Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Re-evaluation Decision Document RRD2005-03

1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride

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 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CTAC) is now complete.

The Pest Management Regulatory Agency (PMRA) has determined that CTAC is acceptable for continued registration, consistent with Proposed Acceptability for Continuing Registration (PACR) document, PACR2004-17, *Re-evaluation of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride*, published on 10 June 2004, provided that the mitigation measures are adopted. Additional data requirements have been identified.

This RRD includes the comments made to the PMRA in response to PACR2004-17, the PMRA's response to the comments and the regulatory decisions resulting from the re-evaluation of CTAC.

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1.0 Introduction

The re-evaluation of the available information for the active ingredient CTAC and its associated uses as a material preservative in many commercial/manufacturing industrial processes has been completed by the PMRA.

2.0 Background

The purpose of this RRD is to notify the registrants, pesticide regulatory officials and the Canadian public that the re-evaluation of CTAC is now complete.

On 10 June 2004, the PMRA published PACR2004-17, *Re-evaluation of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride,* for consultation on the proposed regulatory decision for CTAC. Comments were received from registrants concerning this PACR.

This RRD summarizes these comments as well as the PMRA's response and outlines the regulatory decision resulting from the re-evaluation of CTAC.

3.0 Regulatory decision

The PMRA has reviewed the comments received in response to the proposed regulatory decision for CTAC (Appendix I) and has concluded that these comments did not result in any changes to the regulatory decision as described in PACR2004-17.

The PMRA has determined that CTAC is acceptable for continuing registration provided that the mitigation measures specified in Section 4.0 of the PACR are implemented. These mitigation measures include label statements to protect workers and the environment.

Section 5.0 of the PACR outlined additional requirements for continued registration of CTAC. The registrants will be informed by letter of the specific requirements affecting their product registrations and the regulatory options available to comply with this decision.

Appendix I Comments and responses to PACR2004-17

The PMRA received comments in response to PACR2004-17. The PMRA has summarized the comments received and provides the response below.

Comment on the addition of a formaldehyde release statement on the label

The registrant objects to the addition of a formaldehyde release statement on the label. While the United States Environmental Protection Agency (USEPA) acknowledged the potential release of formaldehyde from the use of CTAC, they did not require such statements on the American labels. It is important to provide users with consistent safety and handling information.

Response

The USEPA concluded in the Registration Eligibility Decision (RED) that "formaldehyde forms as a degradation product of CTAC" and that formaldehyde "is released from the decomposition of Dowicil® CTAC in aqueous solution".

Although it was concluded in the RED that worker exposure to formaldehyde in industrial settings may be low, the USEPA also stated that "the Agency (USEPA) remains concerned [...] about the potential exposure and risks associated with formaldehyde in the workplace".

Based on this information, the PMRA concluded that formaldehyde can be released from the degradation of CTAC when used in an industrial setting and would represent a potential risk to workers.

The USEPA did not require a label statement warning of formaldehyde release but addressed their concern by deferring to the Occupational Safety and Health Administration (OSHA). The USEPA notified OSHA of CTAC potential formaldehyde release and OSHA has agreed to include products containing CTAC in their program to monitor for potential formaldehyde exposure in the workplace.

In Canada, a label statement indicating potential release of formaldehyde during use of CTAC 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 CTAC include a label statement on formaldehyde release as described in Section 4.0 of the PACR2004-17.

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.