PRVD2009-05

Proposed Re-evaluation Decision

Lime Sulphur

(publié aussi en français)

9 February 2009

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

HC Pub: 8094

ISBN: 978-1-100-11819-2 (978-1-100-11820-8)
Catalogue number: H113-27/2009-5E (H113-27/2009-5E-PDF)

Table of Contents

Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the fungicide, insecticide and acaricide lime sulphur, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing the continued registration of products containing lime sulphur for the sale and use in Canada.

An evaluation of available scientific information found that products containing lime sulphur do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of lime sulphur uses, new risk-reduction measures must be included on the labels of all products. No additional data are being requested at this time.

This proposal affects all end-use products containing lime sulphur registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for lime sulphur and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of lime sulphur.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers the potential risks as well as value of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

[1] "Consultation statement" as required by subsection 28 (2) of the *Pest Control Products Act.*

Lime sulphur, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in a 2005 RED, the USEPA concluded that lime sulphur was eligible for reregistration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in this RED were an adequate basis for the proposed Canadian re-evaluation decision.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What Is Lime Sulphur?

Lime sulphur is a fungicide, insecticide and acaricide registered in Canada to control overwintering insects (e.g. scales, Aphid eggs, peach twig borer), mites (blister mites, rust mites, redberry mites) and fungal diseases (anthracnose, black knot, cane and spur blight, leafs curl, leaf and a cane spot, powdery mildew, fruit rot and scab). Both lime sulphur and its dissociation product, elemental sulphur, act as a fungicide. As an insecticide and acaricide, lime sulphur acts by softening the wax of scale insects. Commercially, lime sulphur is applied as a dormant spray using an airblast or groundboom application method. Homeowners can apply lime sulphur using hand-held equipment.

Health Considerations

Can Approved Uses of Lime Sulphur Affect Human Health?

Lime sulphur is unlikely to affect your health when used according to the revised label directions.

People could be exposed to lime sulphur by consuming food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors

when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that lime sulphur was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes by evaluating scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Lime sulphur is currently registered in Canada for use on fruit trees (apples, pears, peaches, plums, prunes, and cherries), berries (strawberries, blackberries, raspberries, loganberries, gooseberries, and currants), grapes and outdoor ornamentals, and could be used in other countries on crops that are imported into Canada. In Canada, no specific MRLs have been established for lime sulphur. Sulphur residues on food crops are exempted from paragraph 4(1)(d) of the *Food and Drugs Act* and Regulations, as outlined in Regulation B.15.002(2) of Division 15.

Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRLs are revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Lime Sulphur Is Introduced Into the Environment?

Lime sulphur is unlikely to affect non-target organisms when used according to the revised label directions.

Aquatic species could be exposed to lime sulphur in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effect endpoints of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of

concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of lime sulphur was acceptable and no risk-reduction measures were required. These conclusions apply to the Canadian situation. Furthermore, the PMRA will require aquatic buffer zones for the commercial end-use products containing lime sulphur to protect aquatic organisms from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of lime sulphur, the PMRA is proposing further risk-reduction measures for product labels.

Additional personal protective equipment for workers involved in handling lime sulphur products.

- A restricted-entry interval to protect workers entering treated sites.
- Buffer zones to protect non-target, sensitive aquatic species.

Next Steps

Before making a final re-evaluation decision on lime sulphur, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] that will include the decision, the reasons for it and a summary of comments received on the proposed decision and the PMRA's response to these comments.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Lime sulphur (SUS), also known as calcium polysulphide or calcium sulphide, is used as a fungicide, insecticide and acaricide. As a fungicide, lime sulphur acts directly and also by decomposition to elemental sulphur. As an insecticide and acaricide, lime sulphur acts by softening the wax of scale insects.

Following the re-evaluation announcement for inorganic polysulphides, which included one chemical, lime sulphur, the registrant of the technical grade active ingredient in Canada indicated their intention to support all uses included on the labels of commercial and domestic end-use products in Canada.

Given lime sulphur degrades rapidly to form calcium hydroxide and sulphur in the environment and in the human body, the PMRA used recent assessments of lime sulphur and sulphur from the USEPA as well as the in-house re-evaluation of sulphur (RRD2004-19) to re-evaluate lime sulphur.

The USEPA RED documents for inorganic polysulphides (2005) and sulphur (1991) and other information on the regulatory status of inorganic polysulphides in the United States can be found on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm. The Re-evaluation Decision Document for sulphur can be found on the PMRA page at healthcanada.gc.ca/pmra.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common Name	Lime sulphur, calcium polysulphide
Function	Fungicide, insecticide, acaricide
Chemical Family	Inorganic polysulphide
Chemical Name	
1 International Union of Pure and Applied Chemistry (IUPAC)	Calcium polysulphide
2 Chemistry Abstracts Service (CAS)	Calcium sulphide ($Ca(S_x)$) (x = 2–7)
CAS Registry Number	1344-81-6
Molecular Formula	CaS_x (x = 2–7)
Structural Formula	CaS_x (x = 2–7)
Molecular Weight	200.4 amu (average, primary calcium pentasulphide)

Purity of the Technical Grade Active Ingredient	29% MU (Registration Number 22873)
Registration Number	Technical grade registration expired as of 31 March 2008; the registration of technical grade active ingredient is currently being reinstated

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the *Canada Gazette*, Part II, Volume 139, No. 24, SI/2005-114 (30 November 2005), including TSMP Track 1 substances, are not expected to be present in the product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure	Not applicable
UV/Visible spectrum	Required–no data on file
Solubility in water	Present in aqueous solution, fully soluble above pH 8.5, unstable below pH 8.5
***n*-Octanol–water partition coefficient**	Not applicable
Dissociation constant	Not applicable

2.3 Comparison of Use Patterns in Canada and the United States

Lime sulphur is a fungicide, insecticide and acaricide registered in Canada to control overwintering insects (e.g. scales, Aphid eggs, peach twig borer), mites (blister mites, rust mites, redberry mites) and fungal diseases (anthracnose, black knot, cane and spur blight, leafs curl, leaf and a cane spot, powdery mildew, fruit rot, and scab). Both lime sulphur and its dissociation product, elemental sulphur, act as a fungicide. As an insecticide and acaricide, lime sulphur acts by softening the wax of scale insects.

Currently there are two commercial and four domestic products containing lime sulphur registered in Canada (see Appendix I, Table 1). Lime sulphur formulated as a solution is primary used as a dormant spray. Additional applications (prebloom, preharvest and postharvest) may be required to keep plants free from pests. Commercially lime sulphur is applied as an air blast or field spray, while homeowner may apply lime sulphur using hand-held equipment.

In Canada, lime sulphur is registered for:

- Commercial use on:
  - grapes at the maximum application rate of 33 kg a.i./ha; and
  - highbush blueberries at the maximum application rate of 16.5 kg a.i./ha.

- Commercial and domestic use on:
    - apples and pears at the maximum application rate of 34.5 kg a.i./ha;
    - peaches at the maximum application rate of 34.5 kg a.i./ha;
    - plums, prunes, cherries at the maximum application rate of 17.25 kg a.i./ha;
    - blackberries at the maximum application rate of 25.9 kg a.i./ha;
    - raspberries and loganberries at the maximum application rate of 12.1 kg a.i./ha;
    - gooseberries at the maximum application rate of 5.2 kg a.i./ha; and
    - strawberries at the maximum application rate of 17.25 kg a.i./ha.

For the domestic use, the maximum application rates are lower than the commercial rates and range from 3 g a.i./L on strawberries to 28.75 g/L on apples.

- Domestic use on:
    - currants at the maximum application rate of 23 g a.i./L, and
    - ornamentals at the maximum application rate of 23 g a.i./L.

The American and Canadian use patterns were compared. Canadian use sites are among those registered in the United States, with the exception of loganberries and strawberries. Canadian formulation types, application methods and rates as well as the number of applications per year are encompassed by the RED document.

Based on this comparison of use patterns, it was concluded that the USEPA RED for inorganic polysulfides is an adequate basis for the re-evaluation of Canadian uses of lime sulphur.

All current uses are being supported by the registrant(s) and were, therefore, considered in the re-evaluation of lime sulphur. Appendix I lists all lime sulphur products that are registered as of 2 September 2008 under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 2005 RED, the USEPA concluded that the end-use products formulated with lime sulphur met the safety standard under the American *Food Quality Protection Act* and would not pose unreasonable risks or adverse effects to humans and the environment if used according to the amended product labels.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

In Canada, exposure to lime sulphur may occur through consumption of food and water, through residential exposure, while working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, the PMRA considers two key factors: the levels at which no health

effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers).

3.1.1 Occupational Exposure and Risk Assessment

Workers can be exposed to lime sulphur when mixing, loading or applying the pesticide and when entering a treated site to conduct activities such as scouting and/or handling of treated crops.

3.1.1.1 Mixer/Loader/Applicator Exposure and Risk

No endpoints of toxicological concern for quantitative risk assessment were identified. Therefore, no occupational risk assessment was performed by the USEPA.

Based on current product labels for lime sulphur the USEPA required personal protective equipment consisting of coveralls over long-sleeved shirt and long pants, waterproof gloves, chemical resistant footwear, protective eyewear, chemical resistant headgear for overhead exposure, chemical resistant apron when cleaning equipment, mixing and loading, and a NIOSH-approved respirator.

The USEPA's conclusions regarding occupational exposure are considered relevant to the Canadian situation and similar mitigation measures are required by the PMRA at this time.

3.1.1.2 Postapplication Exposure and Risk

No toxicological endpoint of concern was identified. Therefore, no occupational postapplication risk assessment was performed by the USEPA. Given technical grade lime sulphur was classified by the USEPA as corrosive to eyes (toxicity category I), a 48-hour restricted-entry interval for all postapplication activities was required by the USEPA as per the Worker Protection Standard.

To further protect workers from postapplication exposure, a 48-hour restricted-entry interval is required by the PMRA. The proposed label amendment is listed in Appendix III.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

Homeowners can be exposed to lime sulphur when mixing, loading or applying the pesticide and when entering a treated site. Toddlers can be exposed via "hand-to-mouth" and "object-to-mouth" activities and through incidental soil ingestion.

Based on the fact that both lime sulphur degradation products did not represent unacceptable risk to human health, the USEPA did not perform the residential risk assessment. In addition, the USEPA determined, based on the toxicity data review for lime sulphur, calcium hydroxide and sulphur, that there was no evidence indicating increased sensitivity of infants and children to lime sulphur.

The RED for inorganic polysulfides adequately addressed Canadian lime sulphur use patterns; therefore inorganic polysulfides, the conclusions derived from this RED are considered applicable to the Canadian situation.

Based on the eye and skin hazard, precautionary label statements are proposed by the PMRA (see Appendix III).

3.1.2.2 Exposure from Food and Drinking Water

No toxicological endpoint of concern was identified by the USEPA. In the United States, both lime sulphur and calcium hydroxide are exempt from the requirement of a tolerance under 40 CFR 180.1232 and 40 CFR 180.910, respectively. In Canada, sulphur residues on food crops are exempted from paragraph 4(1)(d) of the *Food and Drugs Act* and Regulations, as outlined in Regulation B.15.002(2) of Division 15.

The USEPA performed a qualitative dietary risk assessment only. Based on the results for sulphur and calcium hydroxide indicating reasonable certainty of no harm to human health, the USEPA concluded that there was no dietary risk concern, whether from ingestion of food and/or water, for lime sulphur.

Based on rapid dissociation of lime sulphur in the environment and the human body to form calcium hydroxide and sulphur, runoff and/or leaching of lime sulphur into nearby water bodies were assumed by the USEPA to be negligible.

Consequently, no mitigation measure regarding exposure from food and drinking water was required by the USEPA.

3.1.2.3 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to lime sulphur, such as food, water and residential exposures (i.e. exposure of adults and toddlers to limes sulphur applied in residential setting, such as gardens).

The human risk, if any, from both dietary and residential exposures was considered by the USEPA to be low for both sulphur and calcium hydroxide. Consequently, the USEPA determined that aggregate human health risk, resulting from exposure to lime sulphur through food, drinking water and/or residential use, was not of concern.

Overall, the Canadian potential aggregate exposure was adequately addressed by the 2005 RED document and the USEPA's conclusions are considered relevant to the Canadian situation. No mitigation measures are required by the PMRA.

3.1.3 Cumulative Effects

The USEPA has not determined whether lime sulphur has a common mechanism of toxicity with other substances. Therefore, it was assumed that lime sulphur does not share a common mechanism of toxicity with other substance, and a cumulative risk assessment was not required.

3.1.4 Incident Reports

A search of the PMRA's database revealed a single minor incident report (Number 2008-2227) involving a homeowner applying an end-use product (dormant kit) containing lime sulphur on trees. The homeowner suffered nausea and a headache on the day following the application of lime sulphur. No medical treatment was required. Causality was not established.

3.2 Environment

The USEPA determined that the fate of lime sulphur as a pesticide was mostly dependent on the fate of its dissociation products, calcium hydroxide and sulphur. The USEPA found the following.

Lime sulphur was a highly alkaline (pH 11.5–11.8) and corrosive chemical, which once released into the moisture-rich environment would transform quickly into elemental sulphur and calcium ions.

Due to rapid dissociation of lime sulphur in the environment, runoff and/or leaching of the parent compound into nearby water bodies were expected to be negligible.

- As most terrestrial and aquatic environments contain high levels of sulphur, the modest amounts of sulphur resulting from use of lime sulphur were insignificant when compared to their respective natural background levels in the soil and water systems.

- Elemental sulphur was relatively immobile, highly insoluble and precipitated out of the solution.

- The fate of sulphur depended on the oxidation/reduction potential of the systems. Under oxidizing conditions, such as aerobic soil and surface water, sulphur was oxidized to sulphates, while under reducing conditions (anaerobic soils, anaerobic sediments, ground water) sulphur was reduced to form sulphides (hydrogen sulphide, bisulphide). However, the formation of hydrogen sulphide in the environment following lime sulphur application was considered highly unlikely due to the fact that the chance of sulphur entering the reducing environment would be very low.

- Lime sulphur is not expected to affect the pH of water systems because of the buffering capacities of natural systems. However, it may cause small increase in the pH of small water body which possess a low buffering capacity. Although small changes in the pH would not directly affect aquatic life, it may influence the availability and solubility of all chemical forms and, consequently, aggravate nutrition problems.

3.2.1 Environmental Risk Assessment

To assess the ecological risk of lime sulphur to both terrestrial and aquatic non-target plants and animals, the USEPA calculated risk quotients (RQs) based on appropriate toxicity endpoints and expected environmental concentrations (EECs) and compared the resulting RQs to corresponding levels of concern (LOCs).

Based on toxicity studies, lime sulphur was found by the USEPA to be:

- highly toxic to freshwater fish with a 96-hour LC_{50} of 0.97 mg a.i./L;
- moderately toxic to freshwater invertebrates with a 48-hour LC_{50} of 2.9 mg a.i./L for water flea;
- slightly toxic to algae with the a 120-hour EC_{50} of 14.1 mg/L;
- moderately toxic to mammals with a LD_{50} of 86.63 mg a.i./kg body weight for male rats (gavage-dose);
- slightly toxic to birds with an LD_{50} of 560 mg a.i./kg diet for bobwhite quail (gavage-dose);
- not toxic to honey bees (LD_{50} >25 g a.i./bee); and
- possibly phytotoxic to plants (based on the observation studies).

Although lime sulphur can be applied multiple times per year, multiple applications would not result in accumulation of the parent compound in the environment due to rapid dissociation of lime sulphur to sulphur and calcium. Therefore, only acute exposure of aquatic and terrestrial ecosystems to lime sulphur was estimated by the USEPA.

The AgDRIFT spray drift model (a model for estimating near-field spray drift from aerial applications) was used by the USEPA to estimate the fraction of lime sulphur that may be released indirectly to a water body following an air blast application of lime sulphur on grapes (68.9 kg a.i./ha). The peak EEC in surface water was 0.0007 ppm.

The results of the USEPA's acute risk assessment for the aquatic species indicated that the acute aquatic LOC (LOC of 0.5) was not exceeded for freshwater invertebrates (RQ of 0.00022), freshwater fish (RQ of 0.0007), non-listed algae (RQ of 0.00005) or for listed algae (RQ of 0.001).

The Terrestrial Residue Exposure (T-REX) model was used by the USEPA to estimate pesticide concentration on the surface of different types of foliage that may serve as a food source for terrestrial animals, following a single application of lime sulphur on apples (38 kg a.i./ha). The results of the USEPA's acute risk assessment for the terrestrial species indicated the following.

- The acute LOC (LOC of 0.5) was exceeded for all size birds feeding on all forage categories (RQ 0.92 to 23.34), except for 1000 g birds feeding on seeds (RQ of 0.26).

- The acute mammalian LOC (LOC of 0.5) was exceeded for all size mammals feeding on all forage categories (RQ 0.56 to 40.49), except for 35 g and 1000 g mammals feeding on seeds (RQ 0.49 and 0.23, respectively).

However, taking into consideration that mortality observed in gavage-dosed rats and birds was due to corrosive effects of lime sulphur (pH 10.9–11.9) on the lining of the gastrointestinal tract and no mortality was observed (even at the highest doses) when birds were fed with lime sulphur incorporated into the diet, the USEPA determined the exposure of birds and mammals to lime sulphur in the environment was not of concern.

The American use pattern encompasses the Canadian use of lime sulphur and conclusions derived by the USEPA are considered relevant to the Canadian situation. The USEPA did not require any additional mitigation measures specifically to address the risk to the environment. Consequently, based on the RED for inorganic polysulfides, no additional mitigation measures are required by the PMRA.

Aquatic buffer zones were calculated by the PMRA to minimize spray drift to non-target species during ground application; Appendix II and III show the buffer zone calculations and required label statements, respectively.

3.2.2 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the 1995 federal Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

The federal Toxic Substances Management Policy and PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, were taken into account during the re-evaluation of lime sulphur. The PMRA has reached the following conclusions.

- Lime sulphur is not bioaccumulative. Lime sulphur is not persistent, and it dissociates rapidly in the environment to form calcium hydroxide and sulphur. Lime sulphur does not meet all Track 1 criteria; thus, it is not a candidate for Track 1 classification.

- Based on a review of the available chemistry information (see Section 2.1), the technical product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive DIR98-04 or TSMP Track 1 substances as identified in Regulatory Directive DIR99-03, Appendix II.

No other impurities of toxicological concern (as identified in Regulatory Directive DIR98-04, Section 2.13.4) or TSMP Track1 substances (as identified in Regulatory Directive DIR99-03, Appendix II) are expected to be present in the technical product of lime sulphur.

Formulant issues are being addressed through PMRA formulant initiatives and Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document,* published on 31 May 2006.

4.0 OECD Status of Lime Sulphur

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 30 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies. They compare experiences, share information and analyses, seek answers to common problems, and work to co-ordinate domestic and international policies to allow for consistency in practices across nations.

Based on the current available information on the status of lime sulphur in other OECD member countries, it appears to have been assessed by the European Food Safety Authority and is included in Annex I of Directive 91/414/EEC as a fungicide, insecticide and acaricide. However, the final decision is still pending.

As described earlier in this document, the United States, also an OECD member, assessed the registration of all uses of lime sulphur in 2005 and concluded that using lime sulphur as a pesticide does not result in unreasonable adverse effects to human health or the environment.

In addition, the Canadian re-evaluation of lime sulphur is largely based on the 2005 USEPA assessments and includes additional assessments if applicable. As described in Sections 3.1 and 3.2 above, the PMRA has found the USEPA environmental and/or human health risk conclusions to be relevant to the use of lime sulphur in Canada and requires measures to mitigate risk to human health and the environment (see Appendix III).

5.0 Proposed Re-evaluation Decision

The PMRA has determined that lime sulphur (calcium polysulphide) is acceptable for continued registration with the implementation of the proposed risk-reduction measures:

- additional personal protective equipment for workers involved in handling lime sulphur products;
- a restricted-entry interval to protect workers re-entering treated sites; and
- buffer zones to protect non-target, sensitive aquatic species.

These measures are required to further protect human health and the environment. The labels of Canadian end-use products must be amended to include the label statements listed in Appendix III. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

6.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and data code (DACO) tables can be found on our website at www.pmra-arla.gc.ca. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra_infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED documents for inorganic polysulphides and sulphur are available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

List of Abbreviations

µg	microgram
bw	body weight
CAS	Chemical Abstracts Service
DACO	data code
EC_{50}	effective concentration to 50%
EEC	expected environmental concentration
g	gram(s)
ha	hectare
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
L	litre(s)
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
LOC	level of concern
mg	milligram(s)
MRL	maximum residue limit
OECD	Organisation for Economic Co-operation and Development
pH	-log10 hydrogen ion concentration
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
RED	Reregistration Eligibility Decision
RVD	Re-evaluation Decision
RQ	risk quotient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Registered Calcium Polysulphides Products as of 2 September 2008

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
6335	Domestic	Sure-Gro IP Inc.	Later's Lime Sulphur Solution	Solution	22%
7386	Domestic	Sure-Gro IP Inc.	C-I-L Mother Earth Lime Sulphur Concentrate	Solution	23%
7386.06	Domestic	Sure-Gro IP Inc.	Green Earth Lime Sulphur Concentrate	Solution	23%
16465	Commercial	United Agri Products Canada Inc.	Lime Sulphur Insecticide, Miticide, Fungicide	Solution	22%
22873	Technical[1]	Value Garden Supply (SURENCO Inc.)	SureGuard Lime Sulphur Technical Insecticide, Miticide, Fungicide	Solution	29%
23782	Domestic	Sure-Gro IP Inc.	Wilson Liquid Lime Sulphur (1)	Solution	23%
25356	Commercial	Agrium Advanced Technologies RP Inc.	Wilson Professional Lime Sulphur	Solution	23%
27978	Domestic	Superior Control Product Inc.	Lime Sulphur	Solution	23%

[1] The technical class product expired 31 March 2008. Registration is currently being reinstated.

Appendix II Inputs to Buffer Zone Models

Ground Use Data (from Canadian labels)				
Crop	**Formulation Type**	**Method of Application**	**Number of Applications**	**Maximum Application Rate (g a.i./ha)**
Apples/pears/peaches	Solution	Early air blast	3	34 500
		Late air blast	3	34 500
Plums/prunes/cherries	Solution	Early air blast	1	17 250
		Late air blast	1	17 250
Blackberries	Solution	Early air blast	2	25 875
		Late air blast	2	25 875
		Field spray	2	25 875
Blueberries (highbush)	Solution	Early air blast	1	16 500
		Late air blast	1	16 500
		Field spray	1	16 500
Raspberries//oganberries	Solution	Early air blast	1	12 075
		Late air blast	1	12 075
		Field spray	1	12 075
Gooseberries	Solution	Early air blast	2	5175
		Late air blast	2	5175
		Field spray	2	5175
Strawberries	Solution	Field spray	2	5175
Grapes	Solution	Early air blast	1	33 000
		Late air blast	1	33 000

Model Input Data for Aquatic Buffer Zones (from 2005 RED)		
Half-life for aquatic buffer zones	Aerobic whole system	1 day
Most sensitive freshwater species	Rainbow trout	LC_{50} = 0.97 mg/L
Most sensitive estuarine/marine species	N/A	N/A

Model Input Data for Terrestrial Buffer Zones (from 2005 RED)		
Half-life for terrestrial buffer zones	Aerobic soil	1 day
Most sensitive terrestrial plant species	N/A	N/A

Appendix III Label Amendments for Products Containing Lime Sulphur

I) The labels of commercial end-use products in Canada must be amended to include the following statements in the section entitled **PRECAUTIONS.**

Commercial Products

On the principal display panel: **DANGER—CORROSIVE TO EYES**

On the secondary display panel:

> All workers involved in handling lime sulphur products must wear personal protective equipment consisting of: coveralls over long-sleeved shirt and long pants, waterproof gloves, chemical-resistant footwear, protective eyewear, chemical resistant headgear for overhead exposure. In addition, a chemical resistant apron and NIOSH-approved respirator are required when cleaning equipment, mixing and loading.
>
> Do not re-enter or allow the re-entry into treated areas until 48 hours after application.

II) The labels of commercial end-use products in Canada must be amended to include the following statement in the section entitled **ENVIRONMENTAL HAZARDS.**

> **TOXIC** to aquatic organisms. Observe buffer zones specified under **DIRECTIONS FOR USE**.

III) The labels of commercial end-use products in Canada must be amended to include the following statement in the section entitled **DIRECTIONS FOR USE.**

> Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) fine classification. Boom height must be 60 cm or less above the crop or ground.
>
> Air blast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.
>
> **DO NOT** apply by air.

IV) The labels of commercial end-use products in Canada must be amended to include the following statement in the section entitled **Buffer zones.**

Use of the following spray methods or equipments **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:			
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:	
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Field sprayer*	Strawberries Gooseberries		3	1	1	1
	Raspberries Loganberries Blueberries (highbush)		5	1	1	1
	Blackberries		10	1	3	1
Airblast	Raspberries Loganberries	Early growth stage	30	5	15	5
		Late growth stage	25	3	5	3
	Plums, Prunes, Cherries Blueberries (highbush)	Early growth stage	35	10	20	10
		Late growth stage	25	4	10	4
	Blackberries	Early growth stage	40	15	25	15
		Late growth stage	30	5	15	5

	Apples, Pears, Peaches, Grapes	Early growth stage	40	15	25	15
		Late growth stage	30	10	15	10
	Gooseberries	Early growth stage	25	2	5	2
		Late growth stage	15	1	3	1

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of the finalization of the re-evaluation decision.

References

A. List of Studies/Information Submitted by Registrant

List of references from Chemistry Input RCES PMRA#1606956

PMRA 11440433 Technical Chemistry File -Description of beginning materials and manufacturing process, DACO: 2.11,2.11.2,2.11.3,2.11.4 CBI.

PMRA 11440434 1992, Calcium Polysulfide - Product Chemistry, not assigned, DACO: 2.12.1,2.13.3 CBI.

PMRA 1440433 Technical Chemistry File - Impurities of Toxicological Concern, Description of beginning materials and manufacturing process, DACO: 2.11,2.11.2,2.11.3,2.11.4 CBI.

PMRA 11440436 1991, Calcium Polysulfide - Product Chemistry, not assigned, DACO: 2.14, 2.14.1, 2.14.10, 2.14.2, 2.14.3, 2.14.5, 2.14.6, 2.14.7, 2.14.9

PMRA 11440438 1992, Accelerated stability Stability of Lime Sulphur Solution, 917003.3A, DACO: 2.14.13,2.14.14 CBI.

PMRA 11440439 1992, Stability study of Lime Sulphur Solution, 917003.3A, DACO: 2.14.13,2.14.14 CBI.

B. Additional Information Considered

2004 Re-evaluation of Sulphur. PMRA. PACR 2004-10 (This Proposed Acceptability for Continued Registration document can be found on the PMRA page at: www.pmra-arla.gc.ca).