



Proposed Acceptability for Continuing Registration

PACR2005-06

Re-evaluation of Bronopol

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has re-evaluated bronopol (BND). The PMRA has determined that bronopol is acceptable for continued registration provided that the proposed mitigation measures to further protect workers and the environment are adopted. Additional data requirements are identified. Upon finalization of the re-evaluation decision, the PMRA will provide registrants of products containing bronopol with specific direction on how to address these measures and requirements.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for bronopol. 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 Publications at the address below.

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1.0 Background

The PMRA is re-evaluating all pesticides, both active ingredients and formulated end-use products, 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.

Bronopol 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 bronopol 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 1995 RED document for bronopol. In its re-evaluation of bronopol, the PMRA based its conclusions on this 1995 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.

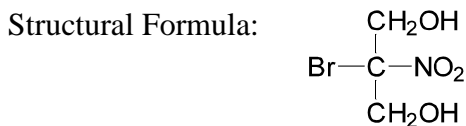
2.0 Re-evaluation of Bronopol

Active substance: Bronopol

Chemical name:

IUPAC	2-Bromo-2-nitropropane-1,3-diol
CAS	2-Bromo-2-nitro-1,3-propanediol

CAS Number: 52-51-7



In Canada, bronopol was first registered as an antimicrobial agent in 1986. According to current Canadian end-use product labels, this active ingredient is registered as a commercial biocide and preservative in many industrial processes. Registered biocidal uses include pulp and paper mills, water cooling towers, waste water treatment, evaporative condensers, heat exchangers, food pasteurizing plants, metal working fluids and oilfield applications. In addition, preservative uses include household products (e.g., dish washing liquids, laundry products), latex emulsions, polymer lattices, pigments, leather and milk samples for analysis. Bronopol is also formulated into granular domestic end use products in the form of cat litter. Currently registered Canadian products containing bronopol are listed in Appendix I.

Based on the comparison of American and Canadian use patterns, the USEPA assessment described in the RED document for bronopol is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the assessments conducted by the USEPA are presented in the RED for bronopol.

The federal TSMP and Regulatory Directive [DIR99-03](#) were taken into consideration during the review of bronopol, and it was concluded that bronopol is not a candidate for TSMP Track 1 classification. The technical product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive [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 bronopol addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of bronopol that are also registered in Canada. The PMRA has determined that bronopol is acceptable for continued registration provided that the mitigation measures specified in Section 4.0 of this PACR are adopted. Additional data requirements are identified in Section 5.0.

It should be noted that for end-use products 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. Registrants of products containing bronopol

should not apply for label amendments or submit the additional data described in Section 5.0 during this comment period; they will be informed by letter of the specific instructions for addressing label changes and data requirements once the re-evaluation decision has been finalized.

4.0 Proposed Regulatory Actions

Canadian commercial/industrial end-use product labels should be amended to include the following statements to further protect workers and the environment.

1. On the principal display panel:
 - “POTENTIAL SKIN SENSITIZER.”
2. In the “**Precautions**” section of all commercial end-use product labels:
 - “POTENTIAL SKIN SENSITIZER.”
 - “Wear goggles or a face shield, chemical-resistant gloves, long pants, a long sleeved-shirt, shoes and socks during mixing/loading, clean up and repair.”
 - “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.”
 - “Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.”
 - “Users should remove clothing/protective equipment immediately if pesticide comes in contact with skin through soaked clothing or spills. Then wash skin thoroughly and put on clean clothing and required protective equipment prior to resuming your previous work activity.”
 - “Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”
3. In addition to the above, for liquid product formulations applied to cooling water systems, in the “**Precautions**” section:
 - “Do not apply by open pouring of the liquid to cooling water systems; a metering pump is required for this use.”

4. All commercial end-use product labels must have an **“Environmental Hazards”** section and it must include the following:
 - “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.”

The label amendments presented above 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 label statements above.

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

5.0 Additional Data Requirements

The technical registrant of bronopol will be 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 bronopol;
- 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 Category (USC) # 17,18 and 19. The following sections of DACO tables must be addressed:
 - for the technical grade active ingredient—DACOs 2 through 9, inclusive
 - for the end-use product—DACOs 5 through 9, inclusive. This should include data from which risk estimates can be derived for machinists/workers using metal working fluids containing bronopol.

The PMRA will be 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.pmra-arla.gc.ca. 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 (*Bronopol*) is available on the Office of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemical Status.

Appendix I Products Containing Bronopol Registered in Canada as of 1 October 2004

Product Name	Registrant Name	Pest Control Product No.	Active Ingredient Code	Guarantee	Marketing Class
Spectrus NX1464 Microbistat	GE Betz Canada	19747	BND	19.6%	Commercial
2K7-Solution Liquid Biocide	OSP Microcheck Inc.	21153	BND	10%	Commercial
2K7 Bugstick—a solid form of biocide	BASF Canada Inc.	21281	BND	84.5%	Commercial
Eclipse 601 Microbiocide	Buckman Labs of Canada Ltd.	21281.04	BND	84.5%	Commercial
Spectrum RX9505 Microbistat	Hercules Canada Inc.	21676	BND	9.8%	Commercial
BIOMATE SAN9362 Microbiocide	GE Betz Canada	21756	BND	84.5%	Commercial
Spectrus NX1423	GE Betz Canada	21757	BND	84.5%	Commercial
Nalco 3D07 Liquid Biocide	Ondeo Nalco Canada Co.	21770	BND	10%	Commercial
2K7 Water Soluble Paks (granular biocide)	OSP Microcheck Inc.	21790	BND	98%	Commercial
Magnatrol 442-A (for cooling towers)	Produits chimiques Magnus Ltée	21869	BND	15%	Commercial
X-Cide 825 Biocide	Baker Petrolite Corporation	21963	BND	84.5%	Commercial
Nalco 6C56 Water Soluble Paks	Ondeo Nalco Canada Co.	22104	BND	98%	Commercial
Brotab "10" Milk Preservative Tablet	SYSTEMS PLUS	22615	BND, PIM ¹	30%, 1.4%	Commercial
Busan 1228SP Granular Microbiocide	Buckman Labs of Canada Ltd.	22860	BND	98%	Commercial
Busan 1228S Solid Microbiocide	Buckman Labs of Canada Ltd.	22861	BND	84.5%	Commercial
Busan 1228DW Liquid Microbiocide	Buckman Labs of Canada Ltd.	22862	BND	10%	Commercial
Busan 1228D Liquid Microbiocide Industrial	Buckman Labs of Canada Ltd.	22863	BND	10%	Commercial
Aquaguard 651 Liquid Microbiocide	Guardian Chemicals Inc.	23159	BND	10%	Commercial
Aquaguard 62K7 Microbiocide Sticks	Guardian Chemicals Inc.	23263	BND	84.5%	Commercial
Bacbuster Granular Biocide (microbial agent)	Constant Laboratories Inc.	23278	BND	98%	Commercial
Biosperse 295	Drew Canada, Division of Ashland Corp.	23322	BND	10%	Commercial

Product Name	Registrant Name	Pest Control Product No.	Active Ingredient Code	Guarantee	Marketing Class
Ipacide Bugstick Solid Biocide	IPAC Chemicals Ltd.	23403	BND	84.5%	Commercial
Ipacide LWT 921 Liquid Biocide	IPAC Chemicals Ltd.	23404	BND	10%	Commercial
Bacbuster L-10 Liquid Biocide	Constant Laboratories Inc.	23861	BND	10%	Commercial
Aquaguard 6505 Liquid Microbiocide	Guardian Chemicals Inc.	23945	BND	5%	Commercial
Spectrum RX9600 Slime Control Agent	Hercules Canada Inc.	23963	BND, QAC ²	5.5%, 10%	Commercial
Ultra-fresh Sab	Thompson Research Associates	24221	BND	98%	Commercial
Controlchem 2663 Liquid Biocide	Controlchem Canada Ltd.	24589	BND	10%	Commercial
2K7 Solution W-M Winterized Liquid Biocide	OSP Microcheck Inc.	24865	BND	10%	Commercial
Jacklyn WC 8314 Biocide	Jacklyn Industries Inc.	24986	BND	84.5%	Commercial
Jacklyn WC 8315 Biocide	Jacklyn Industries Inc.	24987	BND	10%	Commercial
Myacide BT Commercial Microbiocide	BASF Canada Inc.	25224	BND	98%	Commercial
Eclipse 600 Microbiocide	Buckman Labs of Canada Ltd.	25227	BND	10%	Commercial
Spectrus NX1101	GE Betz Canada	25240	BND, QAC	5.5%, 10%	Commercial
2K7 Bugstick Biocide	OSP Microcheck Inc.	25325	BND	84.5%	Commercial
Process B-2011 Solution Liquid Biocide	EQUIP International Inc.	25399	BND	10%	Commercial
Process B 2016 Water Soluble Paks	EQUIP International Inc.	25514	BND	98%	Commercial
Spectrum RX9100 Antimicrobial Agent	Hercules Canada Inc.	25660	BND, ISL ³ , IST ⁴	5.3%, 0.6%, 1.9%	Commercial
Spectrus NX110	GE Betz Canada	25661	BND, ISL, IST	5.3%, 0.6%, 1.9%	Commercial
Biomate SAN9361 Antimicrobial Agent	GE Betz Canada	25722	BND, ISL, IST	5.3%, 0.6%, 1.9%	Commercial
Versatox 910 Liquid Biocide	Versa Chem Inc.	25910	BND	10%	Commercial
Myacide S30 Microbiocide	BASF Canada Inc.	26118	BND	30%	Commercial
Econo-Cide B1006	Innovative Chemical Technologies Canada Limited	26892	BND	84.5%	Commercial
Mazide 20007 Liquid Biocide	Chemfil Canada Ltd.	26900	BND	10%	Commercial
ECONO-CIDE B 1007 Biocide	Innovative Chemical Technologies Canada Limited	26990	BND	98%	Commercial

Product Name	Registrant Name	Pest Control Product No.	Active Ingredient Code	Guarantee	Marketing Class
Nalcon 7639 Biocide	Ondeo Nalco Canada Co.	27134	BND	10%	Commercial
ECONO-CIDE B 1008	Innovative Chemical Technologies Canada Limited	27399	BND	10%	Commercial
Purina Maxx Scoop Clumping Cat Box Filler	Ralston Purina Inc.	24726	BND	0.005%	Domestic
Purina Maxx Cat Box Filler	Ralston Purina, Inc.	24727	BND	0.005%	Domestic
Purina Maxx Multi-Cat Formula Cat Box Filler	Ralston Purina Inc.	24728	BND	0.005%	Domestic
Jonny Cat Premium Cat Litter	Clorox Co. of Canada Ltd.	25172	BND	0.0025%	Domestic
Scoop Away Clumping Cat Litter	Clorox Co. of Canada Ltd.	25219	BND	0.012%	Domestic
Jonny Cat Scoop Clumping Cat Litter Antibacterial	Clorox Co. of Canada Ltd.	25549	BND	0.0095%	Domestic
Everclean Antibacterial Clumping Cat Litter	Clorox Co. of Canada Ltd.	25551	BND	0.012%	Domestic
Simplicity Plus Scented All Purpose Cat Litter Antibacterial	Normerica Inc.	25645	BND	0.005%	Domestic
J.E. Mondou Scented Clumping Cat Litter Antibacterial	J.E. Mondou	25646.01	BND	0.005%	Domestic
Superb Anti-bacterial Scented Scoopable Cat Litter	Great Atlantic & Pacific Co.	25646.02	BND	0.005%	Domestic
Simplicity Plus Scented Scoopable Cat Litter Antibacterial	Normerica Inc.	25646	BND	0.005%	Domestic
Super Saver Plus Scented Clumping Cat Litter Antibacterial	Multi-Mar Pet Products	25646.03	BND	0.005%	Domestic
Simplicity Plus Scoopable Cat Litter Antibacterial	Normerica Inc.	25647	BND	0.005%	Domestic
Simplicity Plus All Purpose Cat Litter Antibacterial	Normerica Inc.	25648	BND	0.005%	Domestic
Kitty Comfort Plus Premium Clumping Cat Litter	Nu-Gro IP Inc.	25698	BND	0.005%	Domestic
Natural Select Plus Cat Litter	Nu-Gro IP Inc.	25699	BND	0.005%	Domestic
Hillview Farms Clumping Kitty Select Cat Litter	Nu-Gro IP Inc.	25700	BND	0.005%	Domestic
Wunder Cat Scented Anti-bacterial World Class Cat Litter	Western Industrial Clay Products Ltd.	25917	BND	0.005%	Domestic

Product Name	Registrant Name	Pest Control Product No.	Active Ingredient Code	Guarantee	Marketing Class
Special Kitty Anti-bacterial Scented Traditional Cat Litter	Wal-Mart Canada Inc.	25919	BND	0.005%	Domestic
Wunder Cat Anti-bacterial Scented Clumping Cat Litter	Western Industrial Clay Products Ltd.	26222	BND	0.005%	Domestic
Clumping Cat Litter—Unscented	Canadian Tire Corp. Ltd.	26483	BND	0.005%	Domestic
Clumping Cat Litter—Scented	Canadian Tire Corp. Ltd.	26486	BND	0.005%	Domestic
Super Saver Plus™ Scented Clumping Cat Litter	Multi-Mar Pet Products	26487	BND	0.005%	Domestic
Our Compliments Scoopable Cat Litter	Sobeys	26504	BND	0.005%	Domestic
Our Compliments Cat Litter	Sobeys	26551	BND	0.005%	Domestic
Our Compliments Scoopable Cat Litter	Sobeys	26559	BND	0.005%	Domestic
Our Compliments Cat Litter	Sobeys	26560	BND	0.005%	Domestic
Truly Friends Scoopable Cat Litter	Zellers Inc.	26569	BND	0.005%	Domestic
Truly Friends Regular Cat Litter	Zellers Inc.	26570	BND	0.005%	Domestic
Merit Selection Clumping Cat Litter	Briska Inc.	26574	BND	0.005%	Domestic
Co-op Anti-bacterial Scented Scoopable Cat Litter	Interprovincial Cooperative Limited	26874	BND	0.005%	Domestic
West Best Anti-bacterial Scented Scoopable Cat Litter	West Best Inc.	26876	BND	0.005%	Domestic
Co-op Anti-bacterial Scented Cat Litter	Interprovincial Cooperative Limited	26877	BND	0.005%	Domestic
Baccara Scoopable Cat Litter	Favorite Products Co. Ltd.	26897	BND	0.005%	Domestic
Hillview Farms Clumping Kitty Select - Scented Cat Litter	Nu-Gro IP Inc.	26936	BND	0.005%	Domestic
Hillview Farms Non-clumping Kitty Select Cat Litter	Nu-Gro IP Inc.	26946	BND	0.005%	Domestic
Hillview Farms Non-clumping Kitty Select—Scented Cat Litter	Nu-Gro IP Inc.	26947	BND	0.005%	Domestic
Safeway Scoopable Anti-bacterial Scented Clumping Cat Litter	Canada Safeway Limited	27148	BND	0.005%	Domestic

Product Name	Registrant Name	Pest Control Product No.	Active Ingredient Code	Guarantee	Marketing Class
Western Family Scoopable Anti-bacterial Scented Cat Litter	Western Family Foods Inc.	27149	BND	0.005%	Domestic
Western Family Anti-bacterial Scented Cat Litter	Western Family Foods Inc.	27150	BND	0.005%	Domestic
Purina Maxx Scoop Multi-cat Cat Box Filler	Ralston Purina Inc.	27320 ¹	BND	0.0005%	Domestic
Myacide as Technical Microbiocide	BASF Canada Inc.	18880	BND	98%	Technical Active

1. PIM: Pimaricin

2. QAC: N-alkyl (40% C12, 50% C14, 10% C16) dimethyl benzyl ammonium chloride

3. ISL: 2-Methyl-4-isothiazolin-3-one

4. IST: 5-Chloro-2-methyl-4-isothiazolin-3-one