Proposed Re-evaluation Decision PRVD2016-24

Antisapstain and Joinery Uses of Didecyl Dimethyl Ammonium Chloride (DDAC)

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Background

This document forms part of a wider assessment of health and environmental risks of the active ingredients used in antisapstain and joinery wood treatments.

In 2004, Health Canada's Pest Management Regulatory Agency (PMRA) completed a re-evaluation of the occupational risks for the antisapstain uses of three antisapstain active ingredients: 2-(thiocyanomethylthio) benzothiazole (TCMTB), copper-8-quinolinolate (copper-8), and disodium octaborate tetrahydrate (boron). The occupational exposure and risk assessments were conducted for workers at lumber processing facilities such as sawmills. The re-evaluation decision (RRD2004-08) identified the need for additional data to refine the occupational risk assessments and required that a product stewardship program (with follow-up monitoring) be implemented for all registered antisapstain chemicals to reduce exposure to workers. In addition, RRD2004-08 indicated that an assessment of the environmental risks of antisapstain products would be communicated in separate documents.

In response to the 2004 decision, the registrants of antisapstain products, the Sapstain Industry Group, developed a product stewardship program, referred to as the Exposure Reduction Program (ERP). This program was approved by PMRA, implemented for all antisapstain products and follow-up occupational exposure field monitoring was conducted. The ERP included additional personal protective equipment and engineering controls, which have shown to be effective in reducing worker exposure.

There are currently five active ingredients registered as joinery wood preservatives. These active ingredients are: boron, didecyl dimethyl ammonium chloride (DDAC), iodocarb, propiconazole and tebuconazole. Considering that the occupational exposure scenarios for antisapstain and joinery uses are similar, and in the interest of efficiencies and consistency in decision making, occupational risk assessments were also conducted for all joinery products using the Sapstain Industry Group's follow-up field monitoring exposure data.

Altogether seven active ingredients registered as antisapstain and/or joinery wood preservatives required updated health and environmental risk assessments. These active ingredients are: TCMTB, copper-8, boron, DDAC, iodocarb, propiconazole, and tebuconazole. The occupational risk assessments for these seven antisapstain and joinery active ingredients have been updated using current use information, current toxicology endpoints and the follow-up field monitoring exposure data. The environmental risk assessments have been conducted using available data and information.

This document addresses the health and environmental risk assessments for the antisapstain and joinery uses of DDAC. The re-evaluation of the antisapstain and joinery uses of the remaining active ingredients listed above will be communicated in separate documents.

Overview

Proposed Re-evaluation Decision for Antisapstain and Joinery Uses of Didecyl Dimethyl Ammonium Chloride (DDAC)

The PMRA has completed the health and environmental risk assessments for the antisapstain and joinery uses of didecyl dimethyl ammonium chloride (DDAC). Under the authority of the *Pest Control Products Act*, the PMRA is proposing continued registration of the antisapstain and joinery uses of DDAC in Canada.

An evaluation of available scientific information found that the antisapstain and joinery uses of DDAC products are not expected to pose risks of concern to human health or the environment when used according to the proposed revised label directions. As a requirement for the continued registration of antisapstain and joinery products containing DDAC, new risk-reduction measures are proposed.

This proposal affects the joinery and antisapstain end-use products containing DDAC 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 document[1] that summarizes the science evaluation for DDAC 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 DDAC.

The PMRA will accept written comments on this proposal up to 90 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 key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[2] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use of, or exposure to, the product under its conditions or proposed conditions of registration. Conditions of registration may include special precautionary measures on the product label to further reduce risk. The Act also requires that products have value[3] when used according to the label directions.

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

2 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

3 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "… the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of potentially sensitive subpopulations in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management section of Health Canada's website.

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

What is DDAC?

DDAC is an antimicrobial with several types of applications. In addition to its uses as an antisapstain and for joinery, DDAC is also registered as a biocide for the control of algae, bacteria, fungi and molluscs in various use sites.

Antisapstain products are wood preservatives used to prevent the growth of staining fungi in freshly cut lumber. They are applied to freshly-cut wood by dipping or spraying to achieve short-term (months) protection against staining fungi.

Wood products that have been manufactured into items such as windows and doors are referred to as joinery or millwork. These items are often used in above-ground settings where they are subject to moderate decay conditions. For this reason, wooden windows and doors are typically protected with a joinery wood preservative to prevent the growth of decay fungi and increase the service life. Unlike antisapstain treatments, which are applied to lumber for short-term protection against aesthetic damage, joinery preservatives provide long-term decay protection to wood that does not require the degree of protection provided by heavy-duty wood preservation.

Health Considerations

Can Approved Uses of DDAC Affect Human Health?

Antisapstain and joinery products containing DDAC are unlikely to affect your health when used according to revised label directions.

Potential exposure to DDAC may occur through the dermal and inhalation route, when workers are handling and applying antisapstain and joinery products containing DDAC or by handling the treated wood. When assessing health risks, two key factors are considered: the levels at which no health effects occur in animal testing 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.

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it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide-containing products are used according to label directions.

In laboratory animals, DDAC was of high acute oral toxicity and low acute dermal toxicity. It was extremely irritating to the eye and to the skin, but did not cause an allergic skin reaction. A waiver request was accepted for the acute inhalation study based on the corrosive nature of the test substance.

Registrant-supplied short-, and long-term (lifetime) animal toxicity tests, as well as information from the published scientific literature were assessed for the potential of DDAC to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. DDAC did not elicit any specific target organ toxicity in short- or long-term studies. The major toxic effects of DDAC reflect its highly irritating properties and include decreases in weight and clinical signs of toxicity.

The risk assessment protects against these affects in workers by including additional risk reduction measures for antisapstain and joinery products.

Risks in Residential and Other Non-Occupational Environments

Non-occupational risks are not of concern.

There are currently no registered residential uses of DDAC antisapstain and joinery products. As such, a risk assessment for a residential handler was not required.

Occupational Risks to Mixer/Loader/Applicator and Postapplication Workers

Occupational risks are not of concern when used according to the revised label directions.

Health risks to handlers are not of concern for all scenarios. Based on the updated personal protective equipment (PPE) required as a result of the Exposure Reduction Program (ERP) for Antisapstain Chemicals (see Section 3.4.2 of the Science Evaluation), health risk estimates associated with mixing, loading, and applying and during handling of treated wood and joinery products are not of concern. Inhalation exposure was expected to be very low for the majority of workers and is mitigated by the use of a NIOSH-respirator for specific job tasks where there is potential for inhalation exposure, as described in the ERP. Current product labels that do not include all of the required elements of the PPE will be updated to conform to the ERP.

Postapplication risks are not of concern.

Postapplication exposure through contact with dried wood is not anticipated as antisapstains are designed to prevent the growth of staining fungi in freshly cut lumber during storage and transit and not for long-term wood protection in residential or commercial areas. Similarly, exposure to consumers from contact with treated wood is expected to be minimal.

Joinery wood is intended for use in millwork, window and door frames and other above ground non-structural decorative exterior wood such as soffits and fascia. Significant human exposure is not expected for this type of wood.

No health risks of concern were identified for workers handling freshly treated wood (wet or dry) in the sawmill. Since this type of exposure is expected to be greater than for workers or bystanders handling treated wood or joinery products after they have left the sawmill, postapplication risks are not of concern.

Environmental Considerations

What Happens When DDAC Is Introduced Into the Environment?

When used as an antisapstain according to the revised label statements, DDAC is not expected to pose risks of concern to the environment.

Antisapstains, such as DDAC, may enter the environment if newly treated wood is exposed to rain. DDAC may reach the aquatic environment if any rainwater containing the chemical is permitted to run-off from the treatment facility and its wood storage areas into nearby waterbodies. Very little exposure to land organisms and their habitats is expected.

DDAC is expected to break down slowly in water and soil. DDAC mixes readily in water and has a high potential to move out of water into aquatic sediments, where it is likely to persist. DDAC is immobile in soil and therefore has a low potential to move through the soil and reach groundwater. DDAC is not expected to be found in air and is not expected to accumulate in the tissues of organisms. DDAC is toxic to fish and aquatic invertebrates if they are exposed to high enough levels. A conservative risk assessment indicated a potential risk to aquatic organisms; however, considering the conservative nature of the assessment and the required mitigation, the risks are considered to be acceptable.

Treated wood joinery products are not subject to significant leaching. Any leaching of joinery preservative that does occur, should be limited to the area around the building in which they were installed. Therefore, due to limited environmental exposure, no quantitative environmental risk assessment was conducted for the joinery uses of DDAC. Furthermore, as most joinery active ingredients are also antisapstain active ingredients, the environmental risk assessment for the antisapstain use of DDAC would be expected to cover any environmental risks posed by joinery products.

Value Considerations

What is the Value of DDAC in Antisapstain Treatment?

DDAC is one of several active ingredients currently registered in Canada for use in antisapstain products. Antisapstain products are wood preservatives used to prevent the growth of staining fungi in freshly cut lumber. These pigmented fungi consume the readily available sugars and starches as they grow throughout the sapwood. While these sapstain fungi do not reduce the

strength of the wood, the aesthetic damage done can result in significant economic losses in terms of the lumber being unmarketable or reduced in value.

What is the Value of DDAC in Joinery Treatment?

DDAC is one of five active ingredients currently registered in Canada for use in joinery products. Joinery products are wood preservatives used to treat products that have been machined or milled, such as window frames or doors. While these window frames and doors tend to be sheltered from excessive rains, they are still susceptible to fungal decay. Treatment with joinery products containing DDAC inhibits the growth of decay fungi and extends the service life of wooden joinery components.

Proposed 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. Following these directions is required by law. As a result of the re-evaluation of the antisapstain and joinery uses of DDAC, the PMRA is proposing further risk-reduction measures in addition to those already identified on DDAC product labels.

Additional Key Risk Reduction Measures

Human Health

- To protect workers, additional general hygiene statements and personal protective equipment are required on all DDAC antisapstain and joinery product labels conforming to the ERP.

Environment

- In order to minimize the amount of DDAC entering aquatic environments, wood treatment facilities for antisapstain products are to be equipped with drip pads (where wood is allowed to sit for a short drying period immediately after treatment) that are roofed and paved.
- Precautionary label statements are required to identify environmental hazards and prevent runoff from treatment facilities to waterbodies.

Next Steps

Before making a final re-evaluation decision on the antisapstain and joinery uses of DDAC, the PMRA will consider any comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on DDAC. The PMRA will then publish a Re-evaluation Decision[4] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA response to these comments.

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

Science Evaluation

1.0 Introduction

DDAC is registered in Canada for use as a molluscicide, sanitizer, slimicide in recirculating cooling towers and for antisapstain and joinery uses.

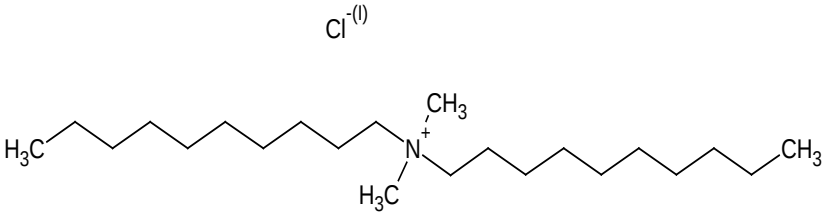
2.0 The Technical Grade Active Ingredient, Its Properties and Uses

A review of the chemistry was previously published in PRVD2008-27.

2.1 Identity of the Technical Grade Active Ingredient

Common name	Didecyl Dimethyl Ammonium Chloride
Function	Antimicrobial
Chemical Family	Quaternary ammonium salt
Chemical name	
1 International Union of Pure and Applied Chemistry (IUPAC)	1-decanaminium, N-decyl-N,N-dimethyl chloride
CAS Registry Number	7173-51-5

Structural Formula



Molecular Formula	$C_{22}H_{48}ClN$
Molecular Weight	361.02 amu

Registration Number and Purity of the Technical Grade Active Ingredient (%)

20321- 80 % N (77.6-82.4%)

24805- 80% MU

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), including TSMP Track 1 substances, are not expected to be present in the product.

2.2 Physical and Chemical Properties

Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure at 25°C	Not required for ionic compounds
Ultraviolet (UV)/visible spectrum	The product is not expected to absorb UV at $\lambda > 350$ nm
Solubility in water	Soluble
n-Octanol/water partition coefficient	Not required for salts
Dissociation constant	Dissociates completely

2.3 Description of Registered DDAC Uses

Appendix I lists the antisapstain and joinery products containing DDAC that are registered under the authority of the *Pest Control Products Act*.

Currently, there are four sources of technical grade active ingredients/manufacturing concentrates and seven end use products registered with DDAC, three of which contain co-biocides (boron, iodocarb and propiconazole) in the formulated end use products. An antisapstain product is applied to freshly-cut wood by dipping or spraying to achieve short-term protection against staining fungi. Joinery products may be applied by dipping, spraying, double vacuum treatment or flow/flood coating.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A review of the toxicity studies conducted with didecyl dimethyl ammonium chloride (DDAC) was published in PRD2007-06, in support of the registration of Carboquat 250T.

Oral administration in rats indicated little absorption of DDAC, as 89-99% was excreted in the feces by 38 or 72 hours in low and high dose rats, respectively. Female rats appeared to have a

more extensive metabolism of DDAC than males and four metabolites were apparent, primarily from oxidative modification of the decyl side chain. Total tissue residues were very low (0.003 - 0.675% of administered dose).

DDAC is highly acutely toxic by the oral route in rats and of low acute dermal toxicity in rabbits. A waiver request was accepted for the acute inhalation study based on the corrosiveness of the test substance. Due to its corrosiveness, DDAC is extremely irritating to the eyes and skin of rabbits, but was not a dermal sensitizer in guinea pigs.

DDAC did not elicit any specific target organ toxicity in sub-chronic or long-term studies. The most prominent effects reflect the highly irritating (corrosive) nature of this class of chemicals. Generalized toxicity in rats, mice and dogs included decreases in body weight and body weight gain. Clinical signs of toxicity at higher doses in rats and mice, including emaciation and hunched posture, were likely related to the corrosive nature of the test compound. Dogs appeared to be more sensitive to DDAC than other test species, exhibiting increased emesis and soft feces at doses ≥10 mg/kg bw/day. An increase in audible/ laboured respiration was noted in developmental toxicity studies in both rats and rabbits. Mortality occurred at higher doses in the 90-day dietary studies in mice and rats, as well as in the developmental toxicity study in rabbits, likely reflecting the corrosive nature of the test substance.

There were no systemic effects noted in a 90-day dermal toxicity study in rats at doses up to 12 mg/kg bw/day. No dermal NOAEL could be established in this study because of the severe irritation noted at all dose levels.

DDAC was not carcinogenic in rat or mouse oncogenicity studies and was non-genotoxic in in vitro and in vivo mutagenicity studies. Decreases in body weight and/or body-weight gain were noted at high doses in both species, with histiocytosis, blood in the sinuses, and increased hemosiderosis of the mesenteric lymph node also noted in rats.

There was no evidence of malformations or effects on reproductive parameters with DDAC, nor was there any evidence of increased sensitivity of the young.

3.1.1 *Pest Control Products Act* Hazard Characterization

For assessing risks from potential residues in food or from products used in and around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, the DDAC database contains developmental toxicity studies in rats and rabbits and a two-generation reproductive toxicity study in rats.

With respect to potential prenatal and postnatal toxicity, no evidence of increased sensitivity of the young was observed in the available reproductive toxicity study in rats. Decreased pup body weights and body weight gains were observed at a dose that was also toxic to the adults.

In the rat developmental toxicity study, no effects were noted in fetuses, while the dams at the mid- and high-dose had an increase in audible respiration. In the rabbit developmental toxicity study, at the highest dose, fetal weights were decreased and there was a slight increase in fetal deaths, but no increase on a litter basis. There was a low level of concern for this finding as the dams suffered severe toxicity, including mortality, at this high dose.

Overall, the database is adequate for determining the sensitivity of the young and effects on the young are well-characterized. On the basis of the above finding, the *Pest Control Products Act* factor was reduced to 1-fold for all exposure scenarios.

3.2 Determination of Acceptable Daily Intake

Not applicable for antisapstain or joinery use.

3.3 Determination of Acute Reference Dose

Not applicable for antisapstain or joinery use.

3.4 Occupational and Non-Occupational Exposure and Risk Assessment

The occupational and non-occupational risk for dermal and inhalation exposure is based on the extreme irritation and corrosiveness of DDAC, rather than systemic toxicity. Hence, a qualitative risk assessment was performed to address the potential health risks associated with the irritation effects of DDAC. Personal protective equipment was selected for the worker tasks that were examined during the Sapstain Industry Group worker exposure study. The additional personal protective equipment outlined in the Exposure Reduction Program is adequate to mitigate dermal and inhalation irritation.

3.4.1 Toxicological Endpoint Selection for Occupational Risk Assessment

Occupational exposure to DDAC is characterized as intermittent long-term in duration and is predominately by the dermal route. Inhalation exposure is expected to be very low. The non-systemic toxicological endpoint of concern for these routes of exposure is irritation resulting from the corrosivity of DDAC.

No dermal endpoint for systemic effects was selected for DDAC because no systemic effects were identified in studies conducted by this route of exposure. Therefore, the PMRA did not conduct a quantitative assessment of occupational risk from dermal exposure. However, DDAC is a severe irritant by the dermal route at all doses tested.

No inhalation studies were conducted due to the severely irritating properties of DDAC. Exposure by the inhalation route is expected to result in significant airway irritation.

3.4.2 Occupational Exposure and Risk Assessment

Workers can be exposed to the antisapstain chemical DDAC while treating wood, handling treated wood and during clean-up, maintenance and repair activities.

The Sapstain Industry Group conducted passive dosimetry worker exposure studies to measure the potential exposure of sawmill workers that are exposed to antisapstain chemicals. The complete study was divided into four phases: Phase I identified an appropriate surrogate chemical; Phase II monitored workers to determine job tasks with a potential for exposure to antisapstain chemicals (handling wet treated lumber, handling dry treated lumber, maintenance (including clean-up) and operating diptanks); Phase III measured workers exposure to those job tasks; and Phase IV measured worker's exposure following the implementation of a Product Stewardship and Exposure Reduction Program (ERP) for the job tasks that demonstrated the highest exposure during Phase III. The workers with the highest potential for exposure included clean-up and maintenance workers and pilers handling freshly treated wood. The ERP also identified areas in sawmills that would benefit from additional mitigation measures to reduce antisapstain chemical exposure, including engineering controls for application systems, instruction on safe handling procedures and proper PPE, and education on the health and safety properties of the antisapstain chemicals. The ERP was shown to reduce exposure for workers handling antisapstain chemicals.

Exposure to workers in a joinery mill is not expected to be underestimated by the Sapstain Industry Group antisapstain exposure study, which measured exposure during treatment by diptank and spraybox systems and while handling treated wood.

3.4.2.1 Occupational Antisapstain and Joinery Exposure and Risk Assessment

Workers can be exposed to DDAC while treating wood, handling treated wood and during clean-up, maintenance and repair activities. Exposure is expected to be long-term in duration and to occur primarily via the dermal route. Inhalation exposure was demonstrated to be very low for the majority of worker activities in the Phase III of the Sapstain Industry Group study and was not assessed during Phase IV. In addition, a NIOSH-respirator is required during clean-up, maintenance and repairs, or if working in areas that are not well ventilated, in order to reduce potential inhalation exposure as defined in the ERP.

A qualitative exposure assessment was conducted to address the extreme irritation and corrosiveness of DDAC for the worker tasks performed in a sawmill that may result in exposure to the active ingredient. Personal protective equipment was selected to protect against dermal and inhalation irritation and follows the personal protective equipment that was outlined in the ERP.

Health risks are not expected for sawmill workers exposed to antisapstain or joinery products containing DDAC provided workers are wearing the appropriate personal protective equipment as outlined in Appendix III.

3.4.3 Postapplication Worker Exposure and Risk Assessment

Postapplication exposure (for wood that has left the sawmill) is not anticipated, as antisapstains are designed to prevent the growth of staining fungi in freshly cut lumber during storage and transit, and not for long-term wood protection in residential or commercial areas.

Joinery wood is intended for use in window and door frames and other above ground non-structural decorative exterior wood such as soffits and fascia. Additionally, joinery wood is

often painted or covered with vinyl or aluminum or other material prior to being sold in the market. Significant human exposure is not expected for this type of wood.

Furthermore, no health risks of concern were identified for workers handling freshly treated wood (wet or dry) in the sawmill whose exposure is expected to be greater than for workers handling of treated wood or joinery products after it has left the sawmill.

3.4.4 Non-Occupational Exposure and Risk Assessment

Non-occupational or residential risk assessment involves estimating risks to the general population, including children and youths, during or after pesticide application. There are no registered domestic class antisapstain or joinery products for DDAC. Residential exposure to individuals contacting wood treated with DDAC for antisapstain or joinery uses is not expected to result in health risks of concern.

3.4.5 Bystander Exposure

Bystander exposure is not anticipated, as DDAC containing antisapstain products are designed to prevent the growth of staining fungi in freshly cut lumber during storage and transit and not for long-term wood protection in residential or commercial areas.

Joinery wood is intended for use in window and door frames and other above ground non-structural decorative exterior wood such as soffits and fascia. Additionally, joinery wood is often painted or covered with vinyl or aluminum or other material prior to being sold in the market. Significant human exposure is not expected for this type of wood.

Furthermore, no health risks of concern were identified for workers handling freshly treated wood (wet or dry) in the sawmill whose exposure is expected to be greater than for bystanders handling of treated wood or joinery products after it has left the sawmill.

Therefore, health risks to bystanders are not of concern.

3.5 Incident Reports Related to Health

Since April 2007, registrants have been required by law to report incidents to the PMRA that include adverse effects to Canadian health or the environment. As of 27 October 2016 no health related incident reports involving the active ingredient DDAC were reported to the PMRA.

3.6 Cumulative Assessment

Cumulative assessment takes into consideration non-occupational exposures (exposure via dietary, drinking water and residential use) to multiple pesticides that share a common mechanism of toxicity. As there are no domestic class registrations for DDAC as an antisapstain, and residential exposure to joinery-type products is anticipated to be minimal, a cumulative assessment is not required for these uses.

4.0 Impact on the Environment

Treated wood joinery products are not subject to significant leaching. The treated window frames and doors are either clad with protective aluminum or vinyl, or are top coated with paint or varnish. The finished windows and doors are installed above-ground in buildings that are generally designed to minimize contact with rain. Any leaching of joinery preservative that does occur, should be limited to the area around the building in which they were installed. Therefore, due to limited environmental exposure, no quantitative environmental risk assessment was conducted for the joinery uses of DDAC. Furthermore, as most joinery active ingredients are also antisapstain active ingredients, the environmental risk assessment for the antisapstain use of DDAC would be expected to cover any environmental risks posed by joinery products.

4.1 Fate and Behaviour in the Environment

Through its use as an antisapstain, DDAC may enter the environment when it leaches from treated wood that has come in contact with water. DDAC is stable to hydrolysis at environmentally relevant pHs, has a phototransformation DT50 of > 100 days on soil, and a biotransformation DT50 of > 1000 days in aerobic soil. Therefore, light, water, and microbial activities are not expected to significantly contribute to the transformation of DDAC in soil. Considering DDAC's slow biotransformation in soil and its adsorption KOC values of > 400000, DDAC is expected to be very persistent and immobile in soil and is unlikely to leach to groundwater.

DDAC is extremely soluble in water, and phototransforms very slowly in aquatic environments (DT50 = 227 days). DDAC appears to be very persistent under both aerobic and anaerobic aquatic conditions with DT50s of 8365 and 6218 days, respectively. DDAC is expected to partition from water to sediment, where it will persist.

Volatilization and subsequent phototransformation of DDAC in air is unlikely due to its low vapour pressure. Bioaccumulation of DDAC is not expected to be a concern in animal tissues or the environment as tests with bluegill sunfish indicated it has a whole body BCF of 81 and it depurates from the whole fish to acceptable concentrations within a 14 day period.

Information regarding the physicochemical properties of DDAC are presented in Appendix II, Table 1. Data on the fate and behaviour of DDAC in the environment are presented in Appendix II, Table 2.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide in the environment.

Environmental exposure from chemicals used to treat wood may result from two scenarios: runoff from wood treatment facilities to adjacent waterbodies and direct leaching from wood in-use to water or soil. Antisapstain products are designed for short-term protection of wood, primarily during its storage and transit. The treated wood is not expected to be in direct contact with soil or water during its use, such as in construction of above-ground components of various structures. Therefore, only an assessment of the potential environmental exposure from treatment facilities was considered to be relevant for antisapstain products.

At wood treatment facilities using antisapstain products, these chemicals may enter the environment when freshly treated wood is exposed to precipitation (primarily rainwater). Although the wood treatment process itself generally occurs in enclosed areas, immediately after the treatment the wood needs to sit for a short period of time to allow excess treatment solution to drip off the freshly-treated wood and for the wood to dry. This initial drying process is to take place outside on a drip pad that is roofed and paved. This minimizes the exposure of the treated wood to rain, while the paved surface aids in containing the drippings from the wood and channeling any excess chemicals to the appropriate receptacles for recycling or disposal. However, once the treated wood is dry, it is stored at the treatment facility until shipment to retailers and may be exposed to rain. Therefore, there is a potential that when used as an antisapstain, DDAC may enter the environment through leaching from the treated wood during storage at wood treatment facilities.

Exposure of terrestrial organisms to DDAC within the vicinity of these storage areas is expected to be negligible. Therefore, the risk to terrestrial organisms was not considered further in the risk assessment. Exposure to aquatic habitats is possible if DDAC leaches from stored, treated wood at treatment facilities and runs-off to adjacent waterbodies.

The EECs of DDAC resulting from this use are based on selected exposure scenarios (Appendix II, Table 3), developed from the OECD Revised Emission Scenario Document for Wood Preservatives. Scenario selection was based on the following considerations:

- DDAC is to be applied only by dipping (including immersion) or automated spraying (large plant / small plant) at treatment facilities.
- As DDAC is not expected to volatilize, EECs in air are expected to be negligible. EECs for this compartment are not required.
- Exposure of non-target organisms in the terrestrial environment is expected to be minimal.
- Environmental exposure to these products when the wood is in use is expected to be limited.
- Treatment facilities, including the drip pad for initial drying of treated wood, consist mostly of paved and roofed areas, except for longer-term storage, so leaching of DDAC from treated wood to soil is expected to be limited to in and around the facilities.
- DDAC may enter the aquatic environment through leaching from treated wood stored at treatment facilities followed by run-off to nearby waterbodies (either freshwater or marine).

4.2.1 Risks to Aquatic Organisms

The exposure scenario for freshwater and estuarine organisms considers surface run-off into adjacent waterbodies from treatment plants using automated spraying (small plant, scenario 1; large plant, scenario 2) and dipping (scenario 3) product application methods. Conservative scenarios were used in the assessments. Specifically, it was assumed that the storage areas were uncovered and unprotected, 100% of the pesticide leached during the storage period, and that 50% of the rainwater ran directly into an adjacent surface water body. Further details for all exposure scenarios are presented in Appendix II, Table 3).

For the OECD scenarios, EECs are derived from the specific scenario parameters identified in Appendix II, Table 3 in combination with the deposition rate of the chemical as stated on the label (Appendix II Table 4). For each scenario, EECs are representative of a daily average taken over the course of the storage period and consider that 100% of the pesticide leaches during that time.

Ecotoxicology information includes acute toxicity data for freshwater fish and invertebrates as well as marine invertebrates. A summary of the available aquatic toxicity data for DDAC is presented in Appendix II, Table 5. Aquatic toxicity values used for this assessment are summarized in Appendix II, Tables 6, 7, and 8.

For characterizing acute risk, acute toxicity values (LC_{50} and EC_{50}) are multiplied by an uncertainty factor. The uncertainty factor is used to account for differences in inter- and intra-species sensitivity as well as varying protection goals (community, population, individual). Thus, the magnitude of the uncertainty factor depends on the group of organisms that are being evaluated (0.1 for fish, 0.5 for aquatic invertebrates).

A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the RQ is then compared to the level of concern (LOC). If the screening level RQ is below the LOC (LOC=1 for aquatic organisms), the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the LOC, then further characterization of the risk is required. Data derived from wood leaching studies may be used in refining a risk assessment. Calculated EECs and RQs for freshwater and marine organisms are located in Appendix II, Table 6.

Freshwater Invertebrates: The risk quotient values for acute toxicity to freshwater invertebrates did not exceed the LOC for surface runoff from either a small spray treatment facility or a dip treatment facility. The risk quotient value did, however, exceed the LOC when considering acute exposure to runoff from a large spray treatment facility (RQ = 3.3).

Freshwater Fish and Amphibians: The risk quotient values for acute toxicity to freshwater fish did not exceed the LOC for surface runoff from either a small spray treatment facility or a dip treatment facility. The risk quotient value did, however, exceed the LOC when considering acute exposure to runoff from a large spray treatment facility (RQ = 4.9). The acute risk to the aquatic life stages of amphibians was assessed based on the generic freshwater environment scenarios, using the most sensitive fish toxicity value as a surrogate endpoint (based on the bluegill sunfish acute toxicity study). The risk quotient value for acute exposure of amphibians to DDAC

exceeded the LOC (RQ = 4.9) when considering acute exposure to runoff from a large treatment facility.

Marine Invertebrates: The risk quotient values for acute toxicity to marine invertebrates did not exceed the LOC for surface runoff from either a small spray treatment facility or a dip treatment facility. The risk quotient value did, however, exceed the LOC when considering acute exposure to runoff from a large spray treatment facility (RQ = 4.5).

Risk quotients for effects of runoff to freshwater and marine organisms range from 3.3 to 4.9 and are based on several conservative assumptions. The estimated exposure considers that all of the active ingredient present in/on stored lumber leaches out of the wood within a relatively short period and that 50% of the pesticide leached will reach the aquatic environment following an average rain pattern. To further characterize the risk to invertebrates, fish and amphibians, available wood leaching data were examined.

Wood Leaching Data

The risk assessment for DDAC antisapstain use was further characterized by considering the results of two studies that measured the amount of DDAC that leached from treated lumber after various simulated rain events. During the PMRA's initial review of DDAC, a 1990 study examining the leaching of DDAC from wood treated with Timbercote II (antisapstain formulation) was obtained from Environment Canada. The study was carried out according to the standard method for antisapstain leaching tests outlined by Environment Canada. The test packages of Douglas fir lumber were treated at the recommended application rate of 100 µg DDAC/cm^2 while two untreated packages were used as a control. The lumber packages were stacked on trays designed to collect all leachate from each package. All packages were subjected to 8 leaching cycles consisting of 91 mm of natural rainfall during 7 rain events over an 18 day period (an average of 13 mm per event).

The concentration of DDAC in the leachate decreased from 73200 µg/L in the first leaching cycle to 9500 µg/L by the fifth cycle. The concentration of DDAC in leachate from the sixth and seventh cycle was 5800 and 6100 µg/L, respectively. To correlate the study to the standard test method, the authors converted the data generated by 13 mm of rain/cycle to the 15 mm of rain/cycle standard conditions by multiplying each value by a factor of 13/15. The rainfall events were correlated to standard conditions by shifting the original data as though each sampling occurred every other day. After the fifth leaching cycle, the decrease in the concentration of DDAC in the leachate was approximated by a negative linear slope. The slope of this portion of the curve was calculated to be -260 µg/L. This slope was extrapolated over the full 16 cycles to correspond with the standard method. The extrapolated data were used to estimate actual yard conditions on the mill yard for 16 cycles, with 15 mm rainfall accumulation per cycle. These data indicated that the average concentration (after 16 cycles) of DDAC in the leachate from the entire yard would be 14459 µg/L. The average yard run-off concentration of DDAC from the entire yard was estimated by dividing average concentration by the mill specific yard dilution factor (for this yard it was calculated to be 17.4 - 19.6). The amount of DDAC that would leach from wood stored at a treatment facility and subsequently run-off the site was calculated to be between 734 – 826 µg/L.

It is expected that the runoff from the yard will be further diluted by the receiving environment, for example, marine estuary or river. In previous scientific evaluations by Health Canada in order to account for the expected dilution, a generic dilution factor of 10 was applied to the concentrations. The generic dilution factor of 10 is affected by many variables including volume, flow rates and mixing characteristics of the receiving water body. Risk quotient values were calculated using all toxicity endpoints in combination with the maximum calculated concentration of DDAC with the 10 fold dilution factor applied to account for further dilution in the receiving environment (Appendix II, Table 7). Using these values, calculated concentrations of DDAC found in runoff from treatment facilities to water bodies slightly exceeded the level of concern for freshwater fish and amphibians as well as freshwater and marine invertebrates (highest RQ = 2.6 for freshwater fish and amphibians).

A 1989 study examined the leaching of DDAC from hem-fir lumber spray-treated with F-2 solution (~6% DDAC) using both protected and unprotected packages. A rotary lawn sprinkler provided a constant and uniform rainfall of about 5.5 mm/hr to each of three packages. Leachates were collected at the tilted end of each package from 30 minutes after the onset of sprinkling, to completion of the study after eight days. Concentrations of DDAC measured in the leachates fell rapidly from an initial level of 48000 µg/L to below 10000 µg/L after 12 hours, and to about 6000 µg/L after 24 hours. Keeping the package protected for 24 hours before simulated rainfall greatly reduced the initial rates of leaching to about 15000 µg/L, but final leaching rates after 48 hours were similar to those from the unprotected package. After 48 hours of rainfall (264 mm), about 6.4% of the DDAC originally applied had been leached from the lumber surfaces of both the unprotected package and the package stored under cover for 24 hours before leaching. As these values represent concentrations of leachate dripping directly from the wood, it is expected that they will be further diluted in runoff water and again upon entry into the receiving environment, for example marine estuary or river. To account for these dilutions, a conservative dilution factor of 100 was applied to the concentrations of leachate dripping directly from the wood. The 100-fold dilution factor was derived by applying a 10-fold dilution factor to account for the dilution of the leachate in runoff from the yard, combined with an additional 10-fold dilution factor to account for the expected dilution once the runoff reaches the receiving environment. As a worst case scenario, risk quotient values were calculated using all toxicity endpoints in combination with the maximum measured concentration of DDAC with the 100-fold dilution factor applied (Appendix II, Table 8). Using these values, concentrations of DDAC leaching from wood at treatment facilities and eventually running off to waterbodies slightly exceeded the level of concern for freshwater fish and amphibians as well as freshwater and marine invertebrates (highest RQ = 1.5 for freshwater fish and amphibians).

The results from both studies examining leaching of DDAC from wood at treatment facilities yield slightly lower RQ values than the results found using the OECD scenarios, although they are all similar in magnitude (highest RQ = 4.9 in large plant OECD scenario, highest RQs = 2.6 and 1.5 in the two wood leaching studies; Tables 6, 7, and 8, respectively). These results indicate a potential for risk to freshwater fish as well as freshwater and marine invertebrates.

Mitigation measures to reduce or prevent runoff of DDAC from wood treatment facilities to aquatic habitats are necessary. This will include protecting treated wood from contact with rain or standing water during drying and storage. The registered label for antisapstain uses of DDAC currently indicates precautions and storage instructions to protect treated wood from rain

washing or coming in contact with water. Additional precautionary statements will be required and are indicated in Appendix III.

Given the conservative nature of the assessment and the small exceedances of the LOC, when the mitigation measures outlined on the label to reduce the ability of DDAC to run-off from treatment facilities to aquatic habitats are followed, the use of DDAC antisapstain is not expected to pose a risk of concern to the environment.

4.2.2 Overall Summary

When used as an antisapstain according to the revised label directions, DDAC is not expected to pose risks of concern to the environment. DDAC has the potential to leach from wood at treatment facilities and subsequently run-off to aquatic environments. Mitigation measures include directions to prevent surface runoff water from wood freshly treated with DDAC from reaching aquatic systems as well as the use of precautionary label statements identifying environmental hazards on the product labels. (Appendix III)

4.2.3 Incident Reports Related to the Environment

There were no environmental incidents involving DDAC in the PMRA database as of October 27, 2016. A review of US incidents in the EIIS database (1992 to 2015) was also conducted. There were no environment incidents involving DDAC in the database.

5.0 Value

Antisapstains

DDAC has value as one of several antisapstain active ingredients for controlling sapstain. The current active ingredients have replaced older antisapstain chemistries based on chlorophenates, which were phased-out in the 1980's for this use due to health and environmental concerns.

The application rates of antisapstain products are expressed both as treatment solution concentrations (%) and as the deposition rate in the treated wood (e.g. µg a.i. per cm^2 wood). They are applied to freshly-cut wood in saw mills by dipping or spraying to achieve a short-term protection of several months. An alternative to antisapstain treatment is kiln-drying of the wood. However, some freshly cut lumber may still require antisapstain treatment while it is stored prior to kiln drying.

Joinery

DDAC has value as one of several joinery active ingredients to protect millwork. The current active ingredients have replaced older joinery chemistries based on tributyltin and organic mercury-based products, which were discontinued in the 1990's due to health and environmental concerns. Joinery products are typically applied by dip and spray, but may also be applied to wood with flood coating or double vacuum treatment. The application rates of joinery products are expressed as treatment solution concentrations (%) and as either a deposition rate (µg a.i. per cm^2 wood surface) or a retention rate (kg a.i. per m^3 wood volume) in the treated wood.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, DDAC was assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- DDAC does not meet TSMP Track 1 criteria, and is not considered a TSMP Track 1 substance. See Appendix II, Table 9 for comparison with Track 1 criteria.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,[8] 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 conclusions:

- DDAC does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*.

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5 DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern and in the order amending this list in the Canada Gazette, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.

7 NOI2005-01, L*ist of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act*.

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

- The end-use products NP-1 Sapstain Control Chemical, F2 Concentrate T2154 Liquid Microbiocide, Mycostat Q, Maquat SSC Sapstain Control, NP-2 Sapstain Control Chemical, Antiblu F2 Concentrate T2154 Liquid Microbiocide, Mycostat PQ, and Antiblu Q-50 do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Proposed Re-evaluation Decision

The PMRA is proposing that antisapstain and joinery uses of products containing DDAC are acceptable for continued registration with additional risk-reduction measures to protect human health and the environment. The proposed mitigation measures are presented in Appendix III. No additional data are being requested at this time.

List of Abbreviations

ai	active ingredient
BAF	bioaccumulation factor
BCFs	bioconcentration factor
bw	body weight
CAS	Chemical Abstracts Service
CEPA	Canadian Environmental Protection Act
cm	centimetre(s)
d	day(s)
DACO	data code
DDAC	didecyldimethylammonium chloride
DIR	Directive
DT_{50}	dissipation time 50% (the time required to observe a 50% decline in concentration)
EC_{50}	effective concentration on 50% of the population
EEC	estimated environmental concentration
ERP	Exposure Reduction Program
EU	European Union
FOB	functional observation battery
g	gram(s)
h	hectare(s)
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{OW}	octanol/water partition coefficient
L	litre(s)
LOC	level of concern
LC_{50}	lethal concentration to 50%
m	meter(s)
mg	milligram(s)
N/A	not applicable
NIOSH	National Institute of Occupational Safety and Health
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
P	parental generation
ppb	parts per billion
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
RBC	red blood cells
RQ	risk quotient
RRD	Re-evaluation Decision
s	second(s)
SIG	Sapstain Industry Group
TGAI	technical grade active ingredient

TCMTB	2-(thiocyanomethylthio) benzothiazole
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet
µg	microgram

Appendix I

Table 1 Antisapstain DDAC Products Currently Registered

Active ingredient	TGAI sources		End-Use Products	
	Registration #	Product Name	Registration #	Product Name
DDAC	20321	Bardac 2280 Quat	21753	NP-1 Sapstain Control Chemical
			26985	NP-2 Sapstain Control Chemical
	24805	Maquat 4480-E	21939	F2 Concentrate T2154 Liquid Microbiocide
			27632	Antiblu F2 Concentrate T2154 Liquid Microbiocide
	24812	Maquat 4450-E	26250	Maquat SSC
			29407	Mycostat PQ Wood Preservative Treatment
	21893	Bardac 2250	25744	Mycostat-Q

Table 2 Joinery DDAC Products Currently Registered

Active ingredient	TGAI Source		End-Use Products	
	Registration #	Product Name	Registration #	Product Name
DDAC	24805	Maquat 4480-E	21939	F2 Concentrate T2154 Liquid Microbiocide
			27632	Antiblu F2 Concentrate T2154 Liquid Microbiocide

Appendix II

Table 1 Summary of Physicochemical Properties of DDAC

Compound	Property	Comments
DDAC	Solubility	Highly Soluble (PMRA# 2646877)
DDAC	Volatility	No measurable vapour pressure and no volatilization (PMRA# 2646877)
DDAC	Octanol-Water Partition Coefficient, log K_{OW}	0 (PMRA# 2646877)
DDAC	UV absorption spectrum	DDAC does not absorb energy in the UV portion of the spectrum (PMRA# 2646877)

Table 2 Fate and Behaviour of DDAC in the Environment

Property	Test substance	Value	Transformation products	Comments	Reference
Abiotic transformation					
Hydrolysis	^{14}C-DDAC (labeled in the N-methyl group)	pH 5, 7 and 9: stable	Not reported	DDAC is stable to hydrolysis at environmentally relevant pHs.	PMRA# 1231531
Phototransformation on soil	^{14}C-DDAC (labeled in the N-methyl group)	DT_{50} (irradiated): 132 d DT_{50} (dark): 169 d	Not reported	Not expected to be an important route of dissipation for DDAC.	PMRA# 1131600
Phototransformation in water	^{14}C-DDAC (labeled in the N-methyl group)	DT_{50} (irradiated): 227 d DT_{50} (dark): stable	Not reported	Not expected to be an important route of dissipation for DDAC.	PMRA# 1231530
Biotransformation					
Biotransformation in aerobic soil	^{14}C-DDAC (labeled in the N-methyl group)	Sandy loam soil (78% sand, 12% clay, 10% silt, 1.8% OM and pH 6.3) DT_{50}: 1048 d (first order kinetics)	Not reported	DDAC is very persistent in aerobic soil.	PMRA# 1239049
Biotransformation in aerobic water systems	^{14}C-DDAC (labeled in the N-methyl group)	Pond water and sediment (1.6% OM, 62% sand, 22% silt, 16% clay, pH 8.0) DT_{50}: 8365 d (first order kinetics)	Not reported	DDAC is very persistent in aerobic flooded sediment.	PMRA# 1239045
Biotransformation in anaerobic water systems	^{14}C-DDAC (labeled in the N-methyl group)	Pond water and sediment (1.6% OM, 62% sand, 22% silt, 16% clay, pH 8.0) DT_{50}: 6218 d (first order kinetics)	Not reported	DDAC is very persistent in anaerobic flooded sediment.	PMRA# 1239047

Property	Test substance	Value	Transformation products	Comments	Reference
Mobility					
Adsorption / desorption in soil	^{14}C-DDAC (labeled in the N-methyl group)	Four soils: Koc: 437805 - 1469081	Not reported	DDAC is immobile in soil.	PMRA# 1236496
Bioconcentration					
Flow-through bioconcentration study in bluegill sunfish	^{14}C-DDAC (labeled in the N-methyl group)	Measured whole body BCF: 81	Not reported	DDAC depurates from the whole fish to acceptable concentrations within a 14 d period	PMRA# 1236499

Table 3 Scenarios considered for the risk assessment

Scenario	Description	Details	
	Scenario for industrial preventive treatment		
	Runoff from storage of treated wood		
1	***Automated spraying (small plant)***	Surface area of the storage place:	79 m^2
		Exposed surface of wood:	11 m^2/m^2
		Duration of storage:	3 d
		Rain fraction reaching water:	0.5
		Flow rate of creek/river:	0.3 m^3s^{-1}
2	***Automated spraying (large plant)***	Surface area of the storage place:	790 m^2
		Exposed surface of wood:	11 m^2/m^2
		Duration of storage:	3 d
		Rain fraction reaching water:	0.5
		Flow rate of creek/river:	0.3 m^3s^{-1}
3	***Dipping/Immersion***	Surface area of the storage place:	700 m^2
		Exposed surface of wood:	11 m^2/m^2
		Duration of storage:	14 d
		Rain fraction reaching water:	0.5
		Flow rate of creek/river:	0.3 m^3s^{-1}

Table 4 Amount of DDAC leached from freshly treated wood

Scenario	Deposition rate (µg/m^2)[a]	Surface area of the storage place (m^2)	Exposed surface of wood (m^2/m^2)	Storage Period (d)	Amount of DDAC leached (kg/d)[b,c]
Automated spraying (small plant)	1 400 000	79	11	3	0.41
Automated spraying (large plant)	1 400 000	790	11	3	4.06
Dipping/Immersion	1 400 000	700	11	14	0.77

[a]Highest deposition rate of DDAC from all antisapstain products currently registered by the PMRA and confirmed by VRD.
[b]Amount of DDAC leached = Deposition rate * Surface area of the storage place * Exposed surface of wood / Storage period.
[c]Emissions from a storage facility are considered stable over time and assume that 100% of the pesticide leaches during the storage period.

Table 5 Toxicity of DDAC to Non-Target Aquatic Species

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[1]	Reference
Freshwater species					
Daphnia magna	48h-Acute	DDAC	EC_{50} = 0.094 mg a.i./L	Very highly toxic	PMRA# 1236489
Bluegill sunfish, *Lepomis macrochirus*	96h-Acute	DDAC	LC_{50}= 0.32 mg a.i./L	Highly toxic	PMRA# 1236498
Coho salmon, *Oncorhynchus kisutch*	96h-Acute	DDAC	LC_{50}= 1.00 mg a.i./L	Highly toxic	PMRA# 1236497
Marine species					
Mysid shrimp, *Mysidopsis bahia*	96h-Acute	DDAC	LC_{50}= 0.069 mg a.i./L	Very highly toxic	PMRA# 1236490
[1] USEPA classification					

Table 6 Expected environmental concentrations (EECs) and risk quotients (RQs) for freshwater and marine organisms based on storage of treated wood (surface runoff from treatment facilities).

Organism	Species Uncertainty Factor	Endpoint[1]			1-d EEC[2] (mg a.i./L)	RQ[3]
Storage after automated spraying (small plant)						
Freshwater organisms						
Daphnia magna	1/2	48-h EC_{50}	= 0.047	mg a.i./L	0.0156	0.333
Bluegill sunfish	1/10	96-h LC_{50}	= 0.032	mg a.i./L	0.0156	0.489
Marine organism						
Mysid shrimp	1/2	96-h LC_{50}	= 0.0345	mg a.i./L	0.0156	0.453
Storage after automated spraying (large plant)						
Freshwater organisms						
Daphnia magna	1/2	48-h EC_{50}	= 0.047	mg a.i./L	0.1565	**3.329**
Bluegill sunfish	1/10	96-h LC_{50}	= 0.032	mg a.i./L	0.1565	**4.889**
Marine organism						
Mysid shrimp	1/2	96-h LC_{50}	= 0.0345	mg a.i./L	0.1565	**4.535**
Storage after dip/immersion						
Freshwater organisms						
Daphnia magna	1/2	48-h EC_{50}	= 0.047	mg a.i./L	0.0297	0.632
Bluegill sunfish	1/10	96-h LC_{50}	= 0.032	mg a.i./L	0.0297	0.928
Marine organism						
Mysid shrimp	1/2	96-h LC_{50}	= 0.0345	mg a.i./L	0.0297	0.861

[1]Endpoints used in the acute exposure risk assessment are derived by multiplying the EC_{50} or LC_{50} from the appropriate laboratory study by the species uncertainty factor.
[2]Expected Environmental Concentration (EEC) = amount of DDAC leached per day (Table 4) / flow rate of a creek or river (Table 3). EECs are calculated on a per day basis.
[3]Risk Quotient (RQ) = exposure/toxicity. RQ > 1 (in bold) indicates exceedance of LOC (Level Of Concern).

Table 7 Expected environmental concentrations (EECs) and risk quotients (RQs) for freshwater and marine organisms based on results from the wood leaching study using Timbercote II.

Organism	Species Uncertainty Factor	Endpoint[1]			1-d EEC (mg a.i./L)	RQ[2]
Freshwater organisms						
Daphnia magna	1/2	48-h EC_{50}	= 0.047	mg a.i./L	0.0826[3]	**1.757**
Bluegill sunfish	1/10	96-h LC_{50}	= 0.032	mg a.i./L	0.0826[3]	**2.581**
Marine organism						
Mysid shrimp	1/2	96-h LC_{50}	= 0.0345	mg a.i./L	0.0826[3]	**2.394**

[1]Endpoints used in the acute exposure risk assessment are derived by multiplying the EC_{50} or LC_{50} from the appropriate laboratory study by the species uncertainty factor.
[2]Risk Quotient (RQ) = exposure/toxicity. RQ > 1 (in bold) indicates exceedance of LOC (Level Of Concern).
[3]Expected Environmental Concentration (EEC) = maximum concentration calculated in yard runoff / generic dilution factor of 10 (PMRA# 2647635).

Table 8 Expected environmental concentrations (EECs) and risk quotients (RQs) for freshwater and marine organisms based on results from the wood leaching study using F-2.

Organism	Species Uncertainty Factor	Endpoint[1]			1-d EEC (mg a.i./L)	RQ[2]
Freshwater organisms						
Daphnia magna	1/2	48-h EC_{50}	= 0.047	mg a.i./L	0.0480[3]	**1.021**
Bluegill sunfish	1/10	96-h LC_{50}	= 0.032	mg a.i./L	0.0480[3]	**1.500**
Marine organism						
Mysid shrimp	1/2	96-h LC_{50}	= 0.0345	mg a.i./L	0.0480[3]	**1.391**

[1]Endpoints used in the acute exposure risk assessment are derived by multiplying the EC_{50} or LC_{50} from the appropriate laboratory study by the species uncertainty factor.
[2]Risk Quotient (RQ) = exposure/toxicity. RQ > 1 (in bold) indicates exceedance of LOC (Level Of Concern).
[3]Expected Environmental Concentration (EEC) = maximum concentration measured in pure leachate / generic dilution factor of 100.

Table 9 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints
CEPA toxic or CEPA toxic equivalent[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]:	Soil	Half-life ≥ 182 days	DT_{50} of 1048 days in aerobic soil.
	Water	Half-life ≥ 182 days	DT_{50} of 6218 - 8365 days in total system of aerobic and anaerobic water/sediment systems.
	Sediment	Half-life ≥ 365 days	DT_{50} of 6218 - 8365 days in total system of aerobic and anaerobic water/sediment systems.
	Air	Half-life ≥ 2 days or evidence of long range transport	DDAC is non-volatile.
Bioaccumulation[4]	Log K_{OW} ≥ 5		0
	BCF ≥ 5000		81
	BAF ≥ 5000		Not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.

[1] All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (i.e., all other TSMP criteria are met).
[2] The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.
[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.
[4] Field data (e.g., BAFs) are preferred over laboratory data (e.g., BCFs) which, in turn, are preferred over chemical properties (e.g., log K_{OW}).

Appendix III Label Statements Proposed for Antisapstain and Joinery Products containing DDAC

The label amendments proposed below do not include all label requirements for individual products, such as first aid statements, disposal statements, precautionary statements and protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

PROPOSED STATEMENTS TO PROTECT HUMAN HEALTH

To protect workers, additional personal protective equipment is required on all DDAC antisapstain and joinery product labels. In order to conform to the ERP, the following statements are proposed to be included on the appropriate product labels in a section entitled **PRECAUTIONS**:

Antisapstain Product Labels

- Wear chemical-resistant coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, goggles or face shield, socks, and chemical-resistant footwear when handling the concentrate or during mixing/loading, application, clean-up, maintenance and repair activities.
- Use a NIOSH-respirator if the area is not well ventilated.
- Use a NIOSH-respirator during clean-up, maintenance and repair activities.
- When piling freshly treated lumber or if there is a potential for getting wet by the treating solution or by handling freshly treated lumber, wear chemical-resistant coveralls or a chemical-resistant apron over long-sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear.
- When working in the dip or spray area, wear long-sleeved shirt, long pants, chemical-resistant gloves, socks and boots. Wear goggles or face shield if there is a possibility of splashing.
- Once dry, the treated wood can be handled with cotton or leather gloves.
- Wash hands and face before eating, drinking, smoking and using the toilet. Change clothes daily. Wash contaminated clothing separately from household laundry. Not for use or storage in or around the home. Clean contaminated equipment thoroughly prior to making welding repairs.

Joinery Product Labels:

- Wear chemical-resistant coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, goggles or face shield, socks, and chemical-resistant footwear when handling the concentrate or during mixing/loading, application, clean-up, maintenance and repair activities.
- Use a NIOSH-respirator if the area is not well ventilated.
- Use a NIOSH-respirator during clean-up, maintenance and repair activities and when opening pressure treatment cylinder doors.
- When handling freshly treated wood or if there is a potential for getting wet by the treating solution, wear chemical-resistant coveralls or a chemical-resistant apron over

long-sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear.
- When working in the application area, wear long-sleeved shirt, long pants, chemical-resistant gloves, socks and boots. Wear goggles or face shield if there is a possibility of splashing.
- Once dry, the treated wood can be handled with cotton or leather gloves.
- Wash hands and face before eating, drinking, smoking and using the toilet. Change clothes daily. Wash contaminated clothing separately from household laundry. Not for use or storage in or around the home. Clean contaminated equipment thoroughly prior to making welding repairs.

PROPOSED ENVIRONMENTAL STATEMENTS

A. Environmental Label statements proposed for TGAIs: Bardac 2250, Maquat 4450-E, Bardac 2280 QUAT, Maquat LC12S-50%, Maquat 4480-E, Barquat 50-65B, Barquat 50-65A

I) **ENVIRONMENTAL PRECAUTIONS**:

TOXIC to aquatic organisms.

DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

II) **DISPOSAL**:

Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal or provincial regulations. For additional details and clean up of spills, contact the manufacturer or the provincial regulatory agency.

B. Label statements proposed for End Use Products: NP-1 Sapstain Control Chemical, F2 Concentrate T2154 Liquid Microbiocide, Mycostat Q, Maquat SSC Sapstain Control, NP-2 Sapstain Control Chemical, Antiblu F2 Concentrate T2154 Liquid Microbiocide, Mycostat PQ, Antiblu Q-50

I) **ENVIRONMENTAL PRECAUTIONS**:

TOXIC to aquatic organisms.

II) **DIRECTION FOR USE**:

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

This product is **TOXIC** to 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. The requirements of applicable laws should be determined before using the product.

Dip tanks and drip aprons must be roofed, paved and drained to prevent dilution and loss of treatment solution.

Store treated lumber on a roofed drip pad until dripping has ceased. Slope lumber on the drip pad to expedite drainage and to ensure that no puddles remain on the surface of the wood. Manage drippage and other related wastes to prevent release in the environment.

DO NOT expose treated lumber to rains immediately after treatment.

For further information on storage, handling, and disposal of treated wood, contact the manufacturer of this product or the provincial regulatory agency.

III) **STORAGE**:

To prevent contamination store this product away from food or feed.

IV) **DISPOSAL**:

DO NOT reuse this container for any other purpose. This is a recyclable container, and is to be disposed of at a container collection site. Contact your local distributor/dealer or municipality for the location of the nearest collection site. Before taking the container to the collection site:

1. Triple- or pressure-rinse the empty container. Dispose of the rinsings in accordance with provincial requirements.

2. Make the empty, rinsed container unsuitable for further use.

   If there is no container collection site in your area, dispose of the container in accordance with provincial requirements.

   For information on disposal of unused, unwanted product, or in the case of a spill or spill clean-up, contact the manufacturer or the provincial regulatory agency.

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

Human Health

PMRA Document Number	Reference
1188767	1999, Generic Anti-Sapstain Worker Exposure Study NP-1 Phase III Field Study, Measurement and Assessment of Dermal and Inhalation Exposures to Didecyldimethylammonium Chloride (DDAC) Used in the Protection of Cut Lumber (Phase III), Final Report, K.T. Bestari Et Al, October 25, 1999 [Antisapstain Products;SUBN.#97-0521;Submitted December 20, 1999;Volume 1 of 7], DACO: 5.1,5.6
1665704	2008, Final Report: Field Monitoring and Re-evaluation of Workers Dermal Exposures to Didecyldimethylammonium Chloride (DDAC) Used in the Protection of Cut Lumber, DACO: 5.4
1289169	2005, Exposure Reduction Program for Antisapstain Chemicals. Green Chain Pullers/Pilers and Cleanup Crew, DACO: 5.14
1726847	DACO: 5.6(A)_DOC Post Application: Passive Dosimetry Data Agricultural

Impact on the Environment

Environmental Fate

PMRA#	Reference
1131600	Schmidt, J. 1992. Determination of the Photolysis Rate of Didecyldimethylammoniumchloride (DDAC) on the Surface of Soil. ABC Laboratories, Inc., Report No. 39505, Lonza Inc., DACO 8.2.1
1231530	Dykes, J. and M. Fennessey. 1989a. Determination of the Photolysis Rate of Didecyldimethylammoniumchloride (DDAC) in pH 7 Buffered Solution at 25ºC. ABC Laboratories, Inc., Report No. 37005, Lonza Inc., DACO 8.2.1
1231531	Dykes, J. and M. Fennessey. 1989b. Hydrolysis of Didecyldimethylammoniumchloride (DDAC) as a Function of pH at 25ºC. ABC Laboratories, Inc., Report No. 37004, Lonza Inc., DACO 8.2.1
1236489	LeLievere, M.K. 1990a. Evaluation of Didecyldimethylammoniumchloride (DDAC) in a Static Acute Toxicity Test with Daphnids, *Daphnia magna*. Springborn Laboratories, Inc., Report No. 89-10-3112, Lonza, Inc., DACO 9.3.1
1236490	LeLievere, M.K. 1990b. Evaluation of

Didecyldimethylammoniumchloride (DDAC) in a Static Acute Toxicity Test with Mysid Shrimp, *Mysidopsis bahia*. Springborn Laboratories, Inc., Report No. 90-2-3233, Lonza, Inc., DACO 9.4.1

1236496 Daly, D. 1989. Soil/Sediment Adsorption-Desorption of ^{14}C-Didecyldimethylammoniumchloride (DDAC). ABC Laboratories, Inc., Report No. 37009, Lonza Inc., DACO 8.2.4.1

1236497 LeLievere, M.K. 1990c. Evaluation of Didecyldimethylammoniumchloride (DDAC) in a Static Acute Toxicity Test with Coho Salmon, *Oncorhynchus kisutch*. Springborn Laboratories, Inc., Report No. 90-4-3290, Lonza, Inc., DACO 9.5.2.1

1236498 LeLievere, M.K. 1990d. Evaluation of Didecyldimethylammoniumchloride (DDAC) in a Static Acute Toxicity Test with Bluegill Sunfish, *Lepomis macrochirus*. Springborn Laboratories, Inc., Report No. 89-10-3111, Lonza, Inc., DACO 9.5.2.1

1236499 Fackler, P.H. 1990. Bioconcentration and Elimination of ^{14}C-Residues by Bluegill (*Lepomis macrochirus*) Exposed to Didecyldimethylammoniumchloride (DDAC). Springborn Laboratories, Inc., Report No. 89-7-3043, Lonza, Inc., DACO 9.5.5

1239045 Cranor, W. 1991a. Aerobic Aquatic Metabolism of ^{14}C-Didecyldimethylammoniumchloride (^{14}C-DDAC). ABC Laboratories, Inc., Report No. 37008, Lonza, Inc., DACO 8.2.3.1

1239047 Cranor, W. 1991b. Anaerobic Aquatic Metabolism of ^{14}C-Didecyldimethylammoniumchloride (^{14}C-DDAC). ABC Laboratories, Inc., Report No. 37007, Lonza, Inc., DACO 8.2.3.1

1239049 Cranor, W. 1991c. Aerobic Soil Metabolism of ^{14}C-Didecyldimethylammoniumchloride (^{14}C-DDAC). ABC Laboratories, Inc., Report No. 37006, Lonza, Inc., DACO 8.2.3.1

B. ADDITIONAL INFORMATION CONSIDERED

i) Published Information

Chemistry

PMRA #	Reference
1668320	Canada 2008, Proposed Re-evaluation Decision, Didecyl Dimethyl Ammonium Chloride Cluster (DDAC). PRVD2008-27

Human and Animal Health

PMRA#	Reference
1450102	Canada 2007, Proposed Registration Decision, Carboquat 250T. PRD2007-06

Environment

PMRA#	Reference
2645034	Krahn, P.K. and R. Strub. 1990. Standard leaching test for antisapstain chemicals. Regional Program Report 90-10. Environment Canada, Pacific and Yukon Region, DACO 8.6
2647633	Henderson, N.D. 1992. A Review of the Environmental Impact and Toxic Effects of DDAC. Environmental Protection Division, BC Environment, DACO 8.6
2647634	Organization for Economic Co-operation and Development (OECD) Environment Directorate. 2003, revised 2013. Revised Emission Scenario Document for Wood Preservatives, Series on Emission Scenario Documents No.2, DACO 8.6
2647635	Health Canada, Environment Canada. 2000. Canadian Environmental Protection Act, 1999, Priority Substances List - Statement of the Science Report for Ethylene Glycol. Appendix B, DACO 8.6

ii) Unpublished Information

Environment

PMRA#	Reference
1449344	Pest Management Regulatory Agency. 1997. Environmental Review of Didecyl Dimethyl Ammonium Chloride (DDAC) For Antisapstain Uses. Special Review. Environmental Assessment Directorate. DACO 9.1
2646877	Agriculture Canada and Health and Welfare Canada, Environment Canada, Department of Fisheries and Oceans, Canadian Forestry Services. 1988. Discussion Document on Antisapstain Chemicals. (Draft copy), DACO 8.6