



# Proposed Acceptability for Continuing Registration

PACR2005-10

## Re-evaluation of Dichlobenil

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 dichlobenil. The PMRA has determined that dichlobenil is acceptable for continued registration provided that the proposed mitigation measures to further protect workers and the environment are adopted. Additional data requirements are identified. Upon finalization of the re-evaluation decision, the PMRA will provide registrants of products containing dichlobenil 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 dichlobenil. 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.

*(publié aussi en français)*

**25 October 2005**

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

**Publications  
Pest Management Regulatory Agency  
Health Canada  
2720 Riverside Drive  
A.L. 6605C  
Ottawa, Ontario  
K1A 0K9**

**Internet: [pmra\\_publications@hc-sc.gc.ca](mailto:pmra_publications@hc-sc.gc.ca)  
[www.pmra-arla.gc.ca](http://www.pmra-arla.gc.ca)  
Information Service:  
1 800 267-6315 or (613) 736-3799  
Facsimile: (613) 736-3798**



ISBN: 0-662-42008-X (0-662-42009-8)

Catalogue number: H113-18/2005-10E (H113-18/2005-10E-PDF)

**© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2005**

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

## 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.

Dichlobenil 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 dichlobenil 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 1998 RED document for dichlobenil. In its re-evaluation of dichlobenil, the PMRA based its conclusions on this 1998 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 Dichlobenil

Active substance	2,6-dichlorobenzonitrile
Common name	dichlobenil
Chemical name	
IUPAC	2,6-dichlorobenzonitrile
CAS	2,6-dichlorobenzonitrile
CAS number	1194-65-6

In Canada, dichlobenil was first registered in 1973. According to current end-use product labels, this active ingredient is registered in Canada for use as follows.

Terrestrial Non-food Sites	Woody ornamentals in nurseries, shelterbelts, hedgerows, windbreaks, poplar plantations, land holding containers of nursery stock
Terrestrial Food Crops	Bush fruits—grapes, high bush blueberries, cranberries, raspberries, saskatoon berries Fruit trees established or in nurseries—apple, cherry, peach, pear, plum
Industrial and Domestic Vegetation Control Non-Food Sites	Sewer lines

Canadian products containing dichlobenil are listed in Appendix I.

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

The federal Toxic Substances Management Policy and Regulatory Directive [DIR99-03](#) were taken into consideration during the review of dichlobenil, and it was concluded that dichlobenil 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 Proposed Re-evaluation Decision**

The USEPA published a RED document for dichlobenil addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed most uses of dichlobenil that are also registered in Canada. The PMRA has determined that dichlobenil is acceptable for continued registration provided that the mitigation measures specified in Section 4.0 of this PACR are adopted.

Landscape treatment using a backpack granular applicator and application to treat sewer pipes could not be assessed during this re-evaluation as the USEPA did not have adequate data concerning exposure of mixers/loaders/applicators at these sites. However, commercial formulations that are flushed down a toilet bowl to clear sewer lines were assessed by the USEPA and are included in this PACR. Registrants will be required to submit the confirmatory data identified in Section 5.0.

It should be noted that for end-use products that 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. Registrants of products containing dichlobenil 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 must be amended to include the following statements to further protect workers and the environment.

1. On the secondary display panel, the following statements must appear under the **“PRECAUTIONS”** section.

For commercial end-use products formulated as granules,

- “Wear long pants and a long-sleeved shirt, shoes and socks during mixing/loading and application. In addition, wear chemical-resistant gloves during mixing/loading, clean-up and repair activities.”
- “Do not apply directly by hand.”

For commercial end-use products formulated as wettable powders (for use in sewer systems),

- “Wear long pants, a long-sleeved shirt, chemical-resistant gloves, shoes and socks during mixing, loading, application, clean-up and repair activities.”
- “When used in inhabited buildings (residences, offices, hospitals, etc.), windows must be open or an exhaust fan must be operating during application.”

For domestic end-use products formulated as granules,

- “Do not apply directly by hand.”

2. On the secondary display panel for commercial products, the following statements must appear under the “**ENVIRONMENTAL HAZARD**” section.
- “This chemical demonstrates the properties and characteristics associated with chemicals detected in groundwater. The use of this chemical may result in contamination of groundwater, particularly in areas where soils are permeable and/or the water table is shallow.”
  - “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.”
3. On the secondary display panel, the following statements must appear under the “**DIRECTIONS FOR USE**” section.

For commercial end-use products formulated as granules,

- “For use on agricultural crops: Do not enter or allow worker entry into treated areas within 12 hours of application. For horticultural/nursery uses: Do not enter or allow worker entry into treated areas within 24 hours of application.”

For domestic end-use products formulated as granules,

- “Do not enter or allow persons or pets to enter the treated area until granules are thoroughly watered-in and the treated soil has dried.”

As per Regulatory Directive [DIR96-04](#), *Aerial Application of Pesticides*, all currently registered commercial products must bear the following statement,

- “**DO NOT** apply by air.”

For all commercial products, the following amendment must also be made to the product labels:

- Registrants are required to amend labels to limit the maximum application rate to  $\leq 11.0$  kg ai/ha.
- Canadian commercial labels should be amended to identify specific areas where dichlobenil is used for nutsedge control (i.e., list non-crop areas).

The PMRA currently requires all label guarantees to be expressed as nominal guarantees. As a result of this re-evaluation, the technical product labels must be revised to indicate the nominal guarantee value. A Statement of Product Specification Form (SPSF) and analytical data from recent batches must be submitted to support the nominal guarantee.

The above information together with 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 dichlobenil on food or feed crops reported in the USEPA RED. This document adequately addresses the Canadian dietary exposure from domestic and imported foods.

Dichlobenil is currently registered in Canada for use on bush fruits (grapes, high bush blueberries, cranberries, raspberries, saskatoon berries) and fruit trees (apple, cherry, peach, plum). As noted, dichlobenil may be used on other crops in other countries that are imported into Canada.

Currently, residues of dichlobenil in all agricultural commodities, including those approved for treatment in Canada are regulated by subsection B.15.002(1). Where no specific maximum residue limit (MRL) for a pest control 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. 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**

Based on the USEPA review of their environmental fate data, dichlobenil has the potential to leach into groundwater and can contaminate surface water through runoff or drift associated with ground application. The USEPA indicated that at the time of the RED, there was insufficient monitoring data in the United States. As such, a drinking water monitoring study was required. Based on this, data are required to confirm that acceptable levels for dichlobenil and its metabolite 2,6-dichlorobenzamide are not exceeded in Canada; the American monitoring data with a scientifically based rationale to show the relevance of this data to Canada may be acceptable. This rationale should include information on dichlobenil use in Canada (e.g., areas of use, quantity used, typical

application rates) and establish the vulnerability of areas of dichlobenil use to groundwater contamination (i.e., provide information on soil type and groundwater depth in areas of use). Any existing Canadian water monitoring data is also required. The above data and/or scientific rationale are required within 24 months of finalization of the re-evaluation decision.

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

- 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 dichlobenil. This should include the data required to evaluate mixer/loader/applicator exposure for sewer treatment and granular backpack applications of dichlobenil; and
- 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 Category (USC) # 4, 14, 16 and 27. The following sections of the DACO tables must be addressed:
  - 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](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 (*Dichlobenil*, EPA-738-R-98-003, October 1998) is available on the Office of Pesticide Programs' website at [www.epa.gov/pesticides/reregistration](http://www.epa.gov/pesticides/reregistration) under Chemical Status.



## Appendix I      Products Containing Dichlobenil Registered in Canada as of 31 January 2005

Product Name	Registrant	Registration Number	Guarantee (%)	Class
Casoron G-4 Granular Herbicide	Crompton Co.	12533	4	Commercial
Sanafoam Vaporooter II	Douglas Products and Packaging	15123	1.95	Commercial
Later's Casoron Weed Preventer	Nu-Gro IP Inc.	16817	2	Domestic
Duphar Technical Dichlobenil	Crompton Co.	19963	98	Technical grade active ingredient
Casoron 85W Manufacturing Use	Crompton Co.	20217	85	Manufacturing concentrate
Casoron Granular Herbicide	Crompton Co.	20233	2	Domestic
Casoron G-2 Granular Herbicide	Crompton Co.	20377	2	Commercial
Casoron G-4 Granular Herbicide	Crompton Co.	23767	4	Commercial
Stryke 4G Herbicide	Crompton Co.	23768	4	Commercial
RootX WP Herbicide	General Chemical Co.	25934	0.55	Commercial
RootX FDU WP Herbicide	General Chemical Co.	26435	0.55	Commercial
Residential RootX 15	General Chemical Co.	26436	0.55	Commercial
Residential RootX 30	General Chemical Co.	26437	0.55	Commercial