RVD2009-04

Re-evaluation Decision

Alkyl Dimethyl Benzyl Ammonium Chloride Cluster (ADBAC)

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Overview

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 *Pest Control Products Act* and Regulations, is granting 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 revised 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 required at this time.

The regulatory approach for the re-evaluation of the ADBAC cluster was first presented in Proposed Re-evaluation Decision document PRVD2008-23, *Alkyl Dimethyl Benzyl Ammonium Chloride Cluster (ADBAC)*, a consultation document.[1] This Re-evaluation Decision document[2] describes this stage of PMRA's regulatory process for the re-evaluation of the ADBAC cluster as well as summarizes the Agency's decision and the reasons for it. Appendix I summarizes the comments received during the consultation process and provides the PMRA's response to these comments. The results did not substantially change the assessment in PRVD2008-23; however, they did result in some revisions to the required label statements. To comply with this decision, registrants of products containing the ADBAC cluster will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

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

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

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

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

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

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

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of ADBAC. In this decision, the PMRA took into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy).

The USEPA re-evaluated ADBAC and published its conclusions in a 2006 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2008-23, *Alkyl Dimethyl Benzyl Ammonium Chloride Cluster (ADBAC).*

What Is ADBAC?

ADBAC is a broad spectrum biocide. It is registered in Canada under the authority of the *Pest Control Products Act* to control 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 decision.

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

The labels of registered pesticide products include specific instructions for use. The 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 and instructions regarding the maximum use rate in a 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

Environment

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

Appendix II lists all required label amendments.

Other Information

Any person may file a notice of objection[3] regarding this decision on ADBAC within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1.0 Comment on the Vapour Pressure Value

The vapour pressure value of ADBAC reported in the Proposed Re-evaluation Decision was inconsistent with what was indicated in the RED.

Response

While the value reported in the RED may represent the vapour pressure of pure ADBAC, the value provided in the Proposed Re-evaluation Decision was for the technical grade active ingredient that contains the model compound used in the assessment of the ADBAC cluster. The value was obtained from the information provided by the registrant of the product.

Given Section 2.2 of the Proposed Re-evaluation Decision is dedicated to the physical and chemical properties of the technical grade active ingredient, the vapour pressure value reported is considered adequate and the original text remains.

2.0 Comment on the Requirement for Use of a Respirator for Manual Applications in Once-Through Cooling Water Tower Systems

By extrapolating the short-term inhalation exposure assessment from a similar use described in the RED, an acceptable margin of exposure (MOE) could be reached and the requirement for a respirator is unnecessary.

Response

In the RED, the assessment of risk associated with the once-through cooling water use was based solely on the metered pump application method. Typically, in Canada, antimicrobials used in once-through cooling water systems can be either poured or pumped into the system. The PMRA agrees with the registrant's proposed approach to extrapolate the swimming pool scenario to assess the once-through cooling water tower scenario and agrees to remove the requirement for a respirator.

3.0 Comment on the Relevance of the RED Occupational Exposure and Risk Assessment to the Canadian Situation for Small Process Water Systems

The Proposed Re-evaluation Decision stated that "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." The USEPA in its RED assumes handling 10 gallons of an 80% ADBAC solution for its assessment.

Response

The USEPA assessed the risks associated with the use of ADBAC in small process water uses for two application methods: liquid pour and metering pump. For the liquid pour scenario, the USEPA assumed that 6.67 lb a.i./gal product (i.e. 80%) was used to treat 10 gallons (38 L) of water per day. However, for the metering pump scenario, an initial dose of 3.34×10^{-4} lb a.i./gal water per day was assumed (see Table 8.1 of the RED). This dose is equivalent to 40 ppm.

The original text of the Proposed Re-evaluation Decision remains because it refers to the metering pump scenario given by the USEPA.

4.0 Comment on the Risk Assessment of Textile Uses of ADBAC

Per the notation regarding the approach to the small water process systems, the nature of this assessment was overly conservative.

Response

In the absence of data supporting a refined assessment of risks associated with the textile use of ADBAC, the PMRA will retain the requirement for the mitigation measures listed in the Proposed Re-evaluation Decision.

5.0 Comment on the Residential Humidifier Use of ADBAC

Data in support of a refined assessment of ADBAC use in residential humidifiers were provided by the registrant after the publication of the Proposed Re-evaluation Decision. These data were developed based on a study using a protocol approved by the USEPA. The registrant indicated that the results of the study should support the removal of the humidifier use restriction.

Response

The PMRA has reviewed the study that showed that ADBAC levels were non-detectable at the method detection limit. The study is deemed adequate; therefore, the use of ADBAC for treating water in residential humidifiers is considered acceptable for continued registration.

6.0 Comment on the Risk-Reduction Measures and Recommended Label Amendment Regarding ADBAC Use in Swimming Pools

The requirement for a 15-minute restricted-entry interval for swimmers after ADBAC application is inconsistent with the PMRA Regulatory Directive DIR93-06, *Model Labels for Pool and Spa Products Not Eligible for Schedule*. The registrant further pointed out that the requirement is also inconsistent with the current understanding of the hazardous properties of the active ingredients in the products.

Response

These statements are not directly related to risk mitigation; they are a requirement to promote good hygiene practices. The PMRA is currently revising the aforementioned document, and updated requirements will be implemented on relevant products once the amendment is completed.

The PMRA will maintain the original requirement.

7.0 Comment on product identification

A registrant has identified that the name of the product with Registration Number 28718 was incorrectly identified in Appendix I of the Proposed Re-evaluation Decision.

Response

The correct name of the product with Registration Number 28718 is Lysol Brand Daily Surface Sanitizer.

Appendix II Revised 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 the labels of currently registered products should not be removed unless it contradicts the label statements below.

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 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 must 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.

- On labels of products used in a pulp and paper treatment process that results in finished products that may have direct or indirect contact with food, the statement "DO NOT use to treat paper or paperboard that 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).

References

Studies/Information Submitted By Applicant/Registrant (Unpublished)

A. Information Considered for the Chemistry Risk Assessment

PMRA Reference Number	Reference
1422965	Technical Chemistry file - Analysis of Quarternary Benzyldimethylalkonium Salts by High Performance Liquid Chromatography, DACO: 2.99 CBI
1318657	2002, UV Visible Absorption, 410-98, DACO: 2.14.12 SPEC
1344056	2006, DACO: 0.1.6003 SPEC
1107286	DACO: 0.1.6003
1319142	2004, UV Visible Absorption, 410-183, DACO: 2.14.12
1102529	Description of Starting Materials, DACO: 2.11.2 CBI
1418028	Material Safety Data Sheet with Percentage Breakdown, DACO: 2.11.2
1319139	Material Safety Data Sheet, DACO: 2.11.2
1102530	Standard Maufacturing Procedures, DACO: 2.11.3 CBI
1102501	Standard Maufacturing Procedures, DACO: 2.11.3 CBI
1491290	Information migrated from TGAI Chemistry paper files ("Brown" Files) QAC-RDA-1, DACO: 2.99, DACO 2.11
1517999	Technical Chemistry file QAC-SPN-1 BTC 8358, DACO: 2.99, DACO 2.11
1518000	1981, Technical Chemistry file QAC-SPN-1 BTC E 8358 Active 1253402 CHEMISTRY, DACO: 3 CBI, DACO 2.11
1102500	Description of Starting Materials, DACO: 2.11.2 CBI
1517999	Technical Chemistry file QAC-SPN-1 BTC 8358, DACO: 2.99, DACO 2.12
1319140	2006, Batch analysis, DACO: 2.11.4, DACO 2.13.3
1318655	2006, MC1412-80E Analysis1, DACO: 2.11.4, DACO 2.13.3
1422970	Technical Chemistry file Maquats, DACO: 2.99 CBI

1319176 2004, UV Visible Absorption, 410-184, DACO: 2.14.12

1504893 Technical Chemistry file QAL-SPN-1 BTC 8248 QC Data, HPLC Analysis, Manufacturing Methods, Progress Report, DACO: 2.99, DACO 2.11, DACO 2.14.2; 2.14.7; 2.13.3

1504896 Technical Chemistry file QAL-SPN-1 BTC 824 - Chemistry and Research and Progress Reports., DACO: 2.99, DACO 2.14.6; 2.14.7; 2.13.3

1102481 Standard Maufacturing Procedures, DACO: 2.11.3 CBI

1319174 2006, Case Consulting Laboratories, Inc., Certificate of Analysis, DACO: 2.11.4; 2.13.3

1349005 Technical Chemistry QAO-MSN-2 Detailed Specifications for Maquats, Methods of Testing - for Maquats, Calculations, DACO: 2.1,2.10,2.11,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI, DACO 2.13.3

1348995 2002, Physical and Chemical Characteristics of Maquat LC12S-50%: UV/Visible Absorption, DACO: 2.14.12

1528585 CBI Cross-Reference Number 4, DACO: 2.11.3

1528583 2002, Manufacturing Summary, DACO: 2.11.1

1528584 Beginning Material Specifications, DACO: 2.11.2

1563077 Correspondence QAO-SPN-1 , DACO: 0.8, DACO 2.13.3

1519108 2002, Technical Chemistry file QAO-LOZ-3 Barquat 50-65B – Preliminary Analysis, SP-02055-A, DACO: 2.13.3

1464341 2002, Technical Chemistry file - Barquat 50-65A, DACO: 2.1,2.10,2.11, 2.12,2.13,2.14,2.15,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9

1340092 Technical Chemistry file QAP-SAH-1 Hyamine 1622 Analytical Methods, Quality Control, Residual Amines in Hyamines, DACO: 2.99, DACO 2.14; DACO 2.11

1565100 1999, Technical Chemistry file QAP-JUN-2. Description of Starting Materials. Product Identity and Composition- Hyamine 1622 Crystals SP99002., DACO: 2.11.2

1565107 1999, Technical Chemistry file QAP-JUN-2. Production Process Description- Description of the Production Process SP-99002 Hyamine 1622., DACO: 2.11.3

1565121 1999, Technical Chemistry file QAP-JUN-2. Batch Data – Chemical Analysis of Hyamine 1622., DACO: 2.13.3

1410337 Maquat LC12S - 80%: Physical and Chemical Properties, DACO: 2.12.2,2.14 CBI

1318845 2004, UV Visible Absorption, 410-184, DACO: 2.14.12

1406296 2006, Correct Manufacturing Summary, DACO: 2.11.3 CBI

1318843 2006, DACO: 2.11.4

B. Information Considered for the Occupational Risk Assessment

PMRA Reference Number	Reference
1625037	2007, Determination of ADBAC Air Concentrations Used in Household Humidifiers, 2007-CT-ADBAC-HUM, DACO: 8.2.4.5