



Proposed Acceptability for Continuing Registration

PACR2004-15

Re-evaluation of Sodium Salt of 2-mercaptobenzothiazole

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 sodium salt of 2-mercaptobenzothiazole. The PMRA has determined that sodium salt of 2-mercaptobenzothiazole 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 sodium salt of 2-mercaptobenzothiazole. 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)

4 June 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
www.hc-sc.gc.ca/pmra-arla/

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



ISBN: 0-662-37346-4 (0-662-37347-2)

Catalogue number: H113-18/2004-15E (H113-18/2004-15E-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*¹, presents the details of the re-evaluation activities and program structure.

Sodium salt of 2-mercaptobenzothiazole 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 that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient 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 sodium salt of 2-mercaptobenzothiazole and concluded, on the basis of a health and environmental risk assessment, that it was eligible for reregistration with implementation of mitigation measures. The PMRA conclusions on sodium salt of 2-mercaptobenzothiazole re-evaluation were based on the USEPA RED document for sodium salt of 2-mercaptobenzothiazole², with consideration of the Canadian use pattern and Canadian issues (e.g., the Canadian Toxic Substance Management Policy [TSMP]).

¹ *PMRA's Re-evaluation Program*, Regulatory Directive DIR2001-03, is 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 or through our website at www.hc-sc.gc.ca/pmra-arla

² The USEPA RED document for sodium salt of 2-mercaptobenzothiazole (*Sodium and Zinc Salts of 2-Mercaptobenzothiazole*, September 1994) is available from the Chemical Status List on the Office of Pesticide Programs webpage at www.epa.gov/pesticides/reregistration

2.0 Re-evaluation of Sodium Salt of 2-mercaptobenzothiazole

Active substance: Sodium salt of 2-mercaptobenzothiazole
CAS number: 2492-26-4

In Canada, sodium salt of 2-mercaptobenzothiazole was first registered in 1957. According to current Canadian end-use product labels, it is registered with PMRA for use as a preservative in the paper industry, in cutting oils, in starch paste, in emulsion resins, in cellulose solutions and in cotton fabrics. Currently registered Canadian products containing sodium salt of 2-mercaptobenzothiazole are listed in Appendix I.

Based on the comparison of the use pattern between the United States and Canada, the USEPA assessment described in the RED document for sodium salt of 2-mercaptobenzothiazole 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 document for sodium salt of 2-mercaptobenzothiazole.

The federal TSMP³ and Regulatory Directive DIR99-03⁴ were taken into consideration during the review of sodium salt of 2-mercaptobenzothiazole, and it was concluded that sodium salt of 2-mercaptobenzothiazole is not a TSMP Track 1 substance.

3.0 Proposed re-evaluation decision

The USEPA published a RED document for sodium salt of 2-mercaptobenzothiazole, addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of sodium salt of 2-mercaptobenzothiazole that are also registered in Canada. Based on the American and Canadian use patterns, the PMRA has determined that sodium salt of 2-mercaptobenzothiazole 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 end-use products which 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.

³ The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics

⁴ *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, Regulatory Directive DIR99-03, is 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 or through our website at www.hc-sc.gc.ca/pmra-arla

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 actions

Based on the USEPA RED document, the Canadian use pattern and basic hygiene practices, end-use labels of sodium salt of 2-mercaptobenzothiazole must be updated to include the following statements to further protect workers and the environment.

For all end-use products, in the “**Precautions**” section:

- “Wear a NIOSH-approved respirator, chemical-resistant gloves and coveralls over a long-sleeved shirt and long pants when handling.”

For all end-use products, in the “**Environmental Hazards**” 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.”

These label amendments 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 for currently registered products should not be removed unless it contradicts these proposed 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 following is required within 24 months of finalization of the re-evaluation decision:

- a submission to register a source of the technical grade active ingredient (TGAI);
- all data (as they relate to the Canadian use pattern) submitted to the USEPA in response to the data call-in in the United States prior to reregistration, and USEPA Data Evaluation Reports (DERs);
- all data (as they relate to the Canadian use pattern) that was required by the USEPA as a condition of reregistration of sodium salt of 2-mercaptobenzothiazole; 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) tables⁵ for use-site categories #17, #18 and #20. The relevant sections of the DACO tables that registrants are required to address are as follows:

For TGAIs: DACOs 2 through 9, inclusive

For EPs: DACOs 5 through 9, inclusive

The above data and additional data may be required sooner if expansion of current uses of sodium salt of 2-mercaptobenzothiazole 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.

⁵ DACO tables are available through the Pest Management Information Service or through the PMRA website at www.hc-sc.gc.ca/pmra-arla/

**Appendix I Registered products of sodium salt of 2-mercaptobenzothiazole in
Canada as of 31 December 2003**

Product name	Registrant	Registration number	Guarantee (%)	Class
Vancide 51	R.T. Vanderbilt Company, Inc.	13928	Sodium salt of 2-mercaptobenzothiazole: 2.4 Sodium dimethyldithiocarbamate: 27.6	Commercial
Busan 52	Buckman Laboratories of Canada Ltd.	12008	Sodium salt of 2-mercaptobenzothiazole: 8.0 Potassium hydroxymethyl-N-methyldithiocarbamate: 32.0	Industrial/ Commercial