Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Acceptability for Continuing Registration

PACR2004-22

Re-evaluation of Bromacil

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of bromacil. The PMRA has determined that bromacil is acceptable for continued registration provided that the proposed mitigation measures are adopted.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for bromacil. 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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1.0 Background

The PMRA is re-evaluating all pesticides, both active ingredients (a.i.) and formulated end-use products (EPs), that were registered prior to 31 December 1994 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03[1], *PMRA Re-evaluation Program*, presents the re-evaluation activities and program structure.

Bromacil 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 itself and its 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 appropriate mitigation measures for Canadian uses of an active ingredient.

The USEPA conducted a re-evaluation of bromacil and concluded that, based on a health and environmental risk assessment, bromacil was eligible for reregistration with implementation of mitigation measures. The PMRA conclusions on the re-evaluation of bromacil were based on the RED document for bromacil[2], with consideration of the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substances Management Policy [TSMP]). A review of the chemistry of Canadian products was also conducted.

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1 Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, 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 website at www.hc-sc.gc.ca/pmra-arla/

2 The USEPA Reregistration Eligibility Decision (RED) document for bromacil is available from the Chemical Status List on the Office of Pesticide Programs website at www.epa.gov/pesticides/reregistration

2.0 Re-evaluation of bromacil

Common name: bromacil

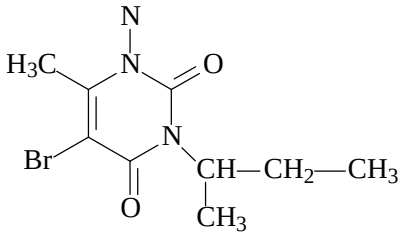
Chemical name:

IUPAC: 5-bromo-3-*sec*-butyl-6-methyluracil

CAS: 5-bromo-6-methyl-3-(1-methylpropyl)-2,4(1*H*,3*H*)-pyrimidinedione

CAS registry number: 314-40-9

Structural formula:



Purity of active: 97.2% (nominal)

Bromacil was first registered in 1963. It is a herbicide used to control broadleaf weeds, grasses and brush on non-cropland areas. Currently registered products of bromacil in Canada are listed in Appendix I.

The use sites, application rates, application methods and formulation types registered in Canada are also registered in the United States, and the USEPA assessment described in the RED document for bromacil is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the health and environmental risk assessments conducted by the USEPA are presented in the USEPA RED for bromacil.

The federal TSMP[3] and Regulatory Directive DIR99-03[4] were taken into consideration during the review of bromacil and it was determined that bromacil is not a TSMP Track 1 substance. The technical grade product of bromacil is not expected to contain impurities

[3] The federal Toxic Substances Management Policy is available through Environment Canada's website at www.ec.gc.ca/toxics

[4] Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, is available through the Pest Management Information Service or through PMRA website at www.hc-sc.gc.ca/pmra-arla/

of toxicological concern as identified in Regulatory Directive DIR98-04[5], 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 bromacil, addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of bromacil that are also registered in Canada. Based on the USEPA RED and the Canadian use pattern, the PMRA has determined that bromacil is acceptable for continued registration provided that the mitigation measures specified in Section 4.0 are adopted. Additional data requirements are identified in Section 6.0.

It should be noted that for EPs which contain more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

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

Based on the USEPA recommendations, the Canadian labels of all bromacil EPs must be amended to limit the maximum application rate to 13.5 kg a.i./ha[6] per year, to include timing of application (e.g., weed growth stage) and number of applications per year, and to remove all references to use on ditch banks, wellheads and bridge approaches. Registrants are also required to provide training material to educate applicators about management practices that can reduce potential for contamination of water resources.

Based on the USEPA recommendations, the Canadian labels of all bromacil EPs must be amended to include the following statements to protect workers and the environment.

i) In the **"Precautions"** section,

- "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 allowed in the area during application."

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5 Regulatory Directive DIR98-04, *The Pest Management Regulatory Agency's Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, is available through the Pest Management Information Service or through the PMRA website at www.hc-sc.gc.ca/pmra-arla/

6 kg (kilogram); ha (hectare); ppm (parts per million)

- "Do not use in residential areas. Residential areas are defined as sites where bystanders including children may be potentially exposed during or after spraying. This includes around homes, on school grounds, in parks, playgrounds, playing fields, around public buildings or any other areas where the general public including children could be exposed."

For EPs formulated as wettable powder, dry flowable and water soluble liquid:

- "Wear long pants, a long-sleeved shirt, shoes and socks when handling this product. In addition, wear chemical resistant gloves during mixing, loading, clean up and repair activities and during application when using a hand wand or a backpack/knapsack sprayer."

- "Avoid entry into treated area until spray has dried."

For EPs formulated as wettable powder and dry flowable:

- "Wear a dust mask during mixing/loading."

  The registrant has the option of packaging the dry flowable/wettable powder EP in water soluble bags, in which case, mixer/loaders would no longer be required to wear a dust mask.

For pellet formulation:

- "Do not apply by hand."

ii) In the **"Directions for Use"** section, for all EPs,

- "**DO NOT** apply during periods of dead calm or when winds are gusty.

  Buffer zones
  A buffer zone of 65 metres is required between the point of direct application and the closest downwind edge of sensitive aquatic habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

  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."

- "**DO NOT apply by air**"

- "Do not spray ditch banks, wellheads, bridge approaches and sites that are adjacent to and surrounding water supply reservoirs, supply streams, lakes and ponds."

- "DO NOT apply directly to aquatic habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats. Do not contaminate the above aquatic habitats when cleaning and rinsing spray equipment or containers."

These label amendments do not include all label requirements for individual EPs, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels for currently registered products should not be removed unless it contradicts these proposed label statements.

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

5.0 Maximum residue limits of bromacil in food

Bromacil is currently not registered for use on any food or feed crops in Canada, and there are currently no maximum residue limits (MRLs) specified for bromacil in Table II, Division 15 of the Canadian Food and Drug Regulations (FDR). Bromacil may be used on agricultural crops in other countries, and it is noted that the United States has established tolerances for residues of bromacil at 0.1 ppm on citrus and pineapple. Currently, any residues of bromacil on food imported into Canada must not exceed 0.1 ppm, a general MRL specified in subsection B.15.002(1) of the FDR. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2003-01, *Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002 (1)]*.

6.0 Additional data requirements

Data to address potential exposure through drinking water in Canada are required. Any existing Canadian water monitoring data and the ground water study requested by the USEPA are also required. Submission of a scientifically based rationale may be acceptable. This is required within 24 months of finalization of the re-evaluation decision. In the interim, the registrants are required to amend labels to reduce the maximum application rate to 13.5 kg a.i./ha per year, and provide training material to educate applicators about management practices that can reduce potential for ground water contamination.

The registrant of the technical grade active ingredient (TGAI) bromacil is also required to submit the following data within 24 months of finalization of the re-evaluation document:

- All data (as they relate to Canadian use pattern) submitted to the USEPA in response to the United States' data call-in prior to the United States reregistration, and the USEPA Data Evaluation Reports (DERs);

- All data (as they relate to Canadian use pattern) that were required by the USEPA as a condition of reregistration of bromacil. These include the water monitoring study and/or scientific-based rationales to support the relevant to Canadian use pattern;

- 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)[7] tables for Use-site Category (USC) # 16. The relevant sections of the DACO tables that registrants are required to address are as follows:
  - USC # 16, TGAI: DACOs 2 through 9, inclusive
  - USC # 16, EP: DACOs 5, 8 and 9

The above data and additional data may be required sooner if expansion of current uses of bromacil is requested.

[7] DACO tables for Use-site Category #16 (Industrial and Domestic Vegetation Control for Non-Food Sites) are available through the Pest Management Information Service or through the PMRA website at www.hc-sc.gc.ca/pmra-arla/

Appendix I Registered products containing bromacil in Canada (as of 31 December 2003)

Product name	Class	Guarantee % w/w	Registrant	Registration number
Bromacil Technical Herbicide	Technical	Bromacil—97.2	DuPont Canada Inc.	20120
Hyvar X Weed & Brush Killer Wettable Powder	Commercial	Bromacil—80	DuPont Canada Inc.	8637
Nufarm Calmix Pellets Weed Killer & Soil Sterilant	Commercial	Bromacil—3 2,4-D present as acid—5	Nufarm Agriculture	9342
Hyvar X-l Weed & Brush Killer	Commercial	Bromacil—0.24	DuPont Canada Inc.	11018
Uragan 80 WP (Bromacil) Commercial Herbicide	Commercial	Bromacil—80	Makhteshim-Agan of North America Inc.	16427
Krovar I DF Herbicide	Commercial	Bromacil—40 Diuron—40	DuPont Canada Inc	22964