



Proposed Acceptability for Continuing Registration

PACR2004-04

Re-evaluation of Soap Salts

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

This Proposed Acceptability for Continuing Registration document provides a rationale for the proposed regulatory decision for soap salts. 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 General background on re-evaluation

The PMRA is re-evaluating all pesticides, both active ingredients and formulated end-use products, 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.

Soap salts have been re-evaluated by the PMRA under Re-evaluation Program 1 as described in Regulatory Directive DIR2001-03. In 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, such as human health and the environment, that are necessary for Canadian regulatory decisions; it addresses the active ingredient itself and its main formulation types registered in Canada; and it is relevant to registered Canadian uses. Based on the outcome of the foreign 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 soap salts and concluded, on the basis of a health and environmental risk assessment, that they were eligible for reregistration with implementation of mitigation measures. These conclusions were published in a RED¹ document for soap salts. In its re-evaluation of soap salts, the PMRA based its conclusions on this RED document, taking into account the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substances Management Policy).

2.0 Re-evaluation of soap salts

Common/Chemical name: Soap Salts (potassium salts of fatty acids [potassium laurate, potassium myristate, potassium oleate, potassium linolenate and potassium palmitate], alkanolamine salts of fatty acids [triethanolamine oleate], ammonium salts of fatty acids [ammonium oleate])

CAS registry number: Not available; these products are mixtures

¹ The USEPA Reregistration Eligibility Decision (RED) document for soap salts is available from the Chemical Status List on the Office of Pesticide Programs Web page at www.epa.gov/pesticides/reregistration

Soap salts were first registered in Canada in 1939. Soap salts are registered for commercial and domestic use as insecticides, acaricides, animal repellants, herbicides and algicides on fruits and vegetables, houseplants, ornamental flowers, trees and shrubs, companion animals, patios, decks and roofs. Thirty-nine end-use products (EPs) are registered in Canada, along with five technical grade active ingredients (TGAI) and one manufacturing concentrate. Soap salts are in liquid form in concentrations of 17 to 50.5% fatty acids, and in ready-to-use liquid sprays with 0.85 to 2.0% fatty acids. Some products contain 0.01% or 0.2% pyrethrins as a second active ingredient. A list of currently registered products containing soap salts is presented in Appendix I.

Use sites, application rates, application methods and formulation types for soap salts registered in Canada are also registered in the United States. The alkanolamine salts of fatty acids are registered in Canada, but these are not specifically addressed in the RED document for soap salts. However, this document is considered to be an adequate basis for the proposed Canadian re-evaluation decision for all Canadian soap salts based on the following:

- use sites and target pests are similar between alkanolamine salts and potassium and ammonium salts;
- all soap salts under re-evaluation are saponified fatty acids between C₈ and C₁₈ and share chemical similarities; and
- soap salts are generally considered to be of low risk (i.e., low acute toxicity and low application rate).

The USEPA health and environmental risk assessments are presented in the RED for soap salts.

The federal Toxic Substances Management Policy (TSMP)² and Regulatory Directive DIR99-03³ were taken into consideration during the re-evaluation of soap salts. The re-evaluation determined that soap salts are not a TSMP Track 1 substance.

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

³ PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, 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 RED document for soap salts published by the USEPA addresses the main science areas that are necessary for Canadian regulatory decisions. This document also addressed uses of soap salts that are registered in Canada. Based on the USEPA RED and in consideration of the Canadian use pattern, the PMRA has determined that soap salts are acceptable for continued registration provided that the mitigation measures specified below are adopted and the data requirements outlined in this document are addressed.

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

The Canadian registrants are required to modify labels of end-use products as follows.

- In the “Environmental Hazard” section of all commercial soap salts labels, the following statement should be added: “This product is toxic to aquatic organisms. Do not allow waste water, effluent or runoff containing this product to enter lakes, streams, ponds or other waters.”
- Labels for products used on companion animals must be modified to comply with Regulatory Directive DIR2002-01, *Canadian Label Improvement Program for Pesticides Used on Companion Animals*⁴.

The active ingredient statement on the labels for technical grade and end-use products must identify the type of soap salts (e.g., ammonium salts of fatty acids, potassium salts of fatty acids or alkanolamine salts of fatty acids).

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

⁴ PMRA Regulatory Directive DIR2002-01, *Canadian Label Improvement Program for Pesticides Used on Companion Animals*, 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/

5.0 Canadian data requirements

The registrants of TGAI's are required to submit the following within 24 months of finalization of the re-evaluation decision.

- All data (as they relate to Canadian use pattern) submitted to the USEPA in response to the data call-in in the United States prior to reregistration, and USEPA Data Evaluation Reports (DERs).
- All data (as they relate to Canadian use pattern) required by the USEPA as a condition of reregistration of soap salts.

The registrant will be required to prepare and submit a comprehensive summary on the health and safety information available for the active ingredient. The summary should be based on a contemporary literature review and any available studies conducted on the active ingredient. It is recommended that the document be organised in accordance with the scientific elements addressed by the DACOs for toxicology and human exposure. As per normal practice, the PMRA will accept for review, sound, scientifically based waivers and rationales to address any of the data elements.

Appendix I Current Canadian registered products containing soap salts

Registrant	Registration number	Salt*	Guarantee	Product name	Formulation	Class
Duxon Aps	26470	P	0.85%	Purus Insecticide	Solution	Domestic
Woodstream Canada Corp.	20562	P	1%	Safer's Vegetable Garden Insecticide	Solution	Domestic
Woodstream Canada Corp.	20563	P	1%	Safer's Trounce Yard & Garden Insecticide	Solution	Domestic
Woodstream Canada Corp.	20565	P	1%	Safer's Trounce Houseplant Insecticide (Natural)	Solution	Domestic
Woodstream Canada Corp.	22300	P	1%	Safer's Trounce Insecticide Ready-to-Use	Solution	Domestic
Woodstream Canada Corp.	23047	P	1%	Safer's Entire Flea & Tick Spray	Solution	Domestic
Woodstream Canada Corp.	25333	P	1%	Safer's Trounce Houseplant Insect Killer	Solution	Domestic
Nu-Gro IP Inc.	21112	A	1.25%	Green Earth Ready-to-Spray Insecticidal Soap	Solution	Domestic
Nu-Gro IP Inc.	21113	A	1.25%	Green Earth Indoor Insecticidal Soap	Solution	Domestic
S.C. Johnson & Son Ltd.	21916	A	1.25%	Raid Insecticidal Soap	Solution	Domestic
Wilson Laboratories Inc.	25260	A	1.25%	C-I-L Mother Earth Insect Soap product discontinued Dec. 2001, registered until Dec. 2004	Solution	Domestic
Woodstream Canada Corp.	18355	P	1.5%	Safer's Rose & Flower Insecticide R.T.U. (Natural)	Solution	Domestic
Woodstream Canada Corp.	20793	P	1.5%	Safer's Rose & Flower Insecticide (Natural)	Solution	Domestic
Woodstream Canada Corp.	16561	P	2%	Safer's Insecticidal Soap for Houseplants (Natural)	Solution	Domestic
Scotts Canada Ltd.	16607	P	2%	Insecticidal Soap for Flowers & Vegetables	Solution	Domestic

Registrant	Registration number	Salt*	Guarantee	Product name	Formulation	Class
Woodstream Canada Corp.	18141	P	2%	Safer's De-moss Moss Killer (For Structural Surfaces)	Solution	Domestic
Woodstream Canada Corp.	19444	P	2%	Safer's Aphid & Whitefly Killer Natural (R.T.U.)	Solution	Domestic
Woodstream Canada Corp.	19445	P	2%	Safer's Spider Mite Spray (Natural)	Solution	Domestic
Woodstream Canada Corp.	22772	P	2%	Safer's Multi-Purpose Insecticidal Soap	Solution	Domestic
Woodstream Canada Corp.	23651	P	2%	Safer's Insecticidal Soap	Solution	Domestic
Duxon Aps	26472	P	17%	Purab Insecticide	Solution	Commercial
Plant Products Co. Ltd.	26864	P	17%	Buds Insecticidal Soap	Solution	Commercial
Duxon Aps	26471	P	17%	Bio-Dux Insecticide Technical	Solution	Technical
Woodstream Canada Corp.	24363	P	20%	Safer's Trounce Insecticide Concentrate	Solution	Commercial
Woodstream Canada Corp.	20564	P	20%	Safer's Trounce Yard & Garden Insecticide	Solution	Domestic
Woodstream Canada Corp.	20566	P	20%	Safer's Natural Houseplant Insecticide Concentrate	Emulsifiable Concentrate or Emulsion	Domestic
Woodstream Canada Corp.	22299	P	20%	Safer's Trounce Insecticide Concentrate	Solution	Domestic
Nu-Gro IP Inc.	21111	A	25%	Green Earth Organic Insecticidal Soap Concentrated	Solution	Domestic
Nu-Gro IP Inc.	21321	A	25%	Green Earth Insecticidal Soap Hose Spray	Solution	Domestic
Nu-Gro IP Inc.	21110	A	25%	Wilson 25% Insecticidal Soap Technical	Solution	Technical
Woodstream Canada Corp.	17307	P	25.20%	Safer's Flea Soap for Dogs	Solution	Domestic
Woodstream Canada Corp.	17709	P	25.20%	Safer's Flea Soap for Cats	Solution	Domestic

Registrant	Registration number	Salt*	Guarantee	Product name	Formulation	Class
Woodstream Canada Corp.	22201	P	25.20%	Safer's Insecticidal Flea Soap	Solution	Manufacturing Concentrate
Woodstream Canada Corp.	18418	U	40%	Safer's De-moss Moss Killer Herbicide	Solution	Domestic
Woodstream Canada Corp.	17102	U	40%	Safer's De-Moss Structural Moss & Algae Killer	Solution	Commercial
Woodstream Canada Corp.	17103	U	40%	Safer's De-Moss Structural Moss & Algae Killer	Solution	Domestic
Woodstream Canada Corp.	18416	U	40%	Safer's De-Moss For Lawns Concentrate	Solution	Commercial
Nu-Gro IP Inc.	22714	A	50%	Wilson 50% Technical Insecticidal Soap	Solution	Technical Active
Woodstream Canada Corp.	14669	P	50.50%	Safer's Insecticide Soap (Agricultural)	Solution	Commercial
Woodstream Canada Corp.	14668	U	50.50%	Safer's Insecticidal Soap Concentrate	Solution	Domestic
Woodstream Canada Corp.	19929	P	50.50%	Safer's Rose & Flower Insecticide	Solution	Domestic
Woodstream Canada Corp.	22208	P	50.50%	Safer's Insecticidal Soap Concentrate	Solution	Domestic
Woodstream Canada Corp.	22182	P	50.50%	Safer's Insecticidal Soap	Solution	Technical
Nu-Gro IP Inc.	21166	AM	0.75%	Ready-Spray Animal Repellant	Solution	Domestic
Pace International	26626	AM	13.8%	Hinder	Solution	Technical

* AM = ammonium salts of fatty acids, P = potassium salts of fatty acids, U = unknown salts of fatty acids (labelled soap), A = Alkanolamine salts of fatty acids