



Re-evaluation Decision Document

RRD2005-08

2-(hydroxymethyl)-2-nitro-1,3-propanediol

The purpose of this Re-evaluation Decision Document (RRD) is to notify registrants, pesticide regulatory officials and the Canadian public that the re-evaluation of 2-(hydroxymethyl)-2-nitro-1,3-propanediol is now complete.

Health Canada's Pest Management Regulatory Agency (PMRA) has determined that 2-(hydroxymethyl)-2-nitro-1,3-propanediol is acceptable for continued registration, consistent with Proposed Acceptability for Continuing Registration (PACR) document [PACR2004-23](#), *Re-evaluation of 2-(hydroxymethyl)-2-nitro-1,3-propanediol*, published on 6 July 2004, provided that the mitigation measures included in the PACR are adopted. Additional data requirements have been identified.

This RRD includes the comments made to the PMRA in response to the PACR, the PMRA's response to the comments and the regulatory decisions resulting from the re-evaluation of 2-(hydroxymethyl)-2-nitro-1,3-propanediol.

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1.0 Introduction

The re-evaluation of the available information for the active ingredient 2-(hydroxymethyl)-2-nitro-1,3-propanediol and its associated uses on industrial metalworking fluids, cooling towers and oil field flooding has been completed by the PMRA.

2.0 Background

The purpose of this RRD is to notify registrants, pesticide regulatory officials and the Canadian public that the re-evaluation of 2-(hydroxymethyl)-2-nitro-1,3-propanediol is now complete.

On 6 July 2004, the PMRA published PACR2004-23, *Re-evaluation of 2-(hydroxymethyl)-2-nitro-1,3-propanediol*, for consultation on the proposed regulatory decision for 2-(hydroxymethyl)-2-nitro-1,3-propanediol. Comments were received from registrants concerning this PACR.

This RRD summarizes these comments and the PMRA's response, and outlines the regulatory decision resulting from the re-evaluation of 2-(hydroxymethyl)-2-nitro-1,3-propanediol.

3.0 Regulatory decision

The PMRA has reviewed the comments received in response to the proposed regulatory decision for 2-(hydroxymethyl)-2-nitro-1,3-propanediol (Appendix I) and has concluded that these comments did not result in substantive changes to the regulatory decision as described in PACR2004-23.

The PMRA has determined that 2-(hydroxymethyl)-2-nitro-1,3-propanediol is acceptable for continuing registration provided that the mitigation measures specified in Section 4.0 of the PACR are implemented. These mitigation measures included label statements to protect workers and the environment. Some changes to the required label statements resulted from the comments received. The revised label amendments are outlined in Appendix II of this RRD.

Section 5.0 of the PACR outlined additional requirements for continued registration of 2-(hydroxymethyl)-2-nitro-1,3-propanediol. The registrants will be informed by letter of the specific requirements and the regulatory options available to comply with this decision.

Appendix I Comments and responses to PACR2004-23

1.0 Comments

1.1 Comment pertaining to formaldehyde statement

The registrant objected to the inclusion of the potential formaldehyde exposure statement as proposed in the PACR because the USEPA Notices of Reregistration for 2-(hydroxymethyl)-2-nitro-1,3-propanediol did not require such a statement to be included on registered product labels.

PMRA response

In Canada, a label statement indicating potential release of formaldehyde during use of 2-(hydroxymethyl)-2-nitro-1,3-propanediol is required to ensure that this information is available to persons responsible for occupational health and safety programs in the workplace and to provincial/territorial jurisdictions responsible for implementing occupational health and safety legislation.

Therefore, the PMRA continues to require that the end-use products containing 2-(hydroxymethyl)-2-nitro-1,3-propanediol include a label statement on formaldehyde release as described in Section 4.0 of the PACR2004-23.

The need for this label statement may be revisited during the next round of re-evaluation if data or a scientific rationale is submitted to demonstrate that exposure to formaldehyde would be negligible.

1.2 Comment pertaining to aquatic toxicity

The registrant objected to the sentence “This product is toxic to fish and other aquatic organisms” because the USEPA Notices of Reregistration for 2-(hydroxymethyl)-2-nitro-1,3-propanediol products did not include this labelling requirement and aquatic toxicity data generated for this material indicate a low order of toxicity to aquatic organisms. Similarly, the registrant also objected to the restriction of use in oil field flooding to terrestrial oil wells, given the relative toxicity of 2-(hydroxymethyl)-2-nitro-1,3-propanediol to aquatic organisms.

PMRA response

After further examination, the PMRA concurs with the registrant that the aquatic toxicity data presented in the 1993 Reregistration Eligibility Decision for 2-(hydroxymethyl)-2-nitro-1,3-propanediol indicate a low order of toxicity to aquatic organisms. As a result, the statement “This product is toxic to fish and other aquatic organisms” will no longer be required; similarly, the restriction of use in oil field flooding to terrestrial oil wells is no longer considered necessary. Please refer to Appendix II for final revised labelling requirements.

Appendix II **Label amendments for 2-(hydroxymethyl)-2-nitro-1,3-propanediol**

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

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**” sub-section of the “**PRECAUTIONS**” section:

- “This product 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 rationale must be provided to support the need for higher application rates in Canada compared with the application rates in the United States for cooling towers (609 ppm in the United States vs 2000 ppm in Canada) and oil field flooding (1159 ppm in the United States vs 2000 ppm in Canada).