern beyond those described above will require an evaluation at Union level in order to establish whether the proposed extensions of use can still satisfy the requirements of Article 23 of Regulation (EC) No 1107/2009.

4. Identity and biological properties

The properties of magnesium hydroxide E 528 are given in Appendix I.

Magnesium hydroxide E 528 should be of food grade meeting the requirements for E 528 under Commission Regulation (EU) No 231/2012.

5. Particular conditions to be taken into account in relation to the uses as basic substance of magnesium hydroxide E 528

Magnesium hydroxide E 528 must be identified by the given specifications in Appendix I and must be used in compliance with the method of preparation and conditions of use as reported in Appendices I and II.

6. List of studies to be generated

No further studies were identified which were at this stage considered necessary.

7. Updating of this review report

The information in this report may require to be updated from time to time to take account of technical and scientific developments, as well as of the results of the examination of any information referred to the Commission in the framework of Article 23 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection, as appropriate, with any amendment of the approval conditions for the magnesium hydroxide E 528 in Part C of Annex of the Regulation (EC) No 540/2011[10].

8. Recommended disclosure of this review report

Considering the importance of the respect of the approved conditions of use and the fact that a basic substance will not be placed on the market as plant protection product hence, no further assessment will have to be carried out on it, it is very important to inform not only applicants but also potential users of the substance on the existence of this review report.

Further to the publication of this review report, it is recommended that the competent authorities of Member States will make it additionally available to the general public and operators by means of their national relevant websites and by any other appropriate form of communication to ensure that the information reaches potential users.

[10] OJ L 153, 11.6.2011, p. 1–186.

APPENDIX I
Identity and biological properties
magnesium hydroxide E 528

Common name (ISO)	magnesium hydroxide E 528 (not ISO)
Chemical name (IUPAC)	magnesium dihydroxide
Chemical name (CA)	magnesium hydroxide
Common names	magnesium hydroxide
CAS No	1309-42-8
CIPAC No and EEC No	Not available (CIPAC No) 215-170-3 (EEC No)
FAO specification	Not available
Minimum purity	95%
Relevant impurities	Lead < 2 mg/kg Arsenic < 3 mg/kg
Molar mass and structural formula	Structural formula: Mg(OH)2 Molar mass: 58.320
Mode of Use	Spray applications
Preparation to be used	Suspension Concentrate 700 g/L (500 g/kg)
Function of plant protection	fungicide

APPENDIX II
List of uses supported by available data
MAGNESIUM HYDROXIDE E528

Crop and/ or situation (EPPO code) (a)	Member State or Country	Example product name as available on the market	FG or I (b)	Pests or Group of pests controlled (EPPO code) (c)	Formulation		Application				Application rate per treatment						PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (g/L) (i)	Method kind (f-h)	Growth stage & season (j)	Number max (k)	Interval between applications Min (days)	kg a.s./hL per application* min-max	water L/ha min-max	kg a.s./ha per application*	L formulated product/ha***	Kg formulated product/ha	Max kg a.s./ha/year		
Grapevine (VITVI)	EU	- (2)	F	*Plasmopara viticola* (PLASVI) *Erysiphe necator* (UNCINE) *Guignardia bidwellii* (GUIGBI)	SC	700	Spraying	BBCH 09-85	1	-	0.437 – 3.5 (1)	100-800	3.5	5	7	3.5	0**	
Olives (OLVEU)	EU		F	*Cycloconium oleaginum (spilocea oleagina)* (CYCLOL)	SC	700	Spraying	BBCH 11-89	1	-	0.7 – 2.33	300-1000	7	10	14	7	0**	-
Banana (MUBPA)	EU		F	*Mycosphaerella spp.* (MYCOSP)	SC	700	Spraying	BBCH 09-89	12	30	1.6 – 7.0	80-350	5.6	8	11.2	67.2	0**	-
Cereals Oat (AVESA) Rye (SECCE) Triticale (TTLSO) Wheat (TRZSS)	EU		F	*Septoria spp.* (SEPTSP)	SC	700	Spraying	BBCH 30-65	3	7	1.6 – 7.0	80-350	5.6	8	11.2	16.8	0**	-
Tomato (LYPES), aubergine (SOLME), sweet pepper (CPSAN), chilli (CPSAN), *Physalis sp.* (PHYSS) and pepino (SOLMU)	EU		F	*Phytophtora Infestans* (PHYTIN)	SC	700	Spraying	BBCH 14-85	3	7	0.56 - 0.93	600-1000	5.6	8	11.2	16.8	0**	-

Crop and/ or situation (EPPO code) (a)	Member State or Country	Example product name as available on the market	F G or I (b)	Pests or Group of pests controlled (EPPO code) (c)	Formulation		Application				Application rate per treatment						PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (g/L) (i)	Method kind (f-h)	Growth stage & season (j)	Number max (k)	Interval between applications Min (days)	kg a.s./hL per application* min-max	water L/ha min-max	kg a.s./ha per application*	L formulated product/ha***	Kg formulated product/ha	Max kg a.s./ha/year		
Potato (SOLTU)	EU		F	*Phytophthora infestans* (PHYTIN)	SC	700	Spraying	BBCH 09-49	10	7	0.84 - 1.4	300-500	4.2	6	8.4	42	0**	-
Rose-Bush (ROSSS)	EU		F	*Sphaerotheca pannosa* (SPHRPA)	SC	700	Spraying	BBCH <49	2	7	0.29 - 0.58	600-1200	3.5	5	7	7	-	-
Ornamental plants (NNNZZ)	EU		F	*Sphaerotheca pannosa* (SPHRPA)	SC	700	Spraying	BBCH <49	2	7	0.29 - 0.58	600-1200	3.5	5	7	7	-	-
Stone fruits: Peach (PRNPS), Apricot (PRNAR), Cherry (PRNCE), Plum (PRNDO), Nectarine (PRNPN), Mirabelle (PRNDS)	EU		F	*Sphaerotheca pannosa* (SPHRPA)	SC	700	Spraying	BBCH <49	2	4	0.29 - 0.58	600-1200	3.5	5	7	7	0**	-
Rice (ORYSA)	EU		F	*Magnaporthe grisea* (PYRIGR)	SC	700	Spraying	BBCH 50-69	3	7	1.6 – 7.0	80-350	5.6	8	11.2	16.8	0**	-

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 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 plants
(i) g/L
(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) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

(1) See reporting table point 3(7) of the Technical report of EFSA
(2) See reporting table point 2(12) of the Technical report of EFSA
*Based on the recipe point 2.5 of the basic substance application (Roullier 2023), considering a purity of magnesium hydroxide of 100%
** Based on the section 6 of the basic substance application (Roullier 2023), no pre-harvest interval following application of the basic substance magnesium hydroxide, provided that it is of food grade regarding relevant impurities, is necessary for all the edible crops.
*** Density = 1.4