

PRVD2008-23

Proposed Re-evaluation Decision

Alkyl Dimethyl Benzyl Ammonium Chloride Cluster (ADBAC)

(publié aussi en français)

26 June 2008

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications Pest Management Regulatory Agency Health Canada 2720 Riverside Drive A.L. 6605C Ottawa, Ontario K1A 0K9 Internet: pmra_publications@hc-sc.gc.ca www.pmra-arla.gc.ca Facsimile: 613-736-3758 Information Service: 1-800-267-6315 or 613-736-3799 pmra_infoserv@hc-sc.gc.ca



ISBN: 978-1-100-10055-5 (978-1-100-10056-2) Catalogue number: H113-27/2008-23E (H113-27/2008-23E-PDF)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2008

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.

Table of Contents

Overvi	Dverview 1 What Is the Proposed Re-evaluation Decision? 1 What Does Health Canada Consider When Making a Re-evaluation Decision? 1 What Is ADBAC? 2 Health Considerations 2 Environmental Considerations 3 Measures to Minimize Risk 3 Next Steps 4								
Science	e Evalu	ation							
1.0	Introdu	action							
2.0	The Te 2.1 2.2 2.3	cchnical Grade Active Ingredients, Their Properties and Uses							
3.0	Impact 3.1 3.2	on Human Health and the Environment9Human Health93.1.1Occupational Exposure and Risk Assessment93.1.2Non-Occupational Exposure and Risk Assessment113.1.3Cumulative Effects15Environment153.2.1Environmental Risk Assessment153.2.2Toxic Substances Management Policy Considerations17							
4.0	Propos	ed Re-evaluation Decision							
5.0	Data R	equired as a Condition of Continued Registration							
6.0	6.0 Supporting Documentation								
List of	Abbrev	viations							
Appen	dix I	Registered Products Containing ADBAC as of April 2008							
Appen	dix II	Label Amendments for Products Containing ADBAC							

Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the alkyl dimethyl benzyl ammonium chloride cluster (ADBAC), Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the <u>Pest Control Products Act</u> and Regulations, is proposing continued registration of products containing ADBAC for sale and use in Canada.

An evaluation of available scientific information found that products containing ADBAC do not present unacceptable risks to human health or the environment when used according to the label directions. As a condition of the continued registration of ADBAC uses, new risk-reduction measures must be included on the labels of all products. No additional data are being requested at this time.

This proposal affects all end-use products containing ADBAC registered in Canada. Once the final re-evaluation decision is made, the registrant will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document¹ that summarizes the science evaluation for ADBAC and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of ADBAC.

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 Publications (please see contact information on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive <u>DIR2001-03</u>, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

ADBAC cluster, a group of active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration

1

[&]quot;Consultation statement" as required by subsection 28(2) of the Pest Control Products Act.

Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in a 2006 RED, the USEPA concluded that ADBAC was eligible for reregistration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in this RED were an adequate basis for the proposed Canadian re-evaluation decision.

For more details on the information presented in this overview, please refer to the Science Evaluation in this consultation document.

What Is ADBAC?

ADBAC is a broad spectrum biocide. It is registered in Canada under the authority of the *Pest Control Products Act* for the control of algae, bacteria, fungi, viruses and molluscs at the following use sites: swimming pools, empty food storage areas (e.g. potato), indoor hard surfaces (e.g. sinks, countertops, musical instrument mouthpieces, garbage pails, shower stalls), other indoor surfaces/water (e.g. upholstery, carpets, closed toilet systems, humidifiers), industrial process fluids (e.g. pulp and paper mill systems, open cooling water tower systems, air washers, industrial scrubbing systems/recirculating water cooling towers and wastewater systems), material (e.g. textiles, leather) and wood.

Wood uses of ADBAC are not included in this re-evaluation.

Health Considerations

Can Approved Uses of ADBAC Affect Human Health?

ADBAC is unlikely to affect your health when used according to the revised label directions.

People could be potentially exposed to ADBAC working as a mixer/loader/applicator or if in contact with treated material. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people

may be exposed. The dose levels used to assess risks are established to protect the most sensitive population group (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that ADBAC was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Environmental Considerations

What Happens When ADBAC Is Introduced Into the Environment?

ADBAC is unlikely to affect non-target organisms when used according to the revised label directions.

Certain aquatic organisms could be exposed to ADBAC in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of ADBAC was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of ADBAC, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect mixers/loaders/applicators as well as instructions regarding maximum use rate in pulp and paper process and maximum yearly applications for once-through cooling water tower use
- Additional advisory label statements and a restricted-entry interval to protect swimmers
- Additional advisory label statements and phase-out of residential humidifier uses to protect consumers

Environment

- Additional advisory label statements
- Instructions regarding maximum yearly applications for once-through cooling water tower use

Next Steps

Before making a final re-evaluation decision on ADBAC, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision² that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

²

[&]quot;Decision statement" as required by subsection 28(5) of the Pest Control Products Act.

Science Evaluation

1.0 Introduction

ADBAC is a group of biocides registered in Canada for use against algae, bacteria, fungi, viruses and molluscs. Following the re-evaluation announcement for ADBAC, the registrant of the technical grade active ingredient in Canada indicated its intention to provide continued support for all uses included on the labels of commercial and domestic end-use products in Canada.

The PMRA used recent assessments of ADBAC from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for ADBAC, dated August 2006, as well as other information on the regulatory status of ADBAC in the United States can be found on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

2.0 The Technical Grade Active Ingredients, Their Properties and Uses

2.1 Identity of the Technical Grade Active Ingredients

The Canadian ADBAC cluster is comprised of 10 chemicals that are structurally similar quaternary ammonium compounds.

Common name:	ADBAC
Function:	Biocide
Chemical family:	Quaternary amines
Chemical name: International Union of Pure and Applied Chemistry (IUPAC)	<i>N</i> -alkyl dimethyl benzyl ammonium chloride

The table below provides information on each individual member of this cluster.

CAS Number	Name	Structure	Chain Length
139-08-2	ADBAC*	R Cl ⁻ CH ₃ CH ₃	R = 25% C12 60% C14 15% C16
Not available	ADBAC	Same as above	R = 40% C12 50% C14 10% C16
68956-79-6	ADBAC*	H ₃ C Cl ⁺ CH ₃ CH ₃	R = 50% C12 30% C14 17% C16 3% C18
Not available	ADBAC	Same as above	R = 68% C12 32% C14
68391-01-5	ADBAC	R CI ⁻ CH ₃	R = 5% C12 60% C14 30% C16 5% C18
68391-01-5	ADBAC	Same as above	R = 67% C12 25% C14 7% C16 1% C18
Not available	ADBAC*	Same as above	R = 3% C12 95% C14 2% C16
63449-41-2	ADBAC	Same as above	R = 61% C12 23% C14 11% C16 5% C18

Table 1Members of the ADBAC Cluster

CAS Number	Name	Structure	Chain Length
Not available	Di-alkyl methyl benzyl ammonium chloride	CI ⁻ CH ₃ R	R = 5% C12 60% C14 30% C16 5% C18
121-54-0	Diisobutylphenoxy ethoxyethyl dimethyl benzyl ammonium chloride		

* These active ingredients were not included in this re-evaluation.

Although these technical active ingredients are registered, no end-use product containing *N*-alkyl (25% C12, 60% C14, 15% C16) dimethyl ethylbenzyl ammonium chloride, *N*-alkyl (50% C12, 30% C14, 17% C16, 3% C18) dimethyl benzyl ammonium chloride, or *N*-alkyl (3% C12, 95% C14, 2% C16) dimethyl benzyl ammonium chloride is currently registered in Canada. Therefore, these three chemicals are not included in the re-evaluation.

Based on the manufacturing process, the products are not expected to contain impurities of human health or environmental concern as identified in Regulatory Directive <u>DIR98-04</u>, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, Section 2.13.4 or Toxic Substances Management Policy (TSMP) Track 1 substances as identified in Regulatory Directive <u>DIR99-03</u>, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, Appendix II.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient (CAS No. 68424-85-1 is used as the model compound)

Property	Result
Vapour pressure	38 mm Hg
UV–visible spectrum	Not expected to absorb at $\lambda > 300 \text{ nm}$ ($\lambda \text{ max} = 208 \text{ nm}$)
Solubility in water	Soluble in water

2.3 Comparison of Use Patterns in Canada and the United States

ADBAC is a group of biocides registered in Canada for use against algae, bacteria, fungi, viruses and molluscs in the following use sites: swimming pools, empty food storage area (e.g. potato), indoor hard surfaces (e.g. sinks, countertops, musical instrument mouthpieces, garbage pails,

shower stalls, other indoor surfaces/water/air (e.g. upholstery, carpets, closed toilet systems, humidifiers), industrial process fluids (e.g. pulp and paper mill systems, open cooling water tower systems, air washers, industrial scrubbing systems/recirculating water cooling towers and wastewater systems), material (e.g. textiles and leather), and wood.

Twenty-nine technical, 24 manufacturing concentrate, 47 commercial, and 123 domestic products containing ADBAC are currently registered in Canada. Most of the end-use products are formulated as a solution, with two formulated as a pressurized product and one as a solid product. ADBAC products are added directly to water in industrial process fluids, swimming pools, laundries and humidifiers or diluted in water to treat hard non-porous surfaces in institutional, commercial, industrial and residential settings by immersion, wiping, mopping, trigger spray or low- or high-pressure spray. The ready-to-use products are applied directly on the site to be treated.

Appendix I lists all ADBAC products registered as of April 2008 under the authority of the *Pest Control Products Act*.

ADBAC products are widely used and have a large number of use patterns. The USEPA's strategy was to use representative scenarios for each use site to typify the wide variety of ADBAC uses. The risk assessment discussed in the RED was thus performed on a number of representative scenarios believed to provide high-end degrees of dermal, inhalation or incidental ingestion exposure.

The American and Canadian use patterns were compared. Except for the textile and leather preservative uses (maximum rate: 10 g a.i./kg material treated), all Canadian uses are encompassed by the American uses. Nonetheless, the potential risk associated with the textile and leather preservation use can be extrapolated from certain American uses that have similar exposures. Therefore, based on this comparison of use patterns, it was concluded that the USEPA RED for ADBAC is an adequate basis for the re-evaluation of Canadian uses.

It should be noted that certain uses of ADBAC are regulated under the *Food and Drugs Act* and are not included in this assessment. However, these uses were assessed by the USEPA. The uses are as follows:

- disinfectant
- commercial sanitizer in food manufacturing/processing plants and areas in which food is prepared or kept (e.g. food processing equipment, food utensils and drinking glasses)

In addition, ADBAC was granted temporary registration in 2002 for use as a heavy-duty wood preservative. Currently, the PMRA is reviewing the submission to convert the status to full registration. The results of the review will be published when completed. Therefore, this assessment does not include the re-evaluation of the heavy-duty wood preservative use.

3.0 Impact on Human Health and the Environment

In its 2006 RED, the USEPA concluded that the end-use products formulated with ADBAC met the safety standard under the American *Food Quality Protection Act* and would not pose unreasonable risks or adverse effects to humans and the environment if used according to the amended product labels.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

In Canada, exposure to ADBAC may occur by using the product, working as a mixer/loader/applicator or contacting the treated material. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive population group (e.g. children and nursing mothers).

3.1.1 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating safety factors protective of the most sensitive population group. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

Workers can be exposed to ADBAC when mixing, loading or applying the pesticide and when handling treated material. In Canada, the use sites include industrial processes and water systems, commercial/institutional/industrial premises and swimming pools.

3.1.1.1 Occupational Handler Exposure and Risk

No dermal endpoint for systemic effects was selected for ADBAC because no systemic effects were identified. Therefore, the USEPA did not assess the occupational risk for the dermal route of exposure. The irritation effect of ADBAC was mitigated by personal protective equipment (PPE) requirements already listed on labels. The level of PPE required was based on the toxicity of the end-use product.

Several inhalation exposure scenarios for handlers were identified in the RED. Among those, the following were considered relevant to the Canadian situation:

- liquid pour
- mopping

- wiping
- low-pressure handwand
- liquid/metering pump
- high-pressure/high-volume spray and medium-pressure spray

Maximum application rates as stated on the product labels, surrogate unit exposure values from the Chemical Manufacturers Association antimicrobial exposure study and the Pesticide Handlers Exposure Database, and the USEPA estimates of daily amount handled/treated were used in the assessment.

The duration of exposure evaluated in the USEPA assessment included short- and intermediateterm exposures. The USEPA reported acceptable MOEs (i.e. greater than target MOE of 100) for all occupational inhalation exposure scenarios ranging from 360 to 31 000, except for the following:

- pulp and paper, liquid pump
- once-through cooling water with high flow streams, metered pump
- small process water systems, liquid pour

To mitigate the risks for occupational handlers in pulp and paper mills, the USEPA required that the maximum application rate be reduced from 20.5 kg a.i./tonne of paper to 7.0 kg a.i./tonne of paper with the use of a metering pump system (a closed system). To mitigate the risks for occupational handlers in once-through cooling water towers, the USEPA required that the maximum number of applications be four per year using a metering pump system (closed system). The USEPA required that a dust mist respirator be used when applying the product containing ADBAC to small process water systems in order to mitigate the inhalation risk at these work locations.

The RED adequately addressed potential occupational exposure scenarios associated with the relevant Canadian uses of products containing ADBAC. Therefore, conclusions derived from the RED are considered applicable to the Canadian uses that are encompassed by those of the United States.

The PMRA also requires that the Canadian use rate in the pulp and paper manufacturing process not exceed 7.0 kg a.i./tonne of paper and that the product be applied with a metered pump.

For the once-through cooling water tower use, the PMRA requires that the maximum number of applications be limited to four per year. Canadian products can also be applied manually. Since the USEPA assessment of occupational risk via inhalation was based on a metering pump application system, the PMRA requires that a respirator be worn when products are applied manually.

For small process water systems, the United States required that a dust mist respirator be used when applying the product. Considering that no occupational risks were assumed for the metered pump scenario, the PMRA requires that either a dust mist respirator be worn or a metered pump be used when applying the product to the water systems. The maximum Canadian use rate in small process water systems (60 ppm) is higher than that assessed in the RED (40 ppm) for the metered pump method. Nonetheless, the USEPA assessment resulted in MOEs well above the target (6200 for short-term exposure and 5200 for intermediate-term exposure) and thus provides sufficient protection to account for the difference in application rates between the United States and Canada.

In Canada, workers may also be exposed to ADBAC while handling the product for commercial treatment of textiles and leather. Although this scenario was not specifically discussed in the RED, the process by which the ADBAC antimicrobial treatment would be added to the textile or leather manufacturing process is similar to other "liquid pour" or "metering pump" scenarios assessed by the USEPA. Based on use information, the amount handled per day in a textile plant is likely to be similar to the amount used for small water process systems and the PMRA requires that a respirator be worn when applying the product, unless a metering pump is used.

The USEPA did not recommend protective equipment for dermal exposure since it did not conduct an occupational dermal risk assessment. In Canada, not all end-use products currently require PPE. As a good hygiene practice, the PMRA requires that, as a minimum, chemical-resistant gloves, long pants, a long-sleeved shirt, shoes and socks be worn by workers handling liquid concentrates. Proposed label amendments are listed in Appendix II.

3.1.1.2 Postapplication Exposure and Risk

The USEPA determined that occupational postapplication dermal and inhalation exposures associated with the above scenarios were negligible.

The RED adequately addressed exposure scenarios associated with the Canadian uses of ADBAC, and conclusions derived from the RED are considered applicable to the Canadian situation. Based on this, the PMRA requires no further mitigation measures with respect to occupational postapplication exposures.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

Residential exposure is estimated using the MOE approach described in Section 3.1.1.

Homeowners can be exposed to ADBAC when mixing or applying the pesticide and when exposed to the treated material. Toddlers can be exposed via "hand-to-mouth" activities and through inhalation.

3.1.2.1.1 Residential Handlers

In Canada and the United States, ADBAC is registered as an antimicrobial for use in swimming pools and on indoor surfaces, such as hard floors, carpets, walls, bathroom fixtures, musical instrument mouthpieces, trash cans, toilet bowls, and as a liquid laundry additive. In addition, ADBAC is registered in the United States for a number of outdoor uses such as decorative ponds

and fountains, and ornamental plants and lawns. Since these uses are not registered in Canada, their risk assessments are not discussed in this document.

Among the potential dermal and inhalation exposure scenarios assessed in the RED for handler risks in residential settings, the following scenarios are considered relevant to the Canadian situation:

- indoor hard surfaces (mopping, wiping)
- swimming pools (liquid pour)
- recreational vehicle (RV) holding tanks (liquid pour)*

* Note that RV holding tank use is not registered in Canada. It is included here because this use is considered to be representative of applications to humidifiers and musical instruments.

Residential handlers were assumed to apply products without using personal protective equipment. Dermal and inhalation unit exposure values from the surrogate data, maximum application rates from the representative product labels and the USEPA-estimated quantities of active ingredient handled/treated per day were used in the RED.

The USEPA concluded that residential handlers were exposed to ADBAC on a short-term (1-30 day) basis because the tasks were assumed to be episodic and homeowners were unlikely to use solely ADBAC products for varying activities.

For all scenarios, MOEs were greater than the target MOEs, ranging from 820 to 50 000 for inhalation exposure (target MOE = 100), and 72 to 54 000 for dermal exposure (target MOE = 10). Therefore, the risks did not exceed the USEPA's level of concern.

The RED adequately addressed potential exposure scenarios associated with the Canadian residential handler. Thus, the conclusions derived from the RED are considered applicable to the Canadian situation. Based on this, the PMRA requires no further mitigation measures with respect to residential handler exposure. It is recommended that residential handlers wear rubber gloves when handling the products as a good hygiene practice.

3.1.2.1.2 Residential Postapplication Exposure

In Canada, potential postapplication exposure could result from uses of ADBAC on/in hard surfaces, carpets, textiles, humidifiers, swimming pools and musical instrument mouthpieces.

Among the scenarios chosen by the USEPA to represent high-end exposure, the following are considered relevant to the Canadian situation:

- crawling on treated hard surfaces and carpets (dermal and incidental oral exposure to children)
- wearing treated clothing (dermal exposure to adults and children and incidental oral exposure to children)
- swimming in treated pools (adult and child incidental ingestion)

- using treated musical instrument mouthpieces and reeds (adult and child incidental oral exposure)
- using portable humidifiers (adult and child inhalation exposure)

For the first three scenarios, the calculated dermal and inhalation MOEs were above the target MOEs of 10 and 100, respectively. Therefore, the risks were not of concern to the USEPA. The RED recommended a 15-minute restricted-entry interval and requested that the statement "DO NOT apply when swimmers are in the immediate vicinity" be included on label.

The RED adequately addressed potential exposure scenarios associated with the Canadian residential uses of ADBAC on treated floors and carpets and in swimming pools. Thus, the conclusions derived from the RED for these exposure scenarios are considered applicable to the Canadian situation. To further protect swimmers, the USEPA's label statement to prohibit application when swimmers are around and its recommendation for a 15-minute restricted-entry interval will also be required on the Canadian labels.

Canadians can be exposed to the use of ADBAC in laundries in hospitals, nursing homes and diaper plants. The potential exposure scenarios were adequately addressed in the RED through the residential uses of ADBAC as a laundry additive. The conclusions derived from the RED are considered applicable to the Canadian situation.

In Canada, adults and children may also be exposed to ADBAC residues in clothing as a result of commercial treatment of textiles and leather. Although this scenario was not specifically discussed in the RED, the process by which textiles are treated commercially is similar to residential laundering of clothing. The USEPA assessment of risk from exposure to clothing residues in residential laundry use can be applied to the Canadian commercial treatment scenario by using the commercial rate. Based on this, exposure to residue on clothing from commercial treatment of textiles with ADBAC is not of concern.

The USEPA did not have residue data to assess oral exposures to children and adults from treated musical instruments. In Canada, there is only one product registered for this use. It is formulated as a liquid and is diluted to a 600 ppm ADBAC solution for sanitizing wind instruments. The risk from oral exposure to ADBAC-treated musical instruments is considered negligible based on the following rationale.

- The treated musical instruments are to be rinsed with tap water before use.
- The application rate is half the maximum rate used for food bottling and packaging in the United States.
- The potential risk from exposure to treated food packaging was assessed by the USEPA, and the result was much below the USEPA's level of concern.

Therefore, no further mitigation measures are required for this use.

In both Canada and the United States, ADBAC can be used in humidifiers to control the buildup of bacteria and algae in water tanks. The USEPA used the Multi-Chamber Concentration and Exposure Model (MCCEM) to estimate the potential inhalation risk to adults and children.

The MCCEM is designed to calculate average/peak indoor air concentrations of chemicals released from products or materials in residences and estimate inhalation exposure to these chemicals for both acute and chronic scenarios. Information on the type of residence, zone volumes, interzonal air flow rates, air exchange rates, the pollutant emission rate and occupant activity pattern are input into the model.

The resulting MOEs were below the target MOE of 100. Therefore, the risk was of concern to the USEPA. The eight-hour MOEs for adults and children were 71 and 11, respectively, and the 24-hour MOEs for adults and children were 10 and 4, respectively. As there are no available mitigation measures for the humidifier use, the USEPA determined that the residential use of ADBAC in humidifiers was not eligible for reregistration.

The RED adequately addressed potential exposure scenarios associated with the Canadian residential uses of ADBAC in humidifiers. ADBAC uses in humidifiers in Canada are very similar to the use assessed in the RED and conclusions derived by the USEPA are applicable. The use of ADBAC in residential humidifiers is of concern and should be phased out unless additional data are provided to refine the assessment. This includes uses in portable humidifiers as well as furnace humidifiers.

Five products are currently registered in Canada with humidifier uses.

3.1.2.2 Aggregate Risk Assessment

3.1.2.2.1 USEPA Assessment

The assessment of aggregate risk combines the different routes of exposure (i.e. from food, water and residential exposures).

Two key factors were considered by the USEPA when selecting exposure scenarios for incorporation into the aggregate assessment: the use patterns of the products and the probability of co-occurrence. Typically, the acute and chronic aggregate risk assessments address the combined risks from the direct and indirect food contact uses and drinking water exposure only. However, since an endpoint representing a single dose effect was not identified in the database for ADBAC, an acute aggregate risk assessment was not conducted.

Tier 1 screening computer models were used to generate screening level estimates of drinking water concentrations. These estimates were based on the American highest label seasonal rate (338 kg a.i./ha, three applications/year) and were used to assess the chronic aggregate risk. The chronic aggregate exposure constituted 3.5% and 10.3% of the chronic population adjusted dose for adults and children, respectively, and was not of concern to the USEPA.

Short- and intermediate-term aggregate risk assessments assumed contributions from food, drinking water and non-occupational exposure (dermal, inhalation, incidental ingestion). In the RED, the following exposure scenarios were considered to likely co-occur on a short-term base.

Adults

- chronic dietary
- applying cleaning products via mopping, wiping and trigger pump spray (dermal, inhalation)
- wearing treated clothing (dermal)

Children

- chronic dietary
- after cleaning products are applied to carpets (oral ingestion, dermal)
- wearing treated clothing (oral ingestion, dermal)

The oral, dermal and inhalation routes of exposures were not aggregated because the ADBAC toxicological endpoints for these three routes were based on different toxic effects. Rather the risks from the co-occurrence of the same routes of exposure were aggregated. Moreover, aerosol inhalation exposure to ADBAC used in humidifiers was not included in the aggregate risk assessment since the risk was of concern and was addressed separately.

For all the routes of exposure considered in the RED, the short-term aggregate MOEs were greater than the target MOEs for both adults and children; therefore, risks were not of concern.

3.1.2.2.2 Canadian Scenario

As the Canadian use pattern is less than that of the United States (e.g. no turf and ornamental uses), the Canadian potential aggregate exposure scenarios were adequately addressed by the USEPA aggregate risk assessment.

3.1.3 Cumulative Effects

The USEPA has not determined whether ADBAC has a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, it was assumed that ADBAC does not share a common mechanism of toxicity with other substances and a cumulative risk assessment was not required.

3.2 Environment

3.2.1 Environmental Risk Assessment

ADBAC is hydrolytically stable under abiotic and buffered conditions over the pH 5–9 range. However, based on a biodegradation study, the USEPA concluded that ADBAC readily degrades into 60% carbon dioxide in 13 days. The soil mobility study indicated that ADBAC is immobile in soil. ADBAC was not expected to pose a concern for bioconcentration in aquatic organisms.

ADBAC is primarily used as an indoor antimicrobial in residential,

commercial/institutional/industrial and public facilities. The USEPA concluded that the indoor uses of ADBAC were not likely to result in an unacceptable ecological risk to non-target

organisms based on minimal exposure potential. Therefore, quantitative risk assessments for these uses were not required.

In the United States, ADBAC can be used on ornamental plants and shrubs, residential lawns and commercial turf and golf courses, and in puddles, ornamental ponds and pools. In addition, ADBAC can be used in the United States for non-pressure treatment (antisapstain) of wood. These uses could result in potential terrestrial or aquatic exposures and effects. However, since these uses are not registered in Canada, they are not considered in this document.

The USEPA decided that the once-through cooling water tower use has potential for direct release of ADBAC into aquatic systems.

To assess the ecological risk of ADBAC to aquatic organisms resulting from the once-through cooling water tower use, the USEPA calculated risk quotients based on appropriate toxicity endpoints and expected environmental concentrations, and compared the resulting risk quotients to corresponding levels of concern.

Exposure was estimated using a screening level computer model. An average-sized plant on small, average and large rivers was used in the modelling, and downstream chemical concentrations from a chemical discharge were calculated assuming a constantly changing flow rate.

The screening level assessment indicated that continuous dosing of ADBAC to once-through cooling water systems located on low-flow streams would result in the highest concentration of the pesticide in the receiving water. High water flow and intermittent dosing had less impact on aquatic organisms than medium to low stream flow. However, levels of concern for all aquatic animals were triggered even at the lowest dosage modelled (2.0 ppm) using a continuous method regardless of the water flow rate.

Terrestrial wildlife was not expected to be impacted from the once-through cooling water tower use.

In order to reduce the environmental risk, the USEPA required that uses for the once-through cooling water towers be limited to no more than four times per year. In addition, all labels supporting this use were required to include statements indicating that discharge of effluent containing ADBAC into aquatic systems be prohibited unless permit requirements were met and the permitting authorities were notified in writing. Directions for bentonite clay treatment (to deactivate ADBAC) were also to be provided. Bentonite clay was found to be an effective agent in reducing the amount of ADBAC in effluent/runoff due to its strong tendency to bind to ADBAC.

The American use pattern for ADBAC in once-through cooling water towers encompasses the Canadian use pattern. Consequently, the USEPA's risk-reduction measures for ADBAC in once-through cooling water towers are applicable to the Canadian situation. These measures include:

- a maximum of four applications per year
- additional effluent discharge statements as well as environmental hazard statements
- a requirement for deactivation of ADBAC in effluent by bentonite clay before discharge

Label amendments are described in detail in Appendix II.

3.2.2 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the 1995 federal Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

The federal Toxic Substances Management Policy and PMRA Regulatory Directive <u>DIR99-03</u>, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, were taken into account during the re-evaluation of ADBAC. The PMRA has reached the following conclusions.

- ADBAC was found to be hydrolytically stable under abiotic and buffered conditions over the pH 5–9 range in aquatic environments (half-lives: 150–379 days) and stable to photodegradation in pH 7 buffered aqueous solutions. However, other information reported in the RED indicates rapid microbial degradation of ADBAC.
- ADBAC substances are not expected to be bioaccumulative. Maximum bioconcentration in freshwater fish was 33 fold for edible tissues, 160 fold for non-edible tissues and 79 fold for whole fish tissues. Therefore, ADBAC active ingredients are not candidates for Track 1 classification.
- Based on a review of the available chemistry information (see Section 2.1), the technical products are 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.

Formulant issues are being addressed through PMRA formulant initiatives and Regulatory Directive <u>DIR2006-02</u>, *Formulants Policy and Implementation Guidance Document*, published on 31 May 2006.

4.0 Proposed Re-evaluation Decision

The PMRA has determined that ADBAC is acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and the environment. The labels of Canadian end-use products must be amended to include the statements listed in Appendix II. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. No additional data are being requested at this time.

In addition, the residential humidifier use is to be phased out unless additional data are provided to refine the assessment.

For ADBAC end-use products that contain other active ingredients under re-evaluation, the reviews for these active ingredients will be included in separate documents.

5.0 Data Required as a Condition of Continued Registration

Registrants of ADBAC in the United States have agreed to conduct an inhalation exposure study that would allow refinement of the risk assessment for humidifier use.

Should Canadian registrants wish to add humidifier use to the label in the future, the same study should be included in the submission data package.

6.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03 and DACO tables, can be found on our website at <u>www.pmra-arla.gc.ca</u>. 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: <u>pmra_infoserv@hc-sc.gc.ca</u>.

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

The USEPA RED document for ADBAC is available on the USEPA Pesticide Registration Status page at <u>www.epa.gov/pesticides/reregistration/status.htm</u>.

List of Abbreviations

λ	wavelength
ADBAC	alkyl dimethyl benzyl ammonium chloride cluster
a.i.	active ingredient
bw	body weight
CAS	Chemical Abstracts Service
DACO	data code
g	gram(s)
kg	kilogram(s)
MCCEM	Multi-Chamber Concentration and Exposure Model
mm Hg	millimetre(s) mercury
MOE	margin of exposure
nm	nanometre(s)
pН	-log10 hydrogen ion concentration
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
RED	Reregistration Eligibility Decision
RV	recreational vehicle
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency

Appendix I Registered Products Containing ADBAC as of April 2008

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee (total ADBAC) (%)
22066	Manufacturing concentrate	Mason Chemical Company	Maquat MC6025 - 50%	Solution	50
22924	Technical	Lonza Inc.	Barquat OJ-50 Virucide, Fungicide, Mildewstat	Solution	50
11899	Domestic	Sani-Marc Inc. D.B.A. Clearwater	Algiban 15 Liquid	Solution	15
12505	Domestic	I.P.G./.G.P.I. Independent Pool Group Inc.	Aqua Pro Algicide 5 Liquid Algaecide	Solution	5
12506	Domestic	I.P.G./.G.P.I. Independent Pool Group Inc.	Aqua Pro Algicide 15 Liquid Algaecide	Solution	15
12791	Domestic	CAPO Industries Ltd. R.B.A. Pool Chemical Industries	Poolchem Liquid Algaecide	Solution	10
14418	Commercial	Laboratoires Choisy Ltee.	Sprint 3431 Sanitizer Degreaser Detergent	Solution	1.6
14937	Domestic	Laboratoire Orleans Inc.	Orleans Algaecide Liquid 10%	Solution	10
14957	Commercial	Ag-Services Inc.	General Storage Disinfectant	Solution	10
15814	Domestic	Les produits industriels Jean-Paul Côté Inc.	Monsieur Piscine Liquid Algaecide 5%	Solution	5
16113	Commercial	Hercules Canada Inc.	Spectrum RX3600 Slime Control Agent	Solution	15.2
16570	Domestic	Arch Chemicals Canada, Inc. D.B.A. Quatic Consumer Products	Pool Care Regular Algaecide	Solution	5
16898	Domestic	Canadian Tire Corp. Ltd.	Canadian Tire Liquid Algaecide	Solution	5
17008	Manufacturing concentrate	Lonza Inc.	Lonza Hyamine 3500 (50%)	Solution	50
17009	Technical	Lonza Inc.	Lonza Hyamine 3500-80%	Solution	80

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee (total ADBAC) (%)
17074	Commercial	Drew Canada, Ashland Canada Corp.	Csw 825 Biocide	Solution	9.6
17336	Domestic	Splendor Pools	Splendor Pools Big Red Algaecide	Solution	50
17367	Domestic	RBF International Ltee.	Cristal Clair Liquid Algaecide 5%	Solution	5
17367.05	Domestic	Distribution du Nord	Pro 5% Liquid Algaecide	Solution	5
17367.17	Domestic	RBF International Ltee	Aqua Solutions Algaecide 5	Solution	5
17367.21	Domestic	Distribution du Nord	Azur 5% Liquid Algaecide	Solution	5
17367.50	Domestic	Rona Inc.	Rona Liquid Algaecide 5%	Solution	5
17368	Domestic	RBF International Ltee	Cristal Clair 10% Liquid Algaecide	Solution	10
17368.05	Domestic	Distribution du Nord	Pro 10 % Liquid Algaecide	Solution	10
17368.21	Domestic	Distribution du Nord	Azur 10% Liquid Algaecide	Solution	10
17368.50	Domestic	Rona Inc.	Rona 10% Liquid Algaecide	Solution	10
17368.71	Domestic	Les Piscines Trevi Inc.	Trevi 10% Liquid Algaecide	Solution	10
17583	Domestic	Capo Industries Ltd.	Algi-Out Liquid Algaecide	Solution	5
17590	Domestic	Laboratoire Orleans Inc.	Orleans Algaecide Liquid 5%	Solution	5
18308	Commercial	Hercules Canada Inc.	Daracide 6215 Microbistat	Solution	25
18699	Domestic	Mursatt Chemicals Limited	Alkil Liquid Algaecide	Solution	5
19124	Technical	Rhodia Canada Inc.	Alkaquat DMB-451 82%	Solution	82
19191	Manufacturing concentrate	Rhodia Canada Inc.	Alkaquat DMB-451 50%	Solution	50
19254	Domestic	Sunfresh Ltd.	No Name Liquid Algaecide	Solution	5

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee (total ADBAC) (%)
19350	Domestic	Charlotte Products Ltd.	Swish Crystal Algaecide for Pools	Solution	10
20042	Domestic	PoolSport Inc.	PoolSport Algaecide	Solution	5
20073	Domestic	Asepsis Inc.	Omni Algae Preventative 50-10 Liquid Algaecide	Solution	10
20285	Domestic	Capo Industries Ltd.	PoolBoss Liquid Algaecide 10%	Solution	10
20285.04	Domestic	Outdoor Depot Pool, Spas, Patios Company Itd	Club Pro Algaecide 10%	Solution	10
20380	Technical	Lonza Inc.	Lonza Barquat MB-80	Solution	80
20397	Commercial	Horticultural Technologies ltd	Floralife Formula D.C.D. Disinfects Cleans Deodorizes	Solution	5
20523	Domestic	Bio-Lab Canada Inc.	BioGuard Back-up (Liquid Algicide)	Solution	40
20525	Domestic	Bio-Lab Canada Inc.	BioGuard Liquid Algaecide	Solution	10
20526	Domestic	Bio-Lab Canada Inc.	BioGuard Liquid Algaecide 28-5	Solution	5
20682	Domestic	RBF International Ltee	Cristal Clair 15% Liquid Algaecide	Solution	15
20682.05	Domestic	Distribution du Nord	Pro 15% Liquid Algaecide	Solution	15
20682.17	Domestic	RBF International Ltee	Aqua Solutions Algeacide 15	Solution	15
20682.26	Domestic	RBF International Ltee	Club Pro 15% Liquid Algaecide	Solution	15
21123	Manufacturing concentrate	Lonza Inc.	Lonza Bio-Quat 80-28R	Solution	80
21339	Technical	Stepan Co.	Stepan BTC 8358 Concentrated Germicide	Solution	80
21481	Manufacturing concentrate	Lonza Inc.	Bio-Quat 50-28R Manufacturing Concentrate	Solution	50
21723	Technical	Lonza Inc.	Bardac 205 M	Solution	20

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee (total ADBAC) (%)
21724	Technical	Mason Chemical Company	Maquat MC 1412-50%	Solution	50
21726	Technical	Lonza Inc.	Bardac 208 M	Solution	32
21727	Technical	Mason Chemical Company	Maquat MC 1412-80%e	Solution	80
21731	Domestic	R.F. Distributeur Enr	Etoile Liquid Algaecide	Solution	5
21820	Manufacturing concentrate	Stepan Company	BTC 835	Solution	50
21848	Domestic	Les Produits Sanitaires Lepine	Algicide Domestic Liquid	Solution	10
21866	Technical	Lonza Inc.	FMB 451-8 Quat Concentrated Liquid Germicide	Solution	80
21895	Manufacturing concentrate	Lonza Inc.	Barquat MB-50	Solution	50
22017	Manufacturing concentrate	Lonza Inc.	FMB 451-5 Quat Concentrated Liquid Germicide	Solution	50
22224	Commercial	Lonza Inc.	Lonza 205M Water Treatment Microbicide	Solution	20
22364	Domestic	Lawrason's, Inc.	Aqua Algaecide 5 Liquid Algaecide	Solution	5
22365	Domestic	Lawrason's, Inc.	Aqua algaecide 10 Liquid Algaecide	Solution	10
22437	Domestic	Hydrotech Chemical Corporation	Guardex Algae Control 10	Solution	10
22470	Domestic	Sani-Marc Inc.	Algicide 10%	Solution	10
22470.06	Domestic	Sani-Marc Inc. D.B.A. Clearwater	Clearwater Algaecide 10%	Solution	10
22470.08	Domestic	Les Piscines Perrin Inc.	Perrin Anti-Algues 10% Liquid Algaecide	Solution	10
22470.30	Domestic	Groupe d'achat M.P. Inc.	Pisci Alg-10	Solution	10
22470.61	Domestic	Sani-Marc Inc.	Algyzine	Solution	10
22471	Domestic	Sani-Marc Inc.	Liquid Algaecide 5%	Solution	5
22472	Domestic	Sani-Marc Inc.	Liquid Algaecide 7.8%	Solution	7.8

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee (total ADBAC) (%)
22605	Commercial	Produits Chimiques Magnus Ltee	Magnatrol 43-A Liquid Microbiocide	Solution	15
22735	Domestic	Lawrason's, Inc.	RO-Tyme Humidifier Freshener and Conditioner	Solution	3.2
22905	Commercial	Produits Chimiques Magnus Ltee	NFTD	Solution	6.75
22917	Domestic	Sani-Marc Inc.	Sani-Marc Liquid Algaecide 6%	Solution	6
22918	Domestic	Sani-Marc Inc.	Sani-Marc Liquid Algaecide 12%	Solution	12
23208	Domestic	N. Jonas & Co., Inc.	On-guard Algae RX Liquid Algaecide	Solution	10
23408	Domestic	Arcale Distributors Inc.	Algaecide 10 % Formula 6	Solution	10
23529	Manufacturing concentrate	Lonza Inc.	Uniquat Qac-80	Solution	80
23530	Manufacturing concentrate	Lonza Inc.	Uniquat Qac-50	Solution	50
23534	Domestic	Sani-Marc Inc.	Liquid Algaecide 15%	Solution	15
23598	Domestic	Les produits industriels Jean-Paul Côté Inc.	JPC Liquid Algaecide 5%	Solution	5
23599	Domestic	Les produits industriels Jean-Paul Côté Inc.	JPC Liquid Algaecide 10%	Solution	10
23804	Commercial	Hercules Canada Inc.	Spectrum RX4700 Slime Control Agent	Solution	8
23805	Commercial	Ge Betz Canada	Spectrus NX1104	Solution	8
23859	Domestic	Sani-Marc Inc.	Sani-Marc Prevention 40 Algaecide	Solution	40
23859.60	Domestic	Sani-Marc Inc.	Algyzine plus	solution	40
23890	Domestic	Recreational Water Products Inc	Aqua Chem algaecide liquid	Solution	10
23920	Domestic	I.P.G./G. P. I. Independent Pool Group Inc.	Aqua Pro Algicide 10 Liquid Algaecide	Solution	10
23922	Domestic	Sani-Marc Inc. D.B.A. Pool Time	Pool Time algicide 5 Liquid Algaecide	Solution	5

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee (total ADBAC) (%)
23923	Domestic	Sani-Marc Inc. D.B.A. Pool Time	Pool Time Algex 10 Liquid Algaecide	Solution	10
23924	Domestic	Sani-Marc Inc. D.B.A. Pool Time	Pool Time algicide 20 Liquid Algaecide	Solution	20
23963	Commercial	Hercules Canada Inc.	Spectrum RX9600 Slime Control Agent	Solution	10
24025	Commercial	Lonza Inc.	Lonza Carpet Sanitizer CS-202	solution	0.8
24041	Commercial	3M Canada Company	3M Sanitizer Concentrate	Solution	1.54
24043	Manufacturing concentrate	Lonza Inc.	FMB 1210-8 Quat Concentrated Liquid Germicide	Solution	32
24044	Manufacturing concentrate	Lonza Inc.	FMB 1210-5 Quat Concentrated Liquid Germicide	Solution	20
24109	Domestic	Lawrason's, Inc.	Aqua Algaecide 15 Liquid Algaecide	Solution	15
24146	Domestic	Sani-Marc Inc. D.B.A. Perfect Logic	Pool Doctor End Algae Liquid Algaecide	Solution	40
24205	Domestic	Arcale Distributors Inc.	Formule 6 Algaecide 5	Solution	5
24206	Domestic	Arcale Distributors Inc.	Formule 6 Algaecide 15	Solution	15
24260	Domestic	Arcale Distributors Inc.	Algicide Preventive (Formule 6) for Closing of swimming pool	Solution	5
24290	Commercial	Union Carbide Corp, A Subsidiary of Dow Chemical Company	Aqucar 542 Water Treatment Microbiocide	Solution	7.5
24291	Domestic	Quatic Industries Inc.	Humidi-care Germ Ban for Furnace & Portable Humidifiers	Solution	5
24385	Domestic	Mursatt Chemicals Limited	No-algi Concentrated liquid algaecide	Solution	20
24405	Domestic	Arcale Distributors Inc.	Formula 6 Algaecide 40	Solution	40
24511	Domestic	Hall-Chem MFG. Inc.	Splash Liquid Algaecide 40%	Solution	40

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee (total ADBAC) (%)
24956	Commercial	Hercules Canada Inc.	Spectrum RX1000 Slime Control Agent	Solution	16
24983	Commercial	Buckman Laboratories of Canada Ltd.	Busan 100 Liquid Microbicide	Solution	50
25119	Domestic	Les produits industriels Jean-Paul Côté Inc.	Super Algi 40%	Solution	40
25165	Domestic	Sani-Marc Inc. D.B.A. Calypso	Germ-a-Side Germicide Algaecide Liquid	Solution	12
25165.01	Domestic	Sani-Marc Inc.	Germ-out Germicide Liquid Algaecide	Solution	12
25165.03	Domestic	I.P.G./G. P. I. Independent Pool Group Inc.	Steri-clean Germicide Liquid Algaecide	Solution	12
25165.04	Domestic	Purity	Germ-away Germicide Liquid Algaecide	Solution	12
25240	Commercial	Ge Betz Canada	Spectrus NX1101	Solution	10
25276	Commercial	Osceola Supply, Inc.	Verticide	Solution	6.14
25371	Domestic	Laboratoire Orleans Inc.	Super Algiclear	Solution	2
25408	Manufacturing concentrate	Mason Chemical Company	Maquat MQ615M	Solution	20
25409	Manufacturing concentrate	Mason Chemical Company	Maquat MQ624M	Solution	32
25503	Commercial	Kemira Chemicals Canada Inc.	Fennosan Q25-C Paper Mill Slimicide	Solution	25
25550	Commercial	Union Carbide Corp, A Subsidiary of Dow Chemical Company	Piror 842 Slimicide	Solution	7.5
25601	Commercial	Union Carbide Corp, A Subsidiary of Dow Chemical Company	Piror 814 Slimicide	Solution	2.5
25606	Commercial	Union Carbide Corp, A Subsidiary of Dow Chemical Company	Aqucar 514 Water Treatment Microbiocide	Solution	2.5
25666	Commercial	GE Betz Canada	Spectrus CT1300	Solution	50
25686	Commercial	Nalco Canada Company	Nalcon 7637 Slimicide	Solution	7.5

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee (total ADBAC) (%)
25703	Commercial	Kay Chemical Int'l Inc.	Kay Surface Sanitizer	Solution	3
25828	Commercial	Buckman Laboratories of Canada Ltd.	Eclipse 606 Microbicide	Solution	7.5
25838	Domestic	Arch Chemicals, Inc	Hth algaecide 10	Solution	10
25839	Domestic	Arch Chemicals, Inc	Pace 10% liquid algaecide	Solution	10
26139	Domestic	Capo industries Ltd.	X-tra Strength algaecide	Solution	40
26168	Manufacturing concentrate	Stepan Company	Stepan BTC 888 Concentrated Germicide	Solution	32
26169	Manufacturing concentrate	Stepan Company	Stepan BTC 885 Concentrated Germicide	Solution	20
26362	Commercial	Innovative Chemical Technologies Canada Limited	Econo-cide B1002	Solution	8.68
26866	Commercial	Innovative Chemical Technologies Canada Limited	Econo-cide B 1001	Solution	20
26925	Domestic	Sani-Marc Inc. D.B.A. Kool Kit	Kool 40 Liquid Algaecide	Solution	40
26934	Domestic	Declic Enr.	Odyssey Liquid Algaecide 5%	Solution	5
26935	Domestic	Sani-Marc Inc. D.B.A. Calypso	Control 40 Liquid Algaecide	Solution	40
26937	Domestic	Sani-Marc Inc. D.B.A. clearwater	Algicide 15% Liquid Algaecide	Solution	15
26938	Domestic	Sani-Marc Inc. D.B.A. Calypso	Calypso Control 10	Solution	10
26939	Domestic	Chimisol Inc.	Liquid Algaecide 5%	Solution	5
26940	Domestic	Sani-Marc Inc. D.B.A. clearwater	Clearwater Algicide 5%	Solution	5
26941	Domestic	Groupe d'achat M.P., Inc.	Piscialg 5 Liquid Algaecide	Solution	5
26954	Domestic	Groupe d'achat M.P., Inc.	Piscialg 40 Liquid Algaecide	Solution	40

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee (total ADBAC) (%)
27084	Domestic	Sima Group/groupe Sima D.B.A Aqua Select	Aqua Select Algaecide 5%	Solution	5
27120	Domestic	Sani-Marc Inc.	End Algae 40 Liquid Algaecide	Solution	40
27186	Domestic	Sani-Marc Inc. D.B.A. Elite	Elite 40 Liquid Algaecide	Solution	40
27215	Domestic	Distribution du Nord	Azur 40% Liquid Algaecide	Solution	40
27217	Domestic	Distribution du Nord	Pro 40% liquid algaecide	Solution	40
27218	Domestic	RBF International Ltee	Cristal Clair 40% Liquid Algaecide	Solution	40
27302	Domestic	Sani-Marc Inc. D.B.A. Perfect Logic	Germicide	Solution	12
27342	Domestic	Lonza Inc.	Barquat MB 40 Swimming Pool Algaecide	Solution	40
27464	Domestic	Les Piscine Trevi Inc.	Trevi Liquid Algaecide 40	Solution	40
27593	Domestic	Purity	Purity Algyzine	Solution	10
27594	Domestic	Purity	Purity Algyzine Plus	Solution	40
27695	Domestic	Arch Chemicals, Inc.	HTH 15% Algaecide	Solution	15
27696	Domestic	Arch Chemicals, Inc.	Pace 15% Algaecide	Solution	15
27720	Domestic	Lawrason's, Inc.	Pool Pure Algaecide 5	Solution	5
27746	Commercial	Servicemaster of Canada Ltd.	Servicemaster Sanimaster Carpet Sanitizer	Solution	0.80
27766	Domestic	Sani-Marc Inc. D.B.A. Perfect Logic	Step 3	Solution	40
28083	Domestic	Sani-Marc Inc. D.B.A. Calypso	Control 5	Solution	5
28130	Domestic	Recreational Water Products Inc.	Pro Care Algaecide 40%	Solution	40
28425	Commercial	Ecolab Co.	82 Carpet Sanitizer	Solution	0.80
28484	Commercial	Microban Systems Inc.	Microban Clean Carpet Sanitizer Plus	Solution	0.80

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee (total ADBAC) (%)
28496	Commercial	CIBA Specialty Chemicals Corporation	Irgacide PT 941	Solution	7.5
28630	Commercial	Dow Chemical Canada Inc.	Glutex GQ1 Sanitizer	Solution	2.5
28718	Domestic	Reckitt Benckiser Canada Inc.	Dell Tech Laboratories Ltd.	Solution	0.008
28749	Domestic	Aqua Chem Algaecide Concentrate 15	Recreational Water Products Inc.	Solution	15
28810	Domestic	Purity	Pure Protect 5	Solution	5
28831	Domestic	Aqua Chem Algaecide Concentrate 20	Recreational Water Products Inc.	Solution	20
22064	Manufacturing concentrate	Mason Chemical Company	Maquat MQ 2525-50%	Solution	25
22072	Technical	Mason Chemical Company	Maquat MQ 2525-80%	Solution	40
12286	Domestic	Mursatt Chemicals Limited	Algon Liquid Algaecide	Solution	10
15248	Commercial	JohnsonDiversey Canada Inc.	Concentrated Neutral Quaternary Sanitizer	Solution	9
16182	Commercial	NCH Canada Inc.	Flash Pressurized Spray Liquid Foaming Cleaner and Sanitizer	Pressurized product	0.3
16368	Commercial	NCH Canada Inc.	Now Pressurized-spray Liquid Foaming Cleaner and Sanitizer	Pressurized product	0.3
17825	Manufacturing concentrate	Bullen Chemical Co.	Actiquat Concentrated Germicide Liquid	Solution	40
18562	Commercial	JohnsonDiversey Canada Inc.	F-501 Liquid Bacteriostatic Fabric Softener	Solution	6.6
19461	Domestic	Stepan Canada Inc.	5% BTC 2125M Swimming Pool Algaecide	Solution	5
19462	Domestic	Stepan Canada Inc.	10% BTC 2125M Swimming Pool Algaecide	Solution	10

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee (total ADBAC) (%)
21337	Technical	Stepan Company	Stepan BTC 2125M Concentrated Germicide	Solution	50
21407	Technical	Stepan Company	Stepan BTC 2125M - 80% Concentrated Germicide	Solution	80
21901	Technical	Lonza Inc.	Barquat 4280-Z	Solution	80
21904	Manufacturing concentrate	Lonza Inc.	Barquat 4250-Z	Solution	50
22062	Technical	Mason Chemical Company	Maquat MQ2525M - 80%	Solution	80
22070	Manufacturing concentrate	Mason Chemical Company	Maquat MQ2525M - 50%	Solution	50
22333	Commercial	Nalco Canada Company	Nalco Viscide EC 6224	Solution	10
23100	Manufacturing concentrate	Stepan Company	SO/SAN 30M Concentrated Germicide	Solution	26
23157	Domestic	R.P.S. Products Inc.	Original BT Humidifier Bacteriostatic Treatment	Solution	2.25
23157.01	Domestic	Bemis Manufacturing Co.	Bemis Waterwick Humidifier Bacteria Treatment	Solution	2.25
23157.02	Domestic	Essick Air Products Inc.	Bemis by Essick Air Humidifier Bacteria Treatment	Solution	2.25
24761	Domestic	Mursatt Chemicals Limited	40-Winks Winterizing Algaecide	Solution	40
24992	Commercial	CDC Products Corporation	CDC Anti-Clog #1 Units	Solid	40
25018	Commercial	Biochem Environmental Solutions Inc.	Bioguard Solution	Solution	1.6
26058	Manufacturing concentrate	Stepan Company	Stepan BTC 2125M P40 Concentrated Germicide	Soluble granules	40
26363	Commercial	Innovative Chemical Technologies Canada Limited	Econo-Cide B1003	Solution	10

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee (total ADBAC) (%)
26661	Domestic	Les Piscines Trevi Inc.	Trevi Permacide 10% Swimming Pool Algaecide	Solution	10
28319	Domestic	Arch Chemicals Inc.	HTH Algae Stop	Solution	30
28320	Domestic	Arch Chemicals Inc.	HTH Super Algae Stop	Solution	60
28423	Domestic	Essick Air Products Inc.	Bemis by Essick Air Humidifier Bacteriostatic Treatment	Solution	2.25
28868	Domestic	Recochem Inc.	Pool Algaecide	Solution	5
21338	Technical	Stepan Company	BTC 824 Concentrated Germicide	Solution	50
21817	Technical	Stepan Company	BTC 8248 Concentrated Germicide	Solution	80
21894	Technical	Mason Chemical Company	Maquat MC1416- 80%	Solution	80
21898	Manufacturing concentrate	Mason Chemical Company	Maquat MC 1416-50%	Solution	50
27130	Commercial	Chemical Specilaties Inc.	ACQ 2102 Wood Preservative Concentrate	Solution	4.6
27131	Commercial	Timber Specilaties Co.	NW 100 Wood Preservative Concentrate	Solution	4.6
22183	Technical	Mason Chemical Company	Maquat LC12S-50%	Solution	50
25425	Technical	Stepan Company	BTC 65 Concentrated Germicide	Solution	50
27952	Technical	Lonza Inc.	Barquat 50-65B	Solution	50
27953	Technical	Lonza Inc.	Barquat 50-65A	Solution	50
17011	Technical	Lonza Inc.	Lonza Hyamine 1622 Crystals	Dust or powder	98.8
24053	Commercial	Grover Musical Products Inc.	Sterisol Germicide Concentrate	Solution	0.94
12880	Commercial	Sanitized Inc.	Sanitized Brand Bacteriostat RB-475 Liquid	Solution	25

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee (total ADBAC) (%)
13534	Commercial	Sanitized Inc.	Sanitized Brand Bacteriostat SQ-50 Liquid	Solution	50
13537	Commercial	Sanitized Inc.	Sanitized Brand Bacteriostat RJX Liquid	Solution	20
22190	Technical	Mason Chemical Company	Maquat LC12S-80%	Solution	80
25420	Technical	Lonza Inc.	Barquat 80-24	Solution	80
17951	Commercial	Nalco Canada company	Nalcon 7648	Solution	32
25821	Domestic	Arch Chemical, Inc.	Baqua Check 50 Swimming Pool Algicide	Solution	50
23445	Manufacturing concentrate	Mason Chemical Company	Maquat 75 A Concentrated Liquid	Solution	50
22179	Technical	Mason Chemical Company	Maquat TC76-50%	Solution	50
25291	Technical	Stepan Company	BTC 776 Concentrated Germicide	Solution	50
25426	Technical	Lonza Inc.	Barquat 1552 - 50	Solution	50
24513	Technical	Lonza Inc.	Barquat MM-55I	Solution	55

Appendix II Label Amendments for Products Containing ADBAC

The label amendments presented below 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 of currently registered products should not be removed unless it contradicts the label statements below.

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

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

For commercial class products:

• The following statements must be added to the **PRECAUTIONS** section of all product labels:

Wear chemical-resistant gloves, long pants, a long-sleeved shirt and shoes when handling this concentrate.

• The following statements must be added to the **DIRECTIONS FOR USE** section for all products used in swimming pools:

DO NOT apply when swimmers are in the immediate vicinity (a 15-minute restricted-entry interval is recommended.)

• The following statements must be added to the **ENVIRONMENTAL HAZARDS** section for products with uses that could lead to discharges into water bodies (except for swimming pools):

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. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. The requirements of applicable laws should be determined before using the product.

• Labels for products used in pulp and paper processes, small process water systems, oncethrough cooling water tower treatment or textile/leather treatment must indicate the following in the **DIRECTIONS FOR USE** section:

If the product is applied manually, a dust mist respirator must be worn during application.

- Registrants of products used in a pulp and paper process should ensure that the maximum application rate does not exceed 7.0 kg a.i./tonne of paper.
- For products used in once-through cooling water tower treatment, the following statements must be included in the **DIRECTIONS FOR USE** section:

Deactivation must be conducted prior to discharge from the system by using bentonite clay at a minimum of 7.5 ppm of clay to 1 ppm of product. DO NOT apply this product more than four (4) times per year. The duration of treatment must not exceed 24 hours per application.

• For product labels involving a pulp and paper treatment process with finished products that may have direct or indirect food contact, the statement "DO NOT use to treat paper or paperboard which will contact food" must be included in the **DIRECTIONS FOR USE** section if there is no Food Directorate of Health Canada clearance for "food contact" uses.

For domestic class products:

• For all products, the following label statement must be included in the **PRECAUTIONS** section:

Wear rubber gloves when handling this concentrate.

• For products used in swimming pools, the following label statement must be included in the **DIRECTIONS FOR USE** section:

DO NOT apply when swimmers are in the immediate vicinity (a 15-minute restricted-entry interval is recommended).