Proposed Re-evaluation Decision PRVD2016-26

Antisapstain Use of Copper-8-quinolinolate

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Table of Contents

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, 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 the 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, dodecyl 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-quinolinolate, 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.

There is no joinery use registered for copper-8-quinolinolate. This document addresses the health and environmental risk assessments for the antisapstain use of copper-8-quinolinolate. 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 Use of Copper-8-quinolinolate

The PMRA has completed the health and environmental risk assessments for the antisapstain use of copper-8-quinolinolate. Under the authority of the *Pest Control Products Act*, the PMRA is proposing continued registration of the antisapstain use of copper-8-quinolinolate in Canada.

An evaluation of available scientific information found that the antisapstain use of copper-8-quinolinolate 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 products containing copper-8-quinolinolate, new risk-reduction measures are proposed.

This proposal affects the antisapstain end-use products containing copper-8-quinolinolate 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 copper-8-quinolinolate 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 copper-8-quinolinolate.

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.

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

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 Copper-8-quinolinolate?

Copper 8-quinolinolate is registered in Canada for the control of sapstain in freshly cut lumber and timber in transit and storage.

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.

Health Considerations

Can Approved Uses of Copper-8-quinolinolate Affect Human Health?

Antisapstain products containing copper-8-quinolinolate are unlikely to affect your health when used according to revised label directions.

Potential exposure to copper-8-quinolinolate may occur through the dermal route, when handling and applying antisapstain products containing copper-8-quinolinolate 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.

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.

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

In laboratory animals, copper-8-quinolinolate was of low acute oral toxicity, low acute dermal toxicity and moderate acute toxicity by the inhalation route of exposure. It was severely irritating to the eye, non-irritating to the skin and did not cause an allergic skin reaction.

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 copper-8-quinolinolate to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. Copper-8-quinolinolate did not elicit any specific target organ toxicity in short- or long-term studies. The most sensitive endpoints for risk assessment included effects on blood and the blood system, and stomach ulceration. Copper-8-quinolinolate is a reproductive toxicant in the presence of maternal toxicity. The risk assessment protects against the above-noted effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occur in animal tests.

Risks in Residential and Other Non-Occupational Environments

Non-occupational risks are not of concern.

There are currently no registered residential uses of copper-8-quinolinolate antisapstain 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 3.4.3 of the Science Evaluation), health risk estimates associated with mixing, loading, and applying activities and during handling of treated wood exceeded target dermal margins of exposure (MOEs) and are not of concern. Inhalation exposure was shown 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 personal protective equipment 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.

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 products after they have left the sawmill, postapplication health risks are not of concern.

Environmental Considerations

What Happens When Copper-8-quinolinolate Is Introduced Into the Environment?

When used as an antisapstain according to the revised label statements, copper-8-quinolinolate is not expected to pose risks of concern to the environment.

Antisapstains, such as copper-8-quinolinolate, may enter the environment if newly treated wood is exposed to rain. Exposure to land organisms and their habitats is expected to be negligible. Copper-8-quinolinolate may reach the aquatic environment if rainwater containing the chemical is permitted to run-off from the treatment facility and its wood storage areas into nearby waterbodies.

Copper-8-quinolinolate does not mix readily in water and cannot move easily through soil. Copper-8-quinolinolate does not break down in the presence of water but breaks down quickly in the presence of light and in the presence of microbes. Studies with copper-8-quinolinolate indicate that it will not seep through soil and contaminate groundwater. Copper-8-quinolinolate is not expected to be found in air and is not expected to accumulate in the tissues of organisms.

Copper-8-quinolinolate is highly toxic to aquatic organisms. However, when used according to the revised label directions, copper-8-quinolinolate is not expected to pose risks of concern to freshwater and marine invertebrates, freshwater fish and amphibians, and marine algae.

Value Considerations

What is the Value of Copper-8-quinolinolate in Antisapstain Treatment?

Copper-8-quinolinolate 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.

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 use of copper-8-quinolinolate, the PMRA is proposing further risk-reduction measures in addition to those already identified on copper-8-quinolinolate product labels.

Additional Key Risk Reduction Measures

Human Health

- To protect workers, additional general hygiene statements and personal protective equipment are required on all copper-8-quinolinolate antisapstain product labels conforming to the ERP.

Environment

- In order to minimize the amount of copper-8-quinolinolate 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 use of copper-8-quinolinolate, 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 copper-8-quinolinolate. 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

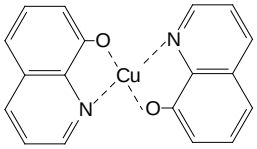
1.0 Introduction

Copper-8-quinolinolate is registered in Canada as a wood preservative to control sapstain in freshly cut lumber.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

A review of the chemistry was previously published in PRVD2010-20.

2.1 Identity of the Technical Grade Active Ingredient

Common name	copper-8-quinolinolate
Function	Antisapstain/ wood preservative fungicide
Chemical Family	Quinoline
Chemical name	
1. **International Union of Pure and Applied Chemistry (IUPAC)**	Bis(quinolin-8-olato)copper (I), Cupric 8-quinolinoxide
2. **Chemical Abstracts Service (CAS)**	Bis(8-quinolinato-N^1,O^8)copper
CAS Registry Number	10380-28-6
Structural Formula	
Molecular Formula	$C_{18}H_{12}CuN_2O_2$
Molecular Weight	351.9 amu
Registration Number and Purity of the Technical Grade Active Ingredient (%)	25882- 96% 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	4.6×10^{-5}mPa
Henry's law constant	2.31×10^{-4} Pa m^3mol^{-1}
Ultraviolet/visible spectrum	Not expected to absorb at $\lambda > 410$ nm (λmax = 410 nm)
Solubility in water	0.07 mg/L
n-Octanol/water partition coefficient	Log K_{ow} = 2.46
Dissociation constant	pK1= 12.2 pK2= 11.2

2.3 Description of Registered Copper-8-quinolinolate Uses

Appendix I lists the antisapstain products containing copper-8-quinolinolate that are registered under the authority of the *Pest Control Products Act*.

Currently, there is one source of technical grade active ingredient and one end use product containing copper-8-quinolinolate registered. The end-use product is applied to freshly-cut wood by dipping to achieve short-term protection against staining fungi.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Following oral administration to rats, copper-8-quinolinolate was readily absorbed and rapidly excreted via both urine and feces. It was widely distributed, with highest levels in liver, kidney and urinary bladder. Copper-8-quinolinolate was rapidly metabolized and eliminated as conjugates as well as parent compound within 72 hours. Only trace levels were detected in tissues after 96 hours.

Copper-8-quinolinolate is of low acute oral toxicity in rats and mice, low acute dermal toxicity in rats and rabbits, and of moderate acute inhalation toxicity in rats. It is severely irritating to the eye of rabbits, non-irritating to rabbit skin and a non-sensitizer in guinea pigs.

Copper-8-quinolinolate did not elicit any specific target organ toxicity in sub-chronic or long-term studies. Effects included haemosiderin accumulation in various visceral organs (liver, spleen, kidney), likely due to intravascular hemolysis from copper toxicity, as well as effects on haematopoiesis, haemolytic parameters and stomach ulceration. In the reproductive toxicity

study, decreased litter size and litter and/or pup weight as well as pathological changes in the offspring (increased liver weight, eye defects and cysts/ hyperplasia in the pituitary) were noted at the high dose in the presence of maternal toxicity. There were no developmental effects in rabbits. In the rat developmental toxicity study, there was an increase in resorptions/post implantation loss at a maternally toxic dose. Thus, in both the rat reproductive study and rat developmental study, there were serious effects in the young in the presence of maternal toxicity.

In a 28-day dermal toxicity study in rats, necrotic thymic lymphocytes were observed at doses ≥200 mg/kg bw/day. No dermal effects were noted.

Copper-8-quinolinolate was not carcinogenic in a supplemental rat study, but an increase in malignant lymphoma of the haematopoetic tissues was noted in female mice. Both negative and positive findings were observed in various in vitro mutagenicity assays, however, all in vivo mutagenicity assays were negative. A threshold approach to risk assessment was used for these effects.

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 database for copper-8-quinolinolate contains a reproductive toxicity study in rats and developmental toxicity studies in rats and rabbits.

With respect to potential prenatal and postnatal toxicity, in the reproductive toxicity study, decreased litter size and litter and/or pup weight as well as pathological changes in the offspring (increased liver weight, eye defects and cysts/ hyperplasia in the pituitary) were noted at the high dose in the presence of maternal toxicity. There were no developmental effects in rabbits. In the rat developmental toxicity study, there was an increase in resorptions/post implantation loss at a maternally toxic dose. Thus, in both the rat reproductive study and rat developmental study, there were serious effects in the young in the presence of maternal toxicity. On the basis of this information, the *Pest Control Products Act* factor was retained at 3-fold for scenarios for which these endpoints were used. For all other endpoints, the *Pest Control Products Act* factor was reduced to 1-fold.

3.2 Determination of Acceptable Daily Intake

Not applicable for antisapstain use.

3.3 Determination of Acute Reference Dose

Not applicable for antisapstain use.

3.4 Occupational and Non-Occupational Exposure and Risk Assessment

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

3.4.1 Toxicological Endpoint Selection for Occupational Risk Assessment

Occupational exposure to copper-8-quinolinolate is characterized as intermittent long-term in duration and is predominately by the dermal route.

Long-term dermal endpoint

For long-term dermal exposure, the no observed adverse effect level (NOAEL) of 5 mg/kg bw/day from the 2-year dietary study in dogs was selected for use in risk assessment. In this study, long-term dietary exposure resulted in decreased body weight, haematopoetic changes, focal accumulation of pigment-laden Kuppfer cells, subplural inflammation of the lung, ulcerated gastric mucosa, and increased copper deposition in the liver, brain, spleen and kidney. The target MOE is 100, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability.

Use of this NOAEL and target MOE of 100 provide margins in excess of 400-fold to the NOAEL for offspring toxicity in the rat reproduction study, a margin of 4000-fold to the NOAEL for developmental effects in the rat developmental toxicity study, and a margin in excess of 1300-fold to the NOAEL for malignant lymphoma in female mice, thus addressing any concerns noted in the *Pest Control Products Act* Hazard Characterization section that are relevant to the worker population as well as any cancer concerns. As such, no additional factor is required.

Table 3.4.1 Toxicology Endpoints for Use in Health Risk Assessment for Copper-8-quinolinolate

Exposure Scenario	Study	Point of Departure and Endpoint	Target MOE
Long-term dermal	2-year dietary study in dogs	NOAEL = 5 mg/kg bw/day based on decreased body weight, haematopoetic changes, focal accumulation of pigment-laden Kuppfer cells; subplural inflammation of the lung; ulcerated gastric mucosa; greenish-tinged liver with copper deposition in liver, spleen kidney & brain	100
Cancer	Threshold approach for cancer risk assessment.		

3.4.2 Dermal Absorption

There is no dermal absorption data on file for copper-8-quinolinolate, therefore a dermal absorption value of 100% was used in the risk assessment.

3.4.3 Occupational Exposure and Risk Assessment

Workers can be exposed to the antisapstain chemical copper-8-quinolinolate 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 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.

3.4.3.1 Occupational Antisapstain Exposure and Risk Assessment

As noted above, workers can be exposed to copper-8-quinolinolate 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.

Dermal exposure was estimated by combining the unit exposure values from the surrogate antisapstain worker exposure study with the amount of product handled per day and the dermal absorption value. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight.

The results of the health risk assessment for sawmill workers exposed to antisapstain products containing copper-8-quinolinolate are shown in Table 3.4.3.1. Calculated MOEs exceeded the target MOE and no health risks of concern were identified for sawmill workers wearing the appropriate personal protective equipment as outlined in Appendix III.

Table 3.4.3.1 Copper-8-quinolinolate Exposure Assessment for Sawmill Workers Exposed to Antisapstain Products.

Tasks	Unit Exposure (µg/mg/mL)	Max Rate [1] (mg/mL)	Daily Exposure [2] (mg/kg bw/day)	MOE [3]
Sapstain Industry Group Phase IV				
Pilers	493.7	0.727	0.004486	1115
Clean-up Crew	203.1	0.727	0.001846	2709
Maintenance Workers	401.4	0.727	0.003648	1371

MOE = Margin of exposure
[1] The maximum treatment solution rate for copper-8-quinolinolate is shown as the most conservative scenario.
[2] Daily Exposure = Unit Exposure (µg/mg/mL) * Max Rate * Dermal Absorption (100%) / Body Weight (80 kg)
[3] Dermal MOEs are based on an oral NOAEL of 5 mg/kg bw/day. Target MOE is 100. MOE = NOAEL / Daily Exposure.

3.4.4 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.

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 after it has left the sawmill.

3.4.5 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 products for copper-8-quinolinolate. Residential exposure to individuals contacting wood treated with copper-8-quinolinolate for antisapstain uses is not expected to result in health risks of concern.

3.4.6 Bystander Exposure

Bystander exposure is not anticipated, as copper-8-quinolinolate 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.

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 treated wood 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 November 25, 2016, no health related incident reports involving the active ingredient copper-8-quinolinolate 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 copper-8-quinolinolate as an antisapstain and no registered joinery uses, a cumulative assessment is not required for these uses.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Through its use as an antisapstain, copper-8-quinolinolate may enter the environment when it leaches from treated wood that has come in contact with water. Copper-8-quinolinolate is a copper complex comprised of Cu^{2+} and its ligand, 8-hydroxyquinoline. As an organometallic-chelate compound, copper-8-quinolinolate is not expected to dissociate quickly in water to release cupric ions.

Copper-8-quinolinolate is insoluble in water. Hydrolysis is not a major route of transformation for copper-8-quinolinolate as shown by its half-lives of > 1 year at pHs 5, 7 and 9. Phototransformation in water is a major route of transformation for copper-8-quinolinolate based on DT_{50} values of 1-3 days and 14 days in aqueous solutions. Copper-8-quinolinolate has a DT_{50} of 2 days in aerobic soil and is non-persistent. Information on the microbial transformation of copper-8-quinolinolate in water was not available. An adsorption K_{oc} value of 14500 indicates that copper-8-quinolinolate is immobile in soil and leaching studies with aged and non-aged soils showed that copper-8-quinolinolate has no tendency to leach, making it unlikely to contaminate groundwater.

Volatilization and subsequent phototransformation of copper-8-quinolinolate in air is unlikely due to its low vapour pressure. Bioaccumulation of copper-8-quinolinolate is not expected to be a concern in animal tissues or the environment as its log K_{ow} value of 2.39 indicates it has limited potential for bioaccumulation.

Information regarding the physicochemical properties of copper-8-quinolinolate is presented in Appendix II, Table 1. Data on the fate and behaviour of copper-8-quinolinolate 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, and for wood that 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, i.e., 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 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, copper-8-quinolinolate may enter the environment through leaching from the treated wood during storage at wood treatment facilities.

Exposure of terrestrial organisms to copper-8-quinolinolate 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 copper-8-quinolinolate leaches from stored, treated wood at treatment facilities and runs-off to adjacent waterbodies.

The EECs of copper-8-quinolinolate 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 (PMRA# 2647634). Scenario selection was based on the following considerations:

- Copper-8-quinolinolate is to be applied only by dipping (including immersion) at treatment facilities.
- As copper-8-quinolinolate 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 copper-8-quinolinolate from treated wood to soil is expected to be limited to in and around the facilities.
- Copper-8-quinolinolate 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 a treatment plant using dipping product application methods. Conservative scenarios were used in the assessment. Specifically, it was assumed that the storage area was uncovered and unprotected, that 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 the exposure scenario are presented in Appendix II, Table 3.

For the OECD scenarios, EECs are derived from the specific scenario parameters identified in Table 3 of Appendix II 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 and chronic toxicity data for freshwater fish and invertebrates, as well as acute toxicity data for marine invertebrates and algae. A summary of the available aquatic toxicity data for copper-8-quinolinolate is presented in Appendix II, Table 5. Aquatic toxicity values used for this assessment are summarized in Appendix II, Table 6.

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). When assessing chronic risk, the no observed effect concentration (NOEC) or no observed effect level (NOEL) is used and an uncertainty factor is not applied.

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 and chronic toxicity to freshwater invertebrates did not exceed the LOC for surface runoff from a dip treatment facility. Copper-8-quinolinolate is not expected to pose a risk to freshwater invertebrates.

Freshwater Fish and Amphibians: The risk quotient values for acute and chronic toxicity to freshwater fish exceeded the LOC for surface runoff from a dip treatment facility (acute RQ = 2.6, chronic RQ = 1.38). The acute and chronic risks to the aquatic life stages of amphibians were assessed based on the generic freshwater environment scenarios, using the most sensitive fish toxicity values as surrogate endpoints (i.e. based on the rainbow trout acute and chronic toxicity studies). The risk quotient values for acute and chronic exposure of amphibians to copper-8-quinolinolate exceeded the LOC (acute RQ = 2.6, chronic RQ = 1.4) when considering acute exposure to runoff from a dip treatment facility.

Marine Algae: The risk quotient value for acute toxicity to marine algae exceeded the LOC for surface runoff from a dip treatment facility (RQ = 2.1).

Marine Invertebrates: The risk quotient value for acute toxicity to marine invertebrates did not exceed the LOC for surface runoff from a dip treatment facility. Copper-8-quinolinolate is not expected to pose a risk to marine invertebrates.

The results indicate a potential for acute and chronic risk to freshwater fish and amphibians, and acute risk to marine algae. Risk quotients for effects of runoff to freshwater and marine organisms were slightly above the level of concern, ranging from 1.4 to 2.6 (freshwater fish).

The risk assessment includes several conservative assumptions. The estimated exposure concentrations were calculated assuming all of the copper-8-quinolinolate, present in/on stored lumber, leaches out of the wood within a relatively short period of time. In addition, the risk assessment assumes that 50% of the copper-8-quinolinolate leached will reach the aquatic environment following an average rain pattern. Given these conservative assumptions, the risks to aquatic organisms are likely overestimated. Nevertheless, mitigation measures are proposed (Appendix III) to reduce or prevent runoff of copper-8-quinolinolate from wood treatment facilities to aquatic habitats.

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 copper-8-quinolinolate to run-off from treatment facilities to aquatic habitats are followed, the antisapstain use of copper-8-quinolinolate 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, copper-8-quinolinolate is not expected to pose risks of concern to the environment. Copper-8-quinolinolate has the potential to leach from wood at treatment facilities and subsequently run-off to aquatic environments. Proposed mitigation measures include directions to prevent surface runoff water from wood freshly treated with copper-8-quinolinolate from reaching aquatic systems as well as the use of precautionary label statements identifying environmental hazards on the product labels (Appendix III).

4.2.4 Incident Reports Related to the Environment

There were no environmental incidents involving copper-8-quinolinolate in the PMRA database as of 25 November 2016. A review of US incidents in the EIIS database (1992 to 2015) was also conducted. There were no environment incidents involving copper-8-quinolinolate in the database.

5.0 Value

Copper-8-quinolinolate 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 (for example, 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.

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, copper-8-quinolinolate 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:

- Copper-8-quinolinolate does not meet TSMP Track 1 criteria, and is not considered a TSMP Track 1 substance. See Appendix II, Table 7 for comparison with Track 1 criteria.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical grade active ingredient 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:

- Copper-8-quinolinolate does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*.
- The end-use product PQ-8 Liquid Fungicide Concentrate does 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 the antisapstain use of products containing copper-8-quinolinolate 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.

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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, *List 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*.

List of Abbreviations

a.i.	active ingredient
BAF	bioaccumulation factor
BCFs	bioconcentration factor
bw	body weight
CAS	Chemical Abstracts Service
CEPA	Canadian Environmental Protection Act
cm	centimetre(s)
CO_2	carbon dioxide
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
g	gram(s)
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	octanol/water partition coefficient
L	litre(s)
LC_{50}	lethal concentration 50%
LOC	level of concern
m	meter(s)
mg	milligram(s)
mL	millilitre(s)
MOE	margin of exposure
mol	mole
N/A	not applicable
nm	nanometre(s)
NIOSH	National Institute of Occupational Safety and Health
NOAEL	no observable adverse effect level
NOEC	No Observed Effect Concentration
NOEL	No Observed Effect Level
OECD	Organisation for Economic Co-operation and Development
Pa	Pascal
PMRA	Pest Management Regulatory Agency

PPE	personal protective equipment
PRVD	Proposed Re-evaluation Decision
RQ	risk quotient
RRD	Re-evaluation Decision
s	second(s)
TCMTB	2-(thiocyanomethylthio) benzothiazole
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
wks	weeks
wt(s)	weight(s)
µg	microgram(s)
µL	microlitre(s)
µm	micrometre(s)

Appendix I

Table 1 Antisapstain Copper-8- Quinolinolate Products Currently Registered

TGAI sources		End-Use Products	
Registration #	**Product Name**	**Registration #**	**Product Name**
25882	Copper 8-Quinolinolate	12143	PQ-8 Liquid Fungicide Concentrate

Appendix II

Table 1 Summary of physicochemical properties of copper-8-quinolinolate

Compound	Type of the study	Value	Comments
Oxine-copper	Solubility	<0.07 mg/L	Insoluble in water (PMRA# 1128994)
Oxine-copper	Molecular weight	351.9 g/mol	PMRA# 1128994
Oxine-copper	Vapour Pressure	4.60×10^{-8} Pa	Non-volatile (PMRA# 1129006)
Oxine-copper	Octanol-Water Partition Coefficient, log K_{OW}	2.39	Limited potential for bioaccumulation (PMRA# 1129006)

Table 2 Fate and behaviour of copper-8-quinolinolate (oxine-copper) in the environment

Property	Test substance	Value	Transformation products	Comments	Reference
Abiotic transformation					
Hydrolysis	[^{14}C]-oxine-copper	pH 5: $t_{1/2}$ = 630 d pH 7: $t_{1/2}$ = >> 30 d pH 9: $t_{1/2}$ = >> 30 d	None	Hydrolysis is not a major route of transformation	PMRA# 1128990
Hydrolysis	Oxine-copper	pH 5: $t_{1/2}$ = > 1 year pH 7: $t_{1/2}$ = > 1 year pH 9: $t_{1/2}$ = > 1 year	Not reported	Hydrolysis is not a major route of transformation	PMRA# 1184444
Phototransformation in aqueous solution	Oxine-copper	DT_{50} (irradiated) = 60 – 96 hrs DT_{50} (dark) = stable	CO_2, a double hydroxylated quinoline	Phototransformation is an important route of transformation	PMRA# 1128991
Phototransformation in water	Oxine-copper	Distilled and sterilized water: DT_{50} = 14 d Natural water: DT_{50} = 2 d Sterilized natural water: DT_{50} = 1 d	Not reported	Phototransformation is an important route of transformation	PMRA# 1184447
Biotransformation					
Biotransformation in aerobic soil	Oxine-copper	Loamy sand (82.9% sand, 6.8% silt, 6.2% clay, 2.4% OM, pH 6.0) DT_{50}: 2 d DT_{90}: 48 d	CO_2, hydroxy-quinoline	Oxine-copper is non-persistent in soil	PMRA# 1128994
Mobility					
Adsorption (K_{OC})	Oxine-copper	Four soils (sandy clay loam, sand, two clay loams) K_{OC} = 14500	Not reported	Oxine-copper is immobile in soil	PMRA# 1184448

Property	Test substance	Value	Transformation products	Comments	Reference
Leaching					
Leaching (in lab, non-aged soils)	Oxine-copper	Four soils (sandy loam, loam, sand, loamy sand), 50.8 cm of simulated rainfall, 30 cm columns. Over 90% of the a.i. remained in the 0 – 6 cm layers of the columns	Not reported	Oxine-copper shows no tendency to leach	PMRA# 1128992
Leaching (in lab, aged soils)	Oxine-copper	Aged (3 days) loamy sand, 50.8 cm of simulated rainfall, 30 cm columns. 87.9% of the a.i. remained in the 0 – 6 cm layers of the columns, 4.3% remained in the 6 – 12 cm layer and < 0.1% remained in the 12 – 30 cm layer	Not reported	Oxine-copper shows no tendency to leach	PMRA# 1128993

Table 3 Scenarios considered for the risk assessment

Scenario	Description	Details
	Scenario for industrial preventive treatment	
	Runoff from storage of treated wood	
1	***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 copper-8-quinolinolate (oxine-copper) 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 oxine-copper leached (kg/d)[b,c]
Dipping/Immersion	110 000	700	11	14	0.06

[a]Highest deposition rate of oxine-copper from all antisapstain products currently registered by the PMRA.
[b]Amount of oxine-copper 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 copper-8-quinolinolate (oxine-copper) to non-target aquatic species

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[1]	Reference
Freshwater species					
Daphnia magna	48h-Acute	Oxine-copper	EC_{50} = 0.177 mg a.i./L	Highly toxic	PMRA# 1158751
Daphnia magna	21d-Chronic	Oxine-copper	NOEC= 0.00640 mg a.i./L		PMRA# 1129055
Rainbow trout, *Onchorhynchus mykiss*	96h-Acute	Oxine-copper	LC_{50} = 0.00894 mg a.i./L	Very highly toxic	PMRA# 1129017
Bluegill sunfish, *Lepomis macrochirus*	96h-Acute	Oxine-copper	LC_{50}= 0.0216 mg a.i./L	Very highly toxic	PMRA# 1129028
Coho salmon, *Onchorhynchus kisutch*	96h-Acute	Oxine-copper	LC_{50}= 0.0139 mg a.i./L	Very highly toxic	PMRA# 1129039
Rainbow trout, *Onchorhynchus mykiss* (early life stage)	60d-Chronic	Oxine-copper	NOEC= 0.00169 mg a.i./L		PMRA# 1129051
Fathead minnow, *Pimephales promelas* (full life cycle)	324d-Chronic	Oxine-copper	NOEC= 0.00299 mg a.i./L		PMRA# 1158997
Marine species					
Green alga, *Dunaliella tertiolecta*	120h-Acute	Oxine-copper	EC_{50}= 0.0154 mg a.i./L	Very highly toxic	PMRA# 1129007
Diatom, *Nitzschia punctata*	120h-Acute	Oxine-copper	EC_{50}= 0.00726 mg a.i./L	Very highly toxic	PMRA# 1129058
Diatom, *Skeletonema costatum*	120h-Acute	Oxine-copper	EC_{50}= 0.00220 mg a.i./L	Very highly toxic	PMRA# 1150154
Eastern oyster, *Crassostrea virginica* (embryo-larvae)	48h-Acute	Oxine-copper	EC_{50}= 0.0378 mg a.i./L	Very highly toxic	PMRA# 1129056
Mysid shrimp, *Mysidopsis bahia*	96h-Acute	Oxine-copper	LC_{50}= 0.0497 mg a.i./L	Very highly toxic	PMRA# 1129057

[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 dip/immersion							
Freshwater organisms							
Daphnia magna	1/2	48-h EC_{50}	=	0.0885	mg a.i./L	0.0023	0.026
Daphnia magna	1	21-d NOEC	=	0.0064	mg a.i./L	0.0023	0.365
Rainbow trout	1/2	96-h LC_{50}	=	0.00447	mg a.i./L	0.0023	**2.611**
Rainbow trout	1	60-d NOEC	=	0.00169	mg a.i./L	0.0023	**1.381**
Marine organism							
Marine diatom	1/2	5-d EC_{50}	=	0.0011	mg a.i./L	0.0023	**2.122**
Eastern oyster	1/2	48-h EC_{50}	=	0.0189	mg a.i./L	0.0023	0.123

[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 copper-8-quinolinolate (oxine-copper) 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 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	Copper-8-quinolinolate has a DT_{50} of 2 days in aerobic soil.
	Water	Half-life ≥ 182 days	Not available
	Sediment	Half-life ≥ 365 days	Not available
	Air	Half-life ≥ 2 days or evidence of long range transport	Copper-8-quinolinolate is non-volatile.
Bioaccumulation[4]	Log K_{ow} ≥ 5		2.39
	BCF ≥ 5000		Not available
	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 Products containing Copper-8-quinolinolate

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 copper-8-quinolinolate antisapstain 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.

PROPOSED ENVIRONMENTAL STATEMENTS

A. Environmental Label statements proposed for TGAI:

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 Product:

I) **ENVIRONMENTAL PRECAUTIONS**:

TOXIC to aquatic organisms.

II) **DIRECTIONS 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 and Animal Health

PMRA Document Number	Reference
1128979	1991, Ro 17-0099/000: 13 week oral (dietary) toxicity in the rat with the fungicide Ro-17-0099/000 (oxine-copper), DACO: 4.3.1.
1144086	1990, Ro 17-0099/000: Determination of the oral toxicity of Ro 17-0099/000 (TGAI) in the rat, DACO: 4.2.1.
1144087	1990, Ro 17-0099/000: Determination of the acute dermal toxicity of Ro 17-0099/000 (TGAI) in the rat , DACO: 4.2.2
1144088	1989, 4-hour, acute inhalation toxicity study with Ro 17-0099/000 in rats, final report, DACO: 4.2.3
1144089	1990, Primary eye irritation study with Ro 17-0099/000 (copper 8-quinolinolate) in rabbits, DACO: 4.24
1144090	1988, Primary skin irritation study with Ro 17-0099/000 in rabbits (4-hour semi-occlusive application on intact and abraded skin), DACO: 4.2.5
1144092	1988, Contact hypersensitivity to Ro 17-0099/000 in albino guinea pigs maximization test, DACO: 4.2.6
1144093	1983, A 13-week toxicity study with Ro 17-0099/000 in mice, DACO: 4.3.1
1144094	1990, Ro 17-0099/000: Oral pilot study with pyramiding doses in male and female dogs with Ro 17-0099/000, DACO: 4.3.8
1144095	1990, Ro 17-0099/000: 13-week oral toxicity study by (by capsules) on dogs with the fungicide Ro 17-0099/000, DACO: 4.3.1
1144096	1987, K37 (copper 8-hydroxyquinolate). Rabbit teratology dose range finding study, DACO: 4.5.2
1144097	1987, K37 (copper 8-hydroxyquinolate). Rabbit teratology study, DACO: 4.5.2
1144098	1989, Ro 17-0099/000: Mutagenicity evaluation of the fungicide Ro 17-0099/000 with Salmonella typhimurium (Ames test), DACO: 4.5.4
1144099	1990, Ro 17-0099/000: Micronucleus test in the mouse bone marrow in vivo after oral administration of the fungicide Ro 17-0099/000: DACO: 4.5.4
1144100	1990, Ro 17-0099/000: In vivo/in vitro rat hepatocyte DNA repair test with the fungicide Ro 17-0099/000 (oxine copper)(unscheduled DNA synthesis test), DACO: 4.5.4
1146607	1994, K37 (copper 8-quinolinolate). 80-week oral (dietary) carcinogenicity study in the mouse, DACO: 4.4.1, 4.4.2
1146608	1994, K37 (copper 8-quinolinolate). 80-week oral (dietary) carcinogenicity study in the mouse, DACO: 4.4.1, 4.4.2

1146609 1994, Technical CGA 281881 (copper 8-quinolinolate). A study of the effect on reproductive function of two generations in the rat, DACO: 4.5.1
1181166 1971, Acute oral toxicity study on rats of copper- 8-hydroxyquinolate, DACO: 4.2.1
1181167 1973, Acute dermal toxicity, rabbits, K-37, DACO: 4.2.2
1181168 1975, Acute inhalation toxicity to the rat of copper oxyquinoleate dust, DACO: 4.2.3
1181169 1973, Eye irritation study, rabbits, K-37, DACO: 4.2.4
1181172 1972, Short summary: Copper-8-hydroxyquinolate subchronic toxicity, results on subacute toxicity of copper 8-hydroxyquinoline in mice and rats, DACO: 4.3.1
1181173 1976, Two-year dietary administration in the rat, K-37; short summary: copper-8-hydroxyquinolate chronic toxicity, DACO: 4.4.1
1181174 1976, Two-year dietary toxicity study in dogs, K-37, DACO: 4.4.1
1181177 1975, A two-generation reproduction study in rats, K-37, DACO: 4.5.1
1181178 1978, Ames metabolic activation test to assess the potential mutagenic effect of copper-8-oxyquinolate, DACO: 4.5.4
1181179 1978, Micronucleus test on copper-8-oxyquinolate, DACO: 4.5.7
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