Proposed Acceptability for Continuing Registration

PACR2004-13

Re-evaluation of Hexahydro-1,3,5-triethyl-s-triazine

The purpose of this document is to inform the registrant, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of hexahydro-1,3,5-triethyl-s-triazine. The PMRA has determined that hexahydro-1,3,5-triethyl-s-triazine 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 hexahydro-1,3,5-triethyl-s-triazine. 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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Publications Coordinator
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: <u>pmra_publications@hc-sc.gc.ca</u>

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 (EPs), that were registered prior to 31 December 1994 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03¹, *PMRA Re-evaluation Program*, outlines the details of the re-evaluation activities and program structure.

Hexahydro-1,3,5-triethyl-s-triazine has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in DIR2001-03. Under Program 1, 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 hexahydro-1,3,5-triethyl-s-triazine and concluded, on the basis of health and environmental risk assessments, that it was eligible for reregistration with implementation of mitigation measures. PMRA conclusions on the hexahydro-1,3,5-triethyl-s-triazine re-evaluation were based on the USEPA RED document for hexahydro-1,3,5-triethyl-s-triazine², with consideration of the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substance Management Policy [TSMP]).

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Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, is available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or (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 USEPA RED document for hexahydro-1,3,5-triethyl-s-triazine (1,3,5-Triethylhexahydro-s-triazine) is available from the Chemical Status List on the Office of Pesticide Programs' webpage at www.epa.gov/pesticides/reregistration

2.0 Re-evaluation of hexahydro-1,3,5-triethyl-s-triazine

Chemical names: hexahydro-1,3,5-triethyl-s-triazine

1,3,5-triethylhexahydro-s-triazine

CAS number: 7779-27-3

Structural formula:

Purity: 95% (min)

Hexahydro-1,3,5-triethyl-s-triazine was first registered in 1976. It is a microbiocide/microbiostat for use as an additive for synthetic rubber latex, adhesives and cutting oils. In Canada, there is one currently registered EP containing hexahydro-1,3,5-triethyl-s-triazine. This product is listed in Appendix I.

Based on the comparison of use pattern between the United States and Canada, it is concluded that the USEPA assessment described in the RED document for hexahydro-1,3,5-triethyl-s-triazine is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the health and risk assessments conducted by the USEPA are outlined in the USEPA RED for hexahydro-1,3,5-triethyl-s-triazine.

The federal TSMP³ and Regulatory Directive DIR99-03⁴ were taken into consideration during the review of hexahydro-1,3,5-triethyl-s-triazine. The review determined that hexahydro-1,3,5-triethyl-s-triazine is not a TSMP Track 1 substance.

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

www.hc-sc.gc.ca/pmra-arla/

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 (613) 736-3799 outside Canada (long distance charges apply); Fax: (613) 736-3798; E-mail: pmra_infosery@hc-sc.gc.ca; or through our website at

3.0 Proposed re-evaluation decision

The USEPA published a RED document for hexahydro-1,3,5-triethyl-s-triazine addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of hexahydro-1,3,5-triethyl-s-triazine that are also registered in Canada. Based on the USEPA RED and the Canadian use pattern, the PMRA has determined that hexahydro-1,3,5-triethyl-s-triazine 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 this product.

4.0 Proposed regulatory action

Based on the USEPA RED, current Canadian label statements and good hygiene practice, the label for the EP must be amended to protect workers and the environment. Therefore, the labels must include the following statements.

In the "**PRECAUTIONS**" section:

- "Wear goggles or a face shield, chemical-resistant gloves, long pants, a long-sleeved shirt, shoes plus socks during mixing/loading, clean-up, repair, and other handling activities."
- "Do not use this product in a way that will contact workers or other persons."
- "Do not apply this product as a spray."
- "For use in synthetic rubber latex and adhesives, the vats to which hexahydro-1,3,5-triethyl-s-triazine is being added must be closed and equipped with mechanical vents to the outdoors."
- "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."

An "ENVIRONMENTAL HAZARDS" section must be created and must include the following information under the heading:

"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."

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

5.0 Additional data requirements

The following is required within 24 months of finalization of the re-evaluation decision:

- a submission to register a source of technical grade active ingredient (TGAI) or an integrated system product;
- all data (as they relate to Canadian use patterns) submitted to the USEPA in response to the United States' data call-in prior to the United States reregistration and 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 hexahydro-1,3,5-triethyl-s-triazine; 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) tables⁵ for Use-site Category # 18. The registrant is required to address the following sections of the DACO tables:

TGAI: DACOs 2 through 9, inclusive EP: DACOs 5 through 9, inclusive

The above data and additional data may be required sooner if expansion of current uses of hexahydro-1,3,5-triethyl-s-triazine 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 the registrant.

Use-site category DACO tables are posted on the PMRA website at www.hc-sc.gc.ca/pmra-arla/

Appendix I Hexahydro-1,3,5-triethyl-s-triazine products currently registered in Canada (as of 30 March 2004)

Registrant	Registration number	Product name	Guarantee	Marketing class
Vanderbilt, R.T. Co. Inc.	13878	Vancide TH Liquid Industrial Preservative	95%	Commercial