Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Acceptability for Continuing Registration

PACR2006-03

Re-evaluation of Etridiazole

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated etridiazole. The PMRA has determined that etridiazole is acceptable for continued registration with the implementation of additional mitigation measures to further protect workers/users, bystanders and the environment. Registrants will be required to submit specified confirmatory data. Upon finalization of the re-evaluation decision, the PMRA will provide registrants of products containing etridiazole with specific direction on how to address these measures and requirements.

This Proposed Acceptability for Continuing Registration document provides a rationale for the proposed regulatory decision for etridiazole. 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 Publications at the address below.

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1.0 Background

Health Canada's 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.

Etridiazole 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 etridiazole 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 2000 RED document for etridiazole. In its re-evaluation of etridiazole, the PMRA based its conclusions on this 2000 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 Etridiazole

Active substance:	Etridiazole
Common name:	Etridiazole
Chemical names:	
IUPAC:	Ethyl 3-trichloromethyl-1,2,4-thiadiazol-5-yl ether
CAS:	5-ethoxy-3-(trichloromethyl)-1,2,4-thiadiazole
CAS number:	2593-15-9

In Canada, etridiazole was first registered in 1973. According to current end-use product labels, this active ingredient (a.i) is registered in Canada for use on turf (golf course greens and sod farms), ornamentals, potting soil, and for domestic use, a liquid root stimulator. Canadian products containing etridiazole are listed in Appendix I.

As a result of re-evaluation, the Canadian registrant no longer supports the use of etridiazole on sod farms. Therefore, the PMRA did not include this use in the re-evaluation of etridiazole.

Based on the comparison of American and Canadian use patterns, the USEPA assessment described in the RED document for etridiazole 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 RED for etridiazole.

The federal Toxic Substances Management Policy and Regulatory Directive DIR99-03 were taken into consideration during the review of etridiazole, and it was concluded that etridiazole 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 TSMP Track 1 substances as identified in Appendix II of DIR99-03.

3.0 Proposed Re-evaluation Decision

The USEPA published a RED document for etridiazole addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of etridiazole that are also registered in Canada. The PMRA has determined that etridiazole is acceptable for continued registration with the implementation of the mitigation measures specified in Section 4.0 of this PACR. Registrants will be required to submit the confirmatory data 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. Registrants of products containing etridiazole should not apply for label amendments or submit the additional data as described in Section 5.0 during this comment period; they will be informed by letter of the specific instructions for addressing label changes and data requirements once the re-evaluation decision has been finalized.

4.0 Proposed Regulatory Actions

The Canadian registrant has indicated that the use of etridiazole on sod farms will no longer be supported in Canada and will be phased out.

Canadian end-use product labels should be amended to include the following statements to further protect workers and the environment.

In the DIRECTIONS FOR USE section of the label for all commercial products, the following statement must appear:

- "Do not enter or allow worker entry into treated areas during the restricted entry interval of 12 hours."

For the wettable powder product label, in the DIRECTIONS FOR USE section, for golf course green application:

- "Do not apply more than 4.26 kg a.i./ha."
- "Do not apply more than twice per season."
- "A minimum of 10 days is required between applications."
- "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 disposing of wastes."
- "DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty."
- "DO NOT apply this product by air."
- "The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of Application	Buffer Zone (metres) Required for the Protection of:					
	Freshwater Habitat at Water Depths of:			Estuarine/Marine Habitat at Water Depths of:		
	< 1 m	1–3 m	> 3 m	< 1 m	1–3 m	> 3 m
Field sprayer	80	30	10	20	5	3
Field sprayer with shrouds	25	10	3	5	2	1
Field sprayer with cones	55	20	5	15	4	2

Self-contained bodies of water within the golf course property, e.g., ponds with no inflow or outflow of water, do not require buffer zones."

For the wettable powder product label, in the PRECAUTIONS section, for mixer/loader/applicators (except as dry soil mix):

- "Wear coveralls over long pants and long-sleeved shirt, shoes plus socks, chemical-resistant gloves and a full-face NIOSH-approved respirator when mixing, loading or applying the wettable powder; wear a chemical-resistant apron when mixing, loading and cleaning equipment."

For the wettable powder product label, in the PRECAUTIONS section, for mixer/loader applicators as a dry soil mix:

- "Wear a long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves and a NIOSH-approved respirator during dry application to dry soil."

For the wettable powder and the emulsifiable concentrate product labels, in the PRECAUTIONS section, for mixer/loader/applicators (wettable powder and emulsifiable concentrate) as well as for handlers (treated soil/media):

- "This product is highly volatile. Continuous ventilation is required whenever the product, treated soil or treated planting media are being handled indoors."

For the emulsifiable concentrate product label, in the PRECAUTIONS section, for application to ornamentals using a low-pressure handwand:

- "Wear a long-sleeved shirt, long pants, chemical-resistant gloves and a NIOSH-approved respirator during mixing, loading and application."

The emulsifiable concentrate end-use product Registration No. 12222 labels must specify if the use on ornamentals is for use in greenhouses, outdoors or both.

For the product having uses on turf, in the ENVIRONMENTAL PRECAUTIONS section of the label:

- "To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to: heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g., soils that are compacted, fine textured or low in organic matter such as clay).

  Avoid application of this product when heavy rain is forecast.

  Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body."

In the ENVIRONMENTAL PRECAUTIONS section of the label for the products having greenhouse uses:

- "Do not allow effluent from greenhouses containing this product to enter lakes, streams, ponds or other waters. For guidance, contact the Provincial Regulatory Agency."

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

5.0 Additional Data Requirements

The registrants of etridiazole will be required to submit the following within 24 months of finalization of the re-evaluation decision:

- a submission to register a source of the technical grade active ingredient;
- efficacy data to support a maximum rate of 4.26 kg a.i./ha etridiazole on golf course greens or a rationale for this rate that includes relevance to the Canadian use pattern;
- all data (as they relate to the 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);
- all data (as they relate to the Canadian use pattern) that were required by the USEPA as a condition of reregistration of etridiazole;
- 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 categories (USC) #6, #27, #28 and #30. The registrant must address the following sections of the DACO tables:

- for the technical grade active ingredient—DACOs 2 through 9, inclusive;
- for the end-use product—DACOs 5 through 9, inclusive.

6.0 Supporting Documentation

PMRA documents, such as DIR2001-03, and DACO tables can be found on our website at 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.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document *Etridiazole (Terrazole®)* is available on the Office of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemical Status.

Appendix I Products Containing Etridiazole Registered in Canada as of 31 August 2005

Product Name	Registrant	Registration Number	Guarantee	Class
Truban Fungicide 30% Wettable Powder	Scotts-Sierra Crop Protection	11460	30%	Commercial
Truban Fungicide 25% Emulsifiable Concentrate	Scotts-Sierra Crop Protection	12222	25%	Commercial
Wilson's Roots Liquid Root Stimulator with Fungicide	Nu-Gro IP Inc.	16515	0.01% (with 0.40% indole butyric acid*)	Domestic

* Regulated under the *Fertilizers Act*.