Proposed Acceptability for Continuing Registration

PACR2004-18

Re-evaluation of Barium Metaborate

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 the re-evaluation of barium metaborate.

The Agency has concluded that the use of barium metaborate and its end-use product does not entail an unacceptable risk to human health and the environment provided that the proposed mitigation measures described in the document are implemented. Additional confirmatory data required to refine the occupational risk assessment are identified.

This Proposed Acceptability for Continuing Registration (PACR) document provides a summary of the data and information reviewed, and the rationale for the proposed regulatory decision.

The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed decision. All comments should be forwarded to the Publications Coordinator at the address below.

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Foreword

The re-evaluation of the active ingredient barium metaborate and its associated uses has been completed by the PMRA. The registrant of the technical grade active ingredient (TGAI) is Buckman Labs of Canada Ltd. The registrant of the TGAI has indicated their support for all registered uses of barium metaborate.

The PMRA has carried out an assessment of available information and has found it sufficient to allow a determination of the safety of barium metaborate and associated end-use product. The Agency has concluded that the use of barium metaborate and its end-use product does not entail an unacceptable risk to human health and the environment provided that the proposed mitigation measures described in the document are implemented. Additional confirmatory data required to refine the occupational risk assessment are identified.

The PMRA will accept written comments on this proposal up to 60 days from the date of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision for these products.

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1.0 Purpose

This document describes the outcome of the PMRA's re-evaluation of the microbiocide barium metaborate and its associated uses. By way of this document, the Agency is soliciting comments from interested parties on the proposed decisions and mitigation measures.

2.0 Re-evaluation of barium metaborate

Products containing barium metaborate were first registered in 1973. Barium metaborate is a material preservative used in paints, coatings and plastics. The TGAI is registered in Canada by Buckman Labs of Canada Ltd. The currently registered products containing barium metaborate are listed in Appendix 1.

As outlined in Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, the PMRA is re-evaluating older active ingredients that were registered, or found in registered products, prior to 1995. This re-evaluation program uses a modern scientific approach to determine the continuing acceptability of older active ingredients in relation to human health and the environment. The current re-evaluation of barium metaborate is being conducted under Program 2, which involves a detailed in-house re-evaluation covering the full range of risk assessments to human health and to the environment. The re-evaluation of barium metaborate and its associated end-use product was conducted based on existing data available to the PMRA. In addition, the review conducted by the United States Environmental Protection Agency (USEPA) was also used. The USEPA review of barium metaborate can be referenced for further details regarding scientific studies used by the PMRA. This review can be found at the website of the USEPA (http://www.epa.gov/oppsrrd1/REDs/0632red.pdf).

2.1 Chemical identification

Active substance: Barium metaborate

Chemical name:

IUPAC: Barium diborate monohydrate CAS: (Meta)boric acid, barium salt

CAS number: 13701-59-2

Molecular formula: BaB₂O₄•H₂O

Structural formula: Ba(BO₂)₂•H₂O

Purity of TGAI: 90% min.

2.2 Description of registered uses supported by the registrant

The following information is based on the current uses of barium metaborate, all of which are supported by the registrant.

2.2.1 Type of pesticide

Barium metaborate is a fungicide, bacteriostat, microbiocide/microbiostat.

2.2.2 Mechanisms of action

Boron inhibits reproduction of fungi by inhibiting the production of spores. The fungicidal mechanism is thought to be by inhibitory interaction of the borate anion with biologically important polyols and the coenzymes NAD⁺ (nicotinamide adenine dinucleotide), NMN⁺ (nicotinamide mononucleotide), and NADP⁺ (nicotinamide adenine dinucleotide phosphate).

2.2.3 Summary of use sites supported by the registrant

In Canada, barium metaborate is registered as a material preservative for use in paints, coatings and plastics.

2.2.4 Target pests supported by the registrant

The target pests are unspecified on the labels. This active can be used for both 'in-can preservation' of aqueous products and 'film preservation' of applied or finished dried products against bacteria and moulds. A wide range of microorganisms can be responsible for in-can spoilage and film defacement.

2.2.5 Formulation types supported by the registrant

The single end-use product containing barium metaborate is formulated as dust or powder containing 90% active ingredient (a.i.).

2.2.6 Application equipment and rates

The methods and rates of application are not specified on the label. In the published literature, the suggested effective fungicidal concentration for barium metaborate used alone in paints and coatings varies from 15–20%. In practice, because of the wide range of microorganisms to be controlled, barium metaborate is likely to be used at lower concentrations in combination with other biocides. The following are the typical concentrations provided by the registrant for various consumer products in Canada.

- Paints 7–16%/wt
- Coatings 1.4–40%/wt:
 - industrial solvent-thinned coatings: ~2%;
 - consumer and industrial coatings: 4–8%;
 - industrial maintenance coatings: 8–16%;
 - bridge coatings: 30–40%
- Plastics 2.5–15%/wt

2.3 Barium metaborate uses not supported by the registrant

In Canada all the registered material preservative uses of barium metaborate are supported by the registrant.

2.4 Barium metaborate uses supported by the registrant in the United States

Barium metaborate use in the United States is supported on the same commodities/sites as in Canada. In addition, barium metaborate is registered in the United States for direct application as a brush or spray treatment to walls, ceilings and pipes.

3.0 Effects having relevance to human health

3.1 Toxicology summary

Based on acute studies in laboratory animals, barium metaborate was of moderate toxicity by the oral route of exposure, and of low toxicity by the dermal and inhalation routes of exposure. In the rabbit, barium metaborate was non-irritating to the skin and a reversible eye irritant. It was not a skin sensitizer in the guinea pig. Although no toxicokinetic studies were available, barium metaborate is likely to be metabolized to barium oxide and boric acid. After short-term exposure to rats, the primary targets were body weight gain reduction in females and changes in clinical chemistry in males. At higher dose levels, animals exhibited mild neurotoxic effects and all males had small, soft testis and aspermatogenesis. Similar testicular effects were noted in animals exposed to equivalent doses of boron alone, as boric acid or borax. All genotoxicity studies for barium metaborate were negative. A rabbit developmental study indicated the potential for qualitative sensitivity in the young, as fetal effects (increased incidences of variations and hydrocephaly) were considered to be more severe relative to the hypoactivity/impaired mobility seen in only two maternal animals at the same dose level.

Reference doses were set on the general toxicological parameters affected in the various studies. These reference doses incorporate uncertainty factors to account for extrapolating between laboratory animals and humans, for variability within the human population and for data gaps, if applicable. Additional safety factors have also been employed, where warranted, to protect pregnant females and their unborn children with respect to sensitivity concerns to both the young (from *in utero* exposure) and expecting mothers, as well as to protect infants and children.

3.2 Applicator, bystander and postapplication risk assessment

Applicators can be exposed to barium metaborate through the addition of the modified barium metaborate pigment, Busan® 11-M1, to paints, other coatings and plastics. Occupational risk is estimated by comparing the potential exposure (in mg a.i./kg bw/day) of workers to the most relevant endpoints from toxicology studies to generate a margin of exposure (MOE). The calculated MOE is compared to a target MOE, which incorporates safety factors protective of the most sensitive subpopulations. The risk exceeds the PMRA's level of concern if the calculated MOE is less than the target MOE.

Based on the use pattern, which is limited to industrial use in the manufacture of paints, coatings and plastics, bystander exposure should be minimal. Busan® 11-M1 is registered as a commercial product for the preservation of paints, coatings and plastics; therefore, it is assumed that the wettable powder will not be directly handled by homeowners. Barium metaborate in paints, coatings and plastics may result in potential postapplication exposure to workers and consumers handling treated materials.

For dermal and inhalation exposure, to estimate the chronic risk of barium metaborate exposure, the no observed adverse effect level (NOAEL) of 10 mg/kg bw/day set in the rabbit developmental study was chosen. At 20 mg/kg bw/day, the pups showed an increase in developmental variants and incidence of malformations (hydrocephaly), and maternal effects included hypoactivity and impaired mobility. The target MOE was 300, which is comprised of a 10-fold uncertainty factor for interspecies extrapolation, a 10-fold uncertainty factor for intraspecies variability, and an extra 3× for qualitative sensitivity in the young. This target MOE is considered protective of all population subgroups for chronic exposure (intermediate to long term), as would be the case for applicators handling barium metaborate. As a result of the lack of an appropriate dermal absorption study to verify a dermal absorption value, the risk assessment assumed 100% dermal absorption (equivalent absorption to the gastrointestinal tract).

3.2.1 Applicator exposure and risk assessment

Although the Busan[®] 11-M1 label does not specify an application methodology for barium metaborate, it is assumed that the wettable powder may be applied to paints, coatings and plastics via an open pour (batch blending) or a closed system. Based on the barium metaborate use pattern, exposure to a mixer/loader/applicator was considered to be intermittent and long term.

The exposure estimate for workers loading or transferring barium metaborate into processing systems for paints was generated from the Chemical Manufacturers' Association (CMA) Antimicrobial Exposure Assessment Study. This study measured occupational exposure of industrial workers during mixing/transfer of antimicrobials to industrial systems. Given limitations of the CMA study (low and variable field and laboratory recoveries), the 90th percentiles generated from the CMA data were used as estimates of exposure potential for operators loading or transferring Busan[®] 11-M1 as a solid open-pour application in the paint, coating and plastic manufacturing industries.

As the Busan® 11-M1 label does not specify the rate of addition for the preservation of paints, coatings and plastics, the amount of active ingredient handled for the open pour, solid formulation scenario in the CMA study was examined and considered to be representative of the amount of barium metaborate potentially used in the paint, coating and plastic preservation processes. Based on open-pour application, the combined dermal and inhalation MOE does not meet the target MOE of 300 (Appendix II, Table 1). Insufficient data was available in the CMA study to estimate exposure using a closed application system with a solid formulation.

Engineering controls (i.e. closed loading) are required to mitigate exposure from barium metaborate application. As these are industrial processes that may be used in closed systems, requiring this engineering control is expected to adequately address any risk to applicators. However, follow-up data is necessary to confirm that closed application systems are in place and adequately mitigate exposure. In addition, label clarification of application rate (both at site of application and in treated substrate) is required. The registrant is also required to list all finished products to be treated with the active ingredient.

All proposed label changes, personal protective equipment, engineering controls and other mitigation measures are described in detail in Section 6.1.

3.2.2 Bystander exposure and risk assessment

As this is an industrial material preservative, the potential for bystander exposure is considered to be negligible during use in industrial paint, coating and plastic manufacturing.

3.2.3 Postapplication exposure and risk assessment

When used in paints, coatings and plastics as a material preservative, there is potential for postapplication exposure to barium metaborate for workers and consumers using these products. However, since the Busan® 11-M1 label does not specify the concentrations of barium metaborate in treated substrates, potential exposure to barium metaborate in finished products cannot be assessed at this time. Information is required to address potential postapplication exposure to consumers and workers, including a comprehensive

list of all finished products that will be manufactured from coatings and plastics treated with barium metaborate.

4.0 Environmental assessment

An environmental risk assessment was not conducted on the boron use patterns described in this document as none of them result in significant environmental exposure.

4.1 Toxic Substances Management Policy

Boron does not meet the Toxic Substances Management Policy (TSMP) Track 1 cut-off criteria for bioaccumulation. The maximum bioconcentration factor (BCF) in fish is 198, which is below the TSMP Track 1 cut-off criterion of BCF \geq 5000. Information on log K_{ow} was not available. Elemental boron is persistent as it is a metalloid. The toxicity of boron compounds is described in Section 3.0.

5.0 Value

5.1 Evaluation method

5.1.1 Material preservative uses of barium metaborate

The importance of barium metaborate end-use products for managing biodeterioration organisms in paint, coatings and plastics in Canada was evaluated based on the following:

- the availability of registered alternative pesticides that are potential substitutes;
- the current field use of barium metaborate products in Canada as assessed from the published literature, information collected from various stakeholders, consultations with material preservative specialists and confidential information provided by the registrant; and
- the expert opinion of provincial pest control specialists, industry groups and other stakeholders.

The material preservative uses of barium metaborate were classified into two value classes as follows.

Key uses

Based on information collected from published literature, information provided by the registrant and the availability of effective registered alternative pesticides, some uses of barium metaborate were considered "key uses" if they matched the following criteria:

- there was a reported use on a site and there are no registered alternatives; OR
- there was reported use and there are registered alternatives, however, barium metaborate is the primary active ingredient for control of the pest; OR

- maintaining registration was considered key for resistance management and/or plays an important role in integrated pest management programs; OR
- the site of use is of large importance to the economy of Canada.

Non-key uses

Based on information collected from published literature, information provided by the registrants and the availability of effective registered alternative pesticides were considered "non-key uses" if they did not match any of the above criteria.

The following discussion on non-antisapstain uses of barium metaborate is based on information currently available to the PMRA.

5.2 Evaluation results

5.2.1 Sites with key uses of barium metaborate

There was no site/pest combination that qualified as a "key use" of barium metaborate based on the information currently available to the PMRA. A large number of alternative actives are registered in Canada for 'in-can preservation' and 'film preservation' of paints, coatings and plastics. The annual use of barium metaborate is relatively small and most of this usage occurs almost exclusively in paints and coatings. However, some non-pesticidal properties of barium metaborate may be important for the manufacture of specialty products where compatibility or interactions among product components and biocides may cause various problems. This active ingredient also has some value as a corrosion inhibitor, an adhesion promoter and an ultraviolet light stabilizer in paints and plastics.

Two major 'in-can' alternative biocides belonging to the isothiazolone group are currently under re-evaluation: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one (commonly known as CIT and MIT, respectively). Two other important alternative 'film preservative' biocides registered for use on the same sites as barium metaborate are also currently under re-evaluation. These include folpet [N-(trichloromethylthio) phthalimide] and chlorothalonil.

6.0 Proposed regulatory action

The PMRA has determined that calculated MOEs do not exceed target MOEs for workers mixing and loading Busan® 11-M1 when using an open pour application methodology. Calculated MOEs for closed application systems are likely to exceed targets provided the risk mitigation measures identified in Section 6.1 are implemented. Additional data requirements are outlined in Section 7.0.

6.1 Proposed regulatory actions relating to human health

6.1.1 Proposed measures to protect mixers/loaders

As an interim measure, the PMRA has determined that calculated MOEs are likely to exceed target MOEs for barium metaborate provided that the mitigation measures below are adopted.

For protection when applying in all industrial scenarios:

• closed mixing, loading and application systems are required.

As calculated MOEs do not meet target MOEs for mixer/loader/applicator exposure using an open application system, closed systems are required for all industrial applications. Using a closed mixing, loading and application system, it is anticipated that target MOEs would be attained; however, confirmatory data is required.

6.1.2 Label statements to protect mixers/loaders

Under the "Precautions" section of the label:

Engineering controls

Busan® 11-M1 must be applied using a closed system. The system must be capable of removing the soluble powder from the shipping container and transferring it into mixing tanks and/or application equipment.

Personal protective equipment (PPE)

Mixers, loaders and other handlers using engineering controls (closed system) must wear the following:

- long-sleeved shirt and long pants
- socks and shoes

6.2 Proposed regulatory action relating to value

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 of affected products.

7.0 Data requirements

7.1 Data requirements related to chemistry

Data are required for the following data codes (DACOs):

•	DACO 1	A revised guarantee statement on the label, stating "boron,
		present as %".

DACO 2.12.2 A Statement of Product Specification Form (SPSF), listing the boron salt weight percent (Box 14) with an additional row stating "boron, present as ...%", with its nominal value and certified lower and upper limits (Boxes 15, 15a and 15b respectively). The SPSF should include all major impurities with their corresponding nominal and upper limits.

• DACO 2.13.3 Data for the active ingredient and all major impurities from

five recent batches of the TGAI analysed to 0.1%, to support the specifications, if the new specifications are not

supported by the batch data on file.

7.2 Data requirements related to toxicology

No additional data are required at this time.

7.3 Data requirements related to exposure

The following confirmatory data is required to support the continued registration of barium metaborate and to support any expansion of its use:

Confirmatory data or acceptable waiver (e.g., detailed description of application methodologies in the paint, coating, and plastic preservation industries) characterizing exposure potential associated with a mixer/loader/applicator using a closed application system. This should include information on the range of engineering controls available in various facilities applying the product.

Before the next round of re-evaluation, the registrant is required to submit the following:

• Information regarding the potential postapplication exposure to industrial workers handling plastics and coatings, painters using paint containing barium metaborate, and consumers contacting finished products identified on the label. If there is potential for postapplication exposure, data may be required to derive estimates of both worker and consumer exposures for each finished product. Relevant data could include passive dosimetry data, migration data, transferable residue data, chemistry data, or scientifically acceptable rationales. Science-based rationales must be provided to justify any extrapolation of data between finished products.

7.4 Data requirements relating to environmental risks

No additional data are required at this time.

7.5 Data requirements related to value

No additional data are required at this time.

8.0 Proposed re-evaluation decision

The PMRA has carried out an assessment of available information and has concluded that the use of barium metaborate and its end-use product does not entail an unacceptable risk to human health and the environment provided that the proposed mitigation measures described in the document are implemented. Additional confirmatory data required are identified in Section 7.0.

The PMRA will accept written comments up to 60 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.

List of Abbreviations

a.i. active ingredientBCF bioconcentration factor

bw body weight

CAS Chemical Abstracts Service

CMA Chemical Manufacturers' Association

DACO data code g gram(s)

GI gastrointestinal

IUPAC International Union of Pure and Applied Chemistry

kg kilogram(s)

K_{ow} *n*-Octanol-water partition coefficient

mg milligram(s)
MOE margin of exposure

NOAEL no observed adverse effect level

PACR Proposed Acceptability for Continuing Registration

PMRA Pest Management Regulatory Agency

PPE personal protective equipment

ppm parts per million

RED Reregistration Eligibility Decision

SPSF Statement of Product Specification Form

TGAI technical grade active ingredient

TSMP Toxic Substances Management Policy

USEPA United States Environmental Protection Agency

μg microgram wt weight

Appendix I Currently registered barium metaborate products (as of 6 May 2004)

Registrant	Registration number	Product name	Market class	Formulation type
Buckman Labs of Canada, Ltd.	27319	Busan® 11-M1 Technical	Commercial	Dust or powder
Buckman Labs of Canada, Ltd.	12033	Busan® 11-M1	Commercial	Dust or powder

Appendix II Exposure Data for Barium Metaborate

Table 1 Dermal, inhalation and combined MOEs for handling of barium metaborate in material preservation process

Data used	kg product		Dermal exposure					Systemic exposure	Margin of exposure		sure	
	used/ day	day	μg/kg ai handled		μg/kg bw/day	μg/kg ai handled	μg/kg bw/	μg/kg bw/	Dermal ^a	Inhalation ^b	Combined ^c	
			Body	Hands	Total	with 100% dermal absorption		day	day			
CMA ^d	n/a	45.7	See Table 2	See Table 2	n/a	1107.43	n/a	8.93	1116.36	9.03	1120	8.96

^a Dermal MOE =
$$\frac{NOAEL_{dermal}}{Exposure_{dermal}}$$
 The dermal NOAEL is 10 mg/kg bw/day; the target MOE is 300.

bInhalation MOE =
$$\frac{NOAEL_{inhalation}}{Exposure_{inhalation}}$$
 The inhalation NOAEL is 10 mg/kg bw/day; the target MOE is 300.

Dermal and inhalation risks were based on the same endpoints; therefore, the risk from these routes were combined in the

following equation:
$$\frac{1}{MOE_{dermal}} + \frac{1}{MOE_{inhalation}} = \frac{1}{MOE_{combined}}$$

^dDermal exposure was assessed via inside and outside gauze patch dosimeters through one layer of clothing. Exposure to the hands was measured with cotton fabric gloves; all workers were protective gloves except replicate S-Po-9 (see Table 2) Respirable exposure was measured via a personal sampling pump. There was significant variability in the types of protective clothing worn; however, most individuals were a long-sleeved shirt and long pants. Each replicate was representative of the time spent performing the antimicrobial-related job task in one day.

Table 2 Exposure to operators handling barium metaborate with solid pour (open) application methods from the CMA Antimicrobial Exposure Assessment Study

Scenario	Rep #	n	kg a.i. handled	Dermal (mg)	Dermal (mg/kg a.i. handled)	Inhalation (mg)	Inhalation (mg/kg a.i. handled)	Total exposure (µg/kg a.i. handled)
Paint & Coating Biocide	S-Po-1	1	19.9	9.198	0.4622	0.0417	0.0021	464.3065
Paint & Coating Biocide	S-Po-2	2	19.9	3.962	0.1991	0.0417	0.0021	201.191
Paint & Coating Biocide	S-Po-3	3	4.14	6.894	1.6652	0.054	0.013	1678.2609
Paint & Coating Biocide	S-Po-4	4	1.58	0.973	0.6158	0.1508	0.0954	711.2658
Paint & Coating Biocide	S-Po-5	5	138	168.9	1.2239	0.0417	0.0003	1224.2152
Paint & Coating Biocide	S-Po-6	6	138	2.511	0.0182	0.0548	0.0004	18.5928
Paint & Coating Biocide	S-Po-7	7	14.6	11.824	0.8099	0.4823	0.033	842.8973
Paint & Coating Biocide	S-Po-8	8	108	13.614	0.1261	0.5315	0.0049	130.9769
Paint & Coating Biocide	S-Po-9	9	0.46	77.52	168.5217	0.0417	0.0907	168612.3913
Paint & Coating Biocide	S-Po-10	10	5.78	27.95	4.8356	0.625	0.1081	4943.7716
Paint & Coating Biocide	S-Po-11	11	52.5	30.955	0.5896	0.625	0.0119	601.5238
Arithmetic Mean	_	_	45.7	32.209	16.2789	0.2446	0.0329	16311.763
Geometric Mean		_	—	12.455	0.8134	0.1267	0.0083	836.5964
90 th Percentile		_	_	77.52	4.8356	0.625	0.0954	4943.7716

Appendix III Proposed mitigation measures for barium metaborate

Engineering controls:

Closed mixing, loading and application systems are required.

Personal protective equipment (PPE):

• Mixers, loaders and other handlers using engineering controls (closed system) must wear a long-sleeved shirt, long pants, socks and shoes.

Appendix IV Use standard for commercial class products containing barium metaborate

(Note: The information in this appendix summarizes the acceptable uses, limitations and minimum PPE for the commercial class products containing barium metaborate resulting from this re-evaluation. This use standard does not identify all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements, and supplementary PPE that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in this use standard.)

COMMON NAME: Barium Metaborate

CHEMICAL NAME: Barium Metaborate (as BaB₂O₄·H₂O)

FORMULATION TYPE: Wettable Powder

SITE CATEGORY: 18 Material

GENERAL LIMITATIONS:

Mixers and loaders handling Busan® 11-M1 must use a closed system designed by the manufacturer to enclose the soluble powder to prevent it from contacting handlers. The system must be capable of removing the soluble powder from the shipping container and transferring it into mixing tanks and/or application equipment. In addition, mixers, loaders and other handlers engaged in any activities that may result in contact with the product must wear the PPE specified in the "Protective Clothing and Equipment" section of this label.

PROTECTIVE CLOTHING AND EQUIPMENT

Mixers, loaders and other handlers using engineering controls (closed system), must wear the following:

- long-sleeved shirt and long pants
- socks and shoes

ACCEPTABLE COMMERCIAL USES FOR BARIUM METABORATE

SITES, PESTS

GUARANTEES, RATES AND DIRECTIONS

General application i	nstructions and limi	Wettable Powder		
Site	Pest	Rate (g a.i.) /material unit	Application instructions and limitations	
material preservative for paints, coatings and plastics	biodeterioration organisms	To be determined	Additional application instructions to be supplied by registrant.	