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Proposed Re-evaluation Decision

PRVD2010-09

3-Trimethoxysilyl Propyldimethyl Octadecyl Ammonium Chloride

(publié aussi en français)

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the antimicrobial 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration for the sale and use of products containing this active ingredient in Canada.

An evaluation of available scientific information found that products containing 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride 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 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride 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 this active ingredient registered in Canada. Once the final re-evaluation decision is made, the registrants 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 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride 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 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride.

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 indicated 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 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*.

The active ingredient, 3-(Trimethoxysilyl) propyldimethyl octadecyl ammonium chloride, 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:

- 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 the 2007 Reregistration Eligibility Decision document, the USEPA concluded that 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride 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 section of this consultation document.

What Is 3-(Trimethoxysilyl) Propyldimethyl Octadecyl Ammonium Chloride?

The active ingredient, 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride, is an antimicrobial active ingredient that is used as a material preservative. It is used in or on textiles, towlettes, tissue wipes, fibers, roofing materials, filters, filter materials, foam, fibreglass, plastic products, rubber products, fan/humidifier belts, and hard indoor surfaces. This chemical is handled by professional workers and is added during the manufacturing process of treated articles. In addition, this active ingredient may be applied in buildings to control microbial growth on surfaces.

Health Considerations

Can Approved Uses of this Active Ingredient Affect Human Health?

The active ingredient, 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride, is unlikely to affect your health when used according to the revised label directions.

People could potentially be exposed to this active ingredient when applying this active ingredient, through postapplication exposure when re-entering treated sites and handling treated articles or through residential exposure (i.e., coming into contact with treated articles). 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 (for example, 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 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride 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 by the PMRA.

Environmental Considerations

What Happens When 3-(Trimethoxysilyl) Propyldimethyl Octadecyl Ammonium Chloride Is Introduced Into the Environment?

The active, 3-(Trimethoxysilyl) propyldimethyl octadecyl ammonium chloride is unlikely to affect non-target organisms when used according to the revised label directions.

The USEPA concluded that indoor uses of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride would result in minimal environmental exposure, and were unlikely to affect non-target organisms. These conclusions apply to the Canadian situation.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride, the PMRA proposes further risk-reduction measures for product labels.

Human Health

- Additional personal protective equipment to protect workers
- Limit use of this active ingredient to materials and products that do not come into direct contact with food or feed
- Additional warning signals, advisory and basic hygiene statements on end-use product labels

Environment

- Update label statements to further protect the environment from effluent discharge

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

Next Steps

Before making a final re-evaluation decision, 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 document that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the Pest Management Regulatory Agency's response to these comments.

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

Science Evaluation

1.0 Introduction

The active ingredient, 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride, is currently registered in Canada as a material preservative. This active ingredient acts as an antimicrobial added to various industrial processes to control microbial growth. It is also used in buildings to control microbial growth on surfaces.

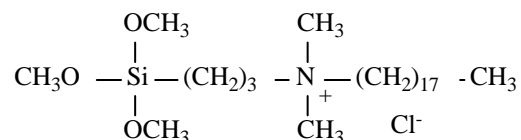
Following the re-evaluation announcement for 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the labels of commercial class end-use products in Canada.

The Pest Management Regulatory Agency (PMRA) used recent assessments of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for Trimethoxysilyl Quaternary Ammonium Chloride compounds, dated 25 September 2007, as well as other information on the regulatory status of this active ingredient 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 Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name	3-(Trimethoxysilyl)-propyldimethyloctadecyl ammonium chloride
Function	Antimicrobial active ingredient
Chemical family	Quaternary ammonium chloride salt
Chemical name	
1 International Union of Pure and Applied Chemistry	3-(Trimethoxysilyl)-propyldimethyloctadecyl ammonium chloride
2 Chemical Abstracts Service	3-(Trimethoxysilyl)-propyldimethyloctadecyl ammonium chloride
Chemical Abstracts Service Registry Number	27668-52-6
Molecular formula	C ₂₆ H ₅₈ ClNO ₃ Si

Structural formula**Molecular weight**

496.28 atomic mass units

Purity of the technical grade active ingredient

72.1 % nominal

Registration Number

23388

Based on the manufacturing process used, contaminants of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), Section 2.13.4 of DIR98-04 and Appendix II of DIR99-03 (Toxic Substances Management Policy Track 1 substances) are not expected to be present in this product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result	Interpretation
Vapour pressure	5.8×10^{-14} mmHg	Low volatility
UV-visible spectrum	No UV absorbing chromophore	Phototransformation is unlikely
Solubility in water	miscible	Highly soluble in water
<i>n</i>-Octanol-water partition coefficient	$\text{Log } K_{ow} < 3$	Bioaccumulation unlikely

2.3 Comparison of Use Patterns in Canada and the United States

The chemical, 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride, is an antimicrobial active ingredient that is used as a material preservative. It is used on textiles, towlettes, tissue wipes, fibres, roofing materials, filters, filter materials, foam, fibreglass, plastic products, rubber products, fan/humidifier belts, and hard indoor surfaces. Commercial class end use products are formulated as a solution and a suspension. They are applied during the manufacturing process of treated materials by brushing on, dipping, padding, soaking, spraying, fogging or by using foam finishing techniques. In addition, it may be applied in buildings by spraying or brushing the product onto surfaces.

The American and Canadian use patterns were compared. The Canadian formulation types of the end-use products and the uses of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride as a material preservative are among those registered in the United States. Based on this comparison of use patterns, it was concluded that the USEPA RED for 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride is an adequate basis for the re-evaluation of uses of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride in Canada.

All current uses are being supported by the registrant and were, therefore, considered in the re-evaluation of this active ingredient. Appendix I lists all 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride products that are registered as of 3 January, 2010, under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 2007 RED, the USEPA concluded that the end-use products formulated with 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride met the safety standard under the American *Federal Insecticide, Fungicide and Rodenticide 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 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride may occur during the application of the pesticide product, through postapplication exposure when re-entering treated sites and handling treated articles or through residential exposure (i.e. coming into contact with treated articles, such as apparel, fibreglass, polyurethane foam, etc.). Formulations containing 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride also contain methanol. Workers may be exposed to methanol when handling the pesticide product or through postapplication exposure (i.e., re-entering treated sites or handling treated articles before the product has dried).

When assessing health risk, 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 human population (for example, children and nursing mothers).

Upon reviewing the available toxicity data, the USEPA concluded that there are no relevant endpoints of toxicological concern for single or repeated oral or dermal exposure to 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride. This conclusion is based on the absence of systemic toxicity observed in subchronic and developmental studies conducted with this chemical.

3.1.1 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies. In Canada, workers can be exposed to 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride and methanol when handling the pesticide product or through postapplication exposure when handling treated products and when re-entering a treated site.

3.1.1.1 Handler Exposure and Risk

The USEPA conducted a qualitative handler occupational exposure risk assessment and concluded that although the potential for exposure to 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride exists, no relevant endpoints of toxicological concern were identified.

The RED adequately addressed the potential risk associated with the uses of products containing 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride in Canada, and some of the conclusions apply to the Canadian situation. Due to the potential for severe eye and skin irritation of this active ingredient and the presence of methanol in end-use products, the PMRA requires additional advisory label statements to further protect workers, including:

- additional personal protective equipment (nitrile, neoprene, butyl or latex rubber gloves);
- update of warning signals on current labels; and
- additional basic hygiene statements.

The proposed label amendments for products containing 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride can be found in Appendix II.

3.1.1.2 Postapplication Exposure and Risk

Postapplication occupational exposure is most likely to occur when handling treated product and re-entering treated sites. No endpoint of toxicological concern was identified by the USEPA for 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride. Based on these conclusions, no risk reduction measures are required.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

In the 2007 RED, it was concluded that there is potential for residential exposure to 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride. However, no endpoint of toxicological concern was identified and, therefore, residential exposure is not of concern.

The conclusions derived from the RED are considered relevant to the Canadian situation, and no risk reduction measures are required.

3.1.2.2 Exposure from Food and Drinking Water

There are no food or feed uses currently registered for 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride in Canada. This chemical has not been granted a “No Objection Letter” from Health Canada and, therefore, it is not permitted for use in packaging materials intended for food contact (e.g., plastics). This active ingredient is a permitted incidental additive for use in food processing plants on ceramic tiles for walls, provided that there is no direct contact of these surfaces with food or feed.

The USEPA concluded that this chemical would not likely result in contamination of surface and ground water, when used as directed. Therefore, exposure through the consumption of drinking water is not expected.

The RED adequately addressed dietary exposure scenarios associated with the use of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride. The conclusions derived from the RED are relevant to the Canadian situation. On this basis, it is concluded that dietary exposures to this chemical are not of concern. Based on the absence of registered food and feed uses in Canada, an additional advisory label statement prohibiting use of this active ingredient in or on surfaces or manufactured goods intended for direct contact with food or feed is required on all end-use products. Appendix II lists all of the proposed label amendments for 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride.

3.1.2.3 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure (i.e., from food, drinking water and residential exposures). Based on the use pattern, aggregate exposure is not expected.

3.1.3 Cumulative Effects

The USEPA has not determined whether 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride 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 it 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

The USEPA concluded that adverse effects to non-target organisms are not anticipated from the indoor use of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride due to the low likelihood of exposure. This active ingredient is practically non-toxic to birds and mammals, moderately toxic to fish and highly toxic to freshwater aquatic invertebrates. The USEPA also concluded that this active ingredient would undergo rapid hydrolysis and, based on the use pattern, is not expected to impact surface or ground water.

The RED adequately addressed risk to non-target organisms, and the conclusions derived from the RED apply to the Canadian situation. Based on the PMRA general practices, advisory label statements are required to further protect the environment. Appendix II lists all of the proposed label amendments for 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride.

3.3 Pest Control Product Policy Considerations

3.3.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The Toxic Substances Management Policy calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy, i.e., toxic or equivalent, predominantly anthropogenic, persistent and bio-accumulative as defined by the *Canadian Environmental Protection Act*).

During the re-evaluation process, 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, and evaluated against the Track 1 criteria for persistence and bioaccumulation. In order for 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride or its transformation products to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one media) must be met.

The active ingredient, 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride, was observed to have a half-life of less than 15 minutes in water, which is below the TSMP Track 1 cut-off criterion of 182 days. Further, volatilisation is not an important route of dissipation and, long-range transport is unlikely based on vapour pressure (5.8×10^{-14} mm Hg). On this basis, it is concluded that the use of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride is not expected to result in the entry of Track 1 substances into the environment.

3.3.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride, contaminants in the technical grade active ingredient are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

- Technical grade 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*.

4.0 Incident Reports

As of 26 April 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA. There were no incident reports submitted for 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride as of 3 January 2010.

5.0 Organisation for Economic Co-operation and Development Status of this Active Ingredient

Canada is part of the Organisation for Economic Co-operation and Development, which groups 30 member countries and provides governments with a setting in which to develop economic and social policies to allow for consistency in practices across nations.

Currently available information indicates that 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride is to undergo re-evaluation in the European Union, where it is currently permitted for use as a material preservative.

The United States, assessed the registration of all uses of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride in 2007. The conclusions of the RED are the basis on which this re-evaluation was conducted and are summarized in this document.

6.0 Proposed Re-evaluation Decision

The PMRA has determined that 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride 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 product must be amended to include the label 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.

7.0 Supporting Documentation

Pest Management Regulatory Agency documents, such as Regulatory Directive DIR2001-03, can be found on the Pesticides and Pest Management portion of Health Canada's website at www.healthcanada.gc.ca/pmra. Pest Management Regulatory Agency 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: pmra.infoserv@hc-sc.gc.ca.

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

The USEPA Reregistration Eligibility Decision document for Trimethoxysilyl Quaternary Ammonium Chloride Compounds is available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

List of Abbreviations

K_{ow}	<i>n</i> -octanol–water partition coefficient
mm Hg	millimetre mercury
PMRA	Pest Management Regulatory Agency
RED	Reregistration Eligibility Decision
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Registered Products Containing 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride as of 3 January 2010

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (per cent)
23388	Technical	Aegis Environmental Management INC	AEM 5772-TA Antimicrobial Agent	Suspension	72.1
15133	Commercial	Aegis Environmental Management INC	AEM 5700 Antimicrobial	Solution	42.0
28541	Commercial	Aegis Environmental Management INC	AEM 5772-EP Antimicrobial	Suspension	72.1

Appendix II Label Amendments for Products Containing 3-(Trimethoxysilyl) Propyldimethyl Octadecyl Ammonium Chloride

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 above label statements.

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 to further protect human health and the environment.

- I) The following must be included in the section **DIRECTIONS FOR USE**.

DO NOT use this product on manufactured products intended for food/feed contact surfaces.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

- II) The following must be included in the section **PRECAUTIONS**.

DANGER CORROSIVE. Causes irreversible eye damage and skin burns.

May be fatal if inhaled

May be harmful or fatal if swallowed or absorbed through the skin

Appropriate measures must be taken to prevent accumulation of hazardous concentrations of methanol vapours in the work area

COMBUSTIBLE. DO NOT use or store near heat or open flame

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Launder clothing separately from other clothing before reuse. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. DO NOT reuse them.

Users should remove personal protective equipment immediately after handling this product. Wash the outside of the gloves before removing. Remove clothing immediately if pesticide comes into contact with skin through soak clothing or spills. Wash skin thoroughly and put on clean clothes.

Avoid touching eyes and face until you have washed your hands.
Never use the mouth to siphon product from containers or to blow out clogged lines, nozzles, etc

Follow manufacturer's instructions for cleaning/maintaining personal protective equipment (PPE). If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

DO NOT apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

DO NOT get in eyes, on skin or on clothes

- III) In the section titled **PRECAUTIONS**, replace “chemical resistant gloves” with “nitrile, neoprene, butyl or latex gloves”
- IV) In the section **ENVIRONMENTAL HAZARDS**, replace “toxic to fish” with “toxic to aquatic organisms”.

References

Studies considered in the Chemistry Assessment

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

PMRA Document Number	Reference
1463625	2006, Chemical Physical Properties, DACO: 2.14.1, 2.14.2, 2.14.3, 2.14.6
1463626	2007, Chemical Physical Properties, DACO: 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.4, 2.14.7, 2.14.8, 2.14.9, 2.15
1545864	M. G. Hales, Dow Corning Corporation, Part 2 Product Chemistry (LSS 92228)