



Re-evaluation Decision Document

RRD2006-10

Diflubenzuron

The purpose of this Re-evaluation Decision Document (RRD) is to notify registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated the active ingredient diflubenzuron and its associated uses as an insect growth regulator to control mosquitoes in temporary pools on non-crop land, gypsy moth in forests and fungus gnats and shore flies in ornamentals.

On 9 August 2004, Proposed Acceptability for Continuing Registration document [PACR2004-35](#), *Re-evaluation of Diflubenzuron*, was published for consultation. The PMRA has reviewed the comments received and provides a response in Appendix I of this RRD. These comments did not result in substantive changes to the regulatory decision as described in PACR2004-35; however, they did result in some changes to the label amendments. The revised label amendments can be found in Appendix II.

The PMRA has determined that this active ingredient is acceptable for continuing registration. Mitigation measures to further protect workers, bystanders and the environment are specified in this RRD. The registrants have been informed by letter of the specific requirements affecting their product registrations and the regulatory options available to comply with this decision.

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Appendix I Comments to PACR2004-35 and Responses

The PMRA received comments in response to PACR2004-35. The PMRA has consolidated and summarized the comments received and provides responses as outlined below.

1.0 Comments Pertaining to the Environment

1.1 Comment on the Proposed Buffer Zones

Implementing the recommended buffer zones in PACR2004-35, despite the acceptable risk, would render dimilin impractical as a tool for forestry quarantine programs. Based on the information presented in the document entitled *Response to EPA to establish a buffer zone for dimilin aerial applications*, which was submitted by the registrant to the United States Environmental Protection Agency (USEPA), buffer zones around aquatic environments are not necessary.

Response

In determining the magnitude of the buffer zones, there are a number of differences in the input parameters between those used by the PMRA and the registrant. These include different assumptions of aircraft use (helicopter vs air tractor), different values for boom height, percent of canopy interaction and pond dimensions (depth, area, volume). In addition, there are differences in spray drift model used by the PMRA (AGDISP Model, version 8.08) and the USEPA (AGDRIFT Model).

Regarding the comment from the registrant that buffer zones would reduce efforts to control gypsy moth, it should be noted that buffer zones apply only to situations where the aquatic habitats are downwind from the point of application. Thus, spraying up to the boundary between the intended target area and the aquatic habitat can be achieved if diflubenzuron is applied upwind from the aquatic habitat.

With regards to the registrant's citation of the study by Sundaram et al. (1991), where it was reported that diflubenzuron was non-persistent in forest aquatic systems, it is to be noted the same authors reported that diflubenzuron was detected in pond water up to 15 days after spraying and that zooplankton (*cladocera* and *copepoda*) populations were reduced at 3 days after treatment and remained suppressed for 2–3 months. Furthermore, the authors concluded that the impact on zooplankton populations, particularly cladoceran, can be reduced by avoiding direct contamination of water during forest spraying. These conclusions, therefore, reflect the position of the PMRA regarding the observance of buffer zones to mitigate the entry of diflubenzuron into forest aquatic habitats.

In conclusion, the PMRA requires the observance of the buffer zones for the aerial application of diflubenzuron in forestry. The buffer zone table in Appendix II outlines the revised buffer zones and precautionary statements to be included on the proposed product label under "Directions for Use". It should be noted that the revised buffer zones in Appendix II provide flexibility to the applicator as the buffer zone distance depends on

the type of aquatic habitat (as reflected in the different water depths) that requires protection from spray drift.

1.2 Comment on the Proposed Label Amendment

Does the proposed label amendment not to use diflubenzuron in residential area or area with potential to bystanders apply to public health uses for mosquitoes? If not, should/could something be added to these statements qualifying that they do not apply to use by public health professionals or their agents?

Response

The PMRA has decided to remove requirement for a label amendment prohibiting the use of diflubenzuron in residential areas, based on the USEPA's conclusion that the risk to bystanders from uses of this active ingredient in these areas is negligible.

1.3 Comment on Temporary Pools

The statement describing temporary pools does not include roadside catch basins. From a public health perspective, this would be a useful addition to the list. While methoprene is the larvicide of choice, it is good to know that there are other options available in case of resistance development.

Response

It is not feasible to include all examples of temporary pools or ponds on the end-use product label. A number of examples are provided to help users determine if the area to be treated falls within the description. The wording of the statement describing temporary pools has been revised to read as follows:

“Examples of temporary pools are 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.”

Appendix II Label Amendments for Diflubenzuron

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

Canadian end-use product labels must be amended as follows to protect workers, bystanders and the environment:

1. In the “Precautions” section pertaining to all uses of diflubenzuron, the following statement must be added:

“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 end-use product in water soluble bags, in which case mixer/loaders would no longer be required to wear a dust/mist respirator.

2. The following statements must also be added to the “Precautions” section of the label:

“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) and 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.”

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3. A section entitled “Environmental Hazards” must be added to the label, which must 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 and Agri-Food Canada.”

with the following:

“FOREST INSECT CONTROL: For use in quarantine programs by the Canadian Food Inspection Agency.”

5. The end-use product 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 diflubenzuron is acceptable for control of gypsy moths in forests. The PMRA concluded that aerial use for application of diflubenzuron must be limited to helicopters only, since estimated buffer zones for fixed-wing aircraft would be too large to be practical. The end-use product label must be amended to specify helicopter application and 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:

Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the ASAE fine to medium classification.”

Buffer zones:

The buffer zones specified in Table 1 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.

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 systems) 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.

Table 1 Buffer Zones for the Application of Diflubenzuron

Method of application	Buffer zone required for the protection of:					
	Freshwater habitat of water depths			Estuarine/marine habitat of water depths:		
	Less than 1 m	1 to 3 m	Greater than 3 m	Less than 1 m	1 to 3 m	Greater than 3 m
Mist blower	10	2	0	15	3	1
Aerial (helicopter only)	125	0	0	275	30	0

6. The registrant is required to amend the label to include the following description of where temporary pools can be found:

“Examples of temporary pools are 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”.