



# Proposed Acceptability for Continuing Registration

PACR2004-12

## Re-evaluation of BTS

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 bis(trichloromethyl)sulfone (BTS). The PMRA has determined that BTS 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 BTS. 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)*

**18 May 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: 0-662-37126-7 (0-662-37127-5)

Catalogue number: H113-18/2004-12E (H113-18/2004-12E-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, 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.

BTS 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 that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient itself and its main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of the USEPA review, 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 BTS and concluded, on the basis of a health and environmental risk assessment, that it was eligible for reregistration with implementation of mitigation measures. PMRA conclusions on the BTS re-evaluation were based on the USEPA RED document for bis(trichloromethyl)sulfone<sup>1</sup>, with consideration of the Canadian use pattern and Canadian issues (e.g., the Canadian Toxic Substance Management Policy [TSMP]).

## 2.0 Re-evaluation of BTS

Active substance: Hexachlorodimethyl sulfone  
Sulfonyl bis(trichloromethane)

Common name: Bis(trichloromethyl)sulfone

CAS number: 3064-70-8

---

<sup>1</sup> The USEPA RED document for BTS (USEPA 1993) is available from the Chemical Status List for Bis(trichloromethyl)sulfone on the Office of Pesticide Programs webpage at [www.epa.gov/pesticides/reregistration](http://www.epa.gov/pesticides/reregistration).

BTS was first registered in 1975. According to current Canadian end-use product labels, it is registered with the PMRA for use only in the pulp and paper industry as a slimicide and a material preservative. Currently registered Canadian products containing BTS are listed in Appendix I.

Based on a comparison between the American and Canadian use patterns, it is concluded that the USEPA assessment described in the RED document for bis(trichloromethyl)sulfone is considered to be an adequate basis for the proposed Canadian re-evaluation decision for BTS. The details of the assessments conducted by the USEPA are outlined in the USEPA RED for bis(trichloromethyl)sulfone.

The federal TSMP<sup>2</sup> and Regulatory Directive DIR99-03<sup>3</sup> were taken into consideration during the review of BTS, and BTS is not considered to be 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 BTS, addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document also addressed uses of BTS that are registered in Canada. Based on the USEPA RED and Canadian use patterns, the PMRA has determined that BTS is acceptable for continued registration provided that the mitigation measures specified below are adopted.

BTS end-use products that contain more than one active ingredient under re-evaluation will be eligible for reregistration only when all of those other active ingredients are determined to be eligible.

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.

---

<sup>2</sup> The federal Toxic Substances Management Policy is available through Environment Canada's website at [www.ec.gc.ca/toxics](http://www.ec.gc.ca/toxics).

<sup>3</sup> *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, DIR99-03, is available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or (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) or through our website at [www.hc-sc.gc.ca/pmra-arla](http://www.hc-sc.gc.ca/pmra-arla).

## 4.0 Proposed regulatory action

Based on findings by the USEPA and good hygiene practice, to protect human health and the environment, labels for all BTS end-use products should be amended as follows:

- The “**ENVIRONMENTAL HAZARDS**” section must bear the following statement:

“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 “**PRECAUTIONS**” section must bear the following statements:

“Wear goggles or a face shield, chemical-resistant gloves, long pants, a long-sleeved shirt, and shoes plus socks during mixing/loading, clean up and repair.”

“Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not re-use them.”

“Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.”

“Users should remove clothing immediately if the 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 before re-use.”

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

## 5.0 Canadian data requirements

The registrant of the technical BTS is required to submit the following within 24 months of finalization of the re-evaluation decision:

- all data (as they relate to Canadian use patterns) submitted to the USEPA in response to the United States data call-in prior to the United States reregistration and the USEPA Data Evaluation Reports (DERs);
- all data (as they relate to Canadian use patterns) that were required by the USEPA as a condition of reregistration of BTS.

- a commitment and schedule to address Canadian requirements that are not addressed through submission of the data outlined above. These data are outlined in the PMRA’s data code (DACO) tables<sup>4</sup> for use-site categories (USCs) #17 and #18 for BTS. The relevant sections of the DACO tables that the registrant is required to address are as follows:
  - USCs#17 and #18 – TGAI: DACOs 2 through 9 inclusive
  - USCs#17 and #18 – EP: DACOs 5 through 9 inclusive

The above data as well as any additional data may be required sooner if expansion of current uses of BTS 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.

---

<sup>4</sup> Use-site category DACO tables can be located at the PMRA website at [www.hc-sc.gc.ca/pmra-arla](http://www.hc-sc.gc.ca/pmra-arla).

## Appendix I Canadian BTS products currently registered

Product name	Registrant	Registration number	Guarantee		Class
			BTS	Other active ingredient	
N-1386®Biocide	Verichem Inc.	18874	99%	–	Technical
N-1386®HG Biocide	Verichem Inc.	19208	34.3%	–	Manufacturing concentrate
N-1386®Han Biocide	Verichem Inc.	24646	39.2%	–	Manufacturing concentrate
Spectrum RX3600	Hercules Canada (2002) Inc.	16113	20%	15.2% – N-Alkyl dimethylbenzyl ammonium chloride	Commercial
Spectrum RX3800	Hercules Canada (2002) Inc.	22974	17%	5% – Methylend bithiocyanate	Commercial
Spectrum RX1000	Hercules Canada (2002) Inc.	24956	5.4%	16% – N-Alkyl dimethylbenzyl ammonium chloride	Commercial
Nalcon 7677	Nalco Canada	21502	5.3%	15.6% – 2-(thiocyanomethylthio) benzothiazole	Commercial
Spectrum RX5200	Betzdearborn Canada Inc.	25285	2.5%	10% – Beta-bromo-beta-nitrostyrene	Commercial
RAISIO 173	Raisio Chemicals Canada Inc.	15313	0.52%	10.5% – Methylene bithiocyanate	Commercial