Proposed Re-evaluation Decision PRVD2021-10

Ancymidol and Its Associated End-use Products

Consultation Document

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Proposed re-evaluation decision

Under the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Ancymidol is a plant growth regulator, used for height control of container-grown lilies, poinsettias and chrysanthemums. It reduces internode elongation resulting in more desirable compact plants through inhibition of gibberellins production within plants. Ancymidol is used with application limited to soil drench to ornamental plants grown in pots and the mechanical planting of treated seeds in pots.

Currently registered products containing ancymidol subject to this proposed re-evaluation decision can be found in Appendix I. Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. As a result of the re-evaluation of ancymidol, these products were shown to have value in providing a pest management solution. When the current label directions are followed, potential risks to human health (occupational, dietary, residential and bystander) and the environment (aquatic and terrestrial organisms and their habitats) are considered to be acceptable. However, label updates are proposed to meet the current labelling standards (Appendix II).

Under the authority of the *Pest Control Products Act* and based on an evaluation of available scientific information, Health Canada is proposing that products containing ancymidol are acceptable for continued registration for use and sale in Canada, provided that the proposed updates to label directions are in place. All products containing ancymidol registered in Canada are subject to this proposed re-evaluation decision.

Next steps

The public, including the registrants and stakeholders, are encouraged to submit comments and information on this proposed decision during the 90-day public consultation period[1] upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of the re-evaluation decision document,[2] which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the Pest Control Products Act.

Additional scientific information

Additional scientific data are not required at this time.

Science evaluation

1.0 Human health assessment

Ancymidol is of low acute toxicity via the oral and dermal routes, is slightly acutely toxic via the inhalation route, is not considered to be a dermal irritant or a skin sensitizer, and is a moderate ocular irritant. In the developmental toxicity study, treatment-related maternal findings included decreased body weight gain and food consumption (NOEL of 50 mg/kg bw/day) while fetal viability and weight were not adversely affected. There was no evidence of genotoxicity or carcinogenicity observed. Toxicological reference values for quantitative risk assessment have not been established; a qualitative approach was used to assess the potential risks of ancymidol to human health based on the limited use pattern and low exposure associated with the use scenarios.

Acute and chronic dietary exposure to ancymidol through food is not anticipated as there are no registered food or feed uses. The currently registered use pattern (soil drench to pots either in a greenhouse or outdoor environment; treated seed to be mechanically sown in containers in greenhouses) is expected to result in limited exposure to the drinking water sources.

Workers can be exposed to ancymidol primarily through mixing, loading, or applying the pesticide, with limited postapplication exposure given the soil drench use and mechanical planting of treated seeds. Given the low toxicity profile, the low exposure potential based on these use scenarios, and existing mitigation measures for ancymidol, occupational exposure, including postapplication exposure, is not expected to be of concern under the current conditions of use. These conditions include a restricted-entry interval (REI) of 12 hours and wearing personal protective equipment of a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing/loading, application, clean up and repair. No further mitigation measures are proposed. Updates to standard label statements (personal protective equipment) and precautions are proposed to meet the current labelling practices.

A residential assessment is not required since there are no domestic-class end-use products and commercial application to residential areas is not expected. For bystanders, the use of ancymidol is expected to result in minimal exposure. No additional risk mitigation measures are proposed.

Since residential exposure is not expected and there are no uses on food or feed crops, an aggregate risk assessment for ancymidol is not required.

The *Pest Control Products Act* requires that Health Canada considers the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, the PMRA did not identify any information indicating that ancymidol shared a common mechanism of toxicity with other pest control products. Therefore, there is no requirement for a cumulative assessment at this time.

2.0 Environmental assessment

Ancymidol is not expected to be persistent in soil under aerobic conditions and is not expected to bioaccumulate. Although sorption studies indicate ancymidol is highly mobile, soil column leaching studies conducted with sand indicated little infiltration.

Ancymidol is practically nontoxic to birds, honey bees, freshwater fish and invertebrates and is slightly toxic to mammals on an acute exposure basis. Ancymidol is toxic to aquatic plants (EC_{50} = 0.29 mg a.i./L); therefore, a precautionary label statement warning users of the potential hazard, is proposed.

Exposure to the environment is expected to be minimal and the potential for risk to non-target organisms (aquatic and terrestrial) is acceptable based on the current use pattern. Updates to standard labels statements (disposal, environmental precautions, directions for use) are proposed to meet the current labelling practices.

Ancymidol is not considered a Track 1 substance as it does not meet all the Track 1 criteria as per the Toxic Substances Management Policy.

3.0 Value assessment

Ancymidol is a plant growth regulator. It reduces internode elongation resulting in more desirable compact plants. Ancymidol provides an alternative approach to enhance aesthetic appearance of economically important ornamentals through producing more desirable, compact and marketable crops. Compared to some alternative active ingredients used as plant growth retardants, ancymidol is effective at lower rates of application.

4.0 Incident reports

As of 9 July 2021, there are no incident reports on-file related to the use of ancymidol.

Appendix I Registered products containing ancymidol

Table 1 Registered products containing ancymidol as of 9 July 2021

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (%/mg/L)
26498	Technical Grade Active Ingredient	Sepro Corporation	A-Rest SG Technical Plant Growth Regulator	Soluble granule	99.6 %
12225	Commercial	Plant Products Inc.	A-Rest Growth Regulator	Solution	264 mg/L
16393	Commercial	Sepro Corporation	A-Rest Solution	Solution	264 mg/L
28968*	Commercial	Sepro Corporation	A-Rest SG Plant Growth Regulator Seed Treatment	Soluble granule	99.6 %

* Not for sale or use in CANADA

Appendix II Label updates for products containing ancymidol

Information on approved labels of currently registered products should not be removed unless it contradicts the label statements provided below.

The following statements must be updated for all products to meet current labelling standards:

On the principal display panel, replace "GUARANTEE" with "ACTIVE INGREDIENT".

The following statements must be updated for all end-use products to meet current labelling standards:

1. PRECAUTIONS:

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

2. DISPOSAL:

   1. Triple- or pressure-rinse the empty container. Add the rinsings to the spray mixture in the tank.
   2. Follow provincial instruction for any required additional cleaning of the container prior to its disposal.
   3. Make the empty container unsuitable for further use.
   4. Dispose of the container in accordance with provincial requirements.
   5. For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.

3. ENVIRONMENTAL PRECAUTIONS:

   "DO NOT allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters."

   Add "TOXIC to aquatic plants."

   For "A-REST SG Plant Growth Regulator Seed Treatment (Registration No. 28968)" and "A-Rest SG Technical Plant Growth Regulator (Registration No. 26498)":

   Replace "Environmental Hazards" with "Environmental Precautions"

   And Remove:
   "This product is toxic to fish."

4. DIRECTIONS FOR USE:

   "DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes."

The following statements must be updated for A-Rest SG Technical Plant Growth Regulator (Registration No. 26498):

1. PRINCIPAL DISPLAY PANEL

   Remove: WARNING Causes substantial, but temporary eye irritation. May cause skin irritation. Harmful is swallowed or inhaled.

   Add: CAUTION (pictogram) POISON
   CAUTION - EYE IRRITANT

2. SECONDARY DISPLAY PANEL

   PRECAUTIONS

   Remove: Avoid contact with skin, eyes or clothing. Avoid breathing dust, vapour or spray mist.

   Add: Harmful if swallowed or inhaled. Avoid inhaling /breathing dusts. May irritate eyes. Avoid contact with eyes.

References

List of additional information considered

PMRA Document Number	Reference
692330	Canada, 2004. Proposed Acceptability for Continuing Registration PACR2004-01 Re-evaluation of Ancymidol
1578513	Evaluation Report for Category B, Subcategory 2.1, Application
3237963	Ancymidol Interim Registration Review Decision Case Number 3017. Docket Number EPA-HQ-OPP-2011-0482. https://www.regulations.gov/document/EPA-HQ-OPP-2011-0482-0019.
3237992	Ancymidol. Preliminary Review Risk Assessment. Donna S. Davis. March 5, 2013. Docket Number EPA-HQ-OPP-2011-0482. https://www.regulations.gov/document/EPA-HQ-OPP-2011-0482-0014.
3238001	Environmental Fate and Effects Division (EFED) Preliminary Risk Assessment to Classify Registered Ancymidol Uses as De Minimus Risk to Listed/Non-Listed Species and "No Effects" Determination. Meghan Radtke. February 25, 2013. Docket Number EPA-HQ-OPP-2011-0482. https://www.regulations.gov/document/EPA-HQ-OPP-2011-0482-0013