



COMMISSION STAFF WORKING DOCUMENT¹

Basic Substance

Calcium hydroxide

SANCO/10148/2015– rev. 1

20 March 2015

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

in view of the approval of *Calcium Hydroxide* as basic substance in accordance with Regulation (EC) No 1107/2009

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of *Calcium hydroxyde* made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009² 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.

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, 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 required scientific assistance on the evaluation of the application to EFSA, who delivered its views on the specific points raised in the commenting phase.

¹ Does not necessarily represent the views of the Commission.

² 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 2014³.

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 current 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.

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 (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**⁴ concerning the approval of *Calcium hydroxide* as basic substance under Regulation (EC) No 1107/2009.

The review report will be made available for public consultation by any interested parties.

Without prejudice to the provisions of Regulation (EC) No 178/2002⁵, 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 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.

⁴ OJ L 120, 13.5.2015, p. 6–9.

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.

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 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 2008/1333⁶, 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 1272/2008⁷ including among others necessary information with respect to specific precautionary measures to apply proper risk mitigation measures.

Considering the EFSA conclusions, 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 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.

⁶ O.J. L.354, 31.12.2008.

⁷ O.J. L. 353, 31.12.2008.

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.

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 (aqueous)	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 (aqueous)	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</p> <p>(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 % Mönsterkalk 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.**