



Proposed Acceptability for Continuing Registration

PACR2004-23

Re-evaluation of 2-(hydroxymethyl)-2-nitro-1,3-propanediol

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 2-(hydroxymethyl)-2-nitro-1,3-propanediol. The PMRA has determined that 2-(hydroxymethyl)-2-nitro-1,3-propanediol is acceptable for continued registration provided that the proposed mitigation measures are adopted. Additional data requirements are identified.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for 2-(hydroxymethyl)-2-nitro-1,3-propanediol. 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 General background on re-evaluation

The PMRA is re-evaluating all pesticides, both technical grade active ingredients (TGAIs) 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.

2-(hydroxymethyl)-2-nitro-1,3-propanediol 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 2-(hydroxymethyl)-2-nitro-1,3-propanediol 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 1993 RED document for 2-(hydroxymethyl)-2-nitro-1,3-propanediol. In its re-evaluation of 2-(hydroxymethyl)-2-nitro-1,3-propanediol, the PMRA based its conclusions on this 1993 RED document, taking into account the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substances Management Policy [TSMP]).

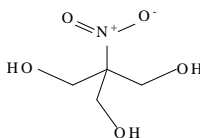
2.0 Re-evaluation of 2-(hydroxymethyl)-2-nitro-1,3-propanediol

Chemical name : 2-(hydroxymethyl)-2-nitro-1,3-propanediol

CAS registry number: 126-11-4

Molecular formula: $C_4H_9NO_5$

Molecular structure:



In Canada, 2-(hydroxymethyl)-2-nitro-1,3-propanediol was first registered in 1981. It is a microbicide/microbiostat that is registered for use as an additive for industrial metalworking fluids, cooling towers and oil field flooding. Canadian products containing 2-(hydroxymethyl)-2-nitro-1,3-propanediol are listed in Appendix I.

Based on the comparison of American and Canadian use patterns, the USEPA assessment described in the RED document for 2-(hydroxymethyl)-2-nitro-1,3-propanediol is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the assessments conducted by the USEPA are outlined in the USEPA RED for 2-(hydroxymethyl)-2-nitro-1,3-propanediol.

The federal TSMP and Regulatory Directive DIR99-03 were taken into consideration during the review of 2-(hydroxymethyl)-2-nitro-1,3-propanediol, and it was concluded that 2-(hydroxymethyl)-2-nitro-1,3-propanediol is not a TSMP Track 1 substance.

3.0 Proposed re-evaluation decision

The USEPA published a RED document for 2-(hydroxymethyl)-2-nitro-1,3-propanediol addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of 2-(hydroxymethyl)-2-nitro-1,3-propanediol that are also registered in Canada. Based on the USEPA RED and Canadian use pattern, the PMRA has determined that 2-(hydroxymethyl)-2-nitro-1,3-propanediol is acceptable for continued registration provided that the mitigation measures specified in Section 4.0 are adopted. Additional data requirements are identified 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.

4.0 Proposed regulatory action

Based on the USEPA RED and good hygiene practices, Canadian EP labels should be amended to include the following statements to further protect workers and the environment.

In the “**PRECAUTIONS**” section:

- “Wear chemical-resistant gloves, long pants, a long-sleeved shirt and shoes plus socks during mixing, loading and other handling activities.”

- “Formaldehyde can be released during 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**” subsection of the “**PRECAUTIONS**” section:

- “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.”
- For uses of oil field flooding, “For use in terrestrial oil wells only. Do not apply in marine and/or estuarine oil fields.”

A rationale must be provided to support the need for higher application rates in Canada compared with the application rates in the United States (U.S.) for cooling towers (609 ppm in the U.S. vs. 2000 ppm in Canada) and oil field flooding (1159 ppm in the U.S. vs. 2000 ppm in Canada). This rationale and a submission to request the above label revisions is required within 90 days of finalization of the re-evaluation decision.

5.0 Additional data requirements

The technical registrant of 2-(hydroxymethyl)-2-nitro-1,3-propanediol is 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 2-(hydroxymethyl)-2-nitro-1,3-propanediol;
- 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 categories (USC) # 17 and # 18. 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 2-(hydroxymethyl)-2-nitro-1,3-propanediol 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.

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 [*Tris(hydroxymethyl)nitromethane*] is available on the Office of Pesticide Programs’ website at www.epa.gov/pesticides/reregistration under Chemical Status.

Appendix I Products containing 2-(hydroxymethyl)-2-nitro-1,3-propanediol registered in Canada as of 30 March 2004)

Product name	Class	Guarantee	Registrant	Registration number
Tris Nitro 50% Aqueous Antimicrobial Agent	Commercial	50%	Dow Chemical Canada Inc.	16821
Tris Nitro 25% Aqueous Antimicrobial Agent	Commercial	25%	Dow Chemical Canada Inc.	16822
Ultra-Fresh LP-50	Commercial	50%	Thomson Research Associates	22479
Klenzoid NitroKlenz TN	Commercial	50%	Klenzoid Co. Ltd.	22707
Tris Nitro Solid Antimicrobial Agent A	Commercial	100%	Dow Chemical Canada Inc.	27103
Tris Nitro Solid Antimicrobial Agent	Technical	97%	Dow Chemical Canada Inc.	16820