



Basic Substance

Calcium hydroxide

SANCO/10148/2015– rev. 2

24 March 2021¹

Final Review report for the basic substance **calcium hydroxide**
finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on 20 March 2015 and amended on 24 March 2021
in view of the approval of calcium hydroxide as basic substance
in accordance with Regulation (EC) No 1107/2009²

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of calcium hydroxide made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009³ 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 19 September 2012 an application from the European group of the International Federation Organic Agriculture Movements (IFOAM), hereafter referred to as the applicant, for the approval of the substance calcium hydroxide as basic substance for use as a fungicide for brush, sprinkler and spray application in pome fruit.

The application and attached information were distributed to the Member States and European Food Safety Authority (EFSA) for comments. The applicant was allowed to address collated comments and provide further information to complete the application, which was finalised in the new version of November 2014.

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 EFSA, who delivered its views on the specific points raised in the commenting phase.

¹ The Standing Committee on Plants, Animals, Food and Feed took note of revision 2 of the review report on 24 March 2021. The review report was amended to include the conclusion on the non-approval of the extension of use of calcium hydroxide as a fungicide in grapevine and peach, and as insecticide in grapevine, plum, peach, apricot, apple, pear, almond and strawberry (see chapter 3).

² 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.

³ OJ L 309, 24.11.2009, p. 1-50.

EFSA submitted to the Commission the results of its work in the form of a technical report for calcium hydroxide on 16 September 2014⁴.

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 on it by the applicant, before finalising the draft review report, which was referred to the Standing Committee on Plants, Animals, Food and Feed for examination. The draft review report was finalised in the meeting of the Standing Committee of 20 March 2015.

In February 2019, the Commission received an application from Lhoist Sud Europe - Agriculture for the extension of use of calcium hydroxide as a fungicide for foliar spray application in grapevine and peach, and as insecticide for foliar spray application in grapevine, plum, peach, apricot, apple, pear, almond and strawberry. The application and attached information were distributed to the Member States and European Food Safety Authority (EFSA) for comments. The applicant was allowed to address collated comments and provide further information to complete the application, which was finalised in a new version in April 2020. For this application for extension of use, in accordance with the provisions of Article 23(4) of Regulation (EC) No 1107/2009, the Commission requested scientific assistance from EFSA for the evaluation of the application and the specific points raised by the Member States and the applicants in the commenting phase. EFSA submitted to the Commission the results of its work in the form of a technical report for the extension of the use of calcium chloride on 30 June 2020⁵. The amended review report was finalised in the meeting of the Standing Committee on 24 March 2021.

The present review report contains the conclusions of the final examination by the Standing Committee of 20 March 2015 and 24 March 2021, respectively. Given the importance of the EFSA technical report(s), and the comments and clarifications submitted (background document C), 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 the **Commission Implementing Regulation (EU) 2015/762**⁶ concerning the approval of calcium hydroxide as basic substance under Regulation (EC) No 1107/2009.

The review report has been made available for public consultation by any interested parties.

⁴ European Food Safety Authority, 2014; Outcome of the consultation with Member States and EFSA on the basic substance application and its update on calcium hydroxide for use in plant protection against fungal diseases on pome fruit. EFSA supporting publication 2014: EN-655. 63 pp.

⁵ EFSA (European Food Safety Authority), 2020. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for approval of calcium hydroxide for the extension of use in plant protection as a fungicide in grapevine and peach, and as insecticide in grapevine, plum, peach, apricot, apple, pear, almond and strawberry. EFSA supporting publication 2020: EN-1897. 35 pp. doi:10.2903/sp.efsa.2020.EN-1897.

⁶ OJ L 120, 13.5.2015, p. 6–9.

Without prejudice to the provisions of Regulation (EC) No 178/2002⁷, in particular with respect to the responsibility of operators, following the approval of calcium hydroxide 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 with the conditions established in the sections 4, 5 and Appendixes I and II of this review report.

EFSA will make available to the public all background documents and the final Technical Report of EFSA, as well as the application without the Appendixes and excluding any information for which confidential treatment is justified 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 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 original 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 EFSA, is that there are clear indications that it may be expected that calcium hydroxide fulfils the criteria of Article 23.

Calcium hydroxide is used for several purposes e.g. building material, paper and drinking water treatments, in agriculture as soil conditioner, in food it is ruled as E526 under Regulation (EU) No 2008/1333⁸, as amended, concerning a Union List of food additives approved for use in food additives, enzymes, flavourings and nutrients.

Calcium hydroxide is considered of essential use in organic farming for its efficacy against fungus such as *Neonectria galligena*.

Calcium hydroxide could be regarded as a substance of concern as it is classified being irritant for the skin, the eye and the respiratory tract. However, the substance is fulfilling the criteria of a foodstuff as defined in Article 2 of Regulation (EC) No 178/2002; hence, it can be considered as a basic substance under Article 23(1) of Regulation (EC) No 1107/2009.

Moreover, the supported basic substance use is referring to products currently on the market as "suspension in water" and packaged and labelled in accordance with Regulation (EC) No 1272/2008⁹ including among others necessary information with respect to specific precautionary measures to apply proper risk mitigation measures.

⁷ 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.

⁸ O.J. L.354, 31.12.2008.

⁹ O.J. L. 353, 31.12.2008.

Considering the EFSA conclusions on the original basic substance application for calcium hydroxide, the rate of application and the conditions of use which are described in detail in Appendix I and II, it is concluded that the use of calcium hydroxide as basic substance when carried out respecting precautionary statements for risk mitigation measures to be taken by the operator, would not lead to harmful effects on human health. Furthermore, no residues or unacceptable effects on the environment are expected as the conditions of use would not significantly increase the environmental exposure due to the nature of the substance and its degradation pathway.

It does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immune-toxic effects and 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.

It can be concluded that the intended use of 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 supported uses as described in section 5 and Appendix II.

In fact, these indications were reached within the framework of the uses which were supported by the applicant in the original application 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 Community 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.

The overall conclusion based on the EFSA Technical Report from 2020 on the application for extension of use of the basic substance calcium hydroxide in plant protection as a fungicide in grapevine and peach, and as insecticide in grapevine, plum, peach, apricot, apple, pear, almond and strawberry, and the comments and further additional information provided by the applicant to address the open points identified in the Technical Report of EFSA, is that there are clear indications that it may not be expected that the proposed extension of use of calcium hydroxide fulfils the criteria of Article 23.

For the intended uses as insecticide for foliar spray application in grapevine, plum, peach, apricot, apple, pear and almond, the application rates per treatment proposed in the extension (72 - 180 kg/ha) are considerably higher than the originally approved application rates for spray and sprinkler use (25 – 50 kg). Additionally, the concentration of calcium hydroxide in the solution applied as foliar spray in fields (6%, 9% and 12%) is higher for all the uses proposed in the extension than for the originally approved uses as spray and sprinkler (0.25% - 5%), except for the use in strawberry (0.18%).

As regards the season of the applications, the uses proposed in the extension of use as spray application in spring and summer, and up to BBCH 87, are different from the already approved uses of calcium hydroxide as a basic substance for applications from end of October until end of December, outside of the vegetation period.

Consequently, the uses proposed in the application for extension of use cannot be considered less or equally critical as the uses included in the original application (i.e. they are not within the same “risk envelope”). Accordingly, the uses proposed in the application for extension of use are not covered by the original evaluation and conclusion presented in the original Review Report finalised in view of the approval of calcium hydroxide as basic substance in 2015.

Given the higher application rates, application outside the dormant phase and claimed insecticidal properties, the uses proposed in the application for extension of use may lead to potentially higher risk to humans, animals or the environment than the uses originally approved.

According to the Technical Report of EFSA, the information provided to support the extension of use was insufficient to finalise the risk assessment for operators, workers, residents and bystanders. As regards the risk for consumers, the exposure assessment for the intended uses was not provided. Lack of such data could be considered acceptable for uses at stages when no fruits are present. However, for the intended uses on strawberry at BBCH 71-87 and grapevine at BBCH 69-81, the consumer risk assessment is considered necessary. In view of the higher application rates proposed in the extension, use in spray application outside of the dormant phase and claimed insecticidal properties, a risk assessment for arthropods including bees would be required. However, the Technical Report of EFSA indicates that information available in the application was not sufficient to demonstrate a low risk to bees and non-target arthropods for the uses included in the extension.

Therefore, the available information does not allow to conclude that calcium hydroxide intended for use in plant protection as a fungicide in grapevine and peach, and as insecticide in grapevine, plum, peach, apricot, apple, pear, almond and strawberry, fulfils the conditions set out in Regulation (EC) No 1107/2009 as regards the approval criteria for basic substances, in particular with regard to the requirement that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment. Potential concerns were identified with regard to the risk to operators, workers, residents and bystanders, the risk to consumers, and the risk to non-target organisms.

4. Identity and biological properties

The main properties of calcium hydroxide are given in Appendix I.

It has been established that for calcium hydroxide as notified by the applicant, the following manufacturing impurities are considered, on the basis of information currently available, of toxicological or environmental concern:

Barium: Not more than 300 mg/kg,

Fluoride: Not more than 50 mg/kg,

Arsenic: Not more than 3 mg/kg,

Lead: Not more than 2 mg/kg.

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

Calcium hydroxide to be used for plant protection must be identified by the specifications given in Appendix I and must be used in compliance with conditions of supported uses as reported in Appendixes I and II and respecting the precautionary statements and safety data sheet of the products labelled for the market.

The following conditions of use deriving from assessment of the application have to be respected by users:

- Only uses as basic substance having a fungicide action in accordance with conditions specified in Appendix I and II.

Users shall respect the conditions of use and precautionary statements reported on the products safety data sheet, which has to be available at purchase phase, and in particular, use the prescribed adequate personal protective equipment and take all precautions to avoid any unacceptable effects on the environment.

The identification of calcium hydroxide as food ingredient implies that the Regulation (EC) No 178/2002 on food safety applies.

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 Articles 23 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, as appropriate, in connection with any amendment of the approval conditions for calcium hydroxide in Part C of Annex of the Regulation (EC) No 540/2011.

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 be not 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 on the existence of this review report.

It is therefore recommended that the competent authorities of Member States will make available such report to 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.

APPENDIX I

Identity and biological properties

CALCIUM HYDROXIDE

Common name (ISO)	Calcium Hydroxide
Chemical name (IUPAC)	Calcium Hydroxide
Chemical Name. (CA)	Calcium dihydroxide
Common names	Lime water
CAS No	1305-62-0
CIPAC No and EEC No	Not available
FAO SPECIFICATION	Not relevant
Minimum purity	920 g/kg
Molecular formula	Calcium hydroxide
Relevant impurities	Limits set under Directive for food additive (dry matter): Barium no more than 300 mg/kg Fluoride 50 mg/kg Arsenic 3 mg/kg Lead 2 mg/kg
Molecular formula and mass	Ca(OH) ₂ - 74.09 g/mol
Mode of Use	Calcium hydroxide as aqueous suspension having concentration from 24 to 33.12%.
Preparation to be used	Calcium hydroxide as fine suspension in water to be used in compliance with rate of application reported in Appendix II.
Function of plant protection	Fungicide.

APPENDIX II

CALCIUM HYDROXIDE

Crop and/or situation (a)	Example product of Calcium hydroxide. as available on the market **	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application of Calcium hydroxide				Application rate of Calcium hydroxide			PHI (days) (m)	Remarks*
				Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage & season (j)	No. of application min/max (k)	Interval between applications (min)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	Water l/ha min max	Total rate each application (l) kg as/ha a) max. rate per appl. b) max. total rate per crop/season		
Pome fruit	24%	F	<i>Neonectria galligena</i>	Liquid suspension (acqueous)	24%	Sprinkler application	Leaf drop end of October till end of December	b) 2-7	(5-14 days)	a) 104-208 l/ha b) 1460 l/ha	5000-10.000 L/ha	a) 25-50 kg/ha b) 350 kg/ha	Not relevant since application out of vegetation period	
Pome fruit and stone fruit	24% or 33,12%	F	<i>Neonectria galligena</i> and other diseases	Liquid suspension (acqueous)	24% or 33,12%	Spray application	Leaf drop end of October till end of December	b) 2-7	5-14 days)	With products at 24% a) 63-104 l/ha b) 728 l/ha with products at 33.12 % a) 45 – 76 l/ha b) 532 l/ha	500-1000 L/ha	a) 15-25 kg/ha b) 175 kg/ha	Not relevant since application out of vegetation period	

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				Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage & season (j)	No. of application min/max (k)	Interval between applications (min)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	Water l/ha min max	Total rate each application (l) kg as/ha a) max. rate per appl. b) max. total rate per crop/season		
Pome fruit and stone fruit	24% Or 33,12%	F	<i>Neonectria galligena</i> and other diseases	Liquid suspension (aqueous)	24% Or 33,12%	Brush application directly on pruning wounds and old cancers on stems ***	Winter to March	b) 1-2	(21 days)	With products at 24% a) 450 l/ha b) 900 L/ha with products at 33.12% a) 450 l/ha b) 900 L/ha	No extra water ***	a) 149,04 kg b) 299,08 kg	Not relevant since application out of vegetation period	

<p>* For uses where the column „Remarks. As above or other conditions to take into account</p> <p>(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)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(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..</p> <p>(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated</p>	<p>(i) g/kg or g/L. Normally the rate should be given for the substance (according to ISO)</p> <p>(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</p> <p>(k) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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*** Two products have been used to support the applications. The product lime water for the supported use (Akdolit) has a content of a.i. of 24 %
The product Ulmer Kalkmilch has a content of a.i. of 33,12 % of a.i. (36 % Münsterkalk with a.i. 92 %) and is used at the same rate as the lime water Akdolit.*

**** The aqueous solutions in this application are applied with few or without dilution. Here the case without dilution is calculated.
Usually, not all trees are treated with brush application but only injured trees. In the calculation of maximum rate it was assumed that 3.000 trees per ha are treated with 0,15 L product per tree. This means that all trees of an orchard would be treated with several big wounds, which would be really the maximum rate and in reality is very improbable.*