



Proposed Acceptability for Continuing Registration

PACR2004-35

Re-evaluation of Diflubenzuron

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 diflubenzuron (DFB). The PMRA has determined that DFB is acceptable for continued registration provided that the proposed mitigation measures are adopted. Additional data requirements are identified. Upon the finalization of the re-evaluation decision, the PMRA will provide registrants of products containing DFB with specific direction on how to address these items.

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

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1.0 Background

The PMRA is re-evaluating all pesticides, both active ingredients 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](#), *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

DFB 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 DFB 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 1997 RED document for DFB. In its re-evaluation of DFB, the PMRA based its conclusions on this 1997 RED document, taking into account the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substance Management Policy [TSM]). A review of the chemistry of Canadian products was also conducted.

2.0 Re-evaluation of DFB

Common name: diflubenzuron

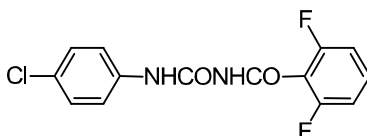
Chemical name:

IUPAC: 1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl)urea

CAS: N-[[4-chlorophenyl]amino]carbonyl]-2,6-difluorobenzamide

CAS number: 35367-38-5

Structural formula:



DFB is an acaricide/insecticide (insect growth regulator) used in Canada to control mosquitoes, gypsy moth, fungus gnats and shore flies. In Canada, the only registered EP containing DFB is a wettable powder, which must be applied as follows:

- by ground and aerial spray in forests by the Plant Health Division of the Canadian Food Inspection Agency;
- on aquatic non-food sites containing temporary pools by Public Health Officials, mosquito abatement officials or other personnel trained in public mosquito programs; or
- by soil drench or spray treatment on potting soil for ornamentals in greenhouses.

Currently registered Canadian products containing DFB are listed in Appendix I.

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

The federal TSMP and Regulatory Directive [DIR99-03](#) were taken into consideration during the review of DFB, and it was concluded that DFB is not a TSMP Track 1 substance. The technical product is not expected to contain impurities of toxicological concern as identified in [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 DFB addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of DFB that are also registered in Canada. Based on the USEPA RED and the Canadian use pattern, the PMRA has determined that DFB is acceptable for continued registration, provided that the mitigation measures specified in Section 4.0 are adopted. Additional data requirements are outlined 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 for these products. Registrants of products containing DFB should not apply for label amendments or submit the additional data 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 action

Based on findings by the USEPA and in consideration of Canadian use pattern, Canadian EP labels must be amended as follows to protect workers and the environment.

1. The following statements must be added to the “Precautions” section of the label:
 - All handlers must wear a long-sleeved shirt and long pants. In addition, wear chemical-resistant gloves and a NIOSH-approved dust/mist respirator during mixing/loading activities. Wear chemical-resistant gloves during application using hand-held equipment.

The registrant has the option of packaging the EP in water-soluble bags, in which case, mixer/loaders would no longer be required to wear a dust/mist respirator.

- 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.
- Apply only when the potential for drift to areas of human habitation or areas of human activity is minimal. Take into consideration meteorological conditions (e.g. wind speed, wind direction, temperature) as well as application equipment and sprayer settings used for application.
- When used in greenhouses: Do not re-enter treated areas until 12 hours after application.

- Users should wash 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. Wash contaminated clothing before reuse.
 - Users should remove protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.
2. A statement has to be added to Canadian labels to prohibit use of DFB in residential areas and to prevent application in any area where there may be potential exposure to bystanders. The following statements must be added to the “Precautions” section of the label:
- 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.
 - Do not apply in areas where there may be potential exposure to bystanders.

If the registrant wants to maintain the use in residential areas, additional data will be required to assess postapplication exposure.

3. A section entitled “Environmental Hazards” must be added to the label and include the following statements:
- **TOXIC TO AQUATIC ORGANISMS. DO NOT** contaminate irrigation / drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.
 - For gypsy moth control, observe buffer zones specified under Directions for Use.

4. The registrant is required to replace the statement:
- **FOREST INSECT CONTROL:** For use only by Plant Protection Division, Agriculture Canada.

with the following:

- **FOREST INSECT CONTROL:** For use only by the Canadian Food Inspection Agency.
5. The EP label must also be amended to include a recommendation to apply buffer zones during ground or aerial application. Current Canadian labels do not specify if fixed wing or helicopter application of DFB is acceptable for control of gypsy moths in forests. The PMRA concluded that aerial use for application of DFB must be limited to helicopters only, since estimated buffer zones for fixed-wing aircraft would be too large to be practical. The EP label must be amended to include the following statements:

- **DO NOT** apply more than 2 applications per season.
- A minimum interval of 7 days between applications is required.
- When using this product to control gypsy moths:

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

Aerial application: Aerial application is permitted using helicopter only.

DO NOT apply using fixed wing aircraft. **DO NOT** apply when average wind speed is greater than 16 km/h at 2 metres. **DO NOT** apply with spray droplets smaller than the ASAE fine to medium classification. Apply the recommended rate in a minimum spray volume of 5 litres per hectare.

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, coulees, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), and estuarine/marine habitats.

For aerial application to forests, sensitive aquatic habitats include all rivers designated as double-sided and all lentic (standing) and lotic (running) water bodies, including impoundments, beaver ponds and bog ponds, that appear on the most recent 1:50 000 topographic map of the area to be treated, or as identified by more up-to-date data (e.g., GPS) in the particular jurisdiction and approved by provincial regulatory authorities.

Lentic and lotic water bodies that do not appear on a 1:50 000 topographic map of the treatment area or a more up-to-date data system, but are visible from the air during pretreatment reconnaissance flights, must also be considered sensitive aquatic habitats.

Method of application	Buffer zone (metres) required for the protection of:	
	Freshwater habitat	Estuarine/marine habitat
Mist blower	10	15
Aerial (helicopter only)	150	325

6. The registrant is required to amend the label to include the following description of where temporary pools can be found:
- Temporary pools can be in shallow, grassy depressions, flooded woodlands, industrial parks, roadway ditches, railway marshalling yards, small temporary sloughs. This product is NOT TO BE USED IN PERMANENT WATER BODIES SUCH AS LAKES, DUGOUTS OR FISH PONDS.

Label amendments presented in this section must be submitted within 90 days of finalization of the re-evaluation decision.

5.0 Additional Data Requirements

The registrant of technical DFB is required to submit the following within 24 months of finalization of the re-evaluation decision:

- all data (as they relate to Canadian use patterns) 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 Canadian use patterns) that were required by the USEPA as a condition of reregistration of DFB; and
- a commitment and schedule to address Canadian requirements which are not addressed through submission of the data outlined above. These are outlined in the PMRA's data code tables (DACO) for use-site categories # 2, 4 and 6. The registrant is required to address the following sections of DACO tables:
 - for the TGAI: DACOs 2 through 9, inclusive
 - for the EP: DACOs 5 through 9 inclusive

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

6.0 Supporting documentation

PMRA documents, such as DIR2001-03, and DACO tables can be found on our website at www.hc-sc.gc.ca/pmra-arla. 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 (*Diﬂubenzuron*) is available on the Office of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemical Status.

**Appendix I Products containing DFB registered in Canada as of
31 March 2004**

Product name	Class	Guarantee	Registrant	Registration number
Dimlin 25% WP Insecticide	Commercial	25%	Crompton Co.	13816
Diflubenzuron Technical Insecticide	Technical	95%	Crompton Co.	25451