Re-evaluation Decision RVD2012-02

# Propiconazole

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# Table of Contents


Re-evaluation Decision ..... 1
What Does Health Canada Consider When Making a Re-evaluation Decision? ..... 1
What Is Propiconazole? ..... 2
Health Considerations ..... 3
Environmental Considerations ..... 5
Measures to Minimize Risk ..... 6
Other Information ..... 7
Appendix I Comments and Responses ..... 9
Appendix II Label Amendments for Products Containing Propiconazole ..... 15
References ..... 21

## Re-evaluation Decision

After a re-evaluation of the agricultural, turf and remedial wood preservative uses of the fungicide propiconazole, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing propiconazole for sale and use in Canada.

An evaluation of available scientific information found that products containing propiconazole do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of propiconazole uses, new risk-reduction measures must be included on the labels of all products. No additional data are required at this time.

The regulatory approach for the re-evaluation of propiconazole was first presented in Proposed Re-evaluation Decision PRVD2011-02, *Propiconazole*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of propiconazole as well as summarizes the Agency's decision and the reasons for it. Comments received during the consultation process did not result in substantial changes to the proposed regulatory decision as described in the PRVD, and Appendix I summarizes the comments and provides the PMRA's response. This decision is consistent with the proposed re-evaluation decision stated in PRVD2011-02. To comply with this decision, registrants of products containing propiconazole will be informed of the specific requirements affecting their product registration(s).

## What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

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

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

Propiconazole, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency Reregistration Eligibility Decision documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of propiconazole. In this decision, the PMRA took into account the Canadian use pattern and issues (such as the federal Toxic Substances Management Policy).

The United States Environmental Protection Agency re-evaluated propiconazole and published its conclusions in a 2006 Reregistration Eligibility Decision.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2011-02, *Propiconazole*.

## What Is Propiconazole?

Propiconazole is a triazole-based fungicide that is used to control fungi in agriculture (food/feed and non-food/non-feed crops), on turf and wood. The mode of action is by inhibition of fungal ergosterol biosynthesis that is essential for cell wall formation. Propiconazole is applied using aerial, ground boom, airblast or handheld equipment, by farm workers or professional applicators. Greenhouse uses are not specified on current propiconazole labels. Homeowners can apply propiconazole using a brush for remedial wood treatment.

## Health Considerations

### Can Approved Uses of Propiconazole Affect Human Health?

**Additional risk-reduction measures are required on propiconazole labels. Propiconazole is unlikely to affect your health when used according to the revised label directions.**

People could be exposed to propiconazole through consumption of food and water, working as a mixer/loader/applicator, by entering treated sites or through non-occupational exposure at golf courses and pick your own operations (such as commercial farm orchards that allow public access for harvesting fruits or vegetables). The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

### Residues in Water and Food

**Dietary risks from food and water are not of concern.**

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Dietary exposure to propiconazole was estimated for the most highly exposed subpopulations (children 1-2 years old and females 13-49 years old). The aggregate acute and chronic exposure estimates represented between 11% and 46% of the reference doses; thus, are below the PMRA's level of concern.

### Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Propiconazole is currently registered in Canada for use on a variety of food/feed crops and could be used in other countries on crops that are imported into Canada. MRLs are currently established on registered domestic and import agricultural uses and published in Health Canada's List of MRLs Regulated under the *Pest Control Products Act* on the Maximum Residue Limits for Pesticides webpage. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL will be implemented in the future, as indicated in the December 2009 Information Note, *Progress on Minimizing Reliance on the 0.1 Parts per Million as a General Maximum Residue Limit for Food Pesticide Residue*. No MRLs were modified during the course of this re-evaluation.

**Triazole metabolites**

Dietary exposure to triazolyl-1-alanine and triazolyl-1-acetic acid may occur from the use of propiconazole on food commodities. Residues of triazolyl-1-alanine in plant commodities are regulated in Canada not to exceed 2.0 ppm. These metabolites are common to all triazole fungicides, including propiconazole. The cumulative risks from triazolyl-1-alanine and triazolyl-1-acetic acid will be addressed in a separate document.

**Risks in Residential and other Non-Occupational Environments**

**The two registered products for residential use are being discontinued due to risk concerns. Other non-occupational scenarios were not of concern.**

There is currently one registered residential use of propiconazole for remedial wood treatment. A quantitative assessment of the potential risk to residential handlers applying the ready-to-use domestic product by brush was conducted. The resulting dermal margins of exposure (MOEs) were below the target MOE, and therefore represented a risk of concern for the PMRA. The registration of the two affected domestic end-use products will be discontinued.

A quantitative assessment of the potential risk of exposure incurred by the public at Pick-Your-Own operations or at public golf courses was conducted to ensure that there was no risk of concern for the public from acute exposure to propiconazole. Aggregate exposure estimates were calculated to determine the risk of exposure for the public from all known potential sources: diet, drinking water and non-occupational exposure events. The combined exposures of diet, drinking water and golfing or Pick-Your-Own activities resulted in MOEs greater than the target MOE and are not of concern.

### Occupational Risks from Handling Propiconazole

**Occupational mixer/loader/applicator risks are not of concern when used according to the revised label directions.**

Quantitative assessments for workers handling propiconazole for agricultural, turf or remedial wood treatment in mushroom houses were conducted. Dermal and inhalation MOEs for all scenarios were above the target MOE, with the implementation of mitigation measures, except for use of a high pressure sprayer in mushroom houses. Overall, additional personal protective equipment is required for workers handling more than 78 kg propiconazole per day for turf uses (such as for use on commercial turf farms), and the use of high pressure sprayers for remedial wood treatment in mushroom houses is prohibited.

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

Postapplication occupational risk assessments were conducted to estimate exposures to workers entering treated sites based on the current product label directions for use. Occupational postapplication dermal MOEs were above the target MOE for all scenarios, and are not of concern when the required protective measures are followed. Restricted-entry intervals (REIs) are required for detasseling and hand harvesting corn, and for hand pruning highbush blueberries. The minimum 12-hour REI is required for the remaining scenarios and uses. Postapplication exposure is not of concern for golf course workers, and a standard label statement is required for workers to wait until the area is dry before re-entry.

## Environmental Considerations

### What Happens When Propiconazole is Introduced Into the Environment?

**Additional risk-reduction measures are required on propiconazole labels. Propiconazole is unlikely to affect non-target organisms when used according to the revised label directions.**

Propiconazole enters the terrestrial environment when it is used as a fungicide on a variety of crops and on golf courses. In the terrestrial environment, propiconazole is expected to be slightly persistent to persistent. Biotransformation is an important route of transformation for propiconazole with major transformation products being 1,2,4-triazole and compounds hydoxylated at the dioxolane moiety. Phototransformation on soil or in air is not expected to be an important route of transformation for propiconazole. Propiconazole appears to have medium to low mobility in soil. An assessment of leaching potential based on a variety of criteria indicates that propiconazole has the potential to reach ground water through leaching, especially in soils with low organic matter contents. Available field studies indicate that propiconazole is typically detected in the upper soil layers, but the transformation products were detected deeper in the soil profile.

Propiconazole can enter the aquatic environment through spray drift and runoff. Propiconazole is very soluble in water, and appears to phototransform slowly and to be stable to hydrolysis. In the aquatic environment, propiconazole is expected to be moderately persistent to persistent. Biotransformation is an important route of transformation with major transformation products being two compounds hydroxylated at the dioxolane moiety. Propiconazole partitions from water to soil or sediment quickly, where it is expected to be persistent under anaerobic conditions. Therefore, propiconazole may contaminate aquatic ecosystems through off-site runoff under heavy rainfall when soil erosion occurs. Limited water monitoring information indicates that propiconazole is detected but with a low detection frequency. Propiconazole depurates rapidly, thus bioaccumulation is not expected to be a major concern for propiconazole.

## Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of propiconazole, the PMRA is requiring further risk-reduction measures for product labels.

**Human Health**

- Additional protective equipment to protect mixers/loaders/applicators.
- Restricted-entry intervals to protect workers re-entering treated sites.
- Prohibition of the use of high pressure sprayers for remedial wood preservative uses in mushroom houses.
- Discontinuation of the domestic ready-to-use remedial wood preservative products.
- Additional label statements regarding the use of propiconazole in greenhouses and around residential areas.

**Environment**

- Risks of propiconazole to non-target terrestrial plants and aquatic organisms are identified. The risks to non-target beneficial insects vary depending on the end-use product being used. Appropriate hazard/precautionary statements are required.
- Spray buffer zones are required to mitigate the risks identified for non-target terrestrial plants and aquatic organisms resulting from spray drift.
- Runoff or discharge of propiconazole to aquatic environments should be avoided and hazard/precautionary statements are required.
- Propiconazole poses a potential risk of groundwater contamination in certain soils. A precautionary groundwater leaching statement is required.
- A standard label statement to minimize surface water contamination by effluent water is required for all products registered for use on cranberries.

Appendix II lists all required label amendments.

## Other Information

Any person may file a notice of objection[3] regarding this decision on propiconazole within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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

# Appendix I Comments and Responses

## 1.0 Comment on Operator Exposure

The PMRA is requiring additional personal protective equipment for workers handling greater than 78 kg of propiconazole per day for use on turf. This amount is significantly greater than what is typically handled per day and does not reflect even the most extreme exposure conditions as outlined in the PRVD. Consequently, stating this threshold value is not required to achieve an acceptable level of worker exposure to propiconazole during use on turf, therefore this statement should not be required on the label.

**Response**

As noted in PRVD2011-02, mixer/loader/applicator exposure was assessed for workers applying propiconazole to turf at a maximum application rate of 3.2 kg a.i./ha. The risk assessment assumed that workers wore a single layer plus chemical-resistant gloves and could treat up to 30 hectares per day. Based on these values, the combined dermal and inhalation MOE was 813 (less than the target MOE of 1000). However, when these workers were assessed wearing coveralls over a single layer plus chemical-resistant gloves, the MOE was 1007 and therefore, not of concern. The turf assessment was further refined to determine the amount of propiconazole handled per day that would result in an acceptable margin of exposure without coveralls. For workers wearing a single layer plus chemical-resistant gloves and assuming a maximum amount handled of 78 kg a.i. per day, the combined dermal and inhalation MOE was 1000 and not of concern.

However, the assumption that 30 hectares are treated per day is applicable specifically to sod farms. Whereas for golf courses the default assumption used by the PMRA is 16 hectares. Therefore, based on an area treated per day of 16 hectares for workers wearing a single layer and chemical-resistant gloves while mixing/loading/applying liquid propiconazole to golf course turf using ground boom equipment at the maximum application rate of 3.2 kg a.i./ha, the MOE is 1520 and not of concern. Based on this, the statement requiring additional personal protective equipment for workers handling greater than 78 kg of propiconazole per day for use on turf is only required for Reg. No. 29295, registered for use on commercial turf farms, as follows:

For commercial turf farm workers handling greater than [X Litres of "Product Name"] (equivalent to 78 kg propiconazole) per day: Wear coveralls over long pants, a long sleeve shirt, shoes and socks and chemical-resistant gloves during mixing/loading/application, clean-up and repair activities.

## 2.0 Comment on the aRfD

The PMRA has retained the 10X PCPA factor for both the aRfD and the ADI. Based on the data, the PCPA factor is not warranted for the aRfD for females 13 to 49 years old and should be reduced to 1X based on the following:

- The aRfD for females 13 to 49 was established using the NOAEL from the rat developmental study. Since this endpoint is inherently protective of the developing foetus the use of the PCPA factor is not warranted.
- Using the same NOAEL, from the rat developmental study, to establish their aRfD the United States Environmental Protection Agency reduced the FQPA factor to 1.
- The use of the PCPA factor to establish the aRfD using the NOAEL from the rat developmental study is an example of double counting safety factors.

**Response**

The selection of toxicology endpoints and uncertainty factors is consistent with current PMRA policy (SPN2008-01, The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides). As part of the toxicological considerations, the PMRA evaluates prenatal and postnatal toxicity on a case-by-case basis taking into account all pertinent information. The level of concern for such effects is evaluated in consideration of several lines of evidence, including the degree to which protection for infants and children is provided by the standard application of uncertainty factors. The principal components in determining the level of concern are the sensitivity of the young noted in the database and the seriousness of the prenatal or postnatal endpoint(s). If the level of concern for the toxicology finding/endpoint is high, the full 10-fold PCPA factor will be retained against that endpoint. The PMRA has been consistent in applying this approach since publication of the new policy. Malformations are considered serious endpoints. Treatment with propiconazole produced cleft palate in the rat developmental toxicity study at doses that were non-toxic to the dams (NOAEL = 30 mg/kg bw/day). Accordingly, the PMRA retained the 10-fold PCPA factor for scenarios for which this endpoint was relevant (such as females 13-49 years of age).

In establishing the ADI, it was important to ensure adequate protection to the findings of cleft palate. The NOAEL of 3.6 mg/kg bw/day from the 2-year rat study represents the lowest NOAEL in the database for systemic toxicity following repeated dosing. However, application of the standard uncertainty factor of 100-fold (10-fold interspecies extrapolation; 10-fold intraspecies variability) to this NOAEL does not provide an adequate margin to the NOAEL for cleft palate. Accordingly, the NOAEL of 30 mg/kg bw/day for cleft palate from the rat developmental study was selected for derivation of the ADI. The comment also states that the United States Environmental Protection Agency considered the NOAEL from the 2-year rat study to be the mid-dose (which would be approximately 18 mg/kg bw/day) whereas the PMRA set the NOAEL in this study at the lowest dose level (3.6 mg/kg bw/day). This is a moot point, however, since the selected toxicology endpoints must ensure coverage to toxicity endpoints of concern in the database, and as it now stands, the use of the NOAEL of 3.6 mg/kg bw/day does not provide an adequate margin to the finding of cleft palate.

## 3.0 Comments on the environmental risk assessment

Three comments regarding the environmental risk assessment of propiconazole were received during the public consultation period of PRVD2011-02. Six studies (PMRA#2071788, 2071789, 2071790, 2071794, 2071792, and 2071793) were submitted by the registrant along with their comments. These studies are considered in the responses below.

## 3.1 Comment on beneficial arthropods

Two additional toxicity studies of propiconazole to non-target arthropods (PMRA#2071788 and 2071789) were submitted by the registrant to support their request to remove the precautionary label statement for beneficial arthropods.

**Response**

One extended laboratory study (PMRA#2071788) and one aged residue study (PMRA#2071789) were submitted. Both studies were conducted with young predatory mites, *Typhlodromus pyri*. The PMRA has reviewed these two studies and found them to be scientifically sound.

In the above two studies, the young mites were exposed to French bean (*Phaseolus vulgaris*) leaves treated with a formulation of CGA64250 (propiconazole). With the data submitted in the extended laboratory study, the $LR_{50}$ based on the cumulative mortality over the 7 days immediately after bioassay initiation was determined by the study author and the PMRA to be 207 g a.i./ha. The 14-d NOEL based on the number of eggs per female produced from day 7 to day 14 after bioassay initiation was determined by the PMRA to be 20 g a.i./ha, and the $ER_{50}$ on the effect of egg production was then given as greater than 20 g a.i./ha and less than 500 g a.i./ha at which no eggs were observed in the study. With the data submitted in the aged residue study, the PMRA calculated the NOELs to be <60, 600, 1200, and <600 g a.i./ha for residues aged 0, 7, 14, and 21 days after treatment (DAT), respectively. These NOEL values appeared to be remarkably decreased from 0 to 7 DAT and remained similar among 7, 14, and 21 DAT. The $LR_{50}$ could not be statistically calculated due to the lack of dose-response relationship of the data.

Prior to the publication of the PRVD, no non-target terrestrial arthropod studies were submitted to the PMRA to allow a calculation of reliable endpoints. As a result, the risk could not be adequately characterized. A precautionary label statement for non-target arthropods was proposed due to the high mortality of *Typhlodromus pyri* (greater than 80%) reported for some propiconazole products in an EU review (PMRA#1819978). The recently submitted extended laboratory study and the aged residue study generated endpoints of a $LR_{50}$ of 207g a.i./ha and an $ER_{50}$ of greater than 20 g a.i./ha and less than 500 g a.i./ha for egg production for *T. pyri* . These endpoints allowed a risk assessment to be conducted for the acute and chronic risks for the predatory mites.

The on-field and off-field risks of the propiconazole product to *T. pyri* were assessed for various use scenarios. For the acute risks, the calculated RQs for on-field exposures exceeded the LOC when propiconazole was applied three or more times at a rate of 125.4 g a.i./ha or greater (RQ=1.2-19.9). The level of concern for off-field exposures was not exceeded for all proposed use scenarios except when the product was applied with a boom sprayer at the maximum annual rate under the most conservative use scenario (RQ=1.2) or for airblast when applied five times at 125.4 g a.i./ha (RQ=1.1). However, further refined risk characterization indicated these off-field RQs did not exceed the LOC when the foliar deposition factor of 10% was taken into consideration.

For chronic risk, at the screening level, the calculated RQs for on-field exposures (RQ<4.7-205.8) and off-field exposure RQs (RQ<1.1-12.4) exceeded the LOC for all proposed uses. However, when off-field foliar deposition factors were taken into consideration in the refinement, the off-field RQs did not exceed the LOC for all use scenarios except for airblast applied four or more times at 125.4 g a.i./ha (LOC<1.0 -1.1), and a boom spray application at the maximum annual rates under the most conservative use scenario (RQ<1.2). These risks slightly exceed the LOC. The PMRA considers these risks to be acceptable due to the rapid reduction in toxicity (increase of the NOEL value) as residues were aged that was observed in the aged residues study. The foliar deposition factor could not be applied as an refinement factor for the on-field risk characterization because the proposed propiconazole uses include application at very early stages of the crop production.

There were no studies submitted for parasitic wasps, therefore a risk assessment for parasitic wasps could not be conducted.

As a result of the current risk assessment, on-field risks for *T. pyri* can not be excluded and risks for parasitic wasps can not be assessed. A precautionary label statement for non-target arthopods is still required on the label of the end-use products as per PRVD2011-02.

### 3.2 Comment on marine invertebrates

Four studies were submitted on the *Mysid* shrimp and Eastern oyster in order to support the establishment of endpoints and a risk assessment for marine invertebrates.

**Response**

Four additional marine invertebrate toxicity studies on the *Mysid* shrimp (PMRA#2071790, 2071794) and the Eastern oyster (PMRA#2071792 and 2071793) were submitted. The PMRA has reviewed these studies.

Both the acute toxicity study (PMRA#2071790) and the 28-d chronic study (PMRA#2071794) with mysid shrimp are considered to be scientifically sound by the PMRA. The PMRA calculated the 96-h $LC_{50}$ to be 524.2 µg a.i./L with the data from the acute toxicity study. The PMRA also calculated the NOEC value on the basis of mortality to be 205 µg a.i./L using the data from the chronic study. Both the EPA and the study authors reported that the 96-h acute $LC_{50}$ was 510 µg a.i./L and the NOEC was 205 µg a.i./L.

For the Eastern oyster, the 48-h embryo and larva toxicity study (PMRA#2071792) was considered to be scientifically sound. The $EC_{50}$ was reported to be 3400 µg/L with 95% confidence limit range of 3100-3700 µg/L. However, the PMRA could not verify this $EC_{50}$ as raw data were not provided. The 96-h shell deposition study (PMRA#2071793) were considered to contain limited amount of toxicity information due to the limited solubility, low shell growth rate in the solvent control, and lack of clear dose-response relationship between measured concentrations/nominal concentration and the shell deposition.

Based on the evaluation of the four marine invertebrate studies submitted, the *Mysid* shrimp appear to be more sensitive than the eastern oyster. The acute and chronic risks of propiconazole to marine invertebrates were estimated using a 96-h $EC_{50}$ of 0.51 mg a.i./L and an 28-d NOEC of 0.205 mg a.i./L on the mortality for *Mysidopsis bahia*, respectively. At the screening level, no unacceptable risks were identified for any of the proposed rates except when propiconazole was applied at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha for turf uses (the acute and chronic RQ=3.5 and 4.4, respectively). Further risk characterization indicated that these RQs did not exceed the LOC when it is applied using a boom sprayer. Negligible risks were identified as a result of runoff at all application rates.

The data gap indicated by the statement "No end-points for marine invertebrates are available for the risk assessment." is considered addressed through the submission and consideration of the studies mentioned above.

### 3.3 Comment on cranberries effluent water

On page 95 of PRVD2011-02, the PMRA stated "To minimize surface water contamination when used on cranberries, all effluent water must be impounded and released only when levels of the active ingredient are ≤ 850 µg a.i./L". How was this value derived?

**Response**

The statement was added to mitigate the potential acute risks for aquatic organisms. This is a standard mitigation measure for pesticides used on cranberries. In this case, the target concentration was based on a toxicity endpoint of 850 µg a.i./L from the most sensitive acute endpoint for fish (96-h $LC_{50}$ for rainbow trout).

# Appendix II Label Amendments for Products Containing Propiconazole

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

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

## Label Amendments Pertaining to Human Health

I) For all uses of propiconazole (except for workers handling greater than 78 kg propiconazole per day for commercial turf use):

**Add to PRECAUTIONS:**

Wear long pants, a long sleeve shirt, shoes and socks and chemical-resistant gloves
during mixing/loading, application, clean-up and repair activities.

II) For agricultural uses of propiconazole:

**Add to PRECAUTIONS:**

**DO NOT** allow entry into treated area for 12 hours following application. See the **DIRECTIONS FOR USE** section for crop specific restricted entry intervals.

**Add to DIRECTIONS FOR USE:**

**DO NOT** use in greenhouses.

A restricted entry interval of 1 day is required for workers hand-harvesting and detasseling treated corn.

A restricted entry interval of 5 days is required for workers hand pruning highbush
blueberries.

III) For commercial turf farm uses of propiconazole:

**Add to PRECAUTIONS:**

For commercial turf farm workers handling greater than [X Litres of "Product Name"] (equivalent to 78 kg propiconazole) per day: Wear coveralls over long pants, a long sleeve shirt, shoes and socks and chemical-resistant gloves during mixing/loading/application, clean-up and repair activities.

**Add to DIRECTIONS FOR USE:**

This product is not to be used around homes or other residential areas such as parks,
school grounds, playing fields. It is not for use by homeowners or other unlicensed users.

**DO NOT** allow entry into treated area until the area is dry.

IV) For remedial wood uses of propiconazole in mushroom houses:

**Add to DIRECTIONS FOR USE:**

**DO NOT** apply this product with a high pressure sprayer.

## Label Amendments Pertaining to the Environment

I) For all uses of propiconazole:

**Add to ENVIRONMENTAL HAZARDS:**

Toxic to aquatic organisms and non-target terrestrial plants.

**Add to DIRECTIONS FOR USE:**

As this product is not registered for the control of pests in aquatic systems, **DO NOT** use to control aquatic pests.

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

**Add to STORAGE:**

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

**Add to DISPOSAL:**

**For recyclable container for commercial use**

**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.

**For returnable containers commercial use**

**DO NOT** reuse this container for any other purpose. This empty container may be returned to the point of purchase (distributor/dealer) for disposal.

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

II) For wood use of propiconazole in mushroom house:

**Add to DIRECTIONS FOR USE:**

**DO NOT** allow effluent or runoff from mushroom houses containing this product to enter lakes, streams, ponds or other waters.

III) For all agricultural and turf uses of propiconazole:

**Add to ENVIRONMENTAL HAZARDS:**

The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g. sandy soil) and/or the depth to the water table is shallow.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

Toxic to certain beneficial insects. Minimize spray drift to reduce harmful effects on beneficial insects in habitats next to the application sites such as hedgerows and woodland.

**Add to DIRECTIONS FOR USE:**

To minimize surface water contamination when used on cranberries, all effluent water must be impounded and released only when levels of the active ingredient are ≤850 µg a.i./L.

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 m/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing- or rotor span.

**Buffer zones:**
Use of the following spray methods or equipment. **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

| Method of application | Crop | | Buffer Zones (metres) Required for the Protection of: | | | | |
|---|---|---|---|---|---|---|---|
| | | | Freshwater Habitat of Depths: | | Estuarine/Marine Habitats of Depths: | | Terrestrial habitat |
| | | | Less than 1 m | Greater than 1 m | Less than 1 m | Greater than 1 m | |
| Field sprayer* | Turf, golf courses | | 3 | 1 | 4 | 2 | 4 |
| | Beans , peas, soybeans, chickpeas, corn, wheat, oats, sugarbeets, rutabagas, turnips, cranberries, strawberries, asparagus, Kentucky bluegrass, canary seed, canola, barley, rye, triticale, Western cedar | | 1 | 0 | 1 | 1 | 1 |
| Airblast | Cherries | Early growth stage | 5 | 0 | 10 | 3 | 10 |
| | | Late growth stage | 2 | 0 | 4 | 2 | 4 |
| | Blueberries, apricots, nectarines, peaches, plums, Saskatoon berries, blackberries, loganberrie, raspberries, other berries | Early growth stage | 4 | 0 | 5 | 2 | 5 |
| | | Late growth stage | 2 | 0 | 3 | 1 | 3 |
| Aerial | Blueberries, beans, corn, oats, wheat, barley, triticale, Kentucky bluegrass (seed prod.) | Fixed wing | 1 | 0 | 3 | 1 | 20 |
| | | Rotary wing | 1 | 0 | 1 | 1 | 20 |

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled bufferzone can be reduced by 70%.When using a spray boom where individual nozzles are fitted with cone-shapedshields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

# References

## LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT


| PMRA# | Reference |
|---|---|
| 2071788 | 2003, CGA64250 (Propiconazole): Tier II Extended Laboratory Bioassay of theEffects of Fresh Residues of a 155.87 g/L EC Formulation (A6780D) on the Predatory Mite Typhlodromus pyri (Acari, Phytoseiidae). , DACO: 9.2.5 |
| 2071789 | 2006, Propiconazole (CGA64250)156 g/L EC Formulation (A6780D): An extended labratory test of the effects of fresh aged residues on the Predatory Mite Typhlodromus pyri (Acari: Phytoseiidae), DACO: 9.2.5 |
| 2071790 | 1981, Acute toxicity of CGA-64250 to mysid shrimp (Mysidopsis bahia) in a 96-hour flow-through test, DACO: 9.4.2 |
| 2071792 | 1984, Acute Toxicity of CGA-64205 to embryo-larvae of Eastern oyster (Crassostrea virginica), DACO: 9.4.3 |
| 2071793 | 1982, Acute toxicity of CGA-64250 to eastern oysters (Crassotrea virginica), DACO: 9.4.4 |
| 2071794 | 1981, Chronic Toxicity of CGA-64205 to mysid shrimp (Mysidopsis bahia), DACO: 9.4.5 |