



Proposed Acceptability for Continuing Registration

PACR2004-05

Re-evaluation of Fosamine Ammonium

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

This Proposed Acceptability for Continuing Registration document provides a rationale for the proposed regulatory decision for fosamine ammonium. 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 (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.

Fosamine ammonium has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in DIR2001-03. Under Program 1, PMRA relies as much as possible on foreign reviews, typically a 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 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.

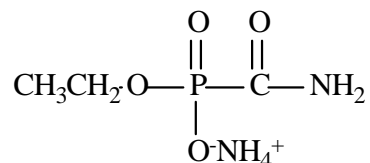
The USEPA conducted a re-evaluation of fosamine ammonium and concluded, on the basis of a health and environmental risk assessment, that it was eligible for reregistration with implementation of mitigation measures. PMRA conclusions on the fosamine ammonium re-evaluation were based on the 1995 USEPA RED¹ document for fosamine ammonium, with consideration of the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substances Management Policy [TSMP]). A review of the chemistry of Canadian products was also conducted.

¹ The USEPA RED document for fosamine ammonium is available from the Chemical Status List on the Office of Pesticide Programs website at www.epa.gov/pesticides/reregistration

2.0 Re-evaluation of fosamine ammonium

Common name:	Fosamine ammonium salt
Chemical name : (IUPAC)	Ammonium ethylcarbamoylphosphonate
(CAS)	Ammonium ethyl (aminocarbonyl)phosphonate
CAS registry number:	25954-13-6

Structural formula:



Fosamine ammonium was first registered in Canada in 1977. It is registered for use in a single EP, Krenite® Brush Control Agent (Du Pont, Canada), which is a water soluble liquid. The EP is a herbicide used to control brush and herbaceous plants on non-cropland. Application of the EP is restricted to non-agricultural rights of way (e.g., highways, railroads and utilities), industrial sites and other similar areas. Fosamine ammonium is effective against alder, ash, large tooth aspen, trembling aspen, beech, birch, cedar, cherry, elm, Balsam fir, Balsam poplar, hazel, hemlock, maple, oak, pine and white spruce. Application is done once annually, from mid June to late September. Products containing fosamine ammonium registered in Canada as of 31 December 2003 are listed in Appendix I.

Use sites, application rates, application method and formulation type registered in Canada are also registered in the United States, and the USEPA assessment described in the RED document for fosamine ammonium 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 USEPA RED for fosamine ammonium.

The federal TSMP² and Regulatory Directive DIR99-03³ were taken into consideration during the re-evaluation of fosamine ammonium. The re-evaluation determined that fosamine ammonium is not a TSMP Track 1 substance. The technical product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade Active Ingredient or an Integrated System Product*, or TSMP Track 1 substances as identified in Appendix II of DIR99-03.

3.0 Proposed re-evaluation decision

The USEPA RED document for fosamine ammonium addresses the main science areas that are necessary for Canadian regulatory decisions. This document addressed uses of fosamine ammonium registered in Canada. Based on the USEPA RED and the Canadian use pattern, the PMRA has determined that fosamine ammonium is 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 label for the Canadian registered fosamine ammonium EP does not currently have a contraindication for aerial application. According to PMRA Regulatory Directive DIR96-04, *Aerial Application of Pesticides*, only products with use instructions for aerial application may be applied by air after 1 January 2000. The PMRA requires that product labels be amended to include the following statement.

- **“Do not apply by air.”**

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 Web site at www.hc-sc.gc.ca/pmra-arla/

The Canadian label for Krenite® Brush Control Agent, which contains fosamine ammonium, must include the following statements, to protect workers and the environment.

(i) In the **Precautions** section:

- “Wear long pants, a long sleeve shirt, shoes and socks when handling this product. In addition, wear chemical resistant gloves during mixing, loading, clean-up and repair activities, and during application using hand wand or back pack sprayers.”
- “Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.”
- “Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.”
- “Users should remove clothing immediately after handling this product. If gloves are worn, wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”
- “Do not enter or allow others to enter the treated area until the spray has dried.”
- “Do not use in residential areas or areas where bystanders maybe in contact with treated foliage.”
- “Residential areas are defined as sites where bystanders, including children, may be potentially exposed during or after spraying. These include areas around homes, schools, parks, playgrounds, playing fields, public buildings or any other areas where the general public, including children, could be exposed.”
- “Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and parks is minimal. Use the best available application strategies to minimize risk to non-target species. Take into consideration meteorological conditions (e.g., wind speed, wind direction, temperature), application equipment and sprayer settings used for application.”
- “Do not graze livestock in treated areas, or cut or feed forage or hay grown in treated areas to livestock.”

(ii) In the **Environmental Hazards** section:

- “Do not directly apply to any aquatic habitats that are traversed by the right of way.”
- “Do not spray ditch banks, sites that are adjacent to and surrounding domestic water supply reservoirs, supply streams, lakes or ponds.”
- “Do not contaminate aquatic habitats when cleaning and rinsing spray equipment or containers.”

The voluntary amendment by the registrant of the American EP label to restructure maximum application rates should also be reflected on the Canadian label. Thus, the Canadian registrant is required to amend the **Directions for use** section of the Canadian label to include the following:

- “This product can be applied only once annually during the period after spring growth has hardened to the development of fall colouration in deciduous species.”
- “The maximum application rate for low shrubs and brushes is 17.9 kg a.i./ha, and for tall, dense, woody species with very heavy foliage is 21.6 kg a.i./ha.”

The statement—“Krenite” Brush Control Agent should be used only in accordance with recommendations on this label or in separate published Du Pont recommendations available through local dealers—should be modified as follows.

- “Krenite” Brush Control Agent should be used only in accordance with recommendations on this label. Separate recommendations published by Du Pont are available through local dealers.”

The above label amendments do not include all label requirements for the EP. Label requirements also include first aid statements, disposal statements, precautionary statements and personal protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts these proposed label statements.

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

5.0 Additional data requirements

The registrant of technical grade active ingredient (TGAI) fosamine ammonium is required to submit the following data 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 fosamine ammonium, as described in the USEPA RED for fosamine ammonium.
- A commitment and schedule to address Canadian requirements that are not addressed through submission of the data outlined above. These are outlined in the PMRA's data code (DACO)⁴ tables for use-site category #16. The registrant is required to address the following sections of the DACO tables:

USC #16, Industrial and Domestic Vegetation Control for Non-food Sites - TGAI: DACOs 2 through 9, inclusive

USC #16, Industrial and Domestic Vegetation Control for Non-food Sites - EP: DACOs 5, 8 and 9

The above and additional data may be required sooner if expansion of current uses of fosamine ammonium is requested.

⁴ Use-site category DACO tables are posted on the PMRA Web site at www.hc-sc.gc.ca/pmra-arla/

**Appendix I Fosamine ammonium products currently registered in Canada
(as of 31 December 2003)**

Product name	Registrant	Registrant number	Guarantee	Class
Krenite® Brush Control Agent	Du Pont Canada	14064	0.48 a.i. kg/L	Commercial
Krenite® Technical	Du Pont Canada	20733	0.48 a.i. kg/L	Technical