



Proposed Acceptability for Continuing Registration

PACR2005-04

Re-evaluation of Terbacil

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

Terbacil 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 terbacil 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 terbacil. In its re-evaluation of terbacil, the PMRA based its conclusions on this 1998 RED document, taking into account 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.

2.0 Re-evaluation of Terbacil

Active substance: Terbacil

Common name: Terbacil

Chemical name:

IUPAC: 3-tert-butyl-5-chloro-6-methyl uracil

CAS: 5-chloro-3-(1,1-dimethylethyl)-6-methyl-2,4(1H,3H)-pyrimidinedione

CAS number: 5902-51-2

In Canada, terbacil was first registered in 1970. It is currently registered in Canada for selective grass and broadleaf weed control in the following crops:

- asparagus, blueberry, raspberry, strawberry, peppermint, spearmint;
- first year apple, apricot, cherry, peach, pear and plum fruit trees; and
- established apple, peach, pear, and sweet and sour cherry fruit trees.

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

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

The federal TSMP and Regulatory Directive [DIR99-03](#) were taken into consideration during the review of terbacil, and it was concluded that terbacil 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 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 terbacil addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of terbacil that are also registered in Canada. The PMRA has determined that terbacil 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.

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 terbacil should not apply for label amendments or address the data requirements listed in Section 6.0 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

The Canadian end-use product label must be amended as follows.

D) The following statements must be included in the section entitled **“Precautions”**:

- Do not enter or allow entry into treated areas within 12 hours after application.

- It is recommended that this product not be applied in a way that will contact workers or other persons, either directly or through drift. Only handlers wearing personal protective equipment may be in the area during application.

II) The following statements must be included in the section entitled “**Directions for Use**”:

For 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:			
	Terrestrial habitat	Aquatic habitat at water depths		
		< 1 m	1–3 m	> 3 m
Field sprayer	35	10	4	2
Field sprayer with cones	25	5	3	1
Field sprayer with shrouds	10	3	1	0

- 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.

III) The following statements must be included in a section entitled “**Environmental Hazards**”:

- The use of this chemical may result in the contamination of groundwater particularly in areas where soils are permeable (e.g., sandy soil) 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 and 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.
- Observe buffer zones specified under “Directions for Use”.

The label amendments presented above do not include all label requirements for the end-use product such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on the label of the currently registered product 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.

5.0 Maximum Residue Limits

Terbacil is currently registered for use on apple, asparagus, apricot, blueberry, raspberry, cherry (sweet and sour), peach, pear, plum, peppermint, spearmint and strawberry in Canada. It is also registered for use in the United States on various commodities for which tolerances have been established. Residues of terbacil on food currently in Canada must not exceed 0.1 ppm, a general maximum residue limits (MRL) specified in Regulation B.15.002(1) of the Canadian Food and Drug Regulations. 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

Based on the USEPA review of their environmental fate data, terbacil has a potential to leach into groundwater and can be expected to runoff or drift into surface water. The USEPA monitoring data indicated that the levels of terbacil did not exceed the USEPA’s drinking water standards for human health in the United States. Data are required to confirm that acceptable levels are not exceeded in Canada. A scientifically based rationale demonstrating the relevance of the existing American monitoring data may be

acceptable. 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 terbacil is also 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 terbacil;
- 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) #14. The registrant is required to address the following sections of DACO tables:
 - for the technical grade active ingredient: DACOs 3 through 9, inclusive
 - for the end-use product: DACOs 5, 8 and 9

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

7.0 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) 736-3758; 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 (*Terbacil*) is available on the Office of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemical Status.

**Appendix I Products Containing Terbacil Registered in Canada
(as of 30 November 2004)**

Product Name	Registrant	Registration Number	Guarantee (% a.i.)	Class
Terbacil Technical Herbicide	E.I. DuPont Canada Company	19276	95	Technical
Sinbar Herbicide	E.I. DuPont Canada Company	10628	80	Commercial