



Proposed Acceptability for Continuing Registration

PACR2004-10

Re-evaluation of Sulphur

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of sulphur. The PMRA has determined that sulphur is acceptable for continued registration provided that the proposed mitigation measures are adopted and the data requirements are addressed.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for 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 the Publications Coordinator at the address below.

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1.0 Background

The PMRA is re-evaluating all pesticides, both active ingredients and formulated end-use products (EPs), that were registered prior to 31 December 1994 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Sulphur has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in DIR2001-03. Under Program 1, the PMRA relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents, to assess Canadian pest control products. For products to be re-evaluated under Program 1, there must exist a suitable foreign review that meets the following conditions:

- it covers the main science areas that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient itself and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of the USEPA review, the PMRA will propose, under Program 1, a regulatory decision and appropriate mitigation measures for Canadian uses of an active ingredient.

The USEPA conducted a re-evaluation of sulphur and concluded, on the basis of a health and environmental risk assessment, that it was eligible for reregistration with implementation of mitigation measures. The PMRA conclusions on the sulphur re-evaluation were based on the USEPA RED¹ document for sulphur, with consideration of the Canadian use pattern and Canadian issues (e.g., the Canadian Toxic Substance Management Policy [TSMP]).

¹ The USEPA RED document for sulphur (May 1991) is available from the Chemical Status List on the Office of Pesticide Programs webpage at www.epa.gov/pesticides/reregistration

2.0 Re-evaluation of sulphur

Active substance:	Sulphur
Common name:	Sulphur
CAS number:	7704-34-9
Purity of active:	99.0–99.9%

Sulphur was first registered in Canada in 1927. It is used as a fungicide, insecticide and acaricide for commercial and domestic crops, and as a rodenticide in a domestic setting. Currently registered uses include the following:

- commercial uses – agricultural outdoor crops, greenhouse vegetable crops, animals, animal beddings as well as animal housing cracks and crevices; and
- domestic sites – ornamentals, fruits, vegetables, outdoor structures and vertebrate burrows.

The Canadian products containing sulphur registered as of 31 December 2003 are listed in Appendix I.

Canadian registered use sites, application rates, application methods and formulation types are also registered in the United States, and the USEPA assessment described in the RED document for sulphur is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the health and environmental risk assessments conducted by the USEPA are outlined in the RED for sulphur.

The federal TSMP² and Regulatory Directive DIR99-03³ were taken into consideration during the review of sulphur, and it was determined that sulphur is not a TSMP Track 1 substance. The technical product is not expected to contain impurities of toxicological concern as identified in DIR98-04 or TSMP Track 1 substances as identified in Appendix II of DIR99-03.

² The federal Toxic Substances Management Policy is available through Environment Canada's website at www.ec.gc.ca/toxics

³ *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, Dir99-03, is available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or (613) 736-3799 outside Canada (long distance charges apply); Fax: (613) 736-3798; E-mail: pmra_infoserv@hc-sc.gc.ca or through our website at www.hc-sc.gc.ca/pmra-arla

3.0 Proposed re-evaluation decision

The USEPA published a RED document for sulphur, addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document also addressed uses of sulphur that are also registered in Canada. Based on the USEPA RED and Canadian use patterns, the PMRA has determined that sulphur is acceptable for continued registration provided that the mitigation measures specified below are adopted and the data requirements outlined in this document are addressed.

It should be noted that EPs that contain several active ingredients under re-evaluation will not be considered acceptable for continued registration until the re-evaluation of all active ingredients is complete.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision for these products.

4.0 Proposed regulatory action

Based on the USEPA RED and in consideration of the Canadian use pattern, Canadian EP labels should be amended to include the following statements:

- 1) For commercial EPs used on field crops:

In the “Precautions” section,

- “Wear goggles or a face shield, chemical-resistant gloves, a hat, a long-sleeved shirt, long pants and rubber boots during mixing/loading, application, clean-up and repair activities.”
- “Do not enter or allow workers to enter into treated areas until 24 hours after application.”

In the “Directions for Use” section,

- “Do not apply more than 8 applications per season.”
- “Do not apply during periods of dead calm or when winds are gusty.”

- “For airblast application: “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.”

As for buffer zones, they are indicated in Table 4.1 below. This table specifies the buffer zones that are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Table 4.1 Buffer zones required for the protection of aquatic habitats

Application method	Crop	Buffer zone (metres) required for the protection of aquatic habitat
Field sprayer	Pea	0
Airblast	Gooseberry Currant Sweet cherry Sour cherry Plum Peach Apple Pear Prune Grape	5
	Rutabaga Rose	0

- 2) For commercial EPs used in greenhouses on bell peppers, tomatoes and cucumbers:

In the “Precautions” section,

- “Wear goggles or a face shield, a NIOSH-approved respirator, chemical-resistant gloves, a hat, a long-sleeved shirt, long pants and rubber boots during mixing/loading, application, clean-up and repair activities.”
- “Do not enter or allow workers to enter into treated areas until 24 hours after application.”

- 3) For commercial EPs used on livestock:

In the “Precautions” section,

- “Wear long pants, a long-sleeved shirt and chemical-resistant gloves during application.”

- 4) For all EP labels:

In the “Environmental Hazards” section,

- “Do not apply directly to aquatic habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs, and wetlands) and estuarine/marine habitats. Do not contaminate water by cleaning equipment or disposing of wastes.”

- 5) The product, Registration Number 23171, is used on roses. This label should be modified to specify whether this is also used in greenhouses.

The label amendments presented above do not include all label requirements for individual EPs, 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 is required within 90 days of finalization of the re-evaluation decision.

The registrants of EPs that are not associated with a registered technical grade active ingredient (TGAI) are required to submit a request to register a technical source. This is required within 24 months of finalization of the re-evaluation decision.

5.0 Additional data requirements

The registrants of the TGAI sulphur are required to submit the following within 24 months of finalization of the re-evaluation decision:

- all data (as they relate to Canadian use patterns) submitted to the USEPA in response to the United States data call-in prior to the United States reregistration, and USEPA Data Evaluation Reports (DERs);
- Canadian requirements that are not addressed through submission of the data outlined above. This can be addressed by submitting a comprehensive summary on the health and safety information available for sulphur. The summary should be based on a contemporary literature review and any available studies conducted on sulphur. Scientifically based waivers and rationales to address any of the data elements may be added.

Appendix I Canadian sulphur products currently registered (as of 31 December 2003)

Registrant	Class*	Guarantee	Product name	Registration number
BASF Canada Inc.	T	99%	BASF Technical Kumulus	18569
Holly Industries	T	99.9%	Hollysul Technical Sulphur	21779
Bartlett, N.M. Inc.	C	92%	Bartlett Microscopic Wettable Sulphur	873
Schering-Plough Animal Health	C	Sulphur 10% Rotenone 0.15%	Dri-Kill Dust	10043
United Agri Products	C	92%	Microscopic Sulphur Fungicide	14653
BASF Canada Inc.	C	80%	BASF Kumulus DF Fungicide Water Dispersable Granular	18836
Later Chemicals Ltd.	D	90%	Later's Garden Sulphur Fungicide	5293
Later Chemicals Ltd.	D	Sulphur 50% Methoxychlor 5% Rotenone 0.75% Zineb 4.5%	Later's Rose & Floral Dust Insecticide-fungicide	9704
Merzat Ind.	D	82.4 litres of gaseous oxides of sulphur released/ cartridge	The Giant Destroyer	12269
Nu-Gro IP Inc.	D	Carbaryl 5% Copper 5% Malathion 2% Sulphur 20%	Wilson Rose & Flower Dust	18632
Woodstream Canada Corporation	D	0.40%	Safer's Defender Natural Garden Fungicide	19061
Woodstream Canada Corporation	D	0.40%	Safer's Liquid Sulphur Fungicide R.T.U.	19451
Woodstream Canada Corporation	D	12.0%	Safer's Natural Garden Fungicide	19691
Woodstream Canada Corporation	D	92.0%	Safer's Sulphur Dust Fungicide Miticide	19703
Woodstream Canada Corporation	D	0.40%	Safer's Defender Garden Fungicide	20812
Nu-Gro IP Inc.	D	0.9%	Green Earth Garden Fungicide/Miticide	21880
Nu-Gro IP Inc.	D	92%	Green Earth Garden Sulphur Fungicide/Miticide	21890
Nu-Gro IP Inc.	D	92%	C-I-L Mother Earth Garden Sulphur Fungicide/Miticide	24180

*T = Technical; D = Domestic; C = Commercial