



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
Unit E.3 - Chemicals, contaminants and pesticides

Lime sulphur
SANCO/10310/2011 final
11 March 2011

Review report for the active substance **lime sulphur**
finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
11 March 2011
in view of the inclusion of lime sulphur to Annex I of Directive 91/414/EEC

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of lime sulphur, made in the context of a new application by the data submitter after the non-inclusion of this substance.

Lime sulphur is a substance that was covered by the fourth stage of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Article 24(e) of Commission Regulation (EC) No 2229/2004 laying down detailed rules for the implementation of the fourth stage offered the possibility for the notifier to withdraw, under specific conditions, its support for the active substance. All notifiers withdrew their support and lime sulphur was not included through Commission Decision 2008/941/EC¹.

In accordance with Article 13 of Regulation (EC) No 33/2008, the applicant Polisenio s.r.l. presented, a request to Spain, the rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

Spain finalised in February 2010 its examination, in the form of an additional report to the original Draft Assessment Report. This Report was sent to the Commission and the European Food Safety Authority on 15 February 2010 and included a recommendation as to include lime sulphur in Annex I for the supported uses.

The EFSA organised the consultation on the draft assessment report and, in accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, on the additional report by all the Member States as well as by Lime sulphur applicants on 16 February 2010 by making it available.

¹ OJ No L 335, 13.12.2008, p. 91.

In accordance with the provisions of Article 20 of Regulation (EC) No 33/2008, the Commission asked EFSA to organise a focused consultation of scientific experts from a certain number of Member States, to review the additional report, draft assessment report and the comments received thereon (peer review) and to deliver its conclusion.

In accordance with the provisions of Article 20 of Regulation (EC) No 33/2008 the EFSA sent to the Commission its conclusion on the risk assessment [Conclusions on the peer review of the pesticide risk assessment of the active substance lime sulphur (issued on 28 October 2010)²]. This conclusion refers to background document A (draft assessment report and additional report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 21 of Regulation (EC) No 33/2008, the Commission referred a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 11 March 2011.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (background document C), 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 hereto, has been developed and finalised in support of Commission **Directive 2011/43/EU**³ concerning the inclusion of lime sulphur in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing lime sulphur they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 22 of Regulation (EC) No 33/2008, this review report will be made available for public consultation by any interested parties.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

² *European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance lime sulphur EFSA Journal 2010; 8(11):1890. [45 pp.]. doi:10.2903/j.efsa.2010.1890 Available online: www.efsa.europa.eu.*

³ OJ L 100, 14.4.2011, p. 39–42

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing lime sulphur will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each lime sulphur containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

The following reference values have been finalised as part of this re-evaluation:

ADI	not applicable
ARfD	not applicable
AOEL	1,5 mg/kg bw/day

No dietary risk assessment needs to be carried out for sulphur and calcium.

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC.

4. Identity

The main identity of lime sulphur is given in Appendix I.

The active substance shall comply with the minimum purity of 290 g/kg (see appendix I).

The review has established that for the active substance notified by the main data submitter none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of the EFSA, and at section 3 of this report.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing lime sulphur

On the basis of the proposed and supported uses (as listed in Appendix II), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted:

Member States should pay particular attention to:

- the operator safety and ensure that conditions of use prescribe the application of adequate personal and respiratory protective equipment in the phase of mixing-loading;
- the protection of aquatic organisms and non target arthropods and shall ensure that the conditions of use include risk mitigation measures as appropriate.

7. List of studies to be generated

No further studies were identified which were at this stage considered necessary in relation to the inclusion of lime sulphur in Annex I under the current inclusion conditions.

Some other endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. The list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Scientific report.

8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC and neither does it commit the Commission.

9. Updating of this review report

The information in this report may require to be updated from time to time in order 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 7, 10 or 11 of Directive 91/414/EEC. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for lime sulphur in Annex I of the Directive.

APPENDIX I**Identity
LIME SULPHUR**

Common name (ISO)	Lime sulfur, calcium polysulfide
Chemical name (IUPAC)	calcium polysulfide
Chemical name (CA)	calcium polysulfide
CIPAC No	17
CAS No	1344-81-6
EEC No	215-709-2
FAO SPECIFICATION	FAO specification 17/13/S2/2 , (1973): the content of calcium polysulfide shall be between 29 and 32% by weight max. 2.5% by weight of the impurity calcium thiosulfate
Minimum purity	290 g/kg calcium polysulfide (given for the TK material)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern)	None
Molecular formula	CaS_x (x= 2-7)
Molecular mass	200.4 g/mol (average, primary calcium pentasulfide)
Structural formula	Not available

APPENDIX II
List of uses supported by available data
LIME SULPHUR

(a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hL min – max (l)	water L/ha min – max	kg as/ha min – max (l)		
Apple	N/S Europe	POLI-S OLFUR O DI CALCIO	F	Mildew	DC	29-30% w/w, 380 g/L	spray 4 Kg/ha product	Pre-flowering	1		0.12	10 hl/ha, depending on dimension of plants	1.2	30	
Apple	N/S Europe	POLI-S OLFUR O DI CALCIO	F	Mildew	DC	29-30% w/w, 380 g/L	spray 2.67 kg/ha a product	Post-flowering	1		0.08	10 hl/ha, depending on dimension of plants	0.8	30	

<p>* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).</p> <p>(a) For crops, the EU and Codex classifications (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. biting and suckling insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Codes - GIFAP Technical Monograph No 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 active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialdicarb-isopropyl).</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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