Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Acceptability for Continuing Registration

PACR2004-07

Re-evaluation of Bromohydroxyacetophenone (BHA)

The purpose of this document is to inform the registrant, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of bromohydroxyacetophenone (BHA). The PMRA has determined that BHA 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 BHA. 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 General background on re-evaluation

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.

Bromohydroxyacetophenone (BHA) has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in Regulatory Directive DIR2001-03. In Program 1, the PMRA relies as much as possible on foreign reviews, typically Reregistration Eligibility Decision (RED) documents from the United States Environmental Protection Agency (USEPA), to assess Canadian pest control products. For products to be re-evaluated under Program 1, there must exist a suitable foreign review which covers the main science areas that are necessary for Canadian regulatory decisions, which address the active ingredient itself and its main formulation types registered in Canada, and which 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 BHA and concluded, based on human health and environmental risk assessments, that it was eligible for reregistration with implementation of mitigation measures. The PMRA's conclusions on the BHA re-evaluation were based on the RED[1] document for BHA, with consideration of the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substance Management Policy). A review of the chemistry of Canadian products was conducted.

[1] The USEPA Reregistration Eligibility Decision (RED) document for BHA is available from the Chemical Status List on the Office of Pesticide Programs webpage at www.epa.gov/pesticides/reregistration

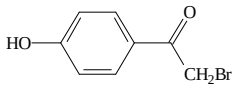
2.0 Re-evaluation of bromohydroxyacetophenone

Common name: 2-Bromo-4'-hydroxyacetophenone

Chemical name: Ethanone 2-bromo-1-(4-hydroxyphenyl)

CAS registry number: 2491-38-5

Structural formula:



Purity of active: 33% (nom) (limits 32.01–33.99%)

Bromohydroxyacetophenone was first registered in 1973. It is a microbiocide used in pulp and paper mill water systems. In Canada, there are currently two end-use products and one technical grade product registered. These products are listed in Appendix I.

Canadian registered use sites, application rates, application method and formulation type are also registered in the United States (U.S.) and the USEPA assessment described in the RED document for BHA 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 outlined in the USEPA RED for BHA.

The federal Toxic Substances Management Policy (TSMP)[2] and Regulatory Directive DIR99-03[3] were taken into consideration during the review of BHA. The review determined that this active ingredient 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 Regulatory Directive DIR99-03, Appendix II.

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[2] The federal Toxic Substances Management Policy is available through Environment Canada's website at www.ec.gc.ca/toxics

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

3.0 Proposed re-evaluation decision

A RED document, addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment, was published for BHA by the USEPA. This document addressed uses of BHA that are also registered in Canada. Based on the USEPA RED and the Canadian use pattern, the PMRA has determined that BHA is acceptable for continued registration provided that the mitigation measures specified below are adopted. Additional data requirements are outlined in Section 5.0.

It should be noted that end-use products that contain several active ingredients under re-evaluation will not be acceptable for continued registration until re-evaluation of all active ingredients is complete.

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 action

For all BHA end-use products, based on findings by the USEPA and good hygiene practice, labels must include the following statements to protect workers and the environment.

(1) In the "Precautions" section:

- "Potential skin sensitizer." (in the primary display panel as well as in the precautions section)
- "Wear chemical resistant gloves, a full-face NIOSH/MSHA approved organic vapour removing cartridge respirator, long pants, a long-sleeved shirt and shoes during mixing/loading, clean-up, repair and other handling activities. When handlers use closed metering systems the handler requirements can be reduced to a long-sleeved shirt, long pants and shoes."
- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
- "Users should remove personal protective equipment immediately after handling this product. Wash the outside of the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

(2) 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."

Label revisions must be submitted 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:

- all data (as they relate to Canadian use pattern) submitted to the USEPA in response to the U.S. data call-in prior to the U.S. reregistration, and USEPA data evaluation reports;

- all data requested by the USEPA as a condition of reregistration in the U.S.; and

- a commitment and schedule to address Canadian data requirements that are not addressed through submission of the data outlined above. These are outlined in the PMRA's data code (DACO)[4] tables for use-site category # 17. The relevant sections of the DACO tables that registrants are required to address are:

  USC # 17, Industrial Process Fluids—TGAI: DACOs 2 through 9 inclusive
  USC # 17, Industrial Process Fluids—EP: DACOs 5, 8, and 9

The above data and additional data may be required sooner if expansion of current uses of BHA 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 these initiatives and any requirements to be addressed by registrants of affected products.

[4] Use-site category DACO tables can be located at the PMRA website at www.hc-sc.gc.ca/pmra-arla

Appendix I Registered Canadian products containing BHA (as of 31 December 2003)

Product name	Class	Guarantee	Registrant	Registration number
BUSAN 90 Liquid Microbiocide Industrial	Commercial	30%	Buckman Labs of Canada Ltd.	12002
BUSAN 93 Liquid Microbiocide	Commercial	20%	Buckman Labs of Canada Ltd.	12007
BHA Technical	Technical	33% (12% related brominated compounds)	Buckman Labs of Canada Ltd.	27379