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Re-evaluation Decision

Lime Sulphur

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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 granting continued registration of products containing lime sulphur for 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.

The regulatory approach for the re-evaluation of lime sulphur was first presented in the consultation document[1] Proposed Re-evaluation Decision PRVD2009-05, *Lime Sulphur*. This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of lime sulphur as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2009-05. To comply with this decision, registrants of products containing lime sulphur will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

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

The PMRA's pesticide re-evaluation program considers 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.

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 regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

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

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

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of lime sulphur. In this decision, the PMRA took into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy).

The USEPA re-evaluated lime sulphur and published its conclusions in a 2005 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the Proposed Re-evaluation Decision PRVD2009-05, *Lime Sulphur*.

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 through consumption of 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 through the evaluation of 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 or 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, blueberries (highbush), gooseberries, and currants), grapes and outdoor ornamentals, and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for lime sulphur in Canada.

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 Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is 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 effects endpoint 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 low 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 requiring further risk-reduction measures for product labels.

Human Health

- A restricted-entry interval to protect workers entering treated sites.

Environment

- Buffer zones to protect non-target, sensitive aquatic species.

Appendix I lists all required label amendments.

Other Information

Any person may file a notice of objection[3] regarding this decision on lime sulphur within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Health Canada website, Request a Reconsideration of Decision, or contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act.*

Appendix I Label Amendments for Products Containing Lime Sulphur

The label amendments presented below 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 label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following statements must be included in the **PRECAUTIONS** section.

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 following statements must be included in the **ENVIRONMENTAL HAZARDS** section.

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

III) The following statements must be included in the **DIRECTIONS FOR USE** section.

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
Air blast	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.