

## CONCLUSION ON PESTICIDE PEER REVIEW

### Conclusion on the peer review of the pesticide risk assessment of the active substance lime sulfur<sup>1</sup>

#### European Food Safety Authority<sup>2</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

Lime sulfur is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004,<sup>3</sup> as amended by Commission Regulation (EC) No 1095/2007.<sup>4</sup> In accordance with the Regulation, at the request of the Commission of the European Communities (hereafter referred to as ‘the Commission’), the EFSA organised a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by Spain, being the designated rapporteur Member State (RMS). The peer review process was subsequently terminated following the applicant’s decision, in accordance with Article 24e, to withdraw support for the inclusion of lime sulfur in Annex I to Council Directive 91/414/EEC.

Following the Commission Decision of 8 December 2008 (2008/941/EC)<sup>5</sup> concerning the non-inclusion of lime sulfur in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Polisenio s.r.l. made a resubmission application for the inclusion of lime sulfur in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008.<sup>6</sup> The resubmission dossier included further data in response to the issues identified in the DAR.

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Spain, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 15 February 2010.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 16 February 2010. The EFSA collated and forwarded all comments received to the Commission on 6 April 2010.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission requested the EFSA to conduct a focused peer review in the area of mammalian toxicology and deliver its conclusions on lime sulfur.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of lime sulfur as a fungicide on apples, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

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<sup>2</sup> Correspondence: [praper@efsa.europa.eu](mailto:praper@efsa.europa.eu)

<sup>3</sup> OJ L 379, 24.12.2004, p.13

<sup>4</sup> OJ L 246, 21.9.2007, p. 19

<sup>5</sup> OJ L 335, 12.12.2008, p.91

<sup>6</sup> OJ L 15, 18.01.2008, p.5

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Data gaps were identified in the section on identity and physical and chemical properties of the formulation.

A data gap was identified for the section on mammalian toxicity however no critical areas of concern were identified. The operator, worker and bystander risk assessment was finalised.

The consumer risk assessment is not finalised. There is uncertainty over whether the presence of remainders of polysulfides on the crop surface can definitely be excluded, and whether this may become an issue for consumer safety.

Concerning the environmental fate and behaviour of lime sulfur, data gaps were identified to address the impact of calcium concentrations in soil and hydrogen sulfide levels in sediment arising from the use of lime sulfur with respect to the natural background concentration levels of calcium in EU agricultural soils and hydrogen sulfide levels in the sediment of natural surface water systems.

The risk assessment for sediment-dwelling organisms and non-target arthropods is not finalised and two data gaps were identified.

#### **KEY WORDS**

calcium polysulfide, calcium polysulphide, lime sulfur, lime sulphur, peer review, risk assessment, pesticide, fungicide

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## BACKGROUND

### Legislative framework

Commission Regulation (EC) No 2229/2004,<sup>7</sup> as amended by Commission Regulation (EC) No 1095/2007,<sup>8</sup> lays down the detailed rules for the implementation of the fourth stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC. This regulates for the European Food Safety Authority (EFSA) the procedure for organising, upon request of the Commission of the European Communities (hereafter referred to as 'the Commission'), a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the designated rapporteur Member State.

Commission Regulation (EC) No 33/2008<sup>9</sup> lays down the detailed rules for the application of Council Directive 91/414/EEC for a regular and accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC but which were not included in Annex I. This regulates for the EFSA the procedure for organising the consultation of Member States and the applicant(s) for comments on the Additional Report provided by the designated RMS, and upon request of the Commission the organisation of a peer review and/or delivery of its conclusions on the active substance.

### Peer review conducted in accordance with Commission Regulation (EC) No 2229/2004

Lime sulfur is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004, as amended by Commission Regulation (EC) No 1095/2007. In accordance with the Regulation, at the request of the Commission, the EFSA organised a peer review of the DAR provided by the designated rapporteur Member State, Spain, which was received by the EFSA on 12 February 2008 (Spain, 2008).

The peer review was initiated on 31 March 2008 by dispatching the DAR to Member States and the applicants Polisenio s.r.l. and S.T.I. Solfotecnica Italiana S.p.A. for consultation and comments.

The peer review process was subsequently terminated following the applicants' decision, in accordance with Article 24e, to withdraw support for the inclusion of lime sulfur in Annex I to Council Directive 91/414/EEC.

### Peer review conducted in accordance with Commission Regulation (EC) No 33/2008

Following the Commission Decision of 8 December 2008 (2008/941/EC)<sup>10</sup> concerning the non-inclusion of lime sulfur in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Polisenio s.r.l. made a resubmission application for the inclusion of lime sulfur in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the issues identified in the DAR, as follows: the identity of the active substance and analytical methods, and the impact on human health and on non-target species.

In accordance with Article 18, Spain, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report (Spain, 2010a). The Additional Report was received by the EFSA on 15 February 2010.

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 16 February 2010. In addition, the EFSA conducted a public consultation

<sup>7</sup> OJ L 379, 24.12.2004, p.13

<sup>8</sup> OJ L 246, 21.9.2007, p.19

<sup>9</sup> OJ L 15, 18.01.2008, p.5

<sup>10</sup> OJ L 335, 12.12.2008, p.91

on the Additional Report and the DAR. The EFSA collated and forwarded all comments received to the Commission on 6 April 2010. At the same time, the collated comments were forwarded to the RMS for compilation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 7 May 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on lime sulfur within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicant in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicant in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission on 7 May 2010; the applicant was also invited to give its view on the need for additional information. On the basis of the comments received, the applicant's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the area of mammalian toxicology and that further information should be requested from the applicant in all areas.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in consultation with Member State experts, and the additional information to be submitted by the applicant, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in September – October 2010.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a fungicide on apple, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion (EFSA, 2010). The Peer Review Report comprises the following documents:

- the comments received,
- the Reporting Table (10 May 2010),
- the Evaluation Table (22 October 2010),
- the report of the scientific consultation with Member State experts (where relevant).

Given the importance of the DAR and the Additional Report including its addendum (compiled version of September 2010 containing all individually submitted addenda; Spain, 2010b) and the Peer

Review Report, both documents are considered respectively as background documents A and B to this conclusion.

## THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Lime sulfur is a common name for calcium polysulfide (IUPAC). This substance is considered by the International Organisation for Standardization not to require a common name. In ISO 765-1976, the names given are “calcium polysulphide” and “lime sulphur”, but ISO now requires the “f” spelling for sulfur and its compounds.

The representative formulated product for the evaluation was ‘Polisulfuro di Calcio’, a dispersible concentrate (DC), containing 380 g/l calcium polysulfide, registered under different trade names in Europe.

The representative uses evaluated comprise foliar spraying on apple against mildew. Full details of the GAP can be found in the list of end points in Appendix A.

## CONCLUSIONS OF THE EVALUATION

### 1. Identity, physical/chemical/technical properties and methods of analysis

Lime sulfur is manufactured as a technical concentrate and the content of calcium polysulfide is between 290 and 320 g/kg. According to the FAO specification AGP:CP/58, 1973 for ‘Lime sulphur liquid concentrate’ the content of calcium polysulfide shall be between 29 and 32 % by weight (17/13/S2/2) and the content of calcium thiosulfate shall not exceed 2.5 % by weight.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of lime sulfur, however data gaps were identified for the determination of the calcium thiosulfate content of the technical concentrate, and for accelerated storage and shelf life studies of the formulation. The main data regarding the identity of lime sulfur and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of lime sulfur and the impurities in the technical concentrate. As there is no residue definition for food of plant and animal origin or the environmental matrices, and the proposal of MRLs for apples is not relevant, monitoring methods are not necessary. Analytical methods for the determination of residues in body fluids and tissues are not required as lime sulfur is not classified as toxic or highly toxic.

### 2. Mammalian toxicity

Lime sulfur was discussed during the PRAPeR expert meeting 81 held in August to September 2010. Lime sulfur is currently classified as R38 “Irritating to skin”, R36 “Irritating to eyes”, R37 “Irritating to the respiratory system”; the data available during the peer review indicated also the need of classifying as Xn; R22 “Harmful if swallowed” and R43 “May cause sensitisation by skin contact”.

The relevant NOAEL after repeated exposures in short-term toxicity studies is 150 mg/kg bw/day, based on metabolic acidosis and local effects (severe burns of the gastro-intestinal mucosa). Lime sulfur showed positive results *in vitro*, but no clastogenic potential *in vivo*. During the meeting, it was discussed whether further testing (i.e. *in vivo* UDS test) was needed in order to conclude on the mutagenic potential of the compound. As the operator exposure to lime sulfur (only possible during mixing and loading) was considered negligible with the use of RPE, an *in vivo* assay to define the mutagenic potential for lime sulfur is not necessary. Should the exposure conditions change, this issue will have to be reconsidered. No data were available for long-term toxicity, carcinogenicity, reproductive and developmental toxicity. However, it was agreed by the experts that no further studies were necessary to finalise the risk assessment. Toxicological studies and medical information were available on hydrogen sulfide, the main metabolite of lime sulfur, indicating that it causes caustic injury to the oesophagus and stomach by inducing metabolic acidosis. The operator exposure to hydrogen sulfide under real conditions is estimated to be below the maximum acceptable concentration (MAK) of 7.1 mg/m<sup>3</sup>, which is set for industrial settings (no need of RPE); the



bystander exposure is of much shorter duration and is expected to be below the calculated trigger of 14 mg/m<sup>3</sup> (considering 15 min. exposure). As for re-entry workers, the exposure is not expected to exceed the operator exposure.

A data gap was identified for the certificate of analysis of the batch tested in the acute oral toxicity study in rats (B.6.2.1 Baudet L. 2002 in Spain, 2008).

### 3. Residues

A case was made that in the spray solution calcium polysulfides are quickly transformed into elemental sulfur and calcium ions. Hence, the Additional Report to the DAR presented a description of the metabolism of sulfur in crops based on a literature review and studies already submitted and peer reviewed for the active substance sulfur. However, the data available and eligible for peer review suggest that the aqueous chemistry of polysulfides is complex. No experimental data are available on the actual composition of the spray solution before application and/or the composition of the residue when the solution had been applied to the crop and dried off. It is undisputed that to a great extent elemental sulfur will be generated and further degraded according to known processes in living matter. As for residues of elemental sulfur, no dietary risk assessment needs to be carried out, since toxicological reference values were not set for sulfur. Yet there is uncertainty over whether the presence of remainders of polysulfides on the crop surface can definitely be excluded, and whether this may become an issue for consumer safety due to generation of hydrogen sulfide in the stomach. Information submitted by the applicant (June 2010) to address the issue is in part not eligible due to restrictions laid down in Commission Regulation (EC) No. 33/2008 and could therefore not be considered for peer review. Therefore, a data gap was set to address the nature of the residue on crops upon application of calcium polysulfide, in particular with regard to the potential presence of polysulfides.

The consumer exposure and risk assessment for calcium as a residue from application of calcium polysulfides was not addressed in the DAR or the Additional Report. However, as calcium is ubiquitous and essential to all known living organisms, and considering further the representative application rate, it is reasonable to conclude that calcium levels from the use of calcium polysulfides will be insignificant compared to the overall calcium exposure.

### 4. Environmental fate and behaviour

Calcium polysulfides in moist soils are expected to dissociate rapidly to form calcium cations and sulfur. Therefore, the environmental behaviour of the active substance is dependent on the fate of the dissociation products.

The DAR presented a description of the environmental fate and behaviour of sulfur in soil based on the literature review and studies already submitted and peer reviewed for the active substance sulfur. An overview of the processes (chemical and biological transformation, oxidation-reduction) that govern the behaviour of naturally occurring sulfur in the environment was provided, in view of the fact that these processes will also govern the fate of lime sulfur added as a fungicide to the same environment. Polysulfides enter the sulfur cycle immediately after application, being transformed into various stages of oxidation (sulfate and sulfite), which are soluble and thus made available for uptake by plants and animals. This is an active uptake process, since sulfur is an essential element required for maintaining crucial life functions. It was concluded that as the sulfur cycle is well known and documented, the environmental fate of polysulfides in soil was satisfactorily addressed and no further assessment was considered necessary.

Calcium cations have an important role in the maintenance of the physical and chemical properties of soils. Therefore it is not expected that the released calcium would adversely impact the environment. A quantitative assessment of the calcium concentrations in soil derived from the use of lime sulfur (according to the representative uses proposed in the resubmission dossier) was provided (Addendum II, July 2010 in Spain, 2010b). However, a comparison of these estimated values with the natural



background concentration levels of calcium in EU agricultural soils was not available for consideration in the EFSA conclusion due to restrictions laid down in Commission Regulation (EC) No. 33/2008 and a data gap was therefore identified.<sup>11</sup>

Predicted environmental concentrations (PEC) in soil for sulfur and calcium oxide were calculated based on the transformation amounts of 33.3 % and 11.9 % for sulfur ions and calcium ions, respectively, and based on a worst case maximum annual application of 2 kg a.s./ha (Addendum II, July 2010 in Spain, 2010b).

PEC of sulfur in surface water via drift and runoff/drainage entries were calculated without consideration of degradation and sorption processes using FOCUS SWASH Drift calculator<sup>12</sup> and assuming an application rate of lime sulfur completely converted to elemental sulfur. After the implementation of no-spray buffer zones of up to 20 metres for the drift entry pathway as risk mitigation measures, the predicted environmental concentrations lead to TER values well above the trigger values. Calculations of PEC in sediment for sulfur were based on the maximum  $PEC_{sw, drift}$  considering a partitioning of 100 % of sulfur from surface water to sediment. In addition, a quantitative assessment of the impact of hydrogen sulfide formed in the aquatic sediment (anaerobic conditions) was provided assuming that all the  $PEC_{sed}$  for sulfur is converted to hydrogen sulfide (Addendum II, July 2010 in Spain, 2010b). However, the impact of this amount of hydrogen sulfide with respect to its natural background concentrations has not been evaluated and a data gap was identified.

Sulfur is not of concern for the contamination of groundwater, but the potential for groundwater contamination by sulfates needed to be addressed, as they are highly mobile in soil. The aim of  $PEC_{gw}$  determination for sulfates was to assess their concentrations against the drinking water limit of 250 mg/L set in the Drinking Water Directive 98/83/CE.<sup>13</sup>  $PEC_{gw}$  calculations were based on a worst case assumption that 100 % of sulfur applied to soil is oxidised to sulfates ( $SO_4^{2-}$ ), and 100 % of sulfates will leach to groundwater. The water volume percolated at 1 m depth determined in each FOCUS scenario<sup>14</sup> over 26 years by the model FOCUS PELMO 3.3.2 was used. The total amount of sulfur applied to soil, and the equivalence in  $SO_4^{2-}$  (1 S<sub>8</sub> giving 8  $SO_4^{2-}$ ) was determined for a period of 26 years, under the consideration of both molecular weights (S<sub>8</sub>: 256.6 g/mol;  $SO_4^{2-}$ : 96.1 g/mol). This amount is based on an application rate of 1.2 kg S/ha pre-flowering and 0.8 kg S/ha post-flowering to apples with 50 % foliar interception for both applications. Results (maximum  $PEC_{gw}$  value of 5.22 mg  $SO_4^{2-}$ /L estimated for Sevilla scenario) indicated that the potential for groundwater contamination from sulfates above the drinking water limit of 250 mg/L from the representative uses of lime sulfur is low.

## 5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a, 2002b, 2002c), SETAC (2001) and EFSA (2009).

The representative use was the application of 1.2 kg a.s./ha and 0.8 kg a.s./ha pre- and post-flowering. From the environmental risk assessment presented in the Additional Report it was unclear whether these are two different uses or one use with two applications. It was clarified in a written procedure that both applications can take place within one growing season. The application interval was not clearly defined and therefore both applications were combined and the risk was assessed for an application rate of 2 kg a.s./ha, which constitutes a worst case for the environmental risk assessment.

<sup>11</sup> Such an assessment was provided, but as it relied on scientific literature that was new to the peer review (not in the information provided to the RMS before the Additional Report was submitted to EFSA) this may not be considered in this conclusion.

<sup>12</sup> FOCUS SWASH Drift calculator is described in FOCUS (2001).

<sup>13</sup> Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

<sup>14</sup> FOCUS groundwater scenarios are described in FOCUS (2000).

No studies with birds were submitted by the applicant in the resubmission dossier. The applicant suggested using the endpoint for mammals instead, assuming that the acute toxicity of lime sulfur would be similar for birds and mammals because it is an inorganic non-specific toxicant. EFSA is of the opinion that such an assumption would need further justification. However, since the endpoint for birds from an acute toxicity study submitted in the original dossier was higher than the mammal endpoint, and in view of animal welfare considerations, it is agreed by EFSA not to require a new study with birds and to use the mammal endpoint as a surrogate. The TER values for uptake of contaminated food and drinking water indicated a low risk.

The acute risk assessment for mammals from uptake of contaminated food according to the old guidance (European Commission, 2002c) resulted in a TER below the trigger. But all TERs exceeded the trigger when calculated according to the new guidance document on birds and mammals (EFSA, 2009) indicating a low risk. The risk from uptake of contaminated drinking water was assessed as low. The long-term risk to birds and mammals was considered to be low on the basis of the breakdown of lime sulfur into two naturally occurring ions, calcium and sulfur. Both ions are essential nutrients for many organisms.

Lime sulfur is toxic to aquatic organisms. The lowest endpoint was observed for fish (96h  $EC_{50} = 2.67$  mg sulfur/L). The first-tier TERs indicated a high acute risk to fish. Risk mitigation measures comparable to a 20 m no-spray buffer zone are required to achieve TERs at or above the Annex VI trigger of 100.

Uncertainty remains with regard to sediment-dwelling organisms. A worst-case estimate for formation of hydrogen sulfide under anaerobic conditions was provided (see section on fate and behaviour). No study with sediment-dwelling organisms and hydrogen sulfide was available to conduct a TER calculation. Further information on natural background levels and toxicity of hydrogen sulfide to sediment-dwelling organisms are needed to finalise the risk assessment and a data gap is identified by EFSA.

Effects of >50 % were observed in extended laboratory studies with *Aphidius rhopalosiphi*, *Typhlodromus pyri* at an application rate of 3 kg a.s./ha. Effects were less than 50 % in a study with *Orius laevigatus*. The RMS is of the opinion that the risk to non-target arthropods is low since the intended application rate is lower (2 kg a.s./ha) than the rate applied in the test and rapid recolonisation of the in-field area was suggested by the RMS assuming low impact on off-field populations and rapid degradation of lime sulfur to calcium and sulfur ions. EFSA agrees that the risk to *A. rhopalosiphi* is likely to be low since effects are <50 % at off-field rates. However for *T. pyri* adverse effects of >50 % cannot be excluded for the off-field area (based on the worst case application rate of 2 kg a.s./ha). Further data are needed to demonstrate that in-field recovery/recolonisation is possible within one year for sensitive arthropod species such as *T. pyri* (data gap).

The risk to all other groups of organisms (bees, earthworms, other soil dwelling macro- and micro-organisms and biological methods of sewage treatment) was considered as low for the representative use evaluated.

## 6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

### 6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Sulfur moieties	The available information only enables a qualitative assessment on the oxidation rates of sulfur.  No data required.	The risk from lime-sulfur to earthworms was assessed as low. No specific risk assessment was provided for sulfur but it is expected that the available risk assessment for lime-sulfur would cover the risk from sulfur.
Calcium	No data available, data required.	The risk from lime-sulfur to earthworms was assessed as low. No specific risk assessment was provided for calcium but it is expected that the available risk assessment for lime-sulfur would cover the risk from calcium.

## 6.2. Ground water

Compound (name and/or code)	Mobility in soil	> drinking water standard for sulfates (250mg/L) <sup>(a)</sup> 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Sulfur moieties	No data available, not required.	no data available, not required	Yes	No data, not needed.	No risk assessment for groundwater becoming surface water was conducted. Not needed.
Sulfates	No data available, not required.	No (estimated max $PEC_{gw} = 5.22 \text{ mg SO}_4^{2-}/\text{L}$ based on a worst case assumption that 100 % of sulfur applied to soil is oxidised to sulfates, and 100 % of sulfates will leach to groundwater; see section 4)	No data submitted, no data needed.	No data, not needed.	No data submitted, no data needed.

(a): Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

### 6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Sulfur moieties	Lime sulfur is toxic to aquatic organisms (fish 96h $LC_{50}$ = 2.67 mg sulfur/L).
Hydrogen sulfide (formed under anaerobic conditions in sediment)	No ecotoxicity data were submitted and the risk assessment could not be finalised (data gap).

### 6.4. Air

Compound (name and/or code)	Toxicology
Sulfur moieties	Data on acute or repeat inhalation toxicity not available, not required.

## **LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED**

- The calcium thiosulfate content of the technical concentrate (relevant for all representative uses evaluated; amended report of the new five batch analysis conducted by Kiefer, R. (2009) submitted by the applicant, however could not be taken into consideration in the peer review due to restrictions laid down in Commission Regulation (EC) No. 33/2008; see section 1).
- Accelerated storage study (relevant for all representative uses evaluated; the applicant submitted amended Report No. S09-02155; Walter, 2009, however this could not be taken into consideration in the peer review due to restrictions laid down in Commission Regulation (EC) No. 33/2008; see section 1).
- Shelf life study (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- The certificate of analysis of the batch tested in the acute oral toxicity study in rats (B.6.2.1 Baudet L. 2002 in Spain, 2008; see section 2).
- Data to address the nature of the residue on crops upon application of calcium polysulfide, in particular with regard to the potential presence of polysulfides (relevant for all representative uses evaluated; a case made by the applicant (June 2010) was not considered since the case was established on information that is in part not eligible for peer review; see section 3)
- An assessment of the impact on the amount of calcium derived from the use of lime sulfur with respect to the natural background concentration levels of calcium in EU agricultural soils (relevant for all representative uses evaluated; information already provided by the applicant and evaluated by the RMS, but not peer reviewed due to restrictions laid down in Commission Regulation (EC) No. 33/2008; see section 4).
- Assessment of the impact of the amounts of sulfur ions (the formation of hydrogen sulfide in particular) in the aquatic environment following the use of lime sulfur (according to the representative uses proposed) with respect to the natural background concentrations of these ions in surface water bodies (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).
- Information on the toxicity of hydrogen sulfide to sediment-dwelling organisms is needed to finalise the risk assessment (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).
- Further data are needed to demonstrate that in-field recovery/recolonisation is possible within one year for sensitive arthropod species (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).

## **PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED**

- Use of RPE during mixing/loading.

## **ISSUES THAT COULD NOT BE FINALISED**

- The consumer risk assessment. There is uncertainty over whether the presence of remainders of polysulfides on the crop surface can definitely be excluded, and whether this may become an issue for consumer safety.

- Information on natural background levels and toxicity of hydrogen sulfide to sediment-dwelling organisms is needed to finalise the aquatic risk assessment.
- Further data are needed to demonstrate that in-field recovery/recolonisation is possible within one year for sensitive arthropod species such as *T. pyri*.

#### **CRITICAL AREAS OF CONCERN**

- None identified.



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## APPENDICES

### APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

#### Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (Common Name) ‡	Lime sulfur, calcium polysulfide
Function ( <i>e.g.</i> fungicide)	Fungicide
Rapporteur Member State	Spain
Co-rapporteur Member State	

#### Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	calcium polysulfide
Chemical name (CA) ‡	calcium polysulfide
CIPAC No ‡	17
CAS No ‡	1344-81-6
EC No (EINECS or ELINCS) ‡	215-709-2
FAO Specification (including year of publication) ‡	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 of the active substance as manufactured ‡	Between 290 and 320 g/kg calcium polysulfide (given for the TK material)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None (provisional)
Molecular formula ‡	CaS <sub>x</sub> (x= 2-7)
Molecular mass ‡	200.4 g/mol (average, primary calcium pentasulfide)
Structural formula ‡	Not available

## Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Not applicable
Boiling point (state purity) ‡	104.8 °C
Temperature of decomposition (state purity)	Not applicable as it is not possible to manufacture pure active substance
Appearance (state purity) ‡	Lime sulfur is an amber liquid with rotten egg odour
Vapour pressure (state temperature, state purity) ‡	Not applicable
Henry's law constant ‡	Not applicable
Solubility in water (state temperature, state purity and pH) ‡	Lime sulfur is soluble in water. Present in aqueous solution, fully soluble above pH 8.5, unstable below pH 8.5.
Solubility in organic solvents ‡ (state temperature, state purity)	Not relevant to an aqueous ionic solution.
Surface tension ‡ (state concentration and temperature, state purity)	71.33 mN/m at 20°C
Partition co-efficient ‡ (state temperature, pH and purity)	Not relevant to an aqueous ionic solution.
Dissociation constant (state purity) ‡	Not applicable
UV/VIS absorption (max.) incl. $\epsilon$ ‡ (state purity, pH)	Not applicable
Flammability ‡ (state purity)	Not applicable Not auto-flammable (29/30 % w/w)
Explosive properties ‡ (state purity)	Not explosive (29/30 % w/w)
Oxidising properties ‡ (state purity)	Not oxidising

### Summary of representative uses evaluated (*calcium polysulfide*)\*

(a)	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days)	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	[1], [2], [3].
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 product	post-flowering	1		0.08	10 hl/ha, depending on dimension of plants	0.8	30	[1], [2], [3].

[1] The consumer risk assessment could not be finalised. There is uncertainty over whether the presence of remainders of polysulfides on the crop surface can definitely be excluded, and whether this may become an issue for consumer safety.

[2] Information on natural background levels and toxicity of hydrogen sulfide to sediment-dwelling organisms is needed to finalise the aquatic risk assessment.

[3] The risk assessment for non-target arthropods is not finalised. Further data are needed to demonstrate that in-field recovery/recolonisation is possible within one year for sensitive arthropod species such as *T. pyri*.

<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. fluoroxypyr). <b>In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</b></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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### Analytical methods for the active substance (OECD data point IIA 4.2)

Technical as (analytical technique)	Iodometric titration.
Impurities in technical as (analytical technique)	ICP-OES.
Plant protection product (analytical technique)	--

### Analytical methods for residues (OECD data points IIA, 4.3 to IIA 4.8)

#### Residue definitions for monitoring purposes

Food of plant origin	Not applicable
Food of animal origin	Not applicable
Soil	No residue definition
Water surface	No residue definition
drinking/ground	No residue definition
Air	No residue definition

#### Monitoring/Enforcement methods

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	No MRLs are set, no further data are required.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not necessary
Soil (principle of method and LOQ)	Not necessary
Water (principle of method and LOQ)	No data validation. Considering the active substance, no residue definition, no further data are required.
Air (principle of method and LOQ)	No data validation. Considering the active substance, no residue definition. no further data are required.
Body fluids and tissues (principle of method and LOQ)	Not required. Lime sulfur is not regarded as toxic or very toxic.

### Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	R31: Contact with acids liberates gases.

## Impact on Human and Animal Health

### Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	No data available, not needed
Distribution ‡	No data available, not needed
Potential for accumulation ‡	No data available, not needed
Rate and extent of excretion ‡	No data available, not needed
Metabolism in animals ‡	No data available, not needed
Toxicologically relevant compounds ‡ (animals and plants)	Hydrogen sulfide
Toxicologically relevant compounds ‡ (environment)	Hydrogen sulfide

### Acute toxicity (Annex IIA, point 5.2)

Rat LD50 oral ‡	1343 mg/kg bw (rat)	R22
Rat LD50 dermal ‡	> 2000 mg/kg bw	
Rat LC50 inhalation ‡	Not required	
Skin irritation ‡	According to Annex I of EU Directive 67/548/EEC	R38
Eye irritation ‡	According to Annex I of EU Directive 67/548/EEC	R36
Skin sensitization ‡	Polisolfuro di calcio induces delayed contact hypersensitivity in guinea pigs with an 80% reaction observed at challenge.	R43
Respiratory system irritation	According to Annex I of EU Directive 67/548/EEC	R37

### Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Local: severe burns of gastro-intestinal mucosa Systemic: metabolic acidosis	
Relevant oral NOAEL ‡	150 mg/kg bw/day (rat)	
Relevant dermal NOAEL ‡	No data, not needed	
Relevant inhalation NOAEL ‡	No data, not needed	

### Genotoxicity ‡ (Annex IIA, point 5.4)

Genotoxic <i>in vitro</i> . No clastogenic potential <i>in vivo</i> . No further data <i>in vivo</i> needed considering the negligible exposure to lime sulfur of operators	
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### Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	No data available, not needed.
Relevant NOAEL ‡	Not applicable
Carcinogenicity ‡	No data available, not needed

### Reproductive toxicity (Annex IIA, point 5.6)

#### Multigeneration study

Reproduction target / critical effect ‡	No data available, not needed.
Relevant parental NOAEL ‡	No data available, not needed.
Relevant reproductive NOAEL ‡	No data available, not needed.
Relevant offspring NOAEL ‡	No data available, not needed.

#### Developmental toxicity

Developmental target / critical effect ‡	No data available, not needed.
Relevant maternal NOAEL ‡	No data available, not needed.
Relevant developmental NOAEL ‡	No data available, not needed.

### Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available, not needed.
Repeated neurotoxicity ‡	No potential to produce neurotoxicity
Delayed neurotoxicity ‡	No data available, not needed.

### Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data available
Studies performed on metabolites or impurities ‡	<b>Hydrogen sulfide</b> Reproductive toxicity. No potential to produce reprotoxicity/teratogenicity Potentially to produce developmental neurotoxicity



## Medical data ‡ (Annex IIA, point 5.9)

Toxicity by direct caustic injury to the oesophagus and stomach, by generation of hydrogen sulfide and sulfate and by inducing metabolic acidosis.  
Treatment symptomatic of patients, that could require aggressive resuscitation with correction for metabolic acidosis.  
The use of nitrites, recommended for treatment of hydrogen sulfide toxicity, is unclear since nitrites are vasodilators and can increase the problems of hypotension leading to further metabolic acidosis.

## Summary (Annex IIA, point 5.10)

	Value	Study	SF
ADI ‡	Not applicable		
AOEL ‡	1.5 mg/kg bw/day	90-day oral in rats	100
ARfD ‡	Not applicable		
MAK <sub>hydrogen sulfide</sub> (UK, Germany)	7.1 mg/m <sup>3</sup>		

## Dermal absorption ‡ (Annex IIIA, point 7.3)

“Polisolfuro di Calcio SL”

No experimental value. Default value 100%.

## Exposure scenarios (Annex IIIA, point 7.2)

Operator	<p>The operator exposure to <u>hydrogen sulfide</u> under real conditions is estimated to be below the MAK of 7.1 mg/m<sup>3</sup>, which is set for industrial settings (no need of RPE)</p> <p>The operator exposure to <u>lime sulfur</u> (only possible during mixing and loading) was considered negligible with the use of RPE</p>
Workers	The exposure to hydrogen sulfide is not expected to exceed the operator exposure
Bystanders	The bystander exposure is of much shorter duration and is expected to be below the trigger of 14 mg/m <sup>3</sup> (considering 1 peak exposure of 30 min per day)

## Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

RMS/peer review proposal

Lime sulfur

Xn; R22 "Harmful if swallowed"  
R43 "May cause sensitisation by skin contact"  
Xi  
R38 "Irritating to skin"  
R36 "Irritating to eyes"  
R37 "Irritating to the respiratory system"

### Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	For elemental sulfur: Metabolism study on wheat. General argumentation covers all plant groups. Uncertainty over presence of polysulfides (data gap)
Rotational crops	Not relevant
Metabolism in rotational crops similar to metabolism in primary crops?	Not relevant
Processed commodities	Not relevant
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not relevant
Plant residue definition for monitoring	Not applicable
Plant residue definition for risk assessment	Currently unable to conclude if a residue definition for risk assessment is required (data gap on polysulfides issue)
Conversion factor (monitoring to risk assessment)	Not applicable

### Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Not relevant
Time needed to reach a plateau concentration in milk and eggs	Not relevant
Animal residue definition for monitoring	Not applicable
Animal residue definition for risk assessment	Not applicable
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Not relevant
Fat soluble residue: (yes/no)	Not relevant

### Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Not required

### Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

Residues of total sulfur in frozen and stored samples of treated crops are expected to remain stable indefinitely.

## Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Expected intakes by livestock  $\geq 0.1$  mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)

Potential for accumulation (yes/no):

Metabolism studies indicate potential level of residues  $\geq 0.01$  mg/kg in edible tissues (yes/no)

Muscle

Liver

Kidney

Fat

Milk

Eggs

Ruminant:	Poultry:	Pig:
no	no	no
n/a	n/a	n/a
n/a	n/a	n/a
Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
n/a	n/a	n/a
n/a	n/a	n/a
n/a	n/a	n/a
n/a	n/a	n/a
n/a		
	n/a	

## Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Country and/or Region	Trials results relevant to the critical GAP (a)	Recommendations/comments	MRL	STMR (b)
Apple	Mediterranean Region	Total sulfur [mg S/kg]: 1x38.2, 1x46.0, 1x 52.8, 1x54.7, 1 x 55.0	Application amounts: 2 trials: 8 x 4.5 kg as*/ha, 3 trials: 1 x 72 to 79 kg as*/ha, 1x 4.5 kg as/ha, 9x, 3 kg as/ha	-	52.8

(a) Number of trials in which particular residue levels were reported e.g. 3 x < 0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue i.e. the median residue level estimated on the basis of supervised trials relating to the critical GAP

\* refers to Ca-Polysulfides

(a) Numbers of trials in which particular residue levels were reported e.g. 3 x < 0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue i.e. the median residue level estimated on the basis of supervised trials relating to the representative use

(c) Highest residue

### Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

- **Note:** Not finalised due to uncertainty over presence of polysulfides (data gap) and whether this may become an issue for consumer safety due to generation of hydrogen sulfide in the stomach.

ADI	Not applicable
TMDI (% ADI) according to WHO European diet	Not applicable
TMDI (% ADI) according to national (to be specified) diets	Not applicable
IEDI (WHO European Diet) (% ADI)	Not applicable
NEDI (specify diet) (% ADI)	Not applicable
Factors included in IEDI and NEDI	Not applicable
ARfD	Not applicable
IENTI (% ARfD)	Not applicable
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not applicable
Factors included in IENTI and NESTI	Not applicable

### Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Not relevant				

### Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Proposed MRLs

As there is no residue definition for monitoring, the proposal of MRLs for apples is not relevant.

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure

### Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡	Not applicable to an active substance that is inorganic
Non-extractable residues after 100 days ‡	Not applicable to an active substance that is inorganic
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Not applicable to an active substance that is inorganic

### Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡	
Mineralization after 100 days	Not applicable to an active substance that is inorganic
Non-extractable residues after 100 days	Not applicable to an active substance that is inorganic
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not applicable to an active substance that is inorganic
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not applicable to an active substance that is inorganic No data submitted. No data required.

### Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

#### Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	X <sup>15</sup>	pH	t. °C / % MWHC	DT <sub>50</sub> /DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20 °C pF2/10kPa	St. (r <sup>2</sup> )	Method of calculation
The available information only enables a qualitative assessment on the oxidation rates							

#### Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X <sup>1</sup>	pH	Depth (cm)	DT <sub>50</sub> (d) actual	DT <sub>90</sub> (d) actual	St. (r <sup>2</sup> )	DT <sub>50</sub> (d) Norm.	Method of calculation
No valid study									

<sup>15</sup> X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.



### Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
No data submitted No required							

### Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	Study not valid
Aged residues leaching ‡	No data submitted No required

### Lysimeter/ field leaching studies ‡

Location: England  
 Study type (e.g.lysimeter, field): lysimeter  
 Soil properties: texture, pH = 6.6, OC = 12.7 g/kg  
 Dates of application : Sept 1996 to Sept 1999  
 Crop : /Interception estimated:  
 Number of applications: 1 application the first year  
 Duration. 3 years  
 Application rate: 50 kg/ha/year + 22 kg atmospheric deposition  
 Average annual rainfall (mm): 615.3  
 Average annual leachate volume (mm): 214  
 Leaching rate of organic forms over the three years:  
 equivalent to 68 kg/ha of Sulfur as SO<sub>42-</sub> + 4.8  
 kg/ha as DOS (dissolved organic Sulfur) = 72.8  
 kg/ha, when 72 kg/ha input. No elemental Sulfur  
 leached.

### PEC (soil) (Annex IIIA, point 9.1.3)

#### Parent

#### Application data

Depth of soil layer: 5 cm  
 Soil bulk density: 1.5g/cm<sup>3</sup>  
 % plant interception: 50%  
 Application rate(s): 2 kg as/ha ( apples)  
 Transformation:  
 33.3% Sulfur  
 11.9% Calcium

<b>PEC<sub>(s)</sub> for sulfur</b> (mg/kg)	Single application Actual	Single application TWA	Multiple application Actual	Multiple application TWA
	Initial	0.44	-	-
<b>PEC<sub>(s)</sub> for Calcium</b> (mg/kg)	Single application Actual	Single application TWA	Multiple application Actual	Multiple application TWA
	Initial	0.16	-	-

### Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡

At neutral to alkaline pH  $S_6^{2-}$ ,  $S_5^{2-}$  and  $S_4^{2-}$  dominate the solution and the shorter chains  $S_3^{2-}$  and  $S_2^{2-}$  were only observed at very high alkalinity (pH > 14).

Under acidic conditions, calcium polysulfides (Sn<sup>2-</sup>) readily form hydrogen sulfide (H<sub>2</sub>S) or metal sulfide. Polysulfide autooxidation yield predominately thiosulfate (S<sub>2</sub>O<sub>3</sub><sup>2-</sup>) or sulfur depending on the average chain length of the polysulfides.

Photolytic degradation of active substance and metabolites above 10 % ‡

The photo transformation will be driven by simultaneous, complex processes involving different species depending on pH value and the oxidation state.

Readily biodegradable ‡  
(yes/no)

No

### Degradation in water / sediment

Parent	Distribution (eg max in water <i>x</i> after <i>n</i> d. Max. sed <i>x</i> % after <i>n</i> d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT <sub>50</sub> -DT <sub>90</sub> whole sys.	St. (r <sup>2</sup> )	DT <sub>50</sub> -DT <sub>90</sub> water	St. (r <sup>2</sup> )	DT <sub>50</sub> -DT <sub>90</sub> sed	St. (r <sup>2</sup> )	Method of calculation
No data submitted No required										

### PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

Parent  
Parameters used in FOCUS<sub>sw</sub>

PEC<sub>sw</sub> (sulfur)  
Drift entry: FOCUS Drift calculator  
Runoff/Drainage

$$PEC_{sw,ini} = \frac{a \times perc}{V_{sw}} * 100$$

*a* = application rate in [μg/m<sup>2</sup>],

*perc* = % of application rate for run-off or drainage according to FOCUS Step 2

Application rate

<p><math>V_{sw}</math> = water volume (300 l/m<sup>2</sup>)</p> <p>PEC<sub>sed</sub></p> <p><math display="block">\frac{100 \cdot APP\_RATE \cdot RUNOFF\_PERC \cdot RATIO}{(SED\_DEPTH \cdot DENS)} / 1000</math></p> <p>APP_RATE: application rate (2000 g/ha step 1; (1200*0.6)+ (800*0.3)= 960 g/ha step 2)</p> <p>RUNOFF_PERC: runoff percentage (related to soil residue) (10% step 1; 5% step 2, worst case)</p> <p>RATIO: ratio of field to water body (10 -)</p> <p>SED_DEPTH: sediment depth of the surface water (5 cm)</p> <p>DENS sediment bulk density (0.8 kg/L)</p> <p>Water body dimensions: water depth of 30 cm overlying sediment depth of 5 cm (50 l/m<sup>2</sup>).</p> <p>Maximum number of applications and application rates according to the GAPs.</p> <p>Application rate of lime sulfur is completely converted to elemental sulfur.</p> <p>No adsorption and degradation processes.</p>
--

Scenario	Water	Crop	Initial drift PEC <sub>sw</sub> (µg S/L)	
	body		Default	20 m drift
Northern and Southern Europe	pond	apples	6.99	N.C.
	stream	apples	111.99	13.17
	Ditch	apples	124.08	13.17

Scenario	Water	Crop	Initial PEC <sub>sw</sub> (µg S/L)			PEC <sub>sed</sub> (µg S/kg)
	body		Runoff/Drainage At 1m	Default (drift+runoff/drainage)	20 m drift + 1 m runoff/drainage	Default (drift+runoff/drainage)
Northern Europe	pond	apples	13.6	20.6	NC	5 mg/kg and 1.2 mg/kg for FOCUS STEPS 1-2, respectively. The RMS propose these values as PEC <sub>sed</sub> as worst case.
	stream	apples	13.6	125.6	26.7	
	Ditch	apples	13.6	137.7	26.7	
Southern Europe	pond	apples	12.8	19.8	NC	
	stream	apples	12.8	124.8	25.9	
	Ditch	apples	12.8	136.88	25.9	

H<sub>2</sub>S

<p>PEC<sub>sed</sub>:</p> <p>According to:</p>
--

$\text{CaSx} + \text{H}_2\text{O} + \text{CO}_2 \rightarrow \text{H}_2\text{S} + \text{CaCO}_3 + 4\text{S}$   
 1.2 mg /Kg and 1.0 mg /kg for FOCUS STEP 1 and 2 respectively.

### PEC (ground water) (Annex IIIA, point 9.2.1)

Mehod of calculation and type of study (e.g. modelling, field leaching, lysimeter )

A simplistic calculation was done

$$PEC_{GW,SO_4^{2-}} = \frac{a(SO_4^{2-}) \times 10^6}{Watervolume \times 10^4}$$

Application rate

Sulfate: 100 % transformation (as worst case assumption)  
 Application rate: 1.2 kg S/ha (pre-flowering) + 0.8 kg S/ha (post-flowering)  
 Number of application: 1 (1.2 + 0.8 kg S/ha)

### PEC(gw) - FOCUS modelling results (80<sup>th</sup> percentile annual average concentration at 1m)

Location	PEC <sub>gw</sub> /26 years application (mg/L) PEC <sub>GW</sub>
Châteaudun	0.90
Hamburg	1.39
Jokioinen	1.93
Kremsmünster	1.25
Okehampton	0.85
Piacenza	0.77
Porto	0.73
Sevilla	5.22
Thiva	2.03

### Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡

Not studied - no data requested

Quantum yield of direct phototransformation

Not studied - no data requested

Photochemical oxidative degradation in air ‡

Not studied - no data requested

Volatilisation ‡

No data submitted. No required

Metabolites

No data submitted. No required

## PEC (air)

Method of calculation

No data submitted. No required

## PEC<sub>(a)</sub>

Maximum concentration

No data submitted. No required

## Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater exposure assessment is triggered.

**Soil :**  
sulfur, calcium ions  
**Surface Water and sediment:**  
sulfur, H<sub>2</sub>S (in the sediment under anaerobic conditions)  
**Ground water:**  
Sulfur and sulfate  
**Air:**  
sulfur

## Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)

No data submitted. No required

Surface water (indicate location and type of study)

No data submitted. No required

Ground water (indicate location and type of study)

No data submitted. No required

Air (indicate location and type of study)

No data submitted. No required

## Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Biodegradability assessment not applicable for a mineral

**Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)**

Species	Test substance	Time scale	End point (mg Dicloran/kg bw/day)	End point (mg/kg feed)
<b>Birds ‡</b>				
Not submitted	Lime sulfur			
<b>Mammals ‡</b>				
rat	Lime sulfur	Acute	LD <sub>50</sub> 1343	
Additional higher tier studies ‡				
No submitted				

**Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)**

Application rate 2 kg a.s./ha in apples

Note: For ethical and welfare reasons the acute LD50 of 1343 mg Lime sulfur/kg in rats as subrogated value for bird risk assessment.

Indicator species/Category <sup>2</sup>	Time scale	ETE	TER <sup>1</sup>	Annex VI Trigger <sup>3</sup>
<b>Tier 1- uptake via diet (Birds)</b>				
insectivorous	Acute	108.16	12.4	10
insectivorous	Short-term	Not calculated		5
insectivorous	Long-term	Not calculated		5
vermivorous	Long-term	No relevant		5
Piscivorous	Long-term	No relevant		5
<b>Higher tier refinement - uptake via diet (Birds)</b>				
Not relevant				
<b>Tier 1- uptake via drinking water (Birds)</b>				
Insectivorous	Acute-contaminated water	Daily intake= 0.000755	1778808	10
Insectivorous	Acute-puddles	108	12.43	10
<b>Tier 1 – secondary poisoning (Birds)</b>				
Earthworm-eating bird	Long-term	Not relevant		5
Fish-eating bird	Long-term	Not relevant		5
<b>Tier 1- uptake via diet (Mammals)</b>				
Large herbivorous	Acute		64	10
Small herbivorous	Acute		16.4	10
Small omnivorous mammal	Acute		129.1	10
herbivorous	Long-term	No calculated		5

Indicator species/Category <sup>2</sup>	Time scale	ETE	TER <sup>1</sup>	Annex VI Trigger <sup>3</sup>
<b>Higher tier refinement (Mammals)</b>				
Not necessary				
Tier 1- uptake via drinking water (Mammals)				
herbivorous	Acute-contaminated water	Daily doses = 0.196	6852	10
herbivorous	Acute-puddles	Daily doses = 62.8	21.38	10
Tier 1 – secondary poisoning (Mammals)				
Earthworm-eating mammals	Long-term	Not relevant		5
Fish-eating mammals	Long-term	Not relevant		5

<sup>1</sup> in higher tier refinement provides brief details of any refinements used (e.g., residues, PT, PD or AV)

<sup>2</sup> for cereals indicate if it is early or late crop stage

<sup>3</sup> If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

**Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)**

Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup> (mg total sulfur/L)
Laboratory tests ‡				
<b>Fish</b>				
<i>Oncorhynchus mykiss</i>	Lime sulfur	96 hr (static)	Mortality, EC <sub>50</sub>	2.67 (mm)
<i>Danio rerio</i>	Lime sulfur	96 hr (static)	Mortality, EC <sub>50</sub>	11.600 (mm)
<b>Aquatic invertebrate</b>				
<i>Daphnia magna</i>	Lime sulfur	48 h (static)	Mortality, EC <sub>50</sub>	12.98 (mm)
<b>Sediment dwelling organisms</b>				
Not available				
<b>Algae</b>				
<i>Pseudokirchneriella subcapitata</i>	Lime sulfur	72 h (static)	Biomass: E <sub>b</sub> C <sub>50</sub>	10.800 (mm)



Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup> (mg total sulfur/L)
<b>Higher plant</b>				
No required				
<b>Microcosm or mesocosm tests</b>				
No data was provide				

<sup>1</sup> indicate whether based on nominal (<sub>nom</sub>) or mean measured concentrations (<sub>mm</sub>). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

#### Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

#### Maximum PEC<sub>sw</sub> values and TER values for Lime sulfur– application to apples (in field) at 2000 g a.s./ha

*Editorial note: TER values should be provided for the most sensitive endpoints for each group (endpoints for sediment dwellers, higher plants and microcosms/mesocosms should be included when required – i.e. by including additional columns). For sediment dwellers TERs should be provided both for water and sediment, with a footnote explaining if PEC<sub>sw</sub> or PEC<sub>sed</sub> has been used. Indicate if twa-PEC was used for chronic fish or Daphnia TER calculation)*

Scenario	PEC global max (µg/L)	Fish acute	Daphnia acute	Algae acute
		<i>O. mykiss</i>	<i>Daphnia magna</i>	<i>S. subspicatus</i>
		96h-LC <sub>50</sub>	48h-EC <sub>50</sub>	72h-EbC <sub>50</sub>
		2670	12980	10800
<b>North Europe</b>				
ditch	125.59	21	103.4	86.0
pond	20.6	129	630.1	524.3
stream	125.59	21	103.4	86.0
<b>South Europe</b>				
ditch	124.79	21	104.0	86.5
pond	19.8	134	655.6	545.5
stream	124.79	21.3	104.0	86.5
<b>Annex VI Trigger**</b>				
		<b>100</b>	<b>100</b>	<b>10</b>

#### FOCUS<sub>sw</sub> step 4

#### Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

#### Maximum PEC<sub>sw</sub> values and TER values for Lime sulfur– application to apples (in field) at 2000 g a.s./ha

Scenario	PEC global max	Fish acute	Daphnia acute	Algae acute
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	(µg L) 20 m buffer zone			
		<i>O. mykiss</i>	<i>Daphnia magna</i>	<i>S. subspicatus</i>
		96h-LC <sub>50</sub>	48h-EC <sub>50</sub>	72h-EbC <sub>50</sub>
		2670	12980	10800
<b>North Europe</b>				
ditch	26.7	100	486.1	404.5
pond	20.6	130	630.1	524.3
stream	26.7	100	486.1	404.5
<b>South Europe</b>				
ditch	25.9	103	501.2	417.0
pond	19.8	134	655.6	545.5
stream	25.9	103	501.2	417.0
<b>Annex VI Trigger**</b>				
		<b>100</b>	<b>100</b>	<b>10</b>

Bioconcentration	Active substance
	Lime sulfur
logP <sub>O/W</sub>	not relevant
Bioconcentration factor (BCF) <sup>1</sup> ‡	not relevant
Annex VI Trigger for the bioconcentration factor	
Clearance time (days) (CT <sub>50</sub> )	
(CT <sub>90</sub> )	
Level and nature of residues (%) in organisms after the 14 day depuration phase	

<sup>1</sup> only required if log P<sub>O/W</sub> > 3.

\* based on total <sup>14</sup>C or on specific compounds

### Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD <sub>50</sub> µg ai/bee)	Acute contact toxicity (LD <sub>50</sub> µg ai/bee)
Lime sulfur	> 69.80	> 593
Metabolite 1		
Field or semi-field tests		
Not required		

<sup>1</sup> for preparations indicate whether end point is expressed in units of a.s. or preparation

### Hazard quotients for honey bees (Annex IIIA, point 10.4)

Apples at 2 kg Lime sulfur/ha

Test substance	Route	Hazard quotient	Annex VI Trigger
Lime sulfur	Contact	< 3.37	50
Lime sulfur	oral	< 28.65	50

### Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect LR <sub>50</sub> (g/ha <sup>1</sup> )
<i>Typhlodromus pyri</i> ‡	Not available		
<i>Aphidius rhopalosiphi</i> ‡	Not available		

<sup>1</sup> for preparations indicate whether end point is expressed in units of a.s. or preparation

No Tier1 risk assessment was conducted.

Further laboratory and extended laboratory studies

Species	Life stage	Test substance, substrate and duration	Dose (g/ha) <sup>1,2</sup>	End point	Effect <sup>3</sup>	Trigger value
<i>Aphidius rhopalosiphi</i>	females less than 48 h old	Lime sulfur, Apple & barley leaves	180 580 1010 1550 3000 6000	Mortality, reproducti on	M      R 7.5    22.7 20    42.3 35    20.6 40    -5.2 55    - 67.5   - LR50 =2438 g as/ha	50%

Species	Life stage	Test substance, substrate and duration	Dose (g/ha) <sup>1,2</sup>	End point	Effect <sup>3</sup>	Trigger value																				
<i>Typhlodromus pyri</i>	Proto-nymphs	Lime sulfur, Apple & barley leaves	180 580 1010 1550 3000 6000	Mortality	7-day LR <sub>50</sub> = 112.9 g a.i./ha	50 %																				
<i>Orius laevigastus</i>	4 day old nymphs	Lime sulfur, Apples leaves	180 580 1010 1550 3000 6000 10000	Mortality, reproduction	<table><tr><td>M</td><td>R</td></tr><tr><td>9</td><td>40</td></tr><tr><td>24.6</td><td>26.7</td></tr><tr><td>29.8</td><td>5.0</td></tr><tr><td>28.5</td><td>16.7</td></tr><tr><td>45.5</td><td>-23.3</td></tr><tr><td>53.2</td><td>n.a.</td></tr><tr><td>55.8</td><td>n.a.</td></tr><tr><td>LR<sub>50</sub> = 4133</td><td></td></tr><tr><td>g a.i./ha</td><td></td></tr></table>	M	R	9	40	24.6	26.7	29.8	5.0	28.5	16.7	45.5	-23.3	53.2	n.a.	55.8	n.a.	LR <sub>50</sub> = 4133		g a.i./ha		50%
M	R																									
9	40																									
24.6	26.7																									
29.8	5.0																									
28.5	16.7																									
45.5	-23.3																									
53.2	n.a.																									
55.8	n.a.																									
LR <sub>50</sub> = 4133																										
g a.i./ha																										

<sup>1</sup> indicate whether initial or aged residues

<sup>2</sup> for preparations indicate whether dose is expressed in units of a.s. or preparation

<sup>3</sup> indicate if positive percentages relate to adverse effects or not

## Tier 2 risk assessment for arthropods the in-field area

The most sensitive species tested was *T. pyri*, for which 96% of mortality was observed at application rates from 580 g as/ha to 6000 g as/ha, in an extended laboratory study. The in-field risk was expected as high for applications rates of 2 kg as/ha. However for *T. pyri* adverse effects of >50 % cannot be excluded for the off-field area (based on the worst case application rate of 2 kg a.s./ha). Further data are needed to demonstrate that in-field recovery/recolonisation is possible within one year for sensitive arthropod species such as *T. pyri* (data gap).

Field or semi-field tests
Field or semi-field studies are not required.

## Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point <sup>1</sup> (mg/kg)
Earthworms			
<i>Eisenia foetida</i>	Lime sulfur	Acute 14 days	LC <sub>50</sub> > 1000
<i>Eisenia foetida</i>		Chronic 8 weeks	No available
Other soil macro-organisms			
Soil mite	a.s. ‡		No available

Test organism	Test substance	Time scale	End point <sup>1</sup> (mg/kg)
	Preparation		No available
	Metabolite 1		No available
Collembola			
	a.s. ‡	Chronic	No available
	Preparation		No available
	Metabolite 1		No available
Soil micro-organisms			
Nitrogen mineralisation	Lime sulfur		< 25 % effect at day 28 at 36 kg a.s/ha (154 times PECsoil)
Carbon mineralisation	Lime sulfur		< 25 % effect at day 28 at 36 kg a.s/ha (154 times PECsoil)
Field studies <sup>2</sup>			
Not required			

<sup>1</sup> indicate where end point has been corrected due to log Pow >2.0 (e.g. LC<sub>50corr</sub>)

<sup>2</sup> litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

### Toxicity/exposure ratios for soil organisms

Test organism	Test substance	Time scale	Soil PEC <sup>2</sup>	TER	Trigger
Earthworms					
<i>Eisenia foetida</i>	Lime sulfur	Acute	1.33	> 751.9	10
	Metabolite 1	No relevant			10
Other soil macro-organisms					
Soil mite	a.s. ‡	No relevant			
	Preparation	No relevant			
	Metabolite 1	No relevant			
Collembola	a.s. ‡	No relevant			
	Preparation	No relevant			
	Metabolite 1	No relevant			

<sup>1</sup> to be completed where first Tier triggers are breached

<sup>2</sup> plateau PEC

### Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

#### Preliminary screening data

Not required for herbicides and fungicides as ER<sub>50</sub> tests should be provided

#### Laboratory dose response tests

Most sensitive species	Test substance	ER <sub>50</sub> (L/ha) <sup>2</sup> growth	ER <sub>50</sub> (g/ha) <sup>2</sup> emergence	Exposure <sup>1</sup> (g a.i/ha) <sup>2</sup>	TER	Trigger
6 species tested	Lime sulfur	> 150	not available	not relevant	Not relevant	

<sup>1</sup> explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)

<sup>2</sup> for preparations indicate whether dose is expressed in units of a.s. or preparation

Additional studies (e.g. semi-field or field studies)

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### Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	end point
Activated sludge	Not information available

**Ecotoxicologically relevant compounds** (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	Lime sulfur
water	Lime sulfur
sediment	Lime sulfur, further assessment required before H <sub>2</sub> S can be excluded.
groundwater	Lime sulfur

### Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

Lime sulfur

RMS/peer review proposal
N, R50

## ABBREVIATIONS

1/n	slope of Freundlich isotherm
$\varepsilon$	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT <sub>50</sub>	period required for 50 percent disappearance (define method of estimation)
DT <sub>90</sub>	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC <sub>50</sub>	effective concentration (biomass)
EC <sub>50</sub>	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER <sub>50</sub>	emergence rate/effective rate, median
ErC <sub>50</sub>	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)

GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography
HPLC-MS	high performance liquid chromatography – mass spectrometry
HQ	hazard quotient
ICP-OES	inductively coupled plasma - optical emission spectrometry
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K <sub>doc</sub>	organic carbon linear adsorption coefficient
kg	kilogram
K <sub>Foc</sub>	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC <sub>50</sub>	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD <sub>50</sub>	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MAK	maximum acceptable concentration
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level



OM	organic matter content
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC <sub>air</sub>	predicted environmental concentration in air
PEC <sub>gw</sub>	predicted environmental concentration in ground water
PEC <sub>sed</sub>	predicted environmental concentration in sediment
PEC <sub>soil</sub>	predicted environmental concentration in soil
PEC <sub>sw</sub>	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK <sub>a</sub>	negative logarithm (to the base 10) of the dissociation constant
P <sub>ow</sub>	partition coefficient between <i>n</i> -octanol and water
PPE	personal protective equipment
ppm	parts per million (10 <sup>-6</sup> )
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r <sup>2</sup>	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
t <sub>1/2</sub>	half-life (define method of estimation)
TER	toxicity exposure ratio
TER <sub>A</sub>	toxicity exposure ratio for acute exposure
TER <sub>LT</sub>	toxicity exposure ratio following chronic exposure
TER <sub>ST</sub>	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year