



# Proposed Acceptability for Continuing Registration

**PACR2004-24**

## Re-evaluation of Daminozide

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 daminozide. The PMRA has determined that daminozide is acceptable for continued registration for non-food uses only provided that the proposed mitigation measures are adopted. Additional data requirements are identified.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for daminozide. 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.

*(publié aussi en français)*

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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.

Daminozide 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, 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.

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

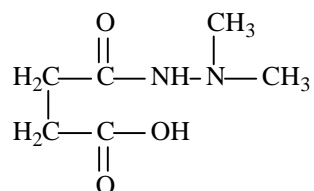
The USEPA conducted a re-evaluation of daminozide and concluded that, on the basis of health and environmental risk assessments, it was eligible for reregistration with implementation of mitigation measures. These conclusions were published in a 1993 RED document for daminozide. In its re-evaluation of daminozide, the PMRA based its conclusions on this 1993 RED, taking into account 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.

## 2.0 Re-evaluation of Daminozide

Common name:	Daminozide
Chemical name :	
(IUPAC)	N-dimethylaminosuccinamic acid
(CAS)	Butanedioic acid mono (2,2-dimethylhydrazide)
CAS registry number:	1596-84-5
Molecular formula:	$C_6H_{12}N_2O_3$

Molecular mass: 160.2

Structural formula:



In Canada, daminozide was first registered in 1983. It is currently registered in Canada for non-food use only, in the nursery/greenhouse industry as a plant growth regulator, controlling plant height and promoting flowering in the following ornamentals: azaleas, bedding plants, chrysanthemums, poinsettias and hydrangeas. Currently registered Canadian products containing daminozide are listed in Appendix I.

Based on the comparison of American and Canadian use patterns, the USEPA assessment described in the RED document for daminozide is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the assessments conducted by the USEPA are presented in the USEPA RED for daminozide.

The federal TSMP and Regulatory Directive DIR99-03 were taken into consideration during the review of daminozide, and it was concluded that daminozide is not a TSMP Track 1 substance. The octanol-water partition coefficient ( $K_{ow}$ ) associated with daminozide is 0.0322 and is below the TSMP Track 1 cut-off criterion.

### 3.0 Proposed re-evaluation decision

The USEPA published a RED document for daminozide addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of daminozide that are also registered in Canada. Based on the USEPA RED and Canadian use pattern, the PMRA has determined that daminozide, for non-food uses only, is acceptable for continued registration provided that the mitigation measures specified in Section 4.0 are adopted. Additional data requirements are identified in Section 5.0.

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 and basic hygiene practices, Canadian EP labels should be amended to include the following statements to further protect workers and the environment.

- In the “**Precautions**” section:
  - “For use only in commercial or research greenhouses or shade houses.”
  - “Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.”
  - “Users should remove clothing immediately if pesticide comes in contact with skin through soaked clothing or spills. Then wash thoroughly and put on clean clothing.”
  - “Wear coveralls over a long-sleeved shirt and long pants, chemical resistant gloves, socks and chemical resistant footwear during mixing, loading, application, clean-up or repair activities. In addition, wear a chemical resistant apron for mixing, loading and cleaning equipment. Wear chemical resistant headgear and a face shield in addition to the personal protective equipment indicated above for overhead application.”
  - “Do not enter or allow worker entry into treated areas within 24 hours of application.”
- In the “**Environmental Hazards**” section:
  - “ Do not contaminate water when disposing of equipment washwater or rinsate. Do not allow discharge from the greenhouse to contaminate aquatic systems.”

The above label amendments do not include all label requirements for individual EPs, such as first aid statements, disposal statements, precautionary statements and supplementary 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 technical registrant of daminozide is 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 prior to the reregistration in the United States and USEPA Data Evaluation Reports (DERs);
- 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) tables for Use-site Category #6 (Greenhouse Non-Food Crops) and Use-site Category #27 (Ornamentals Outdoor). The registrant is required to address the following sections of the applicable DACO table(s):
  - for the TGAI: DACOs 2 through 9, inclusive
  - for the EP: DACOs 5, 8 and 9

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

## 6.0 Supporting documentation

PMRA documents, such as DIR2001-03, and DACO tables can be found on our website at [www.hc-sc.gc.ca/pmra-arla](http://www.hc-sc.gc.ca/pmra-arla). 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](mailto:pmra_infoserv@hc-sc.gc.ca).

The federal TSMP is available through Environment Canada's website at [www.ec.gc.ca/toxics](http://www.ec.gc.ca/toxics).

The USEPA RED document (*Daminozide*) is available on the Office of Pesticide Programs' website at [www.epa.gov/pesticides/reregistration](http://www.epa.gov/pesticides/reregistration) under Chemical Status.

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**Appendix I      Registered daminozide products in Canada as of  
31 March 2004**

<b>Registrant</b>	<b>Registration number</b>	<b>Guarantee</b>	<b>Product name</b>	<b>Class</b>
Crompton Co.	24490	99%	Daminozide	Technical
Crompton Co.	17465	85%	B-Nine-WSG	Commercial
Plant Products Co. Ltd.	17599	85%	B-Nine-SP	Commercial