Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Acceptability for Continuing Registration

PACR2004-17

Re-evaluation of 1-(3-chloroallyl)-3,5,7-triaza-1-azonia adamantane chloride

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 1-(3-chloroallyl)-3,5,7-triaza-1-azonia adamantane chloride (CTAC). The PMRA has determined that CTAC 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 CTAC. 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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Publications Coordinator
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

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

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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.

CTAC 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 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 CTAC and concluded that, on the basis of a health and environmental risk assessment, it was eligible for reregistration with implementation of mitigation measures. In its re-evaluation of CTAC, the PMRA based its conclusions on this 1995 RED document[1], 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 CTAC

Active substance:	1-(3-chloroallyl)-3,5,7-triaza-1-azonia adamantane chloride (CTAC)
Common name:	Dowicil®75 (racemic mixture) Dowicil®200, Dowicil®150 (cis-isomer only)
CAS number:	4080-31-3

[1] The USEPA RED document for CTAC is available from the Chemical Status List for *Dowicil®CTAC* on the Office of Pesticide Programs webpage at www.epa.gov/pesticides/reregistration

CTAC was first registered in 1973. According to current Canadian end-use product labels, it is registered with the PMRA for use as a material preservative in many commercial/manufacturing industrial processes:

- pulp and paper (coatings, finishes and printing colours) adhesives,
- water-based floor waxes and polishes,
- detergents and laundry starch,
- metal working fluids,
- water-based inks (fountain pen, fabric and paper-printing inks),
- latex emulsions,
- textiles (rayon, finishing solutions, printing pastes), as well as
- paints and construction products (caulking, grouting, sparkling, compounds and joint cements).

In Canada, Dowicil®200 is registered as a technical ingredient only. Currently registered Canadian products that contain CTAC are listed in Appendix I.

Based on a comparison of Canadian and American use patterns, the USEPA assessment described in the RED document for Dowicil®CTAC is considered to be an adequate basis for the proposed Canadian re-evaluation decision for CTAC. The details of the assessments conducted by the USEPA are outlined in the USEPA RED for Dowicil®CTAC.

The federal TSMP[2] and Regulatory Directive DIR99-03[3] were taken into consideration during the review of CTAC, and it was concluded that CTAC is not a TSMP Track 1 substance.

3.0 Proposed re-evaluation decision

The USEPA published a RED document for CTAC, addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of CTAC that are also registered in Canada. Based on the USEPA RED and Canadian use pattern, the PMRA has determined that CTAC is acceptable for continued registration, provided that the mitigation measures specified in Section 4.0 are adopted. Additional data requirements are also outlined in Section 5.0.

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

3 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. 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 or through our website at www.hc-sc.gc.ca/pmra-arla

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.

4.0 Proposed regulatory action

1) The label of the technical products must be amended as follows:

   - On the primary display panel of Dowicil®200 label (PCP# 11834), the statement

     "For use in manufacturing processes"

     must be replaced with

     "To be used only in the manufacture of a pesticide that is registered under the PEST CONTROL PRODUCTS ACT."

   - On the primary display panel of Dowicil®75 label (PCP# 11995), the statement

     "For use in manufacturing or reformulating processes only."

     must be replaced with

     "To be used only in the manufacture of a pesticide that is registered under the PEST CONTROL PRODUCTS ACT."

2) For all Dowicil®75 end-use products, based on the USEPA RED and good hygiene practice, labels must be amended to protect workers and the environment by including the following statements:

   - In the **"PRECAUTIONS"** section, the following must be added:

     "Wear chemical-resistant gloves, long pants, a long-sleeved shirt and shoes during the mixing/loading, clean-up, repair and other handling activities."

     "Formaldehyde can be released during the use of this product. It is recommended that this product not be used in circumstances that would result in formaldehyde air concentrations in the workplace exceeding the exposure levels established by occupational health and safety authorities in your jurisdiction. If values exceed this level, it is recommended that NIOSH approved respiratory protection be worn."

- In the **"ENVIRONMENTAL HAZARDS"** section, the following must be added:

  "This product is toxic to fish and other aquatic organisms. It is not to be used in circumstances that would cause or allow it to enter lakes, streams, ponds, estuaries, oceans or other waters in contravention of federal or provincial regulatory requirements. The requirements of applicable laws should be determined before using the product."

  "Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority."

3) According to the information on the current label for Nalcon 7635 (PCP# 21945), this product is being used as a material preservative and not as a slimicide in the pulp and paper industry. The registrant for Nalcon 7635 is required to amend the label to remove the word "slimicide".

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

5.0 Additional data requirements

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

- 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 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 Dowicil®CTAC;

- 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[4] for Use-site Category (USC) #18. The following are the relevant sections of the DACO tables that registrants are required to address:

  USC#18, Material – TGAI: DACOs 2 through 9 inclusive
  USC#18, Material – EP: DACOs 5 through 9 inclusive

[4] Use-site category DACO tables can be located at the PMRA website at www.hc-sc.gc.ca/pmra-arla

The above data as well as additional data may be required sooner if an expansion of current uses of CTAC is requested.

The PMRA is currently undertaking initiatives to address the labelling deficiencies for certain kinds of antimicrobial products, especially with respect to the “Directions for Use” section of product labels. The PMRA will announce in the near future the nature of these initiatives and any requirements to be addressed by registrants.

Appendix I Currently registered Canadian CTAC products

Product name	Registrant	Registration number	Guarantee	Class
Dowicil®200	Dow Chemical Canada Inc.	11834	94% (minimum)	Technical
Dowicil®75	Dow Chemical Canada Inc.	11995	64% (nominal)	Technical
Dowicil®75 (solupak)	Dow Chemical Canada Inc.	22004	64% (minimum)	Commercial
Nalcon 7635 – Pulp & Paper Antimicrobial	Ondeo Nalco Canada Inc.	21945	67.5% (minimum)	Commercial