



## Re-evaluation Note

REV2006-06

### Re-evaluation of Endothall

The purpose of this Re-evaluation Note is to inform registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated the active ingredient endothall and its associated use as a preharvest desiccant on potato crops.

The PMRA has determined that endothall is acceptable for continued registration. Mitigation measures to further protect human health and the environment are identified in this document. The registrant has been informed by letter of the specific requirements affecting their product registration and the regulatory options available to comply with this decision.

*(publié aussi en français)*

**31 May 2006**

This document is published by the Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency. For further information, please contact:

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ISBN: 0-662-43460-9 (0-662-43461-7)

Catalogue number: H113-5/2006-6E (H113-5/2006-6E-PDF)

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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 details of the re-evaluation activities and program structure.

Endothall 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 endothall 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 2005 RED document for endothall.

In its re-evaluation of endothall, the PMRA based its conclusions on this 2005 RED document, taking into account the Canadian use pattern and 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 Endothall

|                   |  |   |
|-------------------|--|---|
| Active substance: | Endothall acid                                   | Endothall present as a mono[N,N-dimethylackylamine] salt                      |
| Chemical name:    |  |   |
| IUPAC:            | 7-oxabicyclo[2.2.1]heptane-2,3-dicarboxylic acid | 7-oxabicyclo[2.2.1]heptane-2,3-dicarboxylic mono[N,N-dimethylackylamine] salt |
| CAS:              | 7-oxabicyclo[2.2.1]heptane-2,3-dicarboxylic acid | 7-oxabicyclo[2.2.1]heptane-2,3-dicarboxylic mono[N,N-dimethylackylamine] salt |
| CAS number:       | 145-73-3   | 66330-88-9  |

In Canada, endothall was first registered in 1959. According to the current end-use product label, this active ingredient is registered in Canada for use as a desiccant on potato crops. Canadian products containing endothall are listed in Appendix I.

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

The federal Toxic Substances Management Policy and Regulatory Directive [DIR99-03](#) were taken into consideration during the review of endothall, and it was concluded that endothall is not a candidate for Track 1 classification. The technical product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive [DIR98-04](#) or Toxic Substances Management Policy Track 1 substances as identified in Appendix II of DIR99-03.

## 3.0 Re-evaluation Decision

The USEPA published a RED document for endothall addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document also addressed the registered Canadian use for endothall. The PMRA has determined that endothall is acceptable for continued registration with the implementation of the mitigation measures specified in Section 4.0 of this Re-evaluation Note. Additional administrative requirements have been identified to the registrant.

The use pattern for endothall is a very limited, and no significant health or environmental issues were identified during the re-evaluation. Therefore, this Re-evaluation Note serves as notice of the PMRA's re-evaluation decision. The completion of required label amendments will conclude the re-evaluation of endothall.

#### 4.0 Regulatory Actions

Canadian end-use product labels must be amended to include the following statements to further protect human health and the environment.

- The **PRECAUTIONS** section of the end-use product label must include the following statements:
  - “Do not apply this product in a way that will cause this product to contact workers or other persons, either directly or through drift. Only handlers (mixers, loaders and applicators) wearing personal protective equipment may be in the area being treated during application.”
  - “Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours.”
  - “Treated crops must be harvested by mechanical means only.”
  - “Do not feed treated forage to dairy animals or to animals intended for slaughter.”
- The **DIRECTIONS FOR USE** section of the end-use product label must include the following statements:
  - “Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the ASAE medium classification.”
  - “**DO NOT** apply by air.”
  - “**Buffer zones**: The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrublands) and sensitive aquatic habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, wetlands and estuarine/marine habitats).”

| Method of Application | Buffer Zones (Metres) Required for the Protection of: |       |                  |                     |
|-----------------------|---|-------|------------------|---------------------|
|                       | Aquatic Habitats of Depths                            |       |                  | Terrestrial Habitat |
|                       | Less than 1 m   | 1–3 m | Greater than 3 m |                     |
| Field sprayer*        | 10  | 3     | 1                | 1                   |

\* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy or ground, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy or ground, the labelled buffer zone can be reduced by 30%.”

- “When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.”
- An **ENVIRONMENTAL HAZARD** section must appear on the end-use product label and must include the following statements:
  - “TOXIC to terrestrial and aquatic plants. Observe buffer zones specified under DIRECTIONS FOR USE.”
  - “TOXIC to aquatic organisms. Do not apply this product directly to freshwater habitats (such as lakes, rivers sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats. Do not contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.”

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

#### 4.1 Maximum Residue Limits

There are no dietary concerns regarding use of endothall on food and feed crops reported in the USEPA RED. This document adequately addresses the Canadian dietary exposure from domestic and imported foods. Endothall is currently registered in Canada for use on potatoes. Endothall may be used in other countries, on crops that are imported into Canada.

Where no specific maximum residue limit (MRL) for a pest control product has been established in the Food and Drug Regulations, subsection B.15.002(1) applies. This requires that residues do not exceed 0.1 ppm and has been considered a general MRL for

enforcement purposes. Currently, residues of endosulfan in all agricultural commodities, including those approved for treatment in Canada are regulated by subsection B.15.002(1). However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document [DIS2003-01](#), *Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be promulgated.

## 5.0 Supporting Documentation

PMRA documents, such as DIR2001-03, and DACO tables can be found on our website at [www.pmra-arla.gc.ca](http://www.pmra-arla.gc.ca). 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 (*Reregistration Eligibility Decision for Endosulfan*) 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 Products Containing Endothall Registered in Canada as of  
26 February 2006**

| <b>Product Name</b>              | <b>Registrant</b> | <b>Registration Number</b> | <b>Guarantee</b>   | <b>Class</b> |
|----------------------------------|-------------------|----------------------------|--|--------------|
| Endothall Technical              | Cerexagri Inc.    | 25324                      | 80% of endothall acid  | Technical    |
| DES-I-CATE®<br>Potato Top Killer | Cerexagri Inc.    | 13894                      | 62 g/L of endothall present as a mono[N,N-dimethylalkylamine] salt | Commercial   |