



Proposed Acceptability for Continuing Registration

PACR2004-26

Re-evaluation of Methylene Bis(thiocyanate)

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of methylene bis(thiocyanate). The PMRA has determined that methylene bis(thiocyanate) 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 methylene bis(thiocyanate). 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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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
www.hc-sc.gc.ca/pmra-arla/

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



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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.

Methylene bis(thiocyanate) 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 methylene bis(thiocyanate) 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 1997 RED document for methylene bis(thiocyanate). In its re-evaluation of methylene bis(thiocyanate), the PMRA based its conclusions on this 1997 RED document, taking into account the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substances Management Policy [TSMP]).

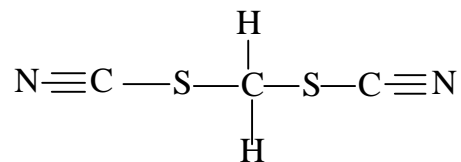
2.0 Re-evaluation of methylene bis(thiocyanate)

Active substance: Methylene bis(thiocyanate)

Common name: Methylene bis(thiocyanate)

CAS number: 6317-18-6

Structural formula:



Purity: 98–99% (by weight)

In Canada, methylene bis(thiocyanate) was first registered in 1973. According to current EP labels, it is registered in Canada for use in the following:

- to control microbial growth in pulp and paper production, including log/thaw ponds, and
- to control/suppress bacteria in industrial cooling water systems, including cooling towers, air washers and evaporative condensers.

Currently registered Canadian products containing methylene bis(thiocyanate) are listed in Appendix I.

The use of methylene bis(thiocyanate) in log and thaw ponds is not being supported by the registrant and has not been re-evaluated by the PMRA.

All Canadian registered use sites (except for log and thaw ponds), application rates, application method and formulation types are also registered in the United States. Based on the comparison of American and Canadian use patterns, the USEPA assessment described in the 1997 RED document for methylene bis(thiocyanate) 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 USEPA RED for methylene bis(thiocyanate).

The federal TSMP and Regulatory Directive [DIR99-03](#) were taken into consideration during the review of methylene bis(thiocyanate), and it was concluded that methylene bis(thiocyanate) is not a TSMP Track 1 substance. 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 methylene bis(thiocyanate) addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of methylene bis(thiocyanate) that are also registered in Canada. Based on the USEPA RED and Canadian use pattern, the PMRA has determined that methylene bis(thiocyanate) 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.

4.0 Proposed regulatory actions

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

- On the primary display panel of the label, the following must be added:
 - “POTENTIAL SKIN SENSITIZER”
- In the “**Precautions**” section, the following must be added:
 - “POTENTIAL SKIN SENSITIZER”
 - “Wear a full-face NIOSH-approved respirator, chemical-resistant gloves, long pants, a long-sleeved shirt, shoes plus socks and a chemical-resistant apron during mixing/loading, clean-up and repair activities.”
 - “Use of this product may cause the liberation of hydrogen cyanide and/or cyanates.”
 - “Users should wash hands before eating, drinking, chewing gum, and when using tobacco or the toilet.”
 - “Users should remove clothing/protective equipment immediately if this product comes in contact with the skin through soaked clothing or spills. Then, thoroughly wash the skin and put on a clean clothing.”
 - “Discard clothing or other absorbent materials that have been drenched or heavily contaminated with the concentrate of this product. Do not re-use them.”

Given that formaldehyde can be released during the use of this product, the following statement must also be included in the “**Precautions**” section:

- “Formaldehyde can be released during the 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**” section, the following must be added:
 - “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.”

In addition, labels should reflect the following changes:

- For liquid product formulations applied to cooling water systems treating $\geq 15\,000$ L (4000 gallons), the following statement is also required 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.”
- For Registration Number 14037, the registrant is required to remove all references from their label regarding the use of methylene bis(thiocyanate) in log/thaw ponds.

The label amendments presented above do not include all label requirements for individual EPs, 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 above label statements.

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

5.0 Additional data requirements

The registrants of the technical grade active ingredient (TGAI) of methylene bis(thiocyanate) 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 the Canadian use pattern) that were required by the USEPA as a condition of reregistration of methylene bis(thiocyanate); 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 Category (USC) #17. The registrant is required to address the following sections of DACO table:
 - for the TGAI: DACOs 2 through 9, inclusive
 - for the EP: DACOs 5, 8 and 9.

The above data and additional data may be required sooner if expansion of current uses of methylene bis(thiocyanate) 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. 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 [*Methylene bis(thiocyanate)*] is available on the Office of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemical Status.

Appendix I Methylene bis(thiocyanate) products currently registered in Canada as of 31 December 2003

Registrant name	Registration number	Active code*	Guarantee	Product name	Marketing class**
Drew Canada, Div. of Ashland Corp.	14037	MBC	10.0%	Amerstat 282 Liquid for Control of Algae, Bacteria & Fungi	C
Drew Canada, Div. of Ashland Corp.	14040	MBC	10.0%	Biosperse 284 Liquid for Control of Bacteria & Fungi	C
Buckman Laboratories of Canada Ltd.	19077	MBC TCM	10% 10.0%	Busan 1009 Liquid Microbicide Industrial	C
Hercules Canada (2002) Inc.	19463	MBC	9.9%	Daracide 6248 Microbistat	C
Buckman Laboratories of Canada Ltd.	19934	MBC	10.0%	Busan 110WB Liquid Microbicide	C
Buckman Laboratories of Canada Ltd.	19935	MBC	10%	Busan 110 Industrial Liquid Microbicide	C
Drew Canada, Div. of Ashland Corp.	20637	MBC	10%	Specialty CSW 842 Cooling Water Biocide	C
Buckman Labs of Canada Ltd.	20938	MBC TCM	2.5% 2.5%	Busan 1071 Liquid Microbicide	C
Buckman Laboratories of Canada Ltd.	20939	MBC TCM	2.5% 2.5%	MECT-5 Liquid Microbicide	C
Diverseylever Canada Inc.	21814	MBC	10.0%	X-Cell 414 Liquid Industrial Microbiocide	C
Ondeo Nalco Canada Co.	22317	MBC	10.0%	Nalcon 7620-WB ***	C
Hercules Canada (2002) Inc.	22837	BRS MBC	9.2% 4.9%	Betz-Dearborn Spectrum RX4100 Slime Control Agent	C
Hercules Canada (2002) Inc.	22974	BTS MBC	17% 5%	Spectrum RX3800 Slime Control Agent	C
Buckman Laboratories of Canada Ltd.	23134	MBC	10%	MTC 10 WB-CW Liquid Microbicide	C
Produits Chimiques Magnus	23264	MBC	10%	Magnatrol 44A Liquid Microbicide	C
Ondeo Nalco Canada Co.	23779	MBC	10%	Nalcon 7619 Microbiological Control Chemical	C
Buckman Laboratories of Canada Ltd.	23997	MBC TCM	2.5% 2.5%	Bulab 6029 Liquid Microbicide	C
Buckman Laboratories of Canada Ltd.	24036	MBC	10%	Bulab 6006 Industrial	C
Buckman Laboratories of Canada Ltd.	24039	MBC TCM	10% 10%	Bulab 6010 Liquid Microbicide	C

Registrant name	Registration number	Active code*	Guarantee	Product name	Marketing class**
Jacklyn Industries Inc.	24233	MBC	10%	WC 8309 Liquid Microbicide	C
Hercules Canada (2002) Inc.	24506	DUW MBC	10% 5%	Spectrum RX3100 Slime Control Agent	C
GE Betz Canada	24507	DUW MBC	10.6% 5%	Spectrus NX1103 Antimicrobial Agent	C
Kemira Chemicals	24924	MBC	10.0%	AMA-10-C Papermill Slime Control	C
Johnsondiversey Canada, Inc.	24924.01	MCB	10.0%	B.I.O. Blast 610	C
ControlChem Canada Ltd.	25530	MBC TCM	2.5% 2.5%	Control Chem 2604 Liquid Microbicide	C
Nim Pro Ltd.	25816	MBC TCM	2.5% 2.5%	Nim Pro B 052 Liquid Microbiocide	C
Quebec-O-Chimie Inc.	25865	MBC TCM	2.5% 2.5%	Unica 310 Liquid Microbicide	C
T. Donovan & Son (1997) Ltd.	25873	MBC TCM	2.5% 2.5%	Triple C Chemical Biocide 597	C
Guardian Chemicals Inc.	26216	MBC TCM	2.5% 2.5%	Aquaguard 602	C
Chem-Aqua, Division of/de NCH Canada Inc.	26485	MBC TCM	2.5% 2.5%	CTB 54 Liquid Microbicide	C
E.Q.U.I.P. International Inc.	26554	MBC	10.0%	Process B 2008 Pulp & Papermill Slimicide	C
LPM Technologies Inc.	27279	MBC	10.0%	LPM 8818	C
Buckman Laboratories of Canada Ltd.	27354	MBC	10.0%	MTC-10CW	C
Buckman Laboratories of Canada Ltd.	20023	MBC	10.0%	MTC-10 Microbicide Concentrate	M
Buckman Laboratories of Canada Ltd.	20024	MBC	10.0%	MTC-10WB Microbicide Concentrate	M
Buckman Laboratories of Canada Ltd.	19030	MBC	98.0%	Methylene bis(thiocyanate) Microbicide	T
Rhodia Consumer Specialties Ltd.	21169	MBC	99.0%	Methylene bis(thiocyanate) Powder	T
Bromine Compounds Ltd.	21596	MBC	99.0%	Methylene bis(thiocyanate) Microbicide	T

* MBC – methylene bis(thiocyanate);
TCM – 2-(thiocyanomethylthio)benzothiazole;
BTS – bis(trichloromethyl)sulfone;
BRS – B-bromo-B-nitrostyrene; and
DUW – dodecylguanidine hydrochloride

** C – Commercial; M – Manufacturing concentrate; T – Technical active

*** Registration of this product will expire on 31 December 2005.