



# Proposed Acceptability for Continuing Registration

**PACR2004-29**

## **Re-evaluation of 1,2-dibromo-2,4-dicyanobutane**

The purpose of this document is to inform the registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of 1,2-dibromo-2,4-dicyanobutane. The PMRA has determined that 1,2-dibromo-2,4-dicyanobutane 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 1,2-dibromo-2,4-dicyanobutane. 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)*

**15 July 2004**

**This document is published by the Alternative Strategies and Regulatory Affairs Division,  
Pest Management Regulatory Agency. For further information, please contact:**

**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](mailto:pmra_publications@hc-sc.gc.ca)  
[www.hc-sc.gc.ca/pmra-arla/](http://www.hc-sc.gc.ca/pmra-arla/)**

**Information Service:  
1 800 267-6315 or (613) 736-3799  
Facsimile: (613) 736-3798**



ISBN: 0-662-37691-9 (0-662-37692-7)

Catalogue number: H113-18/2004-29E (H113-18/2004-29E-PDF)

**© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services  
Canada 2004**

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

## 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 [DIR2001-03](#), *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

1,2-dibromo-2,4-dicyanobutane has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in [DIR2001-03](#). In 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 1,2-dibromo-2,4-dicyanobutane and concluded that, on the basis of a health and environmental risk assessment, it was eligible for reregistration with the implementation of mitigation measures. These conclusions were published in a 1996 RED document for 1,2-dibromo-2,4-dicyanobutane. In its re-evaluation of 1,2-dibromo-2,4-dicyanobutane, the PMRA based its conclusions on this 1996 RED document, taking into account the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substance Management Policy [TSMP]). A review of the chemistry of Canadian products was also conducted.

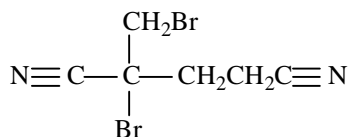
## 2.0 Re-evaluation of 1,2-dibromo-2,4-dicyanobutane

Common name: 2-bromo-2-bromomethyl glutaronitrile

Chemical name : 1,2-dibromo-2,4-dicyanobutane

CAS registry number: 35691-65-7

Structural formula:



Purity of active: 98% (minimum)

In Canada, 1,2-dibromo-2,4-dicyanobutane was first registered in 1978. It is currently registered in Canada as a microbiocide/microbiostat for use as an additive for the following:

- industrial latex emulsions,
- cooling water,
- waxes,
- polishes,
- inks,
- pulp and paper mills,
- adhesives,
- paints,
- pigment slurries,
- coatings,
- metalworking fluids,
- aqueous paints,
- joint cements,
- liquid detergents,
- laundry starches,
- fabric softeners and textile sizes, and
- high viscosity suspensions.

Three EPs and one technical/EP (dual classification) are registered in Canada. Currently registered Canadian products containing 1,2-dibromo-2,4-dicyanobutane are listed in Appendix I.

Based on the comparison of American and Canadian use patterns, the USEPA assessment described in the RED document for 1,2-dibromo-2,4-dicyanobutane 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 1,2-dibromo-2,4-dicyanobutane.

The federal TSMP and Regulatory Directive [DIR99-03](#) were taken into consideration during the review of 1,2-dibromo-2,4-dicyanobutane, and it was concluded that 1,2-dibromo-2,4-dicyanobutane is not a TSMP Track 1 substance. The technical product is not expected to contain impurities of toxicological concern as identified in [DIR98-04](#) or TSMP Track 1 substances as identified in Appendix II of [DIR99-03](#).

### 3.0 Proposed re-evaluation decision

The USEPA published a RED document for 1,2-dibromo-2,4-dicyanobutane addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of 1,2-dibromo-2,4-dicyanobutane that are also registered in Canada. Based on the USEPA RED and the Canadian use pattern, the PMRA has determined that 1,2-dibromo-2,4-dicyanobutane 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.

It should be noted that for EPs that contain more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

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 these products.

### 4.0 Proposed regulatory action

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

- 1) On the **PRIMARY DISPLAY PANEL**:
  - “POTENTIAL SKIN SENSITIZER.”
- 2) In the “**PRECAUTIONS**” section:
  - “Wear goggles or face shield, chemical-resistant gloves, long pants, a long-sleeved shirt, shoes and socks during mixing/loading, clean up, repair, and other handling activities.”
  - “Potential skin sensitizer.”
- 3) 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.”

Furthermore, to mitigate the risk associated with handling a powder, the registrant is required to package the EP Tektamer 38 Powder in water-soluble bags. The “Direction for Use” section of the label should be amended accordingly.

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

Registrants should note that for products with dual classification (i.e. classified both as technical or manufacturing and as commercial), an application to register a separate commercial EP is required and the label of the technical or manufacturing product must be amended to remove references to the commercial uses.

## **5.0 Additional data requirements**

The technical registrant of 1,2-dibromo-2,4-dicyanobutane 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 Canadian use pattern) that were required by the USEPA as a condition of reregistration of 1,2-dibromo-2,4-dicyanobutane; 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) tables for use-site categories (USC) #17 and #18. The relevant sections of the DACO tables that registrants are required to address are as follows:
  - 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 1,2-dibromo-2,4-dicyanobutane 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](http://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](mailto:pmra_infoserv@hc-sc.gc.ca).

The federal TSMP is available through Environment Canada's website at [www.ec.gc.ca/toxics](http://www.ec.gc.ca/toxics).

The USEPA RED document (*Dibromodicyanobutane, List B, Case 2780*) is available on the Office of Pesticide Programs' website at [www.epa.gov/pesticides/reregistration](http://www.epa.gov/pesticides/reregistration) under Chemical Status.

**Appendix I      Canadian 1,2-dibromo-2,4-dicyanobutane products  
currently registered (as of 30 March 2004)**

<b>Product name</b>	<b>Class <sup>1</sup></b>	<b>Guarantee</b>	<b>Registrant</b>	<b>Registration number</b>
Tektamer 2200 Liquid Slimicide	C	20%	Bayer Chemicals	26114
Tektamer 38 A.D. Inhibits Growth of Microorganisms	C	25%	Bayer Chemicals	17325
Tektamer 38 Powder	C+T	98%	Bayer Chemicals	14755
Biochek 430	C	23.725%	Bayer Chemicals	25731

<sup>1</sup> C (commercial); T (technical)