RVD2009-07

Re-evaluation Decision

Didecyl Dimethyl Ammonium Chloride Cluster (DDAC)

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Overview

Re-evaluation Decision

After a re-evaluation of the didecyl dimethyl ammonium chloride (DDAC) cluster, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration for the sale and use of products containing DDAC in Canada.

An evaluation of available scientific information found that products containing DDAC do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of DDAC uses, new risk-reduction measures must be included on the labels of all products.

For DDAC end-use products that contain other active ingredient(s) under re-evaluation, the review(s) for these active ingredient(s) will be included in separate document(s). Note that the antisapstain uses of DDAC are being reviewed together with all antisapstain active ingredients under a separate initiative within the PMRA and are not part of this re-evaluation decision.

The regulatory approach for the re-evaluation of DDAC was first presented in Proposed Re-evaluation Decision PRVD2008-27, *Didecyl Dimethyl Ammonium Chloride Cluster (DDAC)*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of DDAC 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. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-27. To comply with this decision, registrants of products containing DDAC 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 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.

[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*.

The DDAC 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 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.

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 DDAC. 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 DDAC 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 PRVD2008-27, *Didecyl Dimethyl Ammonium Chloride Cluster (DDAC).*

What Is DDAC?

DDAC is a biocide registered in Canada under the authority of the *Pest Control Products Act* for the control of algae, bacteria, fungi or molluscs in the following use sites: indoor hard surfaces (e.g. floors, walls, countertops), other indoor surfaces (e.g. carpet, laundry), industrial process fluids (e.g. open cooling water tower systems, oil field water flood or salt water disposal systems, recirculating water cooling towers) and wood. Wood uses of DDAC are not included in this re-evaluation.

Health Considerations

Can Approved Uses of DDAC Affect Human Health?

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

People could be exposed to DDAC by 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 human population (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 DDAC 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 DDAC Is Introduced Into the Environment?

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

Certain aquatic organisms could be exposed to DDAC 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 DDAC 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 DDAC, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect handlers

Environment

- Additional advisory label statements

Other Information

Any person may file a notice of objection[3] regarding this decision on DDAC 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 Health Canada website, Request a Reconsideration of Decision, or contact the PMRA's Pest Management Information Service.

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

Appendix I Comments and Responses

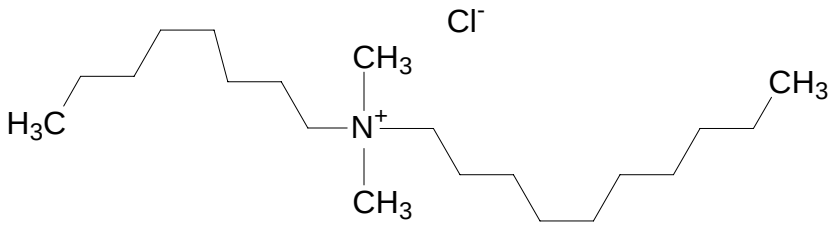
1.0 Chemical Abstracts Service numbers and structural formula for octyl decyl dimethyl ammonium chloride and dioctyl dimethyl ammonium chloride being listed as Not Available

Comment: The USEPA RED has information regarding the Chemical Abstracts Service (CAS) numbers and structural formula for the above-noted chemicals; however, this is not reflected in the PMRA document.

Response: The PMRA acknowledges the following information:

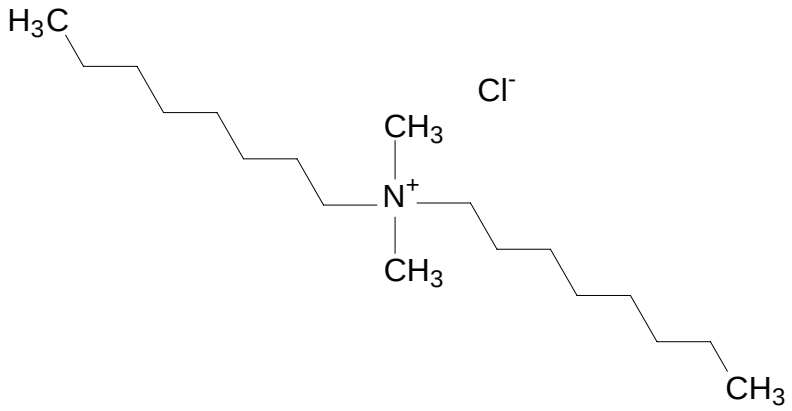
Octyl decyl dimethyl ammonium chloride

CAS number: 32426-11-2
Structural formula:



Dioctyl dimethyl ammonium chloride

CAS number: 5538-94-3
Structural formula:



2.0 Statement in Section 3.2.2 Toxic Substances Management Policy Considerations: "However, impurities of human health or environmental concern cannot be assessed at this time for the co-formulated technical grade active ingredients containing dioctyl dimethyl ammonium chloride and octyl decyl dimethyl ammonium chloride. A detailed manufacturing process for each active is required for this assessment."

Comment: Is the reference intended to address individually these two actives only?

Response: The reference is intended to address individually dioctyl dimethyl ammonium chloride and octyl decyl dimethyl ammonium chloride only.

3.0 Requirement of goggles or a face shield, chemical-resistant gloves, long pants, a long-sleeved shirt and shoes plus socks for all Commercial class end-use products, when handling concentrates

Comment: One comment was concerned with the necessity of requiring the above described personal protective equipment (PPE) for all end-use products, including the one Domestic Class product.

Response: The Agency would like to clarify that the above proposed PPE does not include the Domestic Class product. The requirement is for Commercial Class products only, as indicated in Appendix III of the PRVD2008-27.

Under the re-evaluation program, PPE recommendations are based on the acute toxicity of the active ingredient and not individual formulations.

4.0 Stability of DDAC in aquatic systems

Comment: The validity of the conclusion that DDAC is stable to microbial degradation in aquatic systems was questioned. The registrant cited the following from the Environmental Fate Assessment Chapter of the RED: "However, a report on the biodegradability of DDAC prepared by the Registrant concluded that the degree of DDAC biodegradability is variable and is influenced by the chemical concentration, alkyl chain length, the presence of anionic moieties and the quantity and characteristics of the microbial population. According to this report, DDAC is biodegradable and environmentally acceptable. This report was based on information from the open literature, unpublished sources, and meeting proceedings and has not been reviewed by the Agency."

Response: Although the cited statement appeared in the Environmental Fate Assessment Chapter of the RED, the information was not reviewed by the USEPA. On this basis, the PMRA considers it inappropriate to reference the information.

5.0 Comment on product identification

A registrant has identified that the name of the product with the Registration Number 25665 was incorrectly identified in Appendix I of the PRVD2008-27.

Response

The correct name of the product with Registration Number 25665 is Boracol 10-2 BD Preventive and Remedial Wood Preservative.