Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Acceptability for Continuing Registration

PACR2004-16

Re-evaluation of 2,2-dibromo-3-nitrilopropionamide

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 2,2-dibromo-3-nitrilopropionamide (DBNPA). The PMRA has determined that DBNPA 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 DBNPA. 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)

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1.0 Background

The PMRA is re-evaluating all pesticides, both active ingredients and 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.

DBNPA 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.

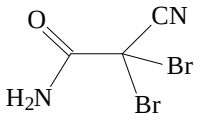
Based on the outcome of foreign reviews, the PMRA will propose, under Program 1, a regulatory decision and appropriate mitigation measures for Canadian uses of an active ingredient.

The USEPA conducted a re-evaluation of DBNPA 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 1994 RED document for DBNPA. In its re-evaluation of DBNPA, the PMRA based its conclusions on this 1994 RED document, taking into account the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substances Management Policy [TSMP]). A review of the chemistry of Canadian products was also conducted.

2.0 Re-evaluation of 2,2-dibromo-3-nitrilopropionamide

Common name:	2,2-dibromo-3-nitrilopropionamide
Chemical name:	2,2-dibromo-2-carbamoylacetonitrile; 2,2-dibromo-2-cyanoacetamide; 2-cyano-2,2-dibromoacetamide; DBNPA
CAS registry number:	10222-01-2

Structural formula:



Purity of active: 97.6–98%

DBNPA was first registered in 1973. It is a material preservative and slimicide:

- it is used as a slimicide to control algae, bacteria, fungi and yeasts in various industrial processes including pulp and paper processes, metal working fluids, air washers, secondary oil recovery systems and water cooling towers; and

- as a material preservative during the manufacture of paint, latex, emulsions, adhesives, joint compounds, waxes, polishes and inks.

Registered products containing DBNPA are listed in Appendix I.

Canadian registered use sites, application rates, application method and formulation types are also registered in the United States, and the USEPA assessment described in the RED document for DBNPA is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the health and environmental risk assessments conducted by the USEPA are presented in the USEPA RED for DBNPA.

The federal TSMP and Regulatory Directive DIR99-03 were taken into consideration during the review of DBNPA and it was concluded that DBNPA 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 DBNPA addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of DBNPA that are also registered in Canada. Based on the USEPA RED and Canadian use pattern, the PMRA has determined that DBNPA 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

Registrants are required to modify the EP labels as follows.

1) On the primary display panel of the technical and manufacturing concentrate labels, the following statements must appear:

   - "To be used only in the manufacture of a pesticide that is registered under the PEST CONTROL PRODUCTS ACT."
   - "POTENTIAL SKIN SENSITIZER"

2) On the primary display panel of all EPs, the following statement must appear:

   - "POTENTIAL SKIN SENSITIZER"

3) On the secondary display panel of all EPs, the following statements must appear under the **"PRECAUTIONS"** section:

   - "POTENTIAL SKIN SENSITIZER"
   - "Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet."
   - "Users should remove clothing immediately if pesticide comes in contact with skin through soaked clothing or spills. Then wash skin thoroughly and put on clean clothing. Wash contaminated clothing separate from other laundry prior to re-use."
   - "Users should remove protective clothing immediately after handling this product. Wash the outside of gloves before removing them. As soon as possible, wash thoroughly and change into clean clothing."

4) For labels for *liquid* products and products in *water-soluble bags*, the following statement must appear in the **"PRECAUTIONS"** section:

   - "Wear a long-sleeved shirt, long pants, shoes and socks when handling."

   If additional protective equipment is required by the current labels, the statement(s) should not be removed unless they contradict the above label statement.

5) For labels of products formulated as powders (not in water-soluble bags), the following statement must appear in the **"PRECAUTIONS"** section:

- "Wear a long-sleeved shirt, long pants, shoes and socks, chemical-resistant gloves, a chemical-resistant apron and a full-face NIOSH-approved respirator when handling."

The registrants of EPs formulated as powders also have the option of repackaging their products in water-soluble bags, in which case a respirator would not be required.

6) On all EP labels, the following statements must appear under **"ENVIRONMENTAL HAZARD"** within 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."

- "Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority."

7) For EPs used in water cooling systems, the following statement must appear under **"DIRECTIONS FOR USE"**:

- "This product is for recirculating water systems only."

8) Based on USEPA recommendations in the RED, registrants are required to amend their labels to indicate that secondary biological effluent treatment is required for all uses of DBNPA with the exception of secondary oil recovery systems.

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

The following products are classified as technical or manufacturing concentrate and commercial:

DBNPA 100 TECH	PCP #13769
DOW ANTIMICROBIAL 7287 LIQUID FORM	PCP #11996
DOW ANTIMICROBIAL 8536 LIQUID	PCP #12771
DOW XD-8259 ANTIMICROBIAL LIQUID FORM	PCP #13770
METASOL RB-20 CONTROLS BACTERIA	PCP #16720

Dual classification is no longer accepted by the PMRA. If registrants want to retain the commercial uses of these products, they are required to submit an application to register a separate commercial EP. A second application is also required to amend labels of technical or manufacturing use products to remove references to commercial uses. This is required within 24 months of finalization of the re-evaluation decision.

5.0 Additional data requirements

The registrant of technical DBNPA 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 DBNPA.

- 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 #17 and #18. The relevant sections of the DACO tables that registrants are required to address are as follows:

  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 DBNPA 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 of affected products.

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 [*2,2-dibromo-3-nitrilopropionamide (DBNPA)*] is available on the Office of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemical Status.

Appendix I Canadian DBNPA products currently registered (as of 31 December 2003)

Product name	Class	Guarantee	Registrant	Registration number
Dow Antimicrobial 7287 Liquid Form	Commercial + Manufacturing Concentrate	20%	Dow Chemical Canada Inc.	11996
Dow Antimicrobial 8536 Liquid	Commercial + Manufacturing Concentrate	5%	Dow Chemical Canada Inc.	12771
DBNPA 100 PTECH Antimicrobial Solid Form	Commercial and Technical Active	95%	Dow Chemical Canada Inc.	13769
Dow XD-8259 Antimicrobial Liquid Form	Commercial + Manufacturing Concentrate	10%	Dow Chemical Canada Inc.	13770
Amerstat 300 Liquid for Control of Bacteria, Fungi & Yeast	Commercial	20%	Drew Canada, Ashland Canada Corp.	15505
Biosperse 244 Liquid for Control of Algae, Bacteria & Fungi	Commercial	20%	Drew Canada, Ashland Canada Corp.	15506
Metasol RB-20 Controls Bacteria	Commercial + Manufacturing Concentrate	20%	Nalco Canada Co.	16720
Spectrum RX5080 Slime Control Agent	Commercial	20%	Hercules Canada (2002) Inc.	17569
Spectrus NX1102	Commercial	20%	GE Betz Canada	17570
Busan 94 Liquid Microbicide	Commercial	20%	Buckman Labs of Canada Ltd	17571
Busan 95 Liquid Microbicide	Commercial	10%	Buckman Labs of Canada Ltd	17572
Busan 96 Liquid Microbicide	Commercial	5%	Buckman Labs of Canada Ltd	17573
Nalco 7320 Cooling Process Water Slimicide	Commercial	20%	Nalco Canada Co.	17574
Nalcon 7649 Deposit Control Chemical	Commercial	20%	Ondeo Nalco Canada Co.	17575
Magnatrol 46-A Liquid Microbicide	Commercial	1%	Produits Chimiques Magnus Ltee	19593
X-Cell 413 Liquid Antimicrobial	Commercial	20%	Diversey Lever Canada Inc.	23250
Dow Antimicrobial 7287A Liquid Form	Commercial	20%	Dow Chemical Canada Inc.	23358
Raisio 951 Industrial	Commercial	20%	Raisio Chemicals Canada Inc.	23641
Bulab 6042 Liquid Microbicide Industrial	Commercial	20%	Buckman Labs of Canada Ltd	24115

Product name	Class	Guarantee	Registrant	Registration number
Biobrom C-103 (DBNPA Technical)	Technical Active	98%	Bromine Compounds Ltd	24353
Dow Time-Release Antimicrobial CT Tablets	Commercial	40%	Dow Chemical Canada Inc.	24769
Biochek 20	Commercial	20%	Ondeo Nalco Canada Co.	24799
Biobrom C103L Microbicide DBNPA	Commercial	20%	Clearon Corporation	25107.00
Eclipse 610 Microbicide	Commercial	5%	Buckman Labs of Canada Ltd.	25456
Process B 2013 Biocide	Commercial	5%	E.QU.I.P. International Inc.	25502
Process B 2014	Commercial	20%	E.QU.I.P. International Inc.	25525
ControlChem 2641 Industrial Liquid Microbicide	Commercial	20%	ControlChem Canada Ltd.	25643
PermaClean PC-11 Microorganism Control Chemical	Commercial	20%	Nalco Canada Co.	25689
AMA-150-C Papermill Slimicide[1]	Commercial	20%	Vinings Industries Inc.	25702
Bio-Clear 1000 Antimicrobial Solid	Commercial	97.6%	Clearwater Inc.	25895
MTL-Bioclear 2000 Antimicrobial	Commercial	97.6%	Millennium Technologies Ltd.	25895.01
Biomate MBC2881	Commercial	20%	GE Betz Canada	26421
Fennosan R 20 V DBNPA Microbicide	Commercial	20%	Kemira Chemicals Canada Inc.	27042
MB-224 Microbicide	Commercial	20%	Chem-Aqua, Division of NCH Canada Inc.	27230
Fennosan 150-C Papermill Slimicide	Commercial	20%	Kemira Chemicals	27267
Sump Buddy WT Antimicrobial Time Release Tablets	Commercial	40%	Dow Chemical Canada Inc.	27289
Bioclense DB	Commercial	20%	Klenzoid Co. Ltd.	27313
Magnatrol 466A	Commercial	5%	Produits Chimiques Magnus Ltee	27571.00
Slitrol	Commercial	20%	Constant America Inc.	27588
Biochek 20	Commercial	20%	Bayer Chemicals Corp.	27625.00

[1] Product 25702 was discontinued on 30 June 2003 and will expire on 30 June 2006.