Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

# Proposed Acceptability for Continuing Registration

**PACR2004-01**

## Re-evaluation of Ancymidol

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 ancymidol. The PMRA has determined that ancymidol 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 document provides a rationale for the proposed regulatory decision for ancymidol. 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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**Publications Coordinator**
**Pest Management Regulatory Agency**
**Health Canada**
**2720 Riverside Drive**
**A.L. 6605C**
**Ottawa, Ontario**
**K1A 0K9**

**Internet:** pmra_publications@hc-sc.gc.ca
www.hc-sc.gc.ca/pmra-arla/
**Information Service:**
**1-800-267-6315 or (613) 736-3799**
**Facsimile: (613) 736-3798**

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## 1.0 Background

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 re-evaluation activities and program structure.

Ancymidol has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in 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 USEPA 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 the USEPA review, the PMRA will propose, under Program 1, a regulatory decision and ppropriate mitigation measures for Canadian uses of an active ingredient.

The USEPA conducted a re-evaluation of ancymidol and concluded, on the basis of a health and environmental risk assessment, that it was eligible for reregistration with implementation of mitigation measures. These conclusions were published in a 1995 Reregistration Eligibility Decision (RED)[1] document for ancymidol. In its re-evaluation of ancymidol, the PMRA based its conclusions on this 1995 RED document, taking into account the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substances Management Policy). A review of the chemistry of Canadian products was also conducted.

## 2.0 Re-evaluation of ancymidol

Common name: Ancymidol

Chemical name:

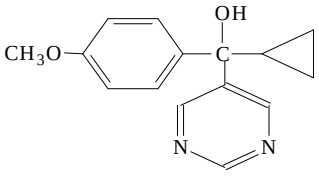
(IUPAC) α-cyclopropyl-4-methoxy-α-(pyrimidin-5-yl)benzyl alcohol

(CAS) α-cyclopropyl-α-(4-methoxyphenyl)-5-pyrimidinemethanol

CAS registry number: 12771-68-5

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

Structural formula:




Purity of active: 99.6% (nominal) (limits 97%, 100%)

Ancymidol was first registered in 1973. It is a plant growth regulator used as a soil drench on container-grown lilies, poinsettias and chrysanthemums. The technical grade active ingredient and one end-use product are registered in Canada by SePRO Corporation and a second end-use product is registered by Plant Products Co. Ltd. These products 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 ancymidol is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The USEPA RED presents the health and environmental risk assessments.

The federal Toxic Substances Management Policy (TSMP)[2] and Regulatory Directive DIR99-03[3] were taken into consideration during the PMRA re-evaluation of ancymidol. The re-evaluation determined that ancymidol is not a TSMP Track 1 substance. The technical product is not expected to contain impurities of toxicological concern as identified in 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.

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2 The federal Toxic Substances Management Policy is available through Environment Canada's Web site 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 Web site at www.hc-sc.gc.ca/pmra-arla/

## 3.0 Proposed re-evaluation decision

The USEPA Reregistration Eligibility Decision (RED) document for ancymidol addresses the main science areas that are necessary for Canadian regulatory decisions. This document also addressed uses of ancymidol that are currently registered in Canada. Based on the USEPA RED and in consideration of the Canadian use pattern, the PMRA has determined that ancymidol is acceptable for continued registration provided that the following mitigation measures are adopted and the data requirements outlined in this document are addressed. Acceptable uses of ancymidol in Canada are presented in Appendix II.

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

For all ancymidol end-use products, labels must be amended to include the following statements to protect workers and the environment.

- "Wear long pants, a long-sleeved shirt, chemical-resistant gloves and boots during mixing/loading, application, clean-up and repair activities."

- "Do not re-enter or allow worker entry into treated areas until 12 hours after application."

- "Do not allow waste water, effluent or runoff containing this product to enter lakes, streams, ponds or other waters."

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 ancymidol is 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 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) requested by the USEPA as a condition of reregistration of ancymidol.

- A commitment and schedule to address Canadian requirements that are not addressed through submission of the data outlined above. These requirements are outlined in the PMRA's data code (DACO) tables[4] for use-site category # 6. The registrants are required to address the following DACO sections:

  USC # 6, Greenhouse Non-Food Crops—TGAI: DACOs 2 through 9, inclusive;
  USC # 6, Greenhouse Non-Food Crops—EP: DACOs 5 through 9, inclusive.

The above data and additional data may be required sooner if expansion of current uses of ancymidol 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 Canadian ancymidol products currently registered

| Product name | Class | Guarantee | Registrant | Registration number |
|---|---|---|---|---|
| A-Rest* SG Technical | Technical | 99.6% | SePRO Corporation | 26498 |
| A-Rest Growth Regulator | Commercial | 264 mg/L | Plants Products Co. | 12225 |
| A-Rest Solution | Commercial | 264 mg/L | SePRO Corporation | 16393 |

# Appendix II Use standard for commercial class products containing ancymidol

**NOTE:** The information in this appendix summarizes the acceptable uses and precautions for commercial class products containing ancymidol, but does not identify all label requirements for such products. Registrants are referred to the PMRA *Registration Handbook* or further guidance on label requirements for pest control products.

**COMMON NAME:** Ancymidol

**CHEMICAL NAME:** (IUPAC) α-cyclopropyl-4-methoxy-α-(pyrimidin-5-yl)benzyl alcohol

(CAS) α-cyclopropyl-α-(4-methoxyphenyl)-5-pyrimidinemethanol

**FORMULATION TYPE:** Solution

**USE-SITE CATEGORY:** Greenhouse Non-Food Crops, USC # 06

**PRECAUTIONARY STATEMENTS:**
**PERSONAL PROTECTIVE EQUIPMENT (PPE):**
Wear long pants, a long sleeved shirt, chemical-resistant gloves and boots during mixing/loading, application, clean up and repair activities.

Do not re-enter or allow worker entry into treated areas until 12 hours after application.

**ENVIRONMENTAL PRECAUTIONS:**
Do not allow waste water, effluent or runoff containing this product to enter lakes, streams, ponds or other waters.

**ACCEPTABLE USES FOR ANCYMIDOL:**

| SITE | PESTS | RATE | APPLICATION |
|---|---|---|---|
| Use-Site Category # 06, Greenhouse Non-Food Crops | | | |
| Container-grown lilies, chrysanthemums and poinsettias | reduces internode elongation | 0.25 to 0.5 mg a.i./15 cm pot | Apply as a drench treatment. |