Proposed Re-evaluation Decision PRVD2016-21

Joinery Use of Tebuconazole

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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 aspects of the joinery use of tebuconazole. 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 Joinery Uses of Tebuconazole

The PMRA has completed the health risk assessment for the joinery use of tebuconazole. An environmental risk assessment was not required as the environmental exposure from the joinery use of tebuconazole is expected to be minimal. Under the authority of the *Pest Control Products Act*, the PMRA is proposing continued registration of the joinery use of tebuconazole in Canada.

An evaluation of available scientific information found that the joinery use of tebuconazole 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 joinery products containing tebuconazole, new risk-reduction measures are proposed.

This proposal affects the joinery end-use product containing tebuconazole 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 tebuconazole and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health.

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 tebuconazole.

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

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 Tebuconazole?

In Canada, there is one registered joinery wood preservative that contains tebuconazole. In addition to the joinery use, tebuconazole is also registered as an agricultural fungicide and as an active ingredient in heavy-duty wood preservatives.

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 Tebuconazole Affect Human Health?

Joinery products containing tebuconazole are unlikely to affect your health when used according to revised label directions.

Potential exposure to tebuconazole may occur through the dermal and inhalation routes, when workers are handling and applying joinery products containing tebuconazole or when 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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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".

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, tebuconazole was of slight acute oral toxicity, low acute dermal toxicity and low acute toxicity by the inhalation route of exposure. It was minimally 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 tebuconazole to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints for risk assessment included effects on the liver, spleen and adrenals across the species tested, and the eyes in dogs. Tebuconazole is a reproductive toxicant in the presence of maternal toxicity. In developmental toxicity studies, malformations occurred at maternally toxic doses. 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 tebuconazole 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 required as a result of the ERP for Antisapstain Chemicals (see Section 3.4.3 of the science evaluation), health risk estimates associated with mixing, loading, and applying and during handling of treated joinery products exceeded target dermal margins of exposure 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 is not anticipated as 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.

Environmental Considerations

The use of tebuconazole for joinery is not expected to pose risks of concern to the environment.

Joinery comprises of wood products that have been machined or milled, such as window frames or doors. Closed systems are used to apply antisapstain products to joinery and the treatment process, including the drying of wood after application, occurs indoors (in a roofed facility). Thus, treated joinery is protected from exposure to precipitation and the potential for environmental exposure is minimal. Treated wood joinery products are not subject to significant leaching when in use. Any leaching of joinery preservative that does occur, should be limited to the area around the building in which they were installed. Because of this use pattern, environmental exposure is expected to be minimal. Therefore, due to limited environmental exposure, no quantitative environmental risk assessment was conducted for the joinery use of tebuconazole.

Value Considerations

What is the Value of Tebuconazole in Joinery Treatment?

Tebuconazole is one of five active ingredients currently registered in Canada for use in joinery products. Joinery products are wood preservatives used to treat wood 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 tebuconazole 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 joinery use of tebuconazole, the PMRA is proposing further risk-reduction measures in addition to those already identified on tebuconazole joinery product labels.

Additional Key Risk Reduction Measures

Human Health

To protect workers, additional general hygiene statements and personal protective equipment are required on all tebuconazole joinery product labels conforming to the Exposure Reduction Program.

Environment

Precautionary label statements and disposal statements are required.

Next Steps

Before making a final re-evaluation decision on the joinery use of tebuconazole, 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 tebuconazole. 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

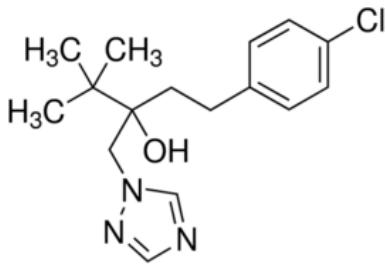
As an active ingredient in antimicrobial products, tebuconazole is registered as a component of one joinery/millwork product. Tebuconazole interferes with ergosterol biosysthesis, disrupting fungal cell membrane formation, leading to cell death.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

A review of the chemistry for tebuconazole was previously published in REG2006-11.

Currently, a review of the chemistry database for tebuconazole is being conducted as part of the cyclical re-evaluation of the agricultural and wood preservative uses of tebuconazole. As such, impurities 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, will be re-assessed during the cyclical re-evaluation.

2.1 Identity of the Technical Grade Active Ingredient

Common Name		Tebuconazole
Function		Fungicide
Chemical Name		
1	**International Union of Pure and Applied Chemistry (IUPAC)**	(RS)-1-p-chlorophenyl-4,4-dimethyl-3-(1*H*-1,2,4-triazol-1-ylmethyl)pentan-3-ol
2	**Chemical Abstracts Service (CAS)**	(±)-α-[2-(4-chlorophenyl)ethyl]-α-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol
CAS Registry Number		107534-96-3
Molecular Formula		$C_{16}H_{22}ClN_3O$
Structural Formula		
Molecular Weight		307.81

Nominal Purity of the Technical Grade Active Ingredient (%)	Nominal purity of active 95% (limits: 93–99.9%)

2.2 Physical and Chemical Properties

Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure at 20°C	1.3×10^{-6} Pa
Ultraviolet (UV)/visible spectrum	Maximum at 220.8 nm in acetonitrile-buffer, at pH 4, 7 and 9. No absorbency at $\lambda > 300$ nm.
Solubility in water at 20°C	32 mg/L
n-Octanol/water partition coefficient	$K_{ow} = 5000$ $\log K_{ow} = 3.70$

2.3 Description of Registered Tebuconazole Uses

Appendix I lists the joinery product containing tebuconazole that is registered under the authority of the *Pest Control Products Act*.

Currently, there is one source of technical grade active ingredient and one joinery end use product registered with tebuconazole. The end use product also contains iodocarb and propiconazole as co-biocides. Joinery products may be applied by dipping, spraying, double vacuum treatment or flow/flood coating. Tebuconazole has been shown to be an effective joinery preservative.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A review of the toxicity studies conducted with tebuconazole was previously published in REG2006-11.

Following oral administration to rats, tebuconazole was rapidly absorbed from the gastrointestinal tract and accumulated in the bile from where it was re-introduced into the intestines to be eliminated via the feces. Excretion via the urine was also significant. Very little remained in the plasma for distribution to the organs and tissues. Tebuconazole was completely metabolized within 48-72 h to an alcohol and an acid. The alcohol was conjugated to give a sulphate and a glucuronide and was further converted to a triol, while the acid was changed to a keto-acid. Tebuconazole was also cleaved to give free triazole as a minor metabolite in the urine.

Tebuconazole is of slight acute toxicity via the oral route of exposure in rats and mice, and of low toxicity via the dermal and inhalation routes of exposure in rats. It is minimally irritating to the eyes of rabbits, non-irritating to rabbit skin and was not a dermal sensitizer in guinea pigs. Clinical signs of neurotoxicity were observed at high doses in the acute oral studies.

In subchronic and chronic studies on laboratory animals, the primary targets were the liver, spleen and adrenals across the species tested, and the eyes in dogs. Effects in rats and mice included increases in liver weight, enzyme activities, and plasma triglyceride concentrations as well as histopathological effects (lipid accumulation) and effects on the adrenals (vacuole formation, enlarged cells). In dogs, in addition to effects on liver, spleen and adrenals, cataracts and degeneration of the lens were noted in the eye.

There was evidence of increased sensitivity of the young in the reproductive toxicity, developmental toxicity and developmental neurotoxicity studies. In the reproductive toxicity study, effects noted in offspring (decreased pup viability and lactation indices, birth weight of pups) were considered more severe than those observed in parental animals. In the rat developmental toxicity study, increased resorptions, a decrease in the number of live fetuses, reduced fetal weight, and increased incidences of visceral and skeletal variations, occurred at a dose that also caused maternal toxicity. In the mouse and rabbit developmental toxicity studies, malformations were observed at doses that elicited maternal toxicity. A dermal study in rats showed no signs of maternal toxicity or developmental effects at the limit dose of 1000 mg/kg bw/day. In the dermal developmental toxicity studies in mice, increased skeletal variations occurred in the presence of less severe toxic effects in maternal animals. In the developmental neurotoxicity (DNT) study, increased duration of gestation, decreased total number of pups born, reduced gestation and viability indices, increased number of stillborn pups, decreased pre-weaning pup body weight, delayed eye opening and decreased brain weights were observed in the presence of maternal toxicity.

There was no evidence of carcinogenicity in rats after longer-term dosing. However, increased hepatocellular adenomas and carcinomas were observed in mice at the highest dose tested in the long-term carcinogenicity study. The proposed mode of action was considered acceptable and a threshold approach was used to assess cancer risk. Tebuconazole was not genotoxic.

Tebuconazole was not considered to be a neurotoxicant and there were no effects on the immune or endocrine systems.

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* (PCPA) 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, extensive data were available for tebuconazole including developmental toxicity studies in mice, rats and rabbits, a 2-generation rat reproductive toxicity study and a rat developmental neurotoxicity study. With respect to

identified concerns relevant to the assessment of risk to infants and children, sensitivity of the young was identified in the developmental toxicity studies across all species tested, as well as in the reproductive toxicity and DNT studies.

In the 2-generation reproductive toxicity study, effects noted in offspring (decreased pup viability and lactation indices, birth weight of pups) were considered more severe than those observed in parental animals.

In the rat developmental toxicity study, there was evidence of developmental toxicity, including increased resorptions, a decrease in the number of live fetuses, reduced fetal weight, and increased incidences of visceral and skeletal variations, at a dose that also caused maternal toxicity. In the mouse and rabbit developmental toxicity studies, serious malformations were observed at doses that elicited maternal toxicity.

In the dermal developmental toxicity studies in mice, increased skeletal variations occurred in the presence of less severe toxic effects in maternal animals. In the DNT study, increased duration of gestation, decreased total number of pups born, reduced gestation and viability indices, increased number of stillborn pups, decreased pre-weaning pup body weight, delayed eye opening and decreased brain weights were observed in the presence of maternal toxicity.

Overall, the database is adequate for determining the sensitivity of the young and effects on the young are well-characterized. The effects observed in the mouse and rabbit developmental toxicity studies are serious endpoints, although the degree of concern is tempered by accompanying maternal toxicity. The PCPA factor would be reduced to 3-fold if malformations from developmental toxicity studies were used to establish the point of departure. However, since the point of departure used in the joinery risk assessment is lower than that for developmental malformations, the PCPA factor was reduced to 1-fold for this scenario.

3.2 Determination of Acceptable Daily Intake

Not applicable for joinery use.

3.3 Determination of Acute Reference Dose

Not applicable for joinery 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 tebuconazole 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 NOAEL of 2.96 mg/kg bw/day from a 1-year dietary study in dogs was selected for use in risk assessment. In this study, long-term dietary exposure resulted in increased hypertrophy in the adrenal zona fasciculata and fatty vacuoles in the adrenal zona glomerulosa cells. 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 a margin of 824-fold to the NOAEL for offspring toxicity in the rat reproduction study, a margin of 338-fold to the NOAEL for developmental effects in the mouse developmental toxicity study, a margin of 1014-fold to the NOAEL for developmental effects in the rabbit developmental toxicity study and a margin in excess of 9000-fold to the dose for hepatocellular adenomas and carcinomas in mice, thus addressing any concerns noted in the PCPA 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 Tebuconazole

Exposure Scenario	Study	Point of Departure and Endpoint	Target MOE
Long-Term Dermal	1-year dietary study in the dog	NOAEL = 2.96 mg/kg bw/day ↑ hypertrophy in the adrenal zona fasciculata, fatty vacuoles in the adrenal zona glomerulosa cells	100
Cancer Assessment	Threshold approach for cancer risk assessment.		

3.4.2 Dermal Absorption

The estimated dermal absorption is based on a chemical-specific in vivo rat dermal absorption study. A dermal absorption value of 25% was used in estimating the systemic dose from dermal exposure of tebuconazole for the risk assessment.

3.4.3 Occupational Exposure and Risk Assessment

Workers can be exposed to the chemical tebuconazole 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 personal protective equipment, 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.

3.4.3.1 Occupational Joinery Exposure and Risk Assessment

Workers can be exposed to tebuconazole 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, and 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 joinery products containing tebuconazole 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 II.

Table 3.4.3.1 Tebuconazole Exposure Assessment for Sawmill Workers Exposed to Joinery Products.

Tasks	Unit Exposure (µg / mg/mL)	Max Rate [1] (mg/mL)	Daily Exposure [2] (mg/kg bw/day)	MOE [3]
SIG Phase IV				
Pilers	493.7	1.69	0.002607	1135
Clean-up Crew	203.1	1.69	0.001073	2760
Maintenance Workers	401.4	1.69	0.002120	1396

MOE = Margin of exposure

[1] The maximum treatment solution rate of all tebuconazole products is shown as the most conservative scenario.

[2] Daily Exposure = Unit Exposure (µg/mg/mL) * Rate * Dermal Absorption (25%) / Body Weight (80 kg)

[3] Dermal MOEs are based on an oral NOAEL of 2.96 mg/kg bw/day. Target MOE is 100. MOE = NOAEL / Daily Exposure.

3.4.4 Postapplication Worker Exposure and Risk Assessment

Postapplication exposure is not anticipated, as 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. Significant human post application 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.

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 joinery products for tebuconazole. Residential exposure to individuals contacting wood treated with tebuconazole for joinery use is not expected to result in health risks of concern.

3.4.6 Bystander Exposure

Bystander exposure is not anticipated, as tebuconazole containing joinery products are 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 treated wood or joinery products.

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 26 October 2016, 21 human and 12 domestic animal incident reports involving tebuconazole have been submitted to the PMRA. For those human incidents in which the symptoms were evaluated as having some association with the reported exposure, the effects were minor. In most cases, the product was spilled onto skin or splashed into eyes. Skin and eye irritation were reported most frequently. The domestic animal incident reports often did not include details regarding how the animals were exposed. Dogs were most frequently affected. Symptoms included vomiting, lethargy and ataxia. None of the tebuconazole incidents involved a joinery use product.

These incident reports were considered in this evaluation and did not affect the risk assessment. No label changes resulting from these incident reports are considered necessary at this time.

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 tebuconazole joinery products, and residential exposure to joinery-type products is anticipated to be minimal, a cumulative assessment is not required for this use.

4.0 Impact on the Environment

Joinery comprises of wood products that have been machined or milled, such as window frames or doors. Closed systems are used to apply antisapstain products to joinery and the treatment process, including the drying of wood after application, occurs indoors (in a roofed facility). Thus, treated joinery is protected from exposure to precipitation and the potential for environmental exposure is minimal. Treated wood joinery products are not subject to significant leaching when in use. 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 tebuconazole.

4.2 Environmental Risk Characterization

The use pattern indicates that the exposure of environmental compartments (soil, aquatic systems and food sources for birds and mammals) to tebuconazole will be minimal. Therefore expected environmental concentrations were not calculated and a quantitative risk assessment was not conducted.

4.2.1 Risks to Terrestrial Organisms

Due to the use pattern, the potential exposure of terrestrial non-target organisms is not expected to be significant. Therefore, the risk to terrestrail organisms is expected to be negligible.

4.2.2 Risks to Aquatic Organisms

Due to the limited outdoor use, exposure of aquatic habitats is expected to be minimal. Therefore, the risk to aquatic organisms is expected to be negligible.

4.3 Overall Conclusion

The use of tebuconazole for joinery is not expected to pose risks of concern to the environment.

5.0 Value

Tebuconazole has value as one of several joinery active ingredients that are options 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, 1999*].

Tebuconazole and its transformation products will be assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria during the cyclical re-evaluation of the agricultural and remedial wood preservative uses of tebuconazole.

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).

Formulants of health or environmental concern identified in the *Canada Gazette* will be identified during the cyclical re-evaluation of the agricultural and remedial wood preservative uses of tebuconazole.

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

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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*.

7.0 Proposed Re-evaluation Decision

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

List of Abbreviations

ai	active ingredient
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetre(s)
d	day(s)
DACO	data code
DDAC	didecyldimethylammonium chloride
DIR	Directive
DNA	deoxyribonucleic acid
DNT	Developmental neurotoxicity study
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
g	gram(s)
h	hectare(s)
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
L	litre(s)
LOC	level of concern
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
m	meter(s)
mg	milligram(s)
mL	millilitre
MOE	margin of exposure
MRID	Master Record Identification Number
N/A	not applicable
NIOSH	National Institute for Occupational Safety and Health
NMRI	Naval Medical Research Institute
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOI	Notice of Intent
PCPA	Pest Control Products Act
ppb	parts per billion
PMRA	Pest Management Regulatory Agency
PRVD	Proposed re-evaluation decision
ppm	parts per million
REG	Regulatory Note
RRD	Re-evaluation Decision

RQ	risk quotient
s	second(s)
SIG	Sapstain Industry Group
TCMTB	2-(thiocyanomethylthio) benzothiazole
TGAI	technical grade active ingredient
TSC	treatment solution concentration
TSMP	Toxic Substances Management Policy
UV	ultraviolet
wt(s)	weight(s)
µg	microgram
µL	microlitre

Appendix I

Table 1 Joinery Tebuconazole Products Currently Registered

Active	Technical Grade Active Ingredient Sources		End-use Products	
	Registration Number	Product Name	Registration Number	Product Name
Tebuconazole	29409	Preventol A8 Technical Fungicide	30584	Woodlife 111 Water Repellent Wood Preservative

Appendix II Label Statements Proposed for Joinery Products containing Tebuconazole

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 the tebuconazole joinery product label. The following statements are proposed to be included in a section entitled **PRECAUTIONS** to the appropriate labels:

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 during clean-up, maintenance and repair activities and when opening pressure treatment cylinder doors.
- Use a NIOSH-respirator if the area is not well ventilated.
- 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 technical grade active ingredient: Preventol A8 Technical Fungicide

I) **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 Woodlife 111 Water Repellent Wood Preservative:

I) **ENVIRONMENTAL PRECAUTIONS**:

This product contains active ingredients and aromatic petroleum distillates which are 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.

III) **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
1038102	1990, Dermal sensitization study with technical grade tebuconazole (Folicur) in guinea pigs, DACO: 4.2.6
1038104	1989, HWG 1608 - symmetric isomer (c.n. tebuconazole [proposed]): Study for acute interpersonal toxicity in rats, DACO: 4.2.9
1038105	1992, Acute oral toxicity study with HWG 2443, a metabolite of tebuconazole (Folicur), in female rats, DACO: 4.2.9
1038106	1992, Acute oral toxicity study with HWG 2061 (a metabolite of tebuconazole, Folicur) in female rats, DACO: 4.2.9
1038113	1990, HWG 1608: (proposed c.n. : tebuconazole) Subacute inhalation toxicity to cats - study for cataracts. report # 100649. 223 pages. , DACO: 4.3.8
1038119	1995, Limit test of embryo toxicity (including teratogenicity) with HWG 1608 technical (c.n. tebuconazole) in the rat (dermal application), DACO: 4.5.2
1038120 - 1038123	1995, HWG 1608 technical (c.n. tebuconazole) Embryotoxicity study (including teratogenicity) and supplementary embryo toxicity study (including teratogenicity) in the mouse, DACO: 4.5.2
1038126, 1038127	1995, HWG 1608 technical (c.n. tebuconazole) Embryotoxicity study (including teratogenicity) and supplementary investigation on the maternal toxicity in pregnant rabbits, DACO: 4.5.3
1038131, 1038132	1998, A subchronic dietary neurotoxicity screening study with technical grade tebuconazole in Fischer 344 rats, DACO: 4.5.11
1038133, 1038134	1997, An acute oral neurotoxicity screening study with technical grade tebuconazole (Folicur) in Fischer 344 rats, DACO: 4.5.12
1038135	1997 (suppl. 1998), An acute oral neurotoxicity screening study with technical grade tebuconazole (Folicur) in Fischer 344 rats, DACO: 4.5.12
1038136 - 1038141	2000, Developmental neurotoxicity study of technical grade tebuconazole administered orally via diet to Crl:CD®BR VAF/Plus presumed pregnant rats, DACO: 4.5.12
1038142 - 1038150	2000 (suppl. 2002), Developmental neurotoxicity study of technical grade tebuconazole administered orally via diet to Crl:CD®BR VAF/Plus presumed pregnant rats, DACO: 4.5.12
1038156	1999, HWG 1608: (c.n. tebuconazole) Mechanistic study on embryotoxic effects in rabbits after oral administration, DACO: 4.8
1136271	1989 (suppl. 1992), Safety evaluation of HWG 1608: Chronic (1 year) feeding study in dogs. Supplemental submission to EPA MRID#420306-01, DACO: 4.4.1
1136272	1989, Safety evaluation of HWG 1608: Chronic (1 year) feeding study in dogs, DACO: 4.4.1

1145289 1988, Folicur (HWG 1608); Chronic toxicity and carcinogenicity in Wistar rats (Administered in diet over a period of 2 years) (pages 403-438 only), DACO: 4.4.1

1145336 1991, Supplemental submission to: HWG 1608 Subchronic toxicological study with rats feeding for thirteen weeks, DACO: 4.3.1

1145366 1986, HWG 1608 Subchronic toxicological study with rats feeding for thirteen weeks, DACO: 4.3.1

1145377 1987, HWG 1608 Subchronic study to dogs with oral administration (Thirteen week feeding study), DACO: 4.3.1

1145388 1987, HWG 1608 Study of chronic toxicity to dogs after oral administration (Twelve-month feeding study), DACO: 4.3.1

1145664 1988, Embryotoxicity study (including teratogenicity) with HWG 1608 technical in the rat, DACO: 4.5.2

1145665 1990, Embryotoxicity study (including teratrogenicity) with HWG 1608 technical in the mouse (dermal application), DACO: 4.5.2

1145666 1988 (suppl. 1991), HWG 1608 Toxic dose range carcinogenicity study in NMRI mice (supplement to Study T 6018953 - Carcinogenicity in NMRI mice with administration in diet over a 21-month period), DACO: 4.4.2

1145676, 2503134, 2504380 1991, Acute oral toxicity study with Folicur 3.6 F in rats + confidential attachment (tebuconazole/raxil), DACO: 4.2.1

1145677, 2503133, 2504381 1991, Acute dermal toxicity study with Folicur 3.6 F in rats + confidential attachment (tebuconazole/raxil), DACO: 4.2.2

1145678, 2503137, 2504382 1991, Acute four-hour inhalation with Folicur 3.6 F in rats + confidential attachment (tebuconazole/raxil), DACO: 4.2.3

1145679, 2503131, 2504383 1991, Primary eye irritation with Folicur 3.6 F in rabbits + confidential attachment (tebuconazole/raxil), DACO: 4.2.4

1145680, 2503132, 2504384 1991, Primary dermal irritation study with Folicur 3.6 F in rabbits + confidential attachment (tebuconazole/raxil), DACO: 4.2.5

1145681, 2503135, 2504385 1991, Dermal sensitization study with Folicur 3.6 F in guinea pigs + confidential attachment (tebuconazole raxil), DACO: 4.2.6

1145682 1988, Supplemental submission to EPA MRID 4821501: HWG 1608 Study of embryotoxic effects on mice after oral administration, DACO: 4.5.2

1184330 1988, Properties and safety assessment of "triazolyl alanine", DACO: 4.1, 6.2, 6.3, 7.1, 9.1

1184331 1989, A review of the environmental fate of 1,2,4-triazole, DACO: 4.1, 7.1, 8.1, 9.1

1524821 2007, A human relevance analysis of information on a proposed carcinogenic mode of action for liver tumors in mice following lifetime dietary exposure to tebuconazole, DACO: 4.8

1908885 2004, Summary of acute toxicity studies submitted in support of registration of tebuconazole technical, DACO: 4.1

1908888 2004, Acute oral toxicity study of tebuconazole technical in rats, DACO: 4.2.1

1908891 2004, Acute dermal toxicity study of tebuconazole technical in rats, DACO: 4.2.2

1908895 2004, Acute eye irritation study of tebuconazole technical in rabbits, DACO: 4.2.4

1908896 2004, Acute dermal irritation study of tebuconazole technical in rabbits, DACO: 4.2.5

1908897 2004, Skin sensitization study of tebuconazole technical in guinea pigs (guinea pig maximization test) , DACO: 4.2.6

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2250370 2012, Tebuconazole 28-day liver mechanistic study in the male and female mice by dietary administration (liver enzyme activity and gene transcript investigation), DACO: 4.8

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2250378 2012, Tebuconazole Evaluation in the immature rat Uterotrophic assay, DACO: 4.8

2250379 2011, Tebuconazole: Evaluation in the in vitro (hela-9903) estrogen receptor transcriptional activation assay, DACO: 4.8

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1038100 1983, HWG 1608 Study for acute toxicity, DACO: 4.2.1

1038101 1987, HWG 1608 technical Study of skin sensitization effect on guinea pigs (Buehler patch test), DACO: 4.2.6

1038103 1991, HWG 1608 technical Acute oral toxicity study on mice (study no. 91A 017), DACO: 4.2.9

1038111 1987, HWG 1608 Subchronic study to dogs with oral administration (thirteen week feeding study)(suppl.), DACO: 4.3.8

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1038118 1988 (suppl. 1993), Folicur (HWG 1608); Chronic toxicity and carcinogenicity in Wistar rate (administration in diet over a period of 2 years)(suppl.), DACO: 4.4.4

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1038125 1988, HWG 1608 Study of embryotoxic effects on mice after oral administration (suppl.). Report # 97411-5, DACO: 4.5.2
1038128 1991, HWG 1608 Reverse mutation assay (Salmonella typhimurium and Escherichia coli) Study no. 91A015, DACO: 4.5.4
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1038130 1992, HWG 1608 Rec-assay with spores in the bacterial system Study no. 91A037, DACO: 4.5.8
1038158 1987, HWG 1608 Supplementary study for maternal toxicity on mice following oral administration, DACO: 4.8
1145300 1987 (suppl. 1990), HWG 1608 Two-generation study in rats (suppl.) , DACO: 4.5.1
1145301 1988 (suppl. 1990), HWG 1608 Study of embryotoxic effects on mice after oral administration (suppl.), DACO: 4.5.2
1145302 1988 (suppl. 1990), HWG 1608 study for cancerogenicity in NMRI mice (suppl.), DACO: 4.4.2
1145303 1988 (suppl. 1990), HWG 1608 study for chronic toxicity and cancerogenicity in Wistar rats (suppl.), DACO: 4.4.2
1149732 1989 (suppl. 1993), Safety evaluation of HWG 1608: Chronic (1 year) feeding study in dogs (suppl.), DACO: 4.4.1
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1229422 1983, HWG 1608 Study for acute toxicity, DACO: 4.1
1229423 1983, HWG 1608 Acute toxicity to the dog after oral administration, DACO: 4.2.1
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1229425 1988, HWG 1608 Study for acute inhalation toxicity to the rat, DACO: 4.2.3
1229426 1988, Primary eye irritation of Folicur (HWG 1608) technical in albino rabbits, DACO: 4.2.3
1229428 1987, HWG 1608 technical Study of skin sensitization effect on guinea pigs (Buehler patch test), DACO: 4.2.6
1229432 1986, HWG 1608 Subchronic toxicological study with rats feeding for thirteen weeks, DACO: 4.3.1
1229474 1988, HWG 1608 Salmonella/microsome test to evaluate for point mutagenic effects, DACO: 4.5.4

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1230727 1988 (suppl. 1990), HWG 1608 Study of embryotoxic effects on mice after oral administration (suppl.), DACO: 4.5.2
1230729 1988 (suppl. 1990), HWG 1608 Study for embryotoxic effects on rats after dermal administration (suppl.), DACO: 4.5.2
1230730 1988 (suppl. 1990), HWG 1608 Study for carcinogenicity in NMRI mice (Administration in diet for up to twenty-one months)(suppl.), DACO: 4.4.2
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1726847 DACO: 5.6(A) Post Application: Passive Dosimetry Data Agricultural
881929 DACO: 5.8 Dermal Absorption (in vivo)
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1701054 Tebuconazole toxicology

B. ADDITIONAL INFORMATION CONSIDERED

i) Published Information

PMRA #	Reference
1417830	Canada 2006, Regulatory Note, Tebuconazole. REG2006-11