



Proposed Acceptability for Continuing Registration

PACR2006-06

Re-evaluation of Prometryn

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 prometryn. The PMRA is proposing that prometryn is acceptable for continued registration. Additional mitigation measures to further protect human health and the environment are identified in this document. Registrants will be required to submit specified confirmatory data. Upon finalization of the re-evaluation decision, the PMRA will provide registrants of products containing prometryn with specific direction on how to address these measures and requirements.

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

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.

Prometryn 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 prometryn 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 1995 RED document for prometryn. The USEPA also published a Proposed Rule to support the establishment of an import tolerance on carrots in the Federal Register in 1998. In its re-evaluation of prometryn, the PMRA based its conclusions on this 1995 RED document and on the 1998 Federal Register Proposed Rule, 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 Prometryn

Active substance:	prometryn
Chemical names:	
IUPAC:	N ² ,N ⁴ -di-isopropyl-6-methylthio-1,3,5-triazine-2,4-diamine
CAS:	N,N'-bis(1-methylethyl)-6-(methylthio)-1,3,5-triazine-2,4-diamine
CAS number:	7287-19-6

In Canada, prometryn was first registered in 1965. According to current end-use product labels, this active ingredient is registered in Canada as a herbicide to control weeds in terrestrial food crops (peas, carrots, celery and leeks). Canadian products containing prometryn are listed in Appendix I.

Based on the comparison of American and Canadian use patterns, the USEPA assessments described in the RED document for prometryn and in the 1998 Federal Register are 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 prometryn and in the 1998 Federal Register.

The federal Toxic Substances Management Policy and Regulatory Directive [DIR99-03](#) were taken into consideration during the review of prometryn, and it was concluded that prometryn is not a candidate for Track 1 classification. Based on the manufacturing process, technical products could be contaminated with hexachlorobenzene; hence, confirmatory batch data are required (see Section 5.0). The technical products are not expected to contain other 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 Proposed Re-evaluation Decision

The USEPA published a RED document in 1995 and a risk assessment in the 1998 Federal Register Proposed Rule addressing the main science areas that are necessary for the Canadian regulatory decision, i.e., human health and the environment. These documents addressed uses of prometryn that are also registered in Canada. The PMRA has determined that prometryn is acceptable for continued registration with the implementation of mitigation measures specified in Section 4.0 of this PACR are implemented. 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 prometryn 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

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

- End-use products formulated as a wettable powder must only be marketed in water soluble packages.
- The **PRECAUTIONS** section of all end-use product labels must include the following statements:
 - “Wear a long-sleeved shirt, long pants and shoes plus socks, during mixing/loading, application, clean-up and repair activities. In addition, wear chemical-resistant gloves during mixing/loading, clean-up and repair activities.”
 - “Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours for celery and 12 hours for all other crops.”
 - “Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”
 - “Users should wash their 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 skin thoroughly and put on clean clothing.”
 - “Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product. Do not reuse them.”
- The **DIRECTIONS FOR USE** section of all end-use product labels must include the following statements:
 - “Rotational crop restrictions: A 3-month plant back interval is required for small grains, an 8-month plant back interval is required for root and tuber vegetables and a 12-month plant back interval is required for all other crops.”

- “Field sprayer application: Do not apply during periods of dead calm or when winds are gusty. Do not apply with spray droplets smaller than the American Society of Agricultural Engineers (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, pastures, rangelands and shrublands), 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:			Estuarine/Marine Habitat at Water Depths:			Terrestrial Habitat
	< 1 m	1–3 m	> 3 m	< 1 m	1–3 m	> 3 m	
Field sprayer	65	20	10	10	5	2	60
Field sprayer with shrouds	20	5	3	3	2	1	20
Field sprayer with cones	45	15	5	5	4	1	40

- If tank mixes are included on the label, the **DIRECTIONS FOR USE** section must include the following statement:
 - “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 be added to all end-use product labels and must include the following statements:
 - “Do not apply directly to aquatic habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs or wetlands) and estuarine/marine habitats.”
 - “Do not contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.”

- “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).”
- “The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g., sandy soil) and/or the depth to the water table is shallow.”

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

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

4.1 Maximum Residue Limits

There are no dietary concerns regarding use of prometryn on food and feed crops reported in the USEPA RED. This document adequately addresses the Canadian dietary exposure from domestic and imported foods. In addition, all Canadian uses, including the ones not considered in the USEPA assessment, were recently evaluated by the PMRA.

Prometryn is currently registered in Canada for use on peas, carrots, celery and leeks. As noted, prometryn may be used on other crops in other countries which 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 prometryn 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 Additional Data Requirements

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

- a batch analysis of the technical grade active ingredient to verify levels of hexachlorobenzene.

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 (*Prometryn*) is available on the Office of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemical Status.

Prometryn; Pesticide Tolerances. Federal Register 1998, Volume 63, Number 37 (pages 9494–9499) is available on the Federal Register Online via Government Printing Office access (www.access.gpo.gov).

**Appendix I Products Containing Prometryn Registered in Canada as of
15 October 2005**

Product Name	Registrant	Registration Number	Guarantee	Class
Prometrex (Prometryn) Technical	Makhteshim-Agan of North America Inc.	22879	97.5%	Technical
Prometryn 80W (Prometrex 80WP)	Makhteshim-Agan of North America Inc.	16253	80%	Commercial
Prometryne Technical	Syngenta Crop Protection Canada Inc.	24325	97%	Technical
Gesagard® 480SC Herbicide	Syngenta Crop Protection Canada Inc.	24771	465.6 g/L	Commercial