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Proposed Re-evaluation Decision

PRVD2021-05

# Triticonazole and Its Associated End-use Products

*Consultation Document*

*(publié aussi en français)*

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## **Proposed re-evaluation decision for triticonazole and associated end use products**

Under the authority of the *Pest Control Products Act*, all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Triticonazole is a systemic fungicide registered for control or suppression of foliar, seed-borne and soil-borne diseases on cereals, corn and turf. Triticonazole is registered alone and as a co-formulation with trifloxystrobin, pyraclostrobin, and metalaxyl. It is applied as a seed treatment (cereals and corn) or via ground equipment (golf courses). Currently registered products containing triticonazole can be found in the [Pesticide Label Search](#) and in Appendix I.

This document presents the proposed re-evaluation decision for triticonazole, including the proposed amendments (risk mitigation measures) to protect human health and the environment, as well as the science evaluation on which the proposed decision is based. All products containing triticonazole that are registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period,<sup>1</sup> during which the public (including the pesticide manufacturers and stakeholders) may submit written comments and additional information to [PMRA Publications](#). The final re-evaluation decision will be published after taking into consideration the comments and information received during the consultation period.

### **Proposed re-evaluation decision for triticonazole**

Under the authority of the *Pest Control Products Act* and based on an evaluation of available scientific information, Health Canada is proposing continued registration of triticonazole and all associated end-use products registered for sale and use in Canada.

With respect to human health, dietary and occupational risks were shown to be acceptable when triticonazole is used according to the proposed conditions of registration, which include new mitigation measures such as updated personal protective equipment, rate reduction for use on golf courses and additional use precautions.

Based on available scientific information, potential risks to the environment were shown to be acceptable when triticonazole is used according to the proposed conditions of registration, which includes new mitigation measures such as additional precautionary label statements and spray buffer zones.

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

Due to its broad spectrum action with preventive properties and compatibility with other fungicides, triticonazole has value to cereal growers and to golf course managers.

## **Risk mitigation measures**

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The proposed label amendments including any revised/updated label statements and/or mitigation measures, as a result of the re-evaluation of triticonazole, are summarized below. Refer to Appendix XV for details.

### **Human health**

As a result of the re-evaluation of triticonazole, the PMRA is proposing additional risk-reduction measures to minimize the potential human health risks. Additional revisions to the triticonazole labels are proposed to update label statements to current policies and language.

Label improvements to meet current standards:

#### **For turf products**

- Update drift and tank mix partner label statements.
- Update re-entry restriction statement for golf courses.
- Update personal protective equipment (PPE) label statements.

#### **For seed treatment products**

- Update PPE label statements.

Risk mitigation:

#### **Dietary exposure**

To protect the general population from dietary exposure including through drinking water:

- For golf course turf use, reduce the maximum label rate to one application at 420 g a.i./ha
- For crops or seeds not listed on labels, add a rotational plantback interval of 30 days.

#### **Non-occupational exposure from seed treatment products**

- Add drift statements to labels.
- Add statements to labels and seed bag/tags to keep products out of reach of children and animals.

#### **Occupational exposure from seed treatment products**

To protect workers treating seed, conducting clean-up and repair activities at seed treatment facilities, and workers handling and planting treated seed, the following requirements are proposed:

- Add/update the standard statements on the label that identify the type of seed treatment facility that can be used for a specific product and seed type.
  - For corn seed treatment, only closed transfer systems in commercial facilities and mobile treaters are permitted. On-farm seed treatment is prohibited.
  - For products used for wheat and other cereal seed treatment that are co-formulated, only closed transfer systems in commercial facilities and mobile treaters are permitted. On-farm seed treatment is permitted.
- Add/update PPE for the following activities:
  - Products for use on wheat and other cereal seeds that are co-formulated.
    - Increased PPE for workers involved in clean-up and repair activities and workers handling and planting treated seed.
  - For planting treated seed (all types) only a closed-cab tractor is permitted.

## Environment

Risk mitigation:

To protect the environment, the following risk-reduction measures are proposed:

- Precautionary statements and additional application instructions on product labels with foliar applications and seed treatments.
- Terrestrial and aquatic buffer zones to mitigate risk from drift.

## International context

Triticonazole is currently acceptable for use in other Organisation for Economic Co-operation and Development (OECD) member countries, including the United States, the European Union, and Australia. No decision by an OECD member country to prohibit all uses of triticonazole for health or environmental reasons has been identified as of 14 December 2020.

## Next steps

Upon publication of this proposed re-evaluation decision, the public, including the registrants and stakeholders are encouraged to submit additional information that could be used to refine risk assessments during the 90-day public consultation period.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of the re-evaluation decision document,<sup>2</sup> which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-

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<sup>2</sup> “Decision statement” as required by subsection 28(5) of the *Pest Control Products Act*.

evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

Refer to Appendix I for details on products impacted by this proposed decision.

### **Additional scientific information**

No additional scientific data are required at this time.

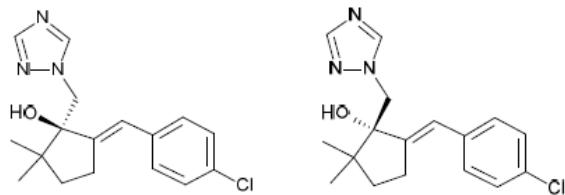
# Science evaluation

## 1.0 Introduction

Triticonazole is a systemic, preventive fungicide registered as a seed treatment to control a wide range of economically important seed-, and soil-borne fungal diseases on various cereal crops, and as a foliar treatment to control important diseases on golf course turf. Appendix I lists all triticonazole products that are registered under the authority of the *Pest Control Products Act*. Appendix II lists all the uses for which triticonazole is presently registered.

## 2.0 Technical grade active ingredient

### 2.1 Identity

<b>Common name</b>	Triticonazole
<b>Function</b>	Fungicide
<b>Chemical Family</b>	Triazole
<b>Chemical name</b>	
1 <b>International Union of Pure and Applied Chemistry (IUPAC)</b>	( <i>RS</i> )-( <i>E</i> )-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)cyclopentanol
2 <b>Chemical Abstracts Service (CAS)</b>	(5 <i>E</i> )-5-[(4-chlorophenyl)methylene]-2,2-dimethyl-1-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)cyclopentanol
<b>CAS Registry Number</b>	131983-72-7
<b>Molecular Formula</b>	C <sub>17</sub> H <sub>20</sub> ClN <sub>3</sub> O
<b>Structural Formula</b>	
<b>Molecular Weight</b>	317.82
<b>Purity of the Technical Grade Active Ingredient</b>	92.5%
<b>Registration Number</b>	26454

## 2.2 Physical and chemical properties

Property	Result
Vapour pressure at 25°C	< 0.01 mPa
Ultraviolet (UV) / visible spectrum	Not expected to absorb at $\lambda > 320$ nm
Solubility in water at 20°C	9.3 mg/L
n-Octanol/water partition coefficient at 20°C	Log $K_{ow}$ = 3.29
Dissociation constant	No dissociable functionality is expected in aqueous solution

## 3.0 Human health assessment

### 3.1 Toxicology summary

Triticonazole belongs to the conazole class of fungicides. The anti-fungal mode of action (MOA) is via the inhibition of demethylation in the ergosterol biosynthesis pathway of higher fungi.

A detailed review of the toxicological database for triticonazole was conducted. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The studies were conducted in accordance with currently accepted international testing protocols and Good Laboratory Practices. The human health risk assessment also considered information in the published scientific literature. No new issues were identified in the published scientific literature since the original evaluation. The scientific quality of the data is high and the database is adequate to characterize the potential health hazards associated with triticonazole.

Toxicokinetic investigations in rats were performed with triticonazole, radiolabelled with  $^{14}\text{C}$  at the phenyl ring position, administered via oral gavage. Triticonazole was rapidly absorbed following either single or repeat low gavage doses, or a single high gavage dose, with plasma concentrations peaking at 0.5 hours following a low dose, or 1.6–2 hours following a high dose in both males and females. The plasma elimination half-life following a low dose was 95–118 hours, and 83–100 hours following a high dose. Repeated dosing over 14 days did not alter the toxicokinetic profile. Triticonazole was widely distributed to tissues with the highest residue levels occurring in liver, adrenals, fat, plasma, skin and fur of both sexes. Tissue residues were generally low, not dose- proportional, and no indication of accumulation was observed.

The majority of the administered dose (AD) was eliminated via the feces with the remainder excreted in urine within 48 hours of dosing in both sexes. No detectable radioactivity was excreted through expired air. Following administration of a single high oral dose, a greater proportion of the AD was excreted in feces relative to urine. These data, collectively, suggest

saturation of absorption at high doses. A bile duct cannulation study indicated that approximately 92% of the low dose and only 33% of the high dose administered via gavage was excreted in the bile in both male and female rats.

Metabolism was almost complete 24 hours after the administration of a single low dose or the final repeat dose, with only trace amounts of triticonazole recovered unchanged from the feces. At the high dose level, triticonazole was identified as the major compound in the fecal extracts after 24 hours, indicating limited absorption. The major fecal metabolites were identified as RPA 405826 and RPA 406972 for the low dose and RPA 405826 for the high dose group of animals (Appendix III, Table 1). Urine from all treatment groups was found to contain up to 12 metabolites, four of which accounted for the majority of the radiolabel. These were identified only as derivatives of the parent compound, and were not further characterized. Based on the identified metabolites in urine and feces, the metabolic pathway involved hydroxylation at different positions of the molecule. Differences in metabolism and excretion between males and females were minor and quantitative, rather than qualitative, in nature.

In acute toxicity studies, triticonazole was of low toxicity by the oral, dermal and inhalation routes in rats. Triticonazole was minimally irritating to rabbit eyes, non-irritating to rabbit skin and was not a skin sensitizer in guinea pigs in either a Buehler or Maximization assay. The major synthesis impurity of triticonazole was of low acute toxicity in rats following oral and dermal exposure. RPA 406341, a hydroxylated metabolite of triticonazole, and RPA 406203, a cis-isomer of triticonazole, were also of low oral acute toxicity in rats.

In short- and long-term oral toxicity studies in mice, rats and dogs the adrenal gland and liver were identified as the primary target organs. In rats and dogs, triticonazole caused dose- and time- related histopathological changes in the cortex of the adrenal gland ranging from fatty vacuolation to degeneration of the adrenal zona reticularis. In mice, increased adrenal weights were not accompanied by any corresponding histopathology. Effects in the liver of rats included increased weight and microsomal enzyme levels accompanied by histopathological effects. These findings were associated with a consistent decrease in body weight and body-weight gain. There were no significant differences observed between males and females in all three species tested. However, following short-term dietary exposure to triticonazole in rats, males demonstrated effects on body weight, adrenal gland, and liver at a lower dose level than did females. Following long-term exposure, rats exhibited similar pathological effects to those observed following short-term exposure but at lower dose levels.

Triticonazole also caused changes in reproductive organs in dogs, rats and mice at higher doses, which included doses well beyond the limit dose of testing in rodents. Effects on ovaries, testes or prostate weights were not accompanied by any corresponding histopathology. Decreased uterine weights were also observed in high dose group rats and mice following short-term dietary exposure with histopathological changes observed only in the rats. No effects in reproductive organs were observed in rodents following long-term dietary exposure at lower doses.

The dog was identified as the most sensitive species, with toxicity manifesting as adrenal cortical histopathology, lenticular cataracts, changes in testes and prostate weights as well as effects on cholesterol and albumin levels. In a one year oral toxicity study, histopathological effects in the adrenal cortex and decreased serum cholesterol were observed in male dogs at the same dose level, suggesting a potential effect on steroid metabolism.

No evidence of systemic toxicity was observed in rats following short-term dermal exposure to 1000 mg/kg bw/day of triticonazole. A short-term inhalation toxicity study for triticonazole was not available.

In a battery of in vivo and in vitro genotoxicity studies conducted with triticonazole, there was no evidence of genotoxicity overall. In one of the in vitro chromosomal aberration assays, a positive result (without metabolic activation) was reported. However, there was no indication of genotoxicity effects in the in vivo micronucleus assay. Two metabolites and one manufacturing impurity that were tested in the in vitro reverse gene mutation assay were also negative.

Following long-term dietary exposure to triticonazole in an 18-month study in mice and a 24-month study in rats, there was no indication of treatment-related oncogenic effects.

In a rat dietary 2-generation reproductive toxicity study, parental systemic effects included mortality, reduced body weight and body-weight gain, and changes in adrenal gland and liver histopathology. These effects were accompanied by treatment-related effects in reproductive parameters such as decreased mating and fertility indices, litter size, and live-birth index in the high dose group animals. These reproductive effects were correlated with the observation of increased ovary weights and associated vacuolation of ovarian cells in females, and with potential perturbations of the endocrine function of the adrenal gland as evidenced by adrenal histopathology in both sexes. Adrenal gland weights were decreased in P and F1 parental females. Histopathological examination of the adrenals in both sexes showed that adrenal effects were more severe in females. Effects in the offspring included a decreased viability index and decreased body weight for both generations. No sensitivity of the young was observed, as effects in the offspring occurred only at maternally toxic dose levels.

In gavage rat and rabbit developmental toxicity studies, skeletal variations such as elongation of the acromion processes and supernumerary ribs occurred in rabbit and rat fetuses, respectively. However, there was no evidence of treatment-related malformations. Developmental effects in the rabbit occurred in the presence of maternal toxicity. Maternal toxicity in rabbits treated at high dose level included increased mortality with severe clinical signs, accompanied by an increased incidence of post-implantation loss. At a lower dose, a body-weight loss in the first few days of treatment initiation was also noted in this study. The developmental variations in the rat occurred in the absence of maternal toxicity. However, there is a low level of concern for the findings, given they were not serious in nature and occurred at the limit dose.

There was no indication of immunotoxic potential in the T-cell dependent antibody response assay with triticonazole when administered via the diet over a period of four weeks to female rats.

The impact of triticonazole on the nervous system was investigated in an acute gavage neurotoxicity study and in a dietary 90-day neurotoxicity study, both in rats. Increased motor activity was observed on Day 1 at the limit dose of testing in females in the acute neurotoxicity study. However, no evidence of selective neurotoxicity was observed in the 90-day neurotoxicity study. There were no treatment-related effects in either the functional observation battery or on motor activity testing. There was no evidence of selective neurotoxicity in other studies in the database.

The identity of select metabolites of triticonazole are provided in Appendix III, Table 1. The results of toxicology studies conducted in laboratory animals with triticonazole and its metabolites and major impurity are summarized in Appendix III, Table 2. The toxicology reference values for human health risk assessment are summarized in Appendix III, Table 3.

### **3.1.1 *Pest Control Products Act* hazard characterization**

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

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, the database contains the full complement of required studies including gavage developmental toxicity studies in rats and rabbits and a 2-generation dietary reproductive toxicity study in rats.

Overall, the database is adequate for determining the sensitivity of the young. There is a low concern for sensitivity of the young and effects in the young are well-characterized. The reproductive effects (decreased fertility indices, litter size) in P and F1 dams in the 2-generation reproductive toxicity study and increased post-implantation loss in high dose dams in the rabbit developmental study were considered serious endpoints, although the concern was tempered by the presence of maternal toxicity. On the basis of this information, the *Pest Control Products Act* factor (PCPA factor) would be reduced to threefold if this endpoint was used as a point of departure for risk assessment. However, the toxicological reference values selected for risk assessment provide an intrinsic margin to the endpoints of decreased fertility and implantations. Consequently, the PCPA factor was reduced to onefold.

### **3.2 Dietary exposure and risk assessment**

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in meat and milk, may be ingested with the daily diet. Exposure to triticonazole from potentially treated imported foods is also included in the assessment. Dietary exposure assessments are age-specific and incorporate the different eating habits of the population at various stages of life (infants, children, adolescents, adults and seniors). For example, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults.

Dietary risk is then determined by the combination of the exposure and the toxicity assessments. High toxicity may not indicate high risk if the exposure is low. Similarly, there may be risk from a pesticide with low toxicity if the exposure is high.

The PMRA considers limiting use of a pesticide when exposure exceeds 100% of the reference dose. Health Canada's Science Policy Note SPN2003-03, *Assessing Exposure from Pesticides, A User's Guide*, presents detailed risk assessment procedures.

Residue estimates used in the dietary risk assessment may be based conservatively (in other words, are high-end estimates) on the maximum residue limits (MRLs) or the field trial data representing the residues that may remain on food after treatment at the maximum label rate. Surveillance data representative of the national food supply may also be used to derive a more accurate estimate of residues that may remain on food when it is purchased. These include the Canadian Food Inspection Agency's (CFIA) National Chemical Residue Monitoring Program and the United States Department of Agriculture Pesticide Data Program (USDA PDP). Specific and empirical processing factors as well as specific information regarding percent of crops treated may also be incorporated to the greatest extent possible.

Sufficient information was available to adequately assess the dietary exposure and risk from triticonazole. Acute and chronic dietary exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model - Food Commodity Intake Database™ (DEEM-FCID™, Version 4.02, 05-10-c) program which incorporates consumption data from the National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA) for the years 2005-2010 available through the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS). Further details on the consumption data are available in Health Canada's Science Policy Note SPN2014-01, *General Exposure Factor Inputs for Dietary, Occupational and Residential Exposure Assessments*. For more information on dietary risk estimates and the residue chemistry information used in the dietary assessment, see Appendix IV and V.

Canadian MRLs for triticonazole are currently specified for plant and animal commodities at the limits of quantitation (LOQs) of the enforcement analytical methods. The current MRLs and enforcement residue definition for triticonazole can be found on the [Pesticides](#) section of the Canada.ca website. No changes are being proposed as a result of this re-evaluation. The only registered food use is seed treatment on all major cereals (except rice) and on canarygrass (for human consumption).

The residue definition in drinking water (for risk assessment) is proposed to be expressed as the sum of parent triticonazole (an alcohol derivative) and its major transformation products (resulting from further hydroxylation of intact triticonazole).

Triticonazole is a triazole-based fungicide. All triazole-based fungicides share common metabolites resulting from the release of the triazole ring (1,2,4-triazole) from the parent compound and its subsequent conjugation to produce triazolylacetic acid (TAA) and triazolylalanine (TA).

Due to their intrinsic toxicological properties, residue chemistry and human health risks associated with these metabolites (resulting from the use of all registered triazole-based fungicides) will be assessed separately and not as part of the re-evaluation of triticonazole (see Section 3.6).

### **3.2.1 Determination of acute reference dose**

To estimate acute dietary risk, the developmental toxicity study in rabbit with a no observed adverse effect level (NOAEL) of 5 mg/kg bw/day was selected for risk assessment. At the LOAEL of 25 mg/kg bw/day, a significant maternal body-weight loss and decrease in food consumption were observed in the first 2 days of dosing. Developmental skeletal variations such as elongation of the acromion processes were also observed at this LOAEL. Increased post-implantation loss occurred at 75 mg/kg bw/day. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed in the PCPA Hazard Characterization section (Section, 3.1.1), the PCPA factor was reduced to onefold. Thus, the composite assessment factor (CAF) is 100.

The ARfD is calculated according to the following formula:

$$\text{ARfD} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{5 \text{ mg/kg bw/day}}{100} = 0.05 \text{ mg/kg bw of triticonazole}$$

The ARfD provide a margin of 1500 to the dose at which increased post-implantation loss was observed in the rabbit developmental toxicity study.

### **3.2.2 Acute dietary exposure and risk assessment**

The acute dietary risk was calculated considering the highest ingestion of triticonazole that would be likely on any one day, and using food and drinking water consumption and residue values. The expected intake of residues is compared to the ARfD, which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake of residues is less than the ARfD, the acute dietary exposure has been shown to be acceptable.

Acute food residue estimates for triticonazole were based on Canadian MRLs or American tolerances. There are no Codex MRLs established for triticonazole. Residues in drinking water were estimated using environmental concentrations modelling based on golf course turf use discussed in Section 3.3. Default processing factors were applied for relevant processed commodities. The assessment considered all foods that may potentially be treated with triticonazole including foods that may be treated in the United States and imported to Canada. All commodities were assumed to be 100% treated.

The acute dietary risk assessment was conducted for the general population and all population subgroups. The acute dietary (food and drinking water) exposure estimates for triticonazole were not shown to be acceptable for all populations when using the drinking water estimated environmental concentration (EEC) resulting from the modelling of golf course turf use at the current maximum seasonal rate (648 g a.i./ha) with 3 applications/season (3 × 648 g a.i./ha). The

acute exposure estimate for the most exposed subpopulation (infants) was 588% of the ARfD, with drinking water exposure accounting for 99.9% of the total exposure. As a risk mitigation measure, EECs resulting from modelling of turf use at the typical rate (420 g a.i./ha) with 2 applications/season ( $2 \times 420$  g a.i./ha) or 1 application/season ( $1 \times 420$  g a.i./ha) were considered. As a result, when using the EEC from the typical rate with 2 applications/season, the acute risk was shown to be acceptable for all populations except infants with an exposure estimate at 117% of the ARfD. The acute exposure estimates were shown to be acceptable for all populations when the EEC from modelling of turf use at the typical application rate with 1 application/season ( $1 \times 420$  g a.i./ha) was used in the exposure assessment. In this case, the exposure estimate for infants, the most exposed subpopulation, was 58% of the ARfD with drinking water exposure accounting for 99% of the total exposure.

Therefore, as a result of the acute dietary risk assessment, it is proposed that the current golf course turf maximum label rate of 648 g a.i./ha with 3 applications/season with a 14-day retreatment interval be removed from the label. The typical rate of 420 g a.i./ha with 1 application/season would then be the proposed maximum seasonal rate on the label.

### 3.2.3 Determination of acceptable daily intake (ADI)

To estimate risk following repeated dietary exposure, the 1-year dog study with a NOAEL of 2.5 mg/kg bw/day was selected for risk assessment. At the LOAEL of 25 mg/kg bw/day, a decrease in body weight, body-weight gain and food consumption was demonstrated in females. Adrenal cortical cell vacuolation and clinical chemistry findings were observed in both sexes. This study provides the lowest NOAEL in the database. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed in the *Pest Control Products Act* hazard characterization section (Section 3.1.1), the PCPA factor was reduced to onefold. The CAF is 100.

The ADI is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{2.5 \text{ mg/kg bw/day}}{100} = 0.03 \text{ mg/kg bw/day of triticonazole}$$

The ADI provides a margin of  $\geq 12000$  to the dose at which reproductive effects in rats were observed and a margin of 2500 to the dose at which increased post-implantation loss occurred in the rabbit developmental toxicity study.

### 3.2.4 Chronic dietary exposure and risk assessment

Generally, the chronic dietary risk (from food and drinking water) is calculated using average consumption of different foods and drinking water, and the average residue values on those foods and drinking water. For triticonazole specifically, the average consumption values were used and the maximum potential residues in food as noted below were used. This would result in conservative (high-end) estimates of exposure from food. The estimated exposure was then compared to the ADI, which 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. When the estimated exposure is less than the ADI, the chronic dietary exposure is shown to be acceptable.

Chronic food residue estimates for triticonazole were based on Canadian MRLs or American Tolerances. There are no Codex MRLs established for triticonazole. As a result of the risk mitigation measures proposed for the acute dietary risk assessment (Section 3.2.2), the EEC resulting from modeling of the typical application rate on golf courses with 1 application/season was considered relevant for the chronic exposure assessment. Default processing factors were applied for processed commodities. The assessment considered all foods that may potentially be treated with triticonazole including foods that may be treated in the United States and imported to Canada. All commodities were assumed to be 100% treated.

The chronic dietary risk assessment (from food and drinking water) was conducted for the general population and all population subgroups. The chronic risk was shown to be acceptable for all populations when using the EEC resulting from modelling of turf use at the typical rate with 1 application/season, ranging from 8–41% of the ADI. Infants were the most exposed subpopulation. It should be noted that when the EEC resulting from modelling of the current turf maximum seasonal rate ( $3 \times 648$  g a.i./ha) was used, the chronic dietary risk was not shown to be acceptable, ranging from 77–405% of the ADI. When using the EEC resulting from modelling of the turf typical rate with 2 applications/season, the chronic risk was shown to be acceptable for all populations, ranging from 16–81% of the ADI. However, as noted in section 3.2.2, this rate ( $2 \times 420$  g a.i./ha) did not show acceptable acute risk for infants. Thus, the typical rate of 420 g a.i./ha with 1 application/season will be the proposed maximum seasonal rate on the label.

### **3.2.5 Cancer assessment**

There was no evidence of oncogenicity and therefore, a cancer risk assessment was not required.

## **3.3 Exposure from drinking water**

Combined residue of triticonazole and its major transformation products in potential sources of drinking water were estimated from modelling.

### **3.3.1 Concentrations in drinking water**

The EECs in potential sources of drinking water were modelled for combined residue of triticonazole and several transformation products formed from hydroxylation (RPA 404766, RPA 406203, RPA 406341, RPA 407922, RPA 406780, RPA 404886, and an unidentified compound of molecular weight 349). The EECs were calculated for surface water and groundwater using the Pesticide Water Calculator model (PWC, version 1.52).

The Level 1 modelling used standard scenarios and a conservative use pattern with regard to application rates and timing. All scenarios were run for 50 years. Level 1 EECs are presented in Table 3.3.1. Dietary risks were not shown to be acceptable when using Level 1 EECs to determine exposure from drinking water. Refined Level 2 modelling was therefore conducted.

**Table 3.3.1 Level 1 Estimated Environmental Concentrations of combined residue of triticonazole and hydroxylated triticonazole in potential sources of drinking water (as the parent equivalent)**

Use pattern	Groundwater (µg a.i./L)		Surface Water (µg a.i./L)	
	Daily <sup>1</sup>	Yearly <sup>2</sup>	Daily <sup>3</sup>	Yearly <sup>4</sup>
3 applications of 648 g a.i./ha at 14-day interval	1610	1605	79	17

<sup>1</sup> 90<sup>th</sup> percentile of daily concentrations

<sup>2</sup> 90<sup>th</sup> percentile of 365-day moving average concentrations

<sup>3</sup> 90<sup>th</sup> percentile of the peak concentrations from each year

<sup>4</sup> 90<sup>th</sup> percentile of yearly average concentrations

The Level 2 modelling was limited to groundwater, given that results of the Level 1 surface water modelling were not of concern. The modelling was conducted on three possible use patterns, based on typical uses of triticonazole on turf:

- The typical use pattern: 2 × 420 g a.i./ha, applied in May and/or September.
- A single application at the typical rate: 1 × 420 g a.i./ha, applied in May or September
- A minimal use pattern: 1 × 420 g a.i./ha every second year, applied in May or September

Results are presented in Table 3.3.2. Level 2 EECs are refined estimates of pesticide concentrations in drinking water. These EECs are valid only for turf, but cover all regions of Canada. The daily EECs of 0.318 ppm and 0.159 ppm from modelling of the typical rate of 420 g a.i./ha with 2 applications/season and 1 application/season, respectively, were used as alternative options in the acute dietary exposure assessments. The corresponding yearly EECs of 0.317 ppm and 0.159 ppm were used as alternative options in the chronic exposure assessments.

**Table 3.3.2 Level 2 Estimated Environmental Concentrations of triticonazole combined residue in potential sources of drinking water, reported as parent equivalent**

Use pattern	Groundwater (µg a.i./L)	
	Daily <sup>1</sup>	Yearly <sup>2</sup>
2 × 420 g a.i./ha	318	317
1 × 420 g a.i./ha	159	159
1 × 420 g a.i./ha, every 2 <sup>nd</sup> year	81	80

<sup>1</sup> 90<sup>th</sup> percentile of daily concentrations

<sup>2</sup> 90<sup>th</sup> percentile of 365-day moving average concentrations

### 3.3.2 Drinking water exposure and risk assessment

Exposure from drinking water and food sources were combined to determine the total dietary exposure and risk. Refer to Sections 3.2.2 and 3.2.4 for the results of the acute and chronic dietary exposure and risk assessments.

### 3.4 Occupational and non-occupational exposure and risk assessment

Occupational and non-occupational (residential) 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 subpopulation. 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 Toxicology endpoint selection for residential and occupational exposure**

#### **3.4.1.1 Short-term and intermediate-term dermal and inhalation**

For short- and intermediate-term dermal risk assessment involving occupational and residential exposure scenarios, the developmental toxicity study in rabbits was selected. The existing short-term dermal toxicity study did not address the endpoint of concern (prenatal toxicity), thus necessitating the use of an oral study for risk assessment. For this purpose, the rabbit developmental toxicity study was deemed appropriate. A NOAEL of 5 mg/kg bw/day was selected. At dose level of 25 mg/kg bw/day, the increased incidences of skeletal variations (elongation of the acromion process) in rabbit were observed in the presence of maternal toxicity, while at higher dose levels post-implantation loss was observed.

For short- and intermediate-term dermal risk assessment involving residential scenarios for children, the 23-day rat dermal toxicity study with a NOAEL of 1000 mg/kg bw/day was selected for risk assessment. Although the available dermal toxicity study did not examine the endpoint of concern in the rabbit developmental study (fetal skeletal variations, increased post-implantation loss), children are not at risk for this effect. The dermal toxicity study did include assessment of effects on body weight and histopathological examination of both the adrenal gland and liver upon which there were no effects.

For occupational and residential scenarios of adult, youth and children, the target Margin of Exposure (MOE) is 100 which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. For residential scenarios, the PCPA factor was reduced to onefold for reasons outlined in the *Pest Control Products Act* hazard characterization section. The selection of the above points of departure and target MOE are considered protective of the unborn children of exposed women.

For short- and intermediate-term inhalation risk assessment involving occupational and residential exposure scenarios, the 1-year oral dog toxicity study with a NOAEL of 2.5 mg/kg bw/day was selected for risk assessment. No repeat dose inhalation toxicity study was available; therefore, oral toxicity studies were considered applicable. In short- and long-term term oral toxicity studies in mice, rats and dogs, the adrenal gland and liver were identified as the primary target organs. These studies established lower NOAEL values based on adrenal and other effects compared to the NOAEL value derived from rabbit developmental toxicity study. Therefore, the choice of the 1-year dog study is protective of the effects noted in the rabbit developmental toxicity study.

For occupational and residential scenarios, the target MOE is 100 which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. For residential scenarios, the PCPA factor was reduced to onefold for reasons outlined in the *Pest Control Products Act* hazard characterization section. The selection of the above point of departure and target MOE are considered protective of the unborn children of exposed women.

#### **3.4.1.2 Cancer assessment**

See Section 3.2.5.

#### **3.4.1.3 Dermal absorption**

A dermal absorption value was not required for the short- to intermediate-term exposure duration for children as the toxicology reference value for the dermal exposure route was derived from a dermal study. For the short- to intermediate-term durations of exposure for all other subpopulations, a dermal absorption value is required, as the toxicology reference values were derived from oral studies.

A dermal absorption value of 36% was used for triticonazole based on a rat in vivo dermal absorption study.

### **3.4.2 Non-occupational (residential) exposure and risk assessment**

Non-occupational (residential) risk assessment involves estimating risks to the general population, including youth and children, during or after pesticide application.

The USEPA has generated standard default procedures for developing residential exposure assessments for both applicator and postapplication exposures when chemical- and/or site-specific field data are limited. These procedures may be used in the absence of, or as a supplement to, chemical- and/or site-specific data and generally result in high-end estimates of exposure. These procedures relevant to the triticonazole re-evaluation are outlined in the 2012 USEPA Standard Operating Procedures (SOP) for Residential Pesticide Exposure Assessments under Section 3: Lawns and Turf.

#### **3.4.2.1 Residential applicator exposure and risk assessment**

A residential applicator assessment was not required, since there are no registered domestic-class products containing triticonazole.

#### **3.4.2.2 Residential postapplication exposure and risk assessment**

Residential postapplication exposure occurs when an individual is exposed through dermal, inhalation, and/or incidental oral (non-dietary ingestion) routes as a result of being in a residential environment that has been previously treated with a pesticide. For triticonazole, postapplication exposure to treated turf from golfing activities was assessed.

Residential postapplication exposure to triticonazole is expected to be intermittent short-term in duration (that is, less than 30 days of continuous exposure). It was assumed that individuals

would enter previously treated areas on the same day the pesticide is applied. For this scenario, adults (> 16 years old), youth (11 < 16 years old) and children (6 < 11 years old) were chosen as the index lifestages to assess, based on behavioral characteristics and the quality of available data. Exposure is expected to be predominately dermal. Postapplication inhalation exposure is expected to be very low while performing activities on previously treated established golf course turf due to the combination of low vapour pressure of triticonazole and the expected dilution in outdoor air. In addition, any spray droplets in the air would be expected to have settled when entry is permitted and residues have dried. Since very young children (1 < 2 years) are typically not expected to be golfing, an incidental oral exposure risk assessment is not required.

Postapplication dermal exposure was calculated using activity-specific transfer coefficients (TCs) and exposure time from the USEPA Residential SOPs (2012) for golfing. Chemical-specific turf transferable residue (TTR) data were used to estimate the amount of residue transferred to the skin. A TC is a factor that relates dermal exposure to the TTR and is based on the amount of treated surface that a person contacts while performing activities in a given period (usually expressed in units of cm<sup>2</sup> per hour). It is specific to a particular population and activity/location (for example, adults golfing on turf).

For the residential postapplication risk assessment, calculated MOEs exceeded the target MOEs for all lifestages and thus, risks were shown to be acceptable.

The results of the residential postapplication risk assessment are summarized in Appendix VI, Table 1.

### **3.4.3 Occupational exposure and risk assessment**

There is potential for exposure to triticonazole in occupational scenarios from workers handling triticonazole products during mixing/loading and application activities, from handling and planting treated seeds, and from workers entering treated areas.

#### **3.4.3.1 Mixer, loader and applicator exposure and risk assessment**

For commercial-class products, there are potential exposures for mixers, loaders, and applicators. The following scenarios were assessed:

- Mixing/loading liquids;
- Groundboom application to established golf course turf;
- Mixing, loading and applying by backpack to established golf course turf;
- Mixing, loading and applying by turf gun to established golf course turf;
- Commercial slurry seed treatment for corn, wheat, oats, barley, rye, triticale, canaryseed and canarygrass;
- On-farm slurry seed treatment for wheat, oats, barley, rye, triticale, canaryseed and canarygrass;
- Handling and planting treated seeds.

Based on the number of applications and the timing of application, workers applying triticonazole to established golf course turf would generally have a short- to intermediate-term (< 30 days to < 6 months) duration of exposure.

Workers in commercial seed treatment facilities and farmers treating and/or planting treated seed on their farm may be handling triticonazole for short to intermediate periods of time. Thus, workers in commercial seed treatment facilities and farmers have the potential for short- to intermediate-term (< 30 days to < 6 months) exposure to triticonazole.

The exposure estimates for mixer/loaders and applicators are based on different levels of personal protective equipment (PPE) and engineering controls:

- Baseline PPE: Long pants, long-sleeved shirt and chemical-resistant gloves (unless specified otherwise).
- Mid-Level PPE: Coveralls over long pants, long-sleeved shirt, and chemical-resistant gloves.
- Maximum PPE: Chemical-resistant coveralls over long pants, long-sleeved shirt, and chemical-resistant gloves.
- Engineering Controls: Represents the use of appropriate engineering controls, such as closed-cab tractor or closed mixing/loading systems.

No appropriate chemical-specific handler exposure data were available for triticonazole. Therefore, dermal and inhalation exposure for turf applications were estimated using data from the Pesticide Handlers Exposure Database (PHED), the Agricultural Handler Exposure Task Force (AHETF), and the Outdoor Residential Exposure Task Force (ORETF).

The PHED version 1.1 is a compilation of generic mixer/loader and applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems and level of personal protective equipment. The mixer/loader/applicator backpack sprayer scenario from PHED was used to assess application of triticonazole to established golf course turf. The open cab groundboom and open mix/load liquid scenarios from AHETF were used. ORETF data were used for the turf gun application scenarios.

Inhalation exposures were based on light inhalation rates (17 L/min) except for the backpack sprayer, which was assessed using a moderate inhalation rate (27 L/min). While there are limitations in the use of generic data, these exposure data represent the most reliable information currently available.

Triticonazole is registered for seed treatment. PHED and AHETF scenarios were not considered to be representative of exposure to workers treating or handling seed. Surrogate commercial and on-farm seed treatment exposure studies, as well as exposure studies for planting treated seeds, were used to estimate worker exposure. These are the best data available for the assessment of worker exposure during the treatment and handling of seeds.

For established golf course turf uses, calculated MOEs exceeded target MOEs for all mixing, loading, and application scenarios at baseline PPE and therefore, risks were shown to be acceptable, as summarized in Appendix VII, Table 1.

For on-farm and commercial seed treatment, calculated MOEs exceeded target MOEs and therefore, risks were shown to be acceptable for all uses, provided the proposed mitigation measures (for example, closed transfer systems, additional PPE) are implemented, as summarized in Appendix VIII, Tables 1–2.

### **3.4.3.2 Postapplication worker exposure and risk assessment**

The postapplication occupational risk assessment considered exposures to workers entering treated sites to conduct agronomic activities involving contact with treated material (for example, foliage). For golf courses, there is potential for intermediate-term (up to several months) postapplication exposure for workers, as information from the registrant indicates that the product is applied three times with a 14 day retreatment interval. Exposure would be predominantly dermal for workers performing postapplication activities on turf treated with a foliar spray. Based on the vapour pressure of triticonazole, inhalation exposure would be low, provided that the minimum restricted-entry interval is followed.

For all scenarios, potential dermal exposure to postapplication workers was estimated using activity-specific TCs and chemical-specific turf transferable residue (TTR) data. The TTR refers to the amount of residue that can be transferred from a surface, such as turf. The TC is a measure of the relationship between exposure and TTRs for individuals engaged in a specific activity and is calculated from data generated in field exposure studies. The TCs are specific to a given crop and activity combination (for example, mowing treated turf) and reflect standard agricultural work clothing worn by adult workers. Activity-specific TCs from the Agricultural Re-Entry Task Force (ARTF) were used. For more information about estimating worker postapplication exposure, refer to Health Canada's Regulatory Proposal PRO2014-02, *Updated Agricultural Transfer Coefficients for Assessing Occupational Exposure to Pesticides*.

A chemical-specific TTR study in which residues of triticonazole were measured following three applications of triticonazole to turf was used to estimate postapplication exposure from turf application. The following values were used in the risk assessment:

- A peak TTR value of 2% of the application rate with a daily dissipation rate of 18% per day.

For workers entering a treated site, restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before people can safely enter after application. An REI is the duration of time that must elapse in order for residues to decline to a level where risks are shown to be acceptable (that is, performance of a specific activity that results in exposures of triticonazole above the target MOE).

Appendix VII, Table 2 summarizes the postapplication occupational exposure and risk assessments for triticonazole used to treat established golf course turf. The calculated MOEs exceed the target MOE on the day of application for all postapplication activities, therefore the risks were shown to be acceptable, provided that entry is permitted after residues have dried.

For loading and planting treated seeds, calculated MOEs exceeded target MOEs and therefore, risks were shown to be acceptable, provided the proposed mitigation measures (for example, additional PPE, closed-cab tractors) are implemented. This is summarized in Appendix VII, Tables 1–2.

### **3.5 Aggregate exposure and risk assessment**

Aggregate exposure is the total exposure to a single pesticide that may occur from dietary (food and drinking water), residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

#### **3.5.1 Toxicology reference values for aggregate risk assessment**

For aggregation in scenarios involving adults or youth, the common toxicological endpoint selected for short-intermediate-term aggregation was skeletal variations in fetuses from the gavage rabbit developmental toxicity study.

A NOAEL of 5 mg/kg bw/day, identified from this study, based on the increased incidences of skeletal anomalies was used for oral aggregate exposure. As the 23-day dermal study did not address the endpoint of concern (prenatal toxicity), the same study with the same NOAEL was used for dermal aggregate exposure. Developmental skeletal variations in pups were noted in this study at the LOAEL of 25 mg/kg bw/day.

For aggregation in scenarios involving children, no common dermal/oral effect was noted.

For all aggregation scenarios, the target MOE is 100, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. The PCPA factor was reduced to 1-fold as outlined in the *Pest Control Products Act* hazard characterization section.

#### **3.5.2 Aggregate exposure and risk assessment**

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential (non-occupational) exposure pathways are assessed. A major consideration is the likelihood of co-occurrence of exposures and durations of exposures. Additionally, only exposures from routes that share common toxicological effects are aggregated.

For triticonazole, aggregate exposures would be expected for adults, youth (11 to < 16 years) and children (6 to <11 years) who would have residential exposure following application to established golf course turf plus dietary exposure from food and drinking water. Exposure would be predominately by the dermal and oral routes. Inhalation exposure is expected to be very low compared to other routes of exposure and, therefore, was not considered quantitatively. The duration of exposure would be short- to intermediate-term.

Aggregate assessments were conducted for adults and youth. However, for children (6 to <11 years), an aggregate assessment was not conducted, since a common toxicological effect for dermal and oral routes of exposure was not identified (See Section 3.5.1).

As noted in Section 3.2.2, dietary risks are shown to be acceptable with proposed mitigation. A reduction in application rate and the number of applications is proposed. For the aggregate assessment, the dermal postapplication exposure is based on the current maximum registered application rate and maximum number of applications on golf course turf; and the chronic dietary exposure is based on the mitigation required from the dietary risk assessment.

The results of the aggregate assessment are presented in Appendix IX.

The calculated aggregate MOEs exceeded the target MOE for all age groups assessed. Therefore, aggregate risks for triticonazole were shown to be acceptable when the proposed mitigation measures from the dietary risk assessment for triticonazole are considered.

### **3.6 Cumulative assessment**

Triticonazole belongs to a group of pesticides known as the conazole fungicides. These pesticides are structurally similar and contain a triazole moiety. As a result of these structural similarities, conazole fungicides share common metabolites including 1, 2, 4-triazole and triazole conjugates. Variable toxicological responses are found for conazoles including hepatotoxicity and hepatocarcinogenicity in mice, thyroid tumours in rats, as well as developmental, reproductive, and neurological effects in rodents. No clear common mechanism for toxicity has been confirmed on which to base a cumulative assessment for any of these effects. However, a cumulative risk assessment for the common triazole metabolites will be addressed in a separate assessment.

### **3.7 Health incident reports**

As of 17 November 2020, two human and four domestic animal incident reports had been submitted to the PMRA.

Both human incidents were considered to be possibly associated with exposure to the pesticide product. In both cases the product reported in the incident was a coformulation of triticonazole with pyraclostrobin and metalaxyl. Both incidents occurred in Canada in occupational settings, and the reported health effects of headache, dizziness, muscle pain, nausea, vomiting, and fever were minor in nature. Based on the low number of incidents and the transient nature of the symptoms reported, in addition to the precautionary statements and PPE proposed on the product label, no additional mitigation measures are recommended based on the incident report review.

Three domestic animal incidents were considered to be at least possibly related to exposure to pesticide products containing triticonazole and other active ingredients. Two dogs exhibited minor effects such as anorexia, vomiting and lethargy after accidentally ingesting treated seed. Lethargy, erythema and trembling were reported in a third dog who had accidentally been sprayed with a seed treatment product. The presence of multiple active ingredients in the reported products introduces confounding elements due to the simultaneous exposure to other pesticides. Therefore, it is not possible to determine which pesticide may have contributed to the reported health effects in animals.

Based on the domestic animal health concerns identified from the incident reports related to seed treatment products, an additional statement “Keep treated seed out of reach of children and animals.” is proposed for triticonazole product labels and seed bags/tags, in order to reduce the likelihood of animal exposure to treated seed.

## **4.0 Environmental assessment**

### **4.1 Fate and behaviour in the environment**

A summary of environmental fate and behaviour data for triticonazole and its transformation products is presented in Appendix X, Table 1.

#### **Terrestrial environment**

Triticonazole has low solubility (8.4 mg/L) and is not expected to volatilize under field conditions or from moist soil or water surfaces (vapour pressure  $<0.1 \times 10^{-5}$  Pa, Henry’s law constant 1/H:  $6.43 \times 10^7$  (unitless)). Hydrolysis and photolysis on soils are not major routes of dissipation in the environment.

In terrestrial and aquatic environments, triticonazole is persistent and partitions to sediment in aquatic systems. The transformation products 1,2,4-triazole, RPA 406780, RPA 406341 and RPA 404766 are considered slightly persistent to persistent in soil, while RPA 407922 is considered non persistent. Triticonazole and RPA 407922 are moderately mobile in soils, while 1,2,4-triazole and RPA 406341 are highly mobile in soil. Triticonazole and RPA 407922 have a low potential to leach, while RPA 406341 has the potential to leach to groundwater. Field dissipation studies demonstrate triticonazole is moderately persistent to persistent in soils. Triticonazole was generally found in the upper 15-cm soil horizon. Carry over into the subsequent growing season from foliar application of triticonazole is not expected.

Triticonazole is rarely detected in Canadian surface water (0.06% of 1725 samples, maximum concentration = 0.14 µg/L, Quebec). Triticonazole was not detected in 2250 Canadian and American groundwater samples and RPA 406341 was not detected in 179 groundwater samples. Triticonazole is not expected to bioaccumulate ( $\log K_{ow} = -0.71$ , metabolism and depuration  $<1$  day in fish).

### **4.2 Environmental risk characterization**

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants.

Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (in other words, protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios and sensitive toxicity endpoints. For characterizing acute risk, acute toxicity values ( $LC_{50}$ ,  $LD_{50}$ , and  $EC_{50}$ ) from the relevant toxicity studies are divided by an uncertainty factor. The uncertainty factor is used to account for differences in inter- and intra-species sensitivity. Thus, the magnitude of the uncertainty factor depends on the group of organisms that are being evaluated (10 for fish, 2 for aquatic invertebrates). The  $EC_{50}$  is the effective concentration estimated to cause an effect to 50 percent of the test population. Similarly, the  $LC_{50}$  or  $LD_{50}$  is the lethal concentration or lethal dose estimated to cause mortality to 50% of the test population. When assessing chronic risk, the NOEC or NOEL is used and an uncertainty factor is not applied.

Integration of the environmental exposure and ecotoxicology is achieved by comparing exposure concentrations with concentrations at which adverse effects occur to derive a risk quotient. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value [ $RQ = \text{exposure}/(\text{toxicity}/\text{uncertainty factor})$ ], and the risk quotient is then compared to the level of concern (Appendix XIII, Table 1 to Table 12). The  $LOC = 1$  for all organisms with the exception of honeybees (acute  $LOC = 0.4$ ) and beneficial terrestrial arthropods ( $LOC = 2$ ).

If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the RQ exceeds the LOC, then a “presumption of risk” exists, and a more refined assessment for effects, exposure and risk characterization may be conducted to better characterize the potential risk in the environment. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

Toxicity data for triticonazole, the major transformation products (RPA 406341, RPA 404766 and RPA 407922) and the minor transformation products (RPA 406780 and 1,2,4-triazole) are presented in Appendix XI, Tables 1 and 2. The estimated EEC values (soil and aquatic) are presented in Appendix XII, Tables 1 and 2.

#### **4.2.1 Risks to non-target terrestrial organisms**

The results of the terrestrial risk assessment are presented in Appendix XIII, Tables 1 to 9.

At the screening level, risks to earthworms and honeybees exposed to triticonazole were not of concern. Potential risks were identified for beneficial arthropods, birds, mammals and terrestrial plants. The potential risks to birds (RQs of 2.1–4.1) and beneficial arthropods (RQs >9.9 to <85.8) from foliar applications are higher on field at screening level with off-field risks being low at refinement (beneficial arthropods  $RQ < 0.15$ , birds  $RQ < 0.2$ ). Label statements are required to protect birds and beneficials from foliar applications of triticonazole.

Due to potential risks to birds and mammals from corn seed treatments (RQ <3.2) any spilled seed must be cleaned up or covered. Potential risk to non-target terrestrial plants from drift at the time of application can be mitigated with spray buffer zones.

Transformation products RPA 406341, RPA 404766, RPA 407922 and 1,2,4-triazole are not expected to pose risks of concern to terrestrial organisms.

#### **4.2.2 Risks to non-target aquatic organisms**

The results of the aquatic risk assessment are presented in Appendix XIII, Tables 10–11.

At the screening level, potential risks were identified for freshwater invertebrates, amphibians, freshwater fish (chronic), marine/estuarine invertebrates (chronic) and marine/estuarine algae. The risk assessment was refined for exposure from drift and runoff. Buffer zones are proposed to mitigate risks posed by spray drift at the time of application. Modelling was used to predict concentration of triticonazole in runoff (Appendix XIII, Table 11). Potential risks from runoff based on water modelling (RQ = 6.86) result in the requirement of hazard statements to warn users of the potential risks to aquatic organisms.

Transformation products (RPA 404766, RPA 406203, RPA 407922, RPA 406341 and 1,2,4-triazole) are not expected to pose risks of concern to aquatic organisms.

#### **4.2.3 Environmental incident reports**

As of 9 December 2020, no environment incidents involving triticonazole had been reported to the PMRA. The USEPA Ecological Incident Information System (EIS), which was last updated 5 October 2015, was searched and no environment incident reports related to triticonazole were found.

### **4.3 Toxic substances management policy considerations**

In accordance with the PMRA Regulatory Directive DIR99-03,<sup>3</sup> the assessment of triticonazole against Track 1 criteria of Toxic Substances Management Policy (TSMP) under Canadian Environmental Protection Act was conducted. Health Canada has reached the conclusions that: triticonazole does not meet all Track 1 criteria, and is not considered a Track 1 substance (refer to Appendix XIV, Table 1)

Triticonazole does not form any transformation products that meet all Track 1 criteria.

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<sup>3</sup> DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

#### 4.3.1 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use products are compared against Parts 1 and 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.<sup>4</sup> The list is used as described in the Health Canada's Science Policy Note SPN2020-01<sup>5</sup> and is based on existing policies and regulations, including the Toxic Substances Management Policy<sup>6</sup> and Formulants Policy,<sup>7</sup> and taking into consideration the Ozone-depleting Substances and Halocarbon Alternatives Regulations under the Canadian Environmental Protection Act, 1999 (substances designated under the Montreal Protocol). Health Canada has reached the following conclusions:

- Triticonazole and its end-use product do not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

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

## 5.0 Value assessment

Triticonazole provides broad spectrum disease control and prevention. As a seed treatment, it controls several pathogens that cause seed rots, seedling blights and head diseases in cereal crops. Additional pathogens are managed when co-formulated with other fungicides. On established golf course turf, triticonazole controls many economically important foliar diseases. The application rate of triticonazole to golf course turf is proposed to be reduced from 648 to 420 g a.i./ha, and number of applications from three to one, in order to mitigate risk to human health. From a value perspective, these reduced rates and frequency are acceptable, as they fall within the registered use pattern.

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<sup>4</sup> SI/2005-114, last amended on 24 June 2020. See Justice Laws website, Consolidated Regulations, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern

<sup>5</sup> PMRA's Science Policy Note SPN2020-01, Policy on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under paragraph 43(5)(b) of the *Pest Control Products Act*.

<sup>6</sup> DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

<sup>7</sup> DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

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**List of abbreviations**

<sup>14</sup> C	carbon-14
abs	absolute
AD	administered dose
ADME	absorption, distribution, metabolism and elimination
ADI	acceptable daily intake
AHETF	Agricultural Handlers Exposure Task Force
a.i.	active ingredient
ALP	alkaline phosphatase
ALT	alanine aminotransferase
Applic.	application
AR	applied radioactivity
ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
AST	aspartate aminotransferase
atm	atmosphere
BAF	bioaccumulation factor
BCF	bioconcentration factor
bw	body weight
bwg	body-weight gain
°C	degree in Celsius
CAF	composite assessment factor
CAS	chemical abstract service
CDC	United States Centers for Disease Control and Prevention
CEC	cation exchange capacity
CEPA	Canadian Environmental Protection Act
CFIA	Canadian Food Inspection Agency
cm	centimeter
C <sub>max</sub>	maximum concentration
d	day(s)
DA	dermal absorption
DEEM	Dietary Exposure Evaluation Model
DFOP	double first order in parallel
DIR	PMRA regulatory directive
DT <sub>50</sub>	time required for 50% dissipation of the initial concentration
EbC <sub>50</sub>	concentration at which 50% reduction of biomass is observed
EC <sub>25</sub>	effective concentration on 25% of the population
EC <sub>50</sub>	effective concentration on 50% of the population
ECHA	European Chemical Agency
EDE	estimated daily exposure
EEC	estimated environmental concentration
EFSA	European Food Safety Authority (agency)
EIIS	Ecological Incident Information System of the EPA
ENASGIPS	European-North America Soil Geographic Information for Pesticide Studies
ErC <sub>50</sub>	concentration at which a 50% inhibition of growth rate is observed
EU	European Union
EXAMS	Exposure-analysis-modeling-system

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F1	first generation
F2	second generation
F3	third generation
fc	food consumption
<i>F. candida</i>	<i>Folsomia candida</i>
FCID™	Food Commodity Intake Database™
fe	food efficiency
FOB	functional observational battery
g	Gram
g/L	Gram per liter
GD	gestation day
GGT	gamma-glutamyl transpeptidase
GUS	Groundwater ubiquity score
ha	Hectare(s)
Hb	hemoglobin
HC	historical control
HDT	Highest dose tested
HPV	High production volume (USEPA)
HTC	Highest tested concentration
HTR	Highest tested rate
hr(s)	hour(s)
IDS	<i>Incident</i> Data System
IORE	Indeterminate order rate equation
irr.	Irradiated
i.v.	intravenous
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
$K_d$	Soil adsorption coefficient
kg	kilogram(s)
$K_{oc}$	Organic carbon-water partition coefficient
$K_{ow}$	Octanol water partition coefficient
L	Litre
LC <sub>50</sub>	Lethal concentration on 50% of the population
LD	lactation day
LD <sub>50</sub>	Lethal dose on 50% of the population
LDD <sub>50</sub>	Median lethal dietary dose
ln	natural logarithm
LOAEC	Lowest observable adverse effect concentration
LOAEL	Lowest observable adverse effect level
LOEC	Lowest observable effect concentration
LOC	Level of concern
Log	Logarithm
LOQ	limit of quantitation
LR <sub>50</sub>	Lethal rate that cause 50% reduction of the population
m <sup>2</sup>	Square meter
MAS	maximum average score for 24, 48 and 72 hours
MCH	mean corpuscular hemoglobin
MCV	mean corpuscular volume
meq	Milli equivalent

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mg	milligram(s)
mid	middle
min	minute(s)
MIS	maximum irritation score
mL	millilitre(s)
MOA	mode of action
MOE	margin of exposure
MRID	Master record identification (USEPA)
MRL	maximum residue limit
MTD	maximum tolerated dose
N	Number
N/A Not	applicable
NCHS	National Center for Health Statistics
ND	Not determined
NHANES	National Health and Nutrition Examination Survey
No.	Number
NOAEC	No observed adverse effect concentration
NOEC	No observed effect concentration
NOED	No observed effect dose
NOEDD	No observed effect dietary dose
NOAEL	No observed adverse effect level
NOEL	No observed effect level
NR	Not reported
OC	Organic carbon
OECD	Organization for Economic Co-operation and Development
OM	Organic matter
ORETF	Outdoor Residential Exposure Task Force
P	parental generation
Pa	Pascal (unit)
PCP#	Pest Control Product number (PMRA)
PCPA	<i>Pest Control Product Act</i>
<i>P. cupreus</i>	<i>Poecilius cupreus</i>
P/F1	Parental generation/first filial generation
PDP	Pesticide Data Program
pH	Potential hydrogen
PHED	Pesticide Handlers Exposure Database
pKa	Acid dissociation constant
PMRA	Pest Management Regulatory Agency (Health Canada)
PND	postnatal day
PPE	personal protective equipment
ppm	Part per million
PRZM	Pesticide Root Zone Model
<i>P. subcapitata</i>	<i>Pseudokirchneriella subcapitata</i> (now <i>Raphidocellis subcapitata</i> )
PWC	Pesticide Water Calculator model
PYA	Pyraclostrobin
RA	Risk assessment
RBC	red blood cells
REI	restricted-entry interval

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RQ	Risk quotient
(s)	Sediment
S9	mammalian metabolic activation system
sdv	Sandy
SENSOR	Sentinel Event Notification System for Occupational Risk
SFO	Single first order kinetics
St	Saint
SOP	standard operating procedures
SRBC	sheep red blood cell
$t_{1/2}$	Half-life
TA	triazolylalanine
TAA	triazolylacetic acid
TC	transfer coefficient
Temp.	Temperature
TP	Transformation product
TPM	Thiophanate-methyl
<i>T. pyri</i>	<i>Typhlodromus pyri</i>
<i>tR</i>	Representative half-life (PMRA)
TRT	Triticonazole
TSMP	Toxic Substances Management Policy
TTR	turf transferable residues
$\mu\text{g}$	Micrograms
UK	United Kingdom
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency
vs	Versus
(w)	Water
WBC	white blood cells
wt	weight
WWEIA	What We Eat in America
♂	Symbol for male
♀	Symbol for female
↓	Symbol for “decreasing”
↑	Symbol for “increasing”
=	Symbol for “equal to”
>	Symbol for “greater than”
<	Symbol for “less than”
%	Symbol for percentage

## Appendix I Registered products containing triticonazole in Canada

**Table 1 Products containing triticonazole currently registered in Canada<sup>1</sup>**

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (% , g/L)
26454	Technical	BASF Canada Inc.	Triticonazole Technical	Solid	Triticonazole 92.5%
30684	Manufacturing Concentrate	BASF Canada Inc.	Insure Cereal Bulk	Suspension	Metalaxyl 10 g/L; Pyraclostrobin 17 g/L; Triticonazole 17 g/L
33211	Manufacturing Concentrate	BASF Canada Inc.	Insure Cereal FX4 Bulk	Suspension	Fluxapyroxad 8.35 g/L; Metalaxyl 10 g/L; Pyraclostrobin 16.7 g/L; Triticonazole 16.7 g/L
28387	Commercial	BASF Canada Inc.	Premis 200 F Fungicide	Suspension	Triticonazole 200 g/L
29109	Commercial	Bayer CropScience Inc.	Chipco Triton Fungicide	Suspension	Triticonazole 19.2 %
29400	Commercial	BASF Canada Inc.	Charter RTU Seed Treatment Fungicide	Suspension	Triticonazole 16.8 g/L
30226	Commercial	BASF Canada Inc.	Armour RTU	Suspension	Triticonazole 16.8 g/L
30685	Commercial	BASF Canada Inc.	Insure Cereal	Suspension	Metalaxyl 10 g/L; Pyraclostrobin 17 g/L; Triticonazole 17 g/L
31114	Commercial	BASF Canada Inc.	Charter HL	Suspension Concentrate	Triticonazole 500 g/L
33210	Commercial	BASF Canada Inc.	Insure Cereal FX4	Suspension	Fluxapyroxad 8.35 g/L; Metalaxyl 10 g/L; Pyraclostrobin 16.7 g/L; Triticonazole 16.7 g/L

1. as of 25 September 2020, excluding discontinued products or products with a submission for discontinuation

## Appendix II Registered commercial class uses of triticonazole in Canada

**Table 1 Registered uses of products containing triticonazole Canada<sup>1</sup>**

Site	Pests	Formulation	Application method and equipment	Maximum single application rate (g a.i./ha)	Maximum cumulative application rate per year	Maximum number of applications per year	Minimum interval between applications (days)
<b>Use-site category 10 – Seed and Plant Propagation Materials Food and Feed</b>							
Barley	Seed rot, seedling blight, root rot, smut	Suspension	[Applied using standard slurry, gravity flow or mist-type seed treatment application equipment.] On-farm or commercial seed treatment plants.	(6.2 g a.i./ha)	(6.2 g a.i./ha/yr)	1	Not applicable
Canaryseed canarygrass	Seed rot, seedling blight, root rot	Suspension	[Applied using standard slurry, gravity flow or mist-type seed treatment application equipment.] On-farm or commercial seed treatment plants.	(2.3 g a.i./ha)	(2.3 g a.i./ha/yr)	1	Not applicable
Corn (field, pop, sweet, corn for seed production)	Seed rot, seedling blight, damping off, head smut	Suspension concentrate	[Applied using standard slurry, gravity flow or mist-type seed treatment application equipment.] Commercial seed treatment plants only.	(15.8 g a.i./ha)	(15.8 g a.i./ha/yr)	1	Not applicable
Oats	Seed rot, seedling blight, root rot, smut	Suspension	[Applied using standard slurry, gravity flow or mist-type seed treatment	(5.8 g a.i./ha)	(5.8 g a.i./ha/yr)	1	Not applicable

Site	Pests	Formulation	Application method and equipment	Maximum single application rate (g a.i./ha)	Maximum cumulative application rate per year	Maximum number of applications per year	Minimum interval between applications (days)
			application equipment.] On-farm or commercial seed treatment plants.				
Rye	Seed rot, seedling blight, root rot, smut, bunt	Suspension	[Applied using standard slurry, gravity flow or mist-type seed treatment application equipment.] On-farm or commercial seed treatment plants.	(3.4 g a.i./ha)	(3.4 g a.i./ha/yr)	1	Not applicable
Triticale	Seed rot, seedling blight, root rot, smut, bunt	Suspension	[Applied using standard slurry, gravity flow or mist-type seed treatment application equipment.] On-farm or commercial seed treatment plants.	(10.7 g a.i./ha)	(10.7 g a.i./ha/yr)	1	Not applicable
Wheat (all types)	Seed rot, seedling blight, root rot, smut, bunt	Suspension	[Applied using standard slurry, gravity flow or mist-type seed treatment application equipment.]	(8.9 g a.i./ha)	(8.9 g a.i./ha/yr)	1	Not applicable
<b>Use-site category 30 - Turf</b>							
Turf on golf courses	Anthraxnose, brown patch, dollar spot, red thread, rust, snow mold, summer patch	Suspension	Applied using ground sprayer (foliar).	(648 g a.i./ha)	(1944 g a.i./ha/yr)	3	14

<sup>1</sup> As of 27 January 2020, excluding discontinued products or products with a submission for discontinuation

<sup>2</sup> All information is derived from registered product labels, except for information provided by registrants which is indicated by [ ], and data calculated by PMRA which is indicated by ( ).

## Appendix III Toxicological risk assessment

**Table 1 Identification of select metabolites of triticonazole**

Common name (Other names)	Chemical name (IUPAC)
Triticonazole	( <i>RS</i> )-( <i>E</i> )-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)cyclopentanol
T- metabolite	1,2,4-triazole
TA- metabolite	Triazole alanine or triazolylalanine
TAA-metabolite	Triazole acetic acid or triazolyl acetic acid
RPA406341, alpha-hydroxy parent	( <i>E</i> )-2-(4-chlorobenzylidene)-5,5-dimethyl-1-(1 <i>H</i> -1,2,4-triazole-1-ylmethyl)cyclopentane-1,3-trans-diol
RPA 406203, cis-isomer of triticonazole	( <i>z</i> )-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1 <i>H</i> -1,2,4-triazole-1-ylmethyl)-cyclopentane-1-ol
RPA405826	Erythro-2-(4-chlorobenzylidene)-5-methyl-5-hydroxymethyl-1-(1 <i>H</i> -1,2,4-triazole-1-ylmethyl)-1-cyclopentanol
RPA406972	Erythro-2-(4-chlorobenzylidene)-5-methyl-5-carboxymethyl-1-(1 <i>H</i> -1,2,4-triazole-1-ylmethyl)-1-cyclopentanol
RPA 407922	(1 <i>RS</i> , <i>E</i> )-5-(4-chloro-3-hydroxybenzylidene)-2,2-dimethyl-1-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)-cyclopentane-1-ol
RPA 404766	(1 <i>RS</i> ,2 <i>E</i> ,3 <i>SR</i> )-2-(4-chlorobenzylidene)-5,5-dimethyl-1-(1 <i>H</i> -1,2,4-triazole-1-ylmethyl)-1,3-cyclopentanediol
RPA 406780	<i>E</i> -5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1 <i>H</i> -1,2,4-triazole-1-ylmethyl)cyclopentane-1,3-diol

**Table 2 Summary of toxicology studies for triticonazole**

NOTE: Effects noted below are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons. Effects on organ weights are known or assumed to reflect changes in absolute weight and relative (to body weight) weight unless otherwise noted.

Study type/ Animal/PMRA#	Study results
<b>Toxicokinetic Studies</b>	
Toxicokinetics Oral (gavage)  Rat (SD)  PMRA# 1180264, 1180263, 3172244	<p><b>Absorption/excretion</b></p> <p>Toxicokinetics and metabolism profile of triticonazole radiolabeled with <sup>14</sup>C at the phenyl ring was investigated in rats at a low dose level (single and repeated application) of 5 mg/kg bw/day and at a high dose level of 500 mg/kg bw/day. Single or repeated doses of 5 mg/kg bw of triticonazole in rats were well absorbed and metabolized (via hydrolysis), and subsequently excreted primarily in the feces as unconjugated metabolites. The plasma C<sub>max</sub> was reached at 0.6 hours in both sexes. Most of the radioactive material was excreted within 48 hours. By 7 days post-dosing, 14–15% (♂) and 26–32% (♀) of the AD was excreted via the urine and 81–83% (♂) and 65–71% (♀) of the AD was excreted via the feces. The terminal biological half-life (elimination) was 95–118 hours. Repeated dosing over 14 days did not alter the toxicokinetic profile of the compound. After a single oral dose of 500 mg/kg bw, absorption was limited with up to 70% of the dose excreted in the feces as unchanged parent compound. The plasma C<sub>max</sub> was reached at 2.0 hours (♂) and 1.6 hours (♀) and the plasma elimination half-life was 83–100 hours in the high dose group. Excretion of the radioactive label was largely via the feces in both males and females (96.2 and 95.7%), respectively. Urinary excretion was 3.3% and 4.7% for males and females, respectively, by 7 days post-dosing in the 500 mg/kg group.</p> <p><b>Distribution</b></p>

Study type/ Animal/PMRA#	Study results
	<p>Tissue residues after each of the three protocols were low, were not dose proportional, and no indication of accumulation was observed. The highest residues were found in the skin and fur, liver (<math>&lt; 1 \mu\text{g/g}</math> in high dose) and in adrenals and plasma in males and adrenals and fat in females (<math>&lt; 0.2 \mu\text{g/g}</math> in low dose).</p> <p><b>Metabolism</b></p> <p>Metabolism was extensive at the low dose level (single and repeated application), with no unchanged triticonazole via urine and only very low amounts found in the feces 24 hours after dosing. At the high dose level, triticonazole was identified as the major compound in the fecal extracts after 24 hours indicating limited absorption.</p> <p>Differences in metabolism between males and females were minor and quantitative rather than qualitative.</p> <p>The major fecal metabolites were identified as RPA 405826 and RPA 406972 (low doses) and RPA 405826 (high dose). Urine from all three dose groups was found to contain up to 12 metabolites, four of which (RPA 406972, 404766, 406780, 406341) accounted for the majority of the radiolabel. These were identified only as derivatives of the parent compound.</p> <p>Bile duct cannulation at the lower dose, showed that 95% and 88% of the administered dose was eliminated via the bile of the males and females, respectively. At the higher treatment level, the total absorbed dose was 32 and 34% of the administered dose for the males and females, respectively.</p>
<b>Acute Toxicity Studies</b>	
Oral (gavage)  Rat PMRA# 1180232	<p><b>LD<sub>50</sub> &gt; 2000 mg/kg bw</b></p> <p>↓ motor activity and ataxia in one ♂ and all ♀ on Day1</p> <p><b>Low acute toxicity</b></p>
Oral (gavage)  Rat PMRA# 1180233	<p><b>LD<sub>50</sub> &gt; 2000 mg/kg bw</b></p> <p>No treatment-related clinical signs</p> <p><b>Low acute toxicity</b></p>
Dermal (limit test)  Rat  PMRA# 1180235	<p><b>LD<sub>50</sub> &gt; 2000 mg/kg bw</b></p> <p>Dermal irritation noted at administration site</p> <p><b>Low acute toxicity</b></p>
Inhalation  Rat  PMRA# 1180238	<p><b>LC<sub>50</sub> &gt; 1.40 mg/L</b></p> <p>Clinical signs included: excessive salivation, wet fur on the day after treatment</p> <p><b>Slight acute toxicity</b></p>
Inhalation  Rat  PMRA# 2801205, 2801206	<p><b>LC<sub>50</sub> &gt; 5.61 mg/L</b></p> <p>↓ bwg, ↓ activity, ↑ piloerection (♂/♀), ↑ sensitivity to touch (♀)</p> <p><b>Low acute toxicity</b></p>

Study type/ Animal/PMRA#	Study results
	<b>LC<sub>50</sub> &gt; 2.63 mg/L</b> ↓ activity, ↑ piloerection (♂/♀)  <b>Low acute toxicity</b>
Dermal Irritation  Rabbit  PMRA# 1180241	<b>MAS = 0</b> <b>MIS = 0</b>  <b>Non-irritating</b>
Eye irritation  Rabbit PMRA# 1180240	<b>MAS = 0.6</b> <b>MIS:</b> 4.7 at 1 hour 1.8 at 24 hours 0 at 48 hours post instillation  <b>Minimally irritating to the eye</b>
Eye irritation  Rabbit PMRA# 1180239	<b>MAS = 0</b> <b>MIS:</b> 2.7 at 1 hour, 0 at 24 hour post instillation  <b>Non-irritating</b>
Dermal sensitization  Guinea pigs (Buehler test and in the Magnusson and Kligman)  PMRA# 1180243	<b>Negative</b>
Dermal sensitization  Guinea Pig Maximization Test (GPMT)  Guinea pig PMRA# 1180242	<b>Negative</b>
Acute Oral (an impurity of Triticonazole)  Rat  PMRA# 1180234	<b>LD<sub>50</sub> &gt; 2000 mg/kg bw</b>  <b>Low acute toxicity</b>
Acute Dermal (an impurity of Triticonazole,) limit test  Rat PMRA# 1180236	<b>LD<sub>50</sub> &gt; 2000 mg/kg bw</b>  <b>Low acute toxicity</b>
Acute Oral (RPA 406341, a hydroxylated metabolite of triticonazole) limit test  Rat PMRA# 2801211	<b>LD<sub>50</sub> &gt; 2000 mg/kg bw</b>  <b>Low acute toxicity</b>

Study type/ Animal/PMRA#	Study results
Acute oral (RPA 406203, cis-isomer of triticonazole) limit test (summary)  Rat  PMRA# 2801212	<b>LD<sub>50</sub> &gt; 2000 mg/kg bw</b>  <b>Low acute toxicity</b>
<b>Short-Term Toxicity Studies</b>	
42-day oral dietary (dose range finding study)  Mice  PMRA# 1180244	<b>Supplemental</b>  <b>≥ 233/286 mg/kg bw/day:</b> ↑ liver wt, ↑ hepatocyte hypertrophy (adaptive) (♂/♀)  <b>≥ 851/982 mg/kg bw/day:</b> ↓ bw (first 3 days), ↓ bwg, ↑ liver histopathology (fatty vacuolation, multiple nuclei, focal mineralization) (♂)  <b>≥ 3270/4091 mg/kg bw/day:</b> ↓ fc, ↑ mortality and clinical signs (piloerection, pallor, hunched posture) (♂/♀); bile duct proliferation (♂); ↑ uterus wt (no histopathology) (♀)
42-day oral dietary (dose range finding study)  Mice  PMRA# 1180244	<b>Supplemental</b>  <b>73/99 mg/kg bw/day:</b> ↑ liver wt (slight) (♂/♀); ↑ hepatocyte hypertrophy (♂); (adaptive response)
90-day oral dietary (preliminary)  Mice PMRA# 1180245	<b>Supplemental</b>  <b>≥ 383/504 mg/kg bw/day:</b> ↓ bw/bwg, ↓ fc, enlarged livers, ↑ liver wt, ↑ hepatocyte hypertrophy, periportal hepatocytic fatty vacuolation, necrosis (♂/♀); bile plug formation (♂), ↑ uterus wt (no histopathology) (♀).  <b>≥ 808/970 mg/kg bw/day:</b> ↑ hepatocyte mitotic activity (♂/♀); bile plug formation (♀)
14-Day Comparative Oral (gavage)  Rat  PMRA# 1180300	<b>Supplemental</b>  Triticonazole: <b>1000 mg/kg bw/day:</b> ↑ liver wt, ↑ hepatocyte vacuolation (♂/♀); ↑ kidney wt, thickening of the forestomach epithelium (♀); thickening of the glandular gastric epithelium (♂).  Impurity of triticonazole: <b>1000 mg/kg bw/day:</b> ↑ liver wt, ↑ hepatocyte vacuolation (♂/♀); ↑ minimal to slight hyperkeratosis and acanthosis of forestomach (♂); ↑ kidney wt (♀);
28-day oral dietary  Rat  PMRA# 1180247	<b>Supplemental</b>  <b>≥ 513/489 mg/kg bw/day:</b> ↓ bwg, ↓ fc/fe, ↓ prostate wt (no histopathology) (♂)  <b>≥ 1494/1476 mg/kg bw/day:</b> ↓ food efficiency, ↑ cholesterol, ↑ platelet counts, ↑ liver wt, ↑ hepatocyte vacuolation (♂/♀); ↑ hepatic necrosis (♂); ↓ uterus wt with reduced uterine endometrial stroma (♀)  <b>4800/4945 mg/kg bw/day:</b> ↓ serum glucose, ketonuria, hepatocyte hypertrophy (♂/♀); ↓ prostate wt (♂); ↓ ovary wt (no histopath), hunched posture, ↓ bwg (♀)

Study type/ Animal/PMRA#	Study results
90-day oral dietary  Rat  PMRA# 1049910, 1049911, 1180246	<b>NOAEL: 2 mg/kg bw/day (♂)</b> <b>NOAEL: 23 mg/kg bw/day (♀)</b>  <b>≥ 20/23 mg/kg bw/day:</b> ↑ adrenocortical fatty vacuolation, ↑ hepatocyte hypertrophy (♂)  <b>≥ 1117/1183 mg/kg bw/day:</b> ↑ generalized hair loss, ↓ body wt, ↓ bwg, ↓ fc/fe, ↓ thymus wt, ↑ liver wt, ↑ serum cholesterol, ↓ RBC (♂/♀); ↑ hepatocyte hypertrophy, ↑ centriacinar hepatocytic fatty vacuolation, ↑ adrenocortical fatty vacuolation, ↑ degeneration of the adrenal zona reticularis (♀).
Oral (capsule) Determination of MTD  Beagle dogs  <b>Group 1:</b> treated with increasing doses for 3–6 days at each level. <b>Group 2:</b> treated at 1000 mg/kg bw/day for 3 days, untreated for 11 days, followed by 14 days at 500 mg/kg bw/day. <b>Group 3:</b> treated for 14 days  PMRA# 1180249	<b>Supplemental</b> <b>Group 1:</b> <b>≥ 40 mg/kg bw/day:</b> ↓ body wt gain (♂) <b>≥ 80 mg/kg bw/day:</b> ↓ body wt gain (♀) 1000 mg/kg bw/day: overt clinical signs (ataxia, torpor, tremors, disorientation and convulsions) (♂)  <b>Group 2</b> 1000/500 mg/kg bw/day: ↓ bw, ↑ liver wt, ↑ hepatic enzyme parameters, overt clinical signs of intoxication (ataxia, torpor, tremors, disorientation and convulsions) (♂/♀); one ♂ killed in extremis following the second dose.  <b>Group 3</b> 300 mg/kg bw/day: ↑ liver wt, ↑ hepatic enzyme parameters. Clinical signs in dogs (ataxia, torpor, tremors, disorientation and convulsions) treated at 300 mg/kg bw/day cleared within the first few days of dosing. (♂/♀)  <b>MTD = 300 mg/kg bw/day</b>
28-day oral (capsule) dose range finding  Beagle dogs  PMRA# 1049889	<b>Supplemental</b>  <b>≥ 100 mg/kg bw/day:</b> ↑ ALP; ↑ rel liver wt (♀)  <b>≥ 300 mg/kg bw/day:</b> ↑ overt clinical signs (ataxia, abnormal gait, underactivity, circling and head shaking) 5–6 hr after dosing on Days 3–5, ↑ active resistance to dosing on Days 9–11, ↓ bw first 3 days of dosing, ↑ liver wt, ↑ periacinar hypertrophy with fatty microvesiculation (♂); ↓ bwg, ↓ fc, ↑ PCV, Hgb, RBC (♀).
1-year oral (capsule)  Beagle dogs  PMRA# 1180250, 1049913, 1049914	<b>NOAEL: 2.5 mg/kg bw/day</b> <b>LOAEL: 25 mg/kg bw/day</b>  <b>≥ 25 mg/kg bw/day:</b> ↑ vacuolation of adrenal cortical cells (zona fasciculata), ↓ albumin (♂); ↓ bw, ↓ bwg, ↓ fc, ↑ ALP (♀)  <b>≥ 150 mg/kg/day:</b> ↑ overt clinical signs for week 6–11 (ataxia, tremor, hyperactivity, convulsion post-dosing) ↑ lenticular cataracts, ↑ thickened skin, ↓ cholesterol (♂/♀); ↓ bw, ↓ bwg, ↓ albumin, ↑ ALP, ↑ testes wt, ↓ prostate wt (♂)
23-day dermal  Rat  PMRA# 1180312	<b>NOAEL ≥ 1000 mg/kg bw/day</b>  No systemic treatment-related effects Dermal irritation was not observed at any dose level.

Study type/ Animal/PMRA#	Study results
<b>Chronic Toxicity/Oncogenicity Studies</b>	
18 month dietary chronic  Mice PMRA# 1180254, 1180170	<b>NOAEL: 17/20 mg/kg bw/day</b>  <b>202/210 mg/kg/day:</b> ↓ bw, ↓ bwg, ↑ liver wt, enlarged livers, ↑ adrenal wt (at interim sacrifice only, no histopathology), ↓ food efficiency, ↑ periadrenal hepatocyte fatty vacuolation (♂/♀); ↑ hepatocyte hypertrophy (♂)  <b>No evidence of tumorigenicity</b>
24 month chronic/oncogenicity dietary  Rat PMRA# 1180171, 1180172	<b>NOAEL: 29/38 mg/kg bw/day</b>  <b>203/286 mg/kg bw/day:</b> ↓ bwg, ↓ platelet count, ↓ ATP, ↓ total cholesterol (♂/♀); ↑ incidence of thyroid follicular adenomas (♂); ↓ bw, ↑ prothrombin time, ↑ incidence of multi-nucleated cells of adrenal, ↑ chronic inflammation of adrenal cortex, ↑ incidence of hepatocytes centrilobular fatty vacuolation (♀); <b>No evidence of tumorigenicity</b>
<b>Developmental/Reproductive Toxicity Studies</b>	
Dose range finding summary Oral developmental (gavage)  Rat  PMRA# 1180268	<b>Supplemental</b>  Maternal <b>≥ 50 mg/kg bw/day:</b> ↑ dosage related incidence of hydronephrosis  <b>≥ 1250 mg/kg bw/day:</b> ↑ brown head, body or perigenital staining, ↓ bwg, ↑ placental wt  Developmental <b>≥ 50 mg/kg bw/day:</b> ↑ dosage related incidence of hydronephrosis  <b>≥ 1250 mg/kg bw/day:</b> ↓ mean fetal weight
Developmental oral gavage  Rat  PMRA# 1180268, 1049916	Maternal <b>NOAEL: ≥ 1000 mg/kg bw/day</b>  <b>≥ 1000 mg/kg bw/day:</b> ↓ marginal bwg, ↓ fc (slight)  Developmental <b>NOAEL: 200 mg/kg bw/day</b>  <b>≥ 1000 mg/kg bw/day:</b> ↑ incidence of unilateral and bilateral supernumerary ribs  <b>Evidence of sensitivity of the young</b> <b>No evidence of treatment-related malformation</b>
Developmental oral gavage  Rabbit  PMRA# 1180269, 1049917	<b>Maternal</b>  <b>NOAEL: 5 mg/kg bw/day</b>  <b>≥ 25 mg/kg bw/day:</b> ↓ bw loss (GD 6–8), ↓ fc (GD 6–12)  <b>≥ 50 mg/kg bw/day:</b> ↑ maternal deaths (1, 6 dams for 50 and 75 mg/kg bw/day, respectively) after 7–9 days of treatment, ↑ respiration rate, ↓ fecal output  <b>≥ 75 mg/kg bw/day:</b> ↑ post-implantation loss

Study type/ Animal/PMRA#	Study results
	<p><b>Developmental</b></p> <p><b>NOAEL: 5 mg/kg bw/day</b>  <b>≥ 25 mg/kg bw/day:</b> ↑ elongation acromion process of the scapula (dose related)</p> <p><b>≥ 50 mg/kg bw /day:</b> ↑ various skeletal abnormalities (↑ incidence of delayed ossification of digits).</p> <p><b>≥ 75 mg/kg bw/day:</b> ↑ post-implantation loss , ↑ percent of fetuses with variations in midline cranial sutures</p> <p><b>No evidence of sensitivity of the young</b>  <b>No evidence of treatment related malformation</b></p>
<p>Dietary Reproductive 2-generation study</p> <p>Rat</p> <p>PMRA# 1180173, 1180261</p>	<p><b>Parental toxicity</b></p> <p><b>NOAEL: 49.4/54.7 mg/kg bw/day</b></p> <p><b>307/387 mg/kg bw/day:</b> ↓ bw (prematuring, gestation and lactation) P/F1, ↓ bwg (prematuring, gestation and lactation) P/F1, ↓ fc (prematuring, gestation and lactation) P/F1; ↑ incidence and severity of adrenal cortical vacuolation P/F1 (♂); ↑ mortality, ↓ adrenal wt, ↑ liver wt and liver vacuolization, ↑ histopathology of adrenals (cortical cell degeneration, presence of giant cells, pigment deposition) P/F1, ↑ collagen deposition P (♀);</p> <p><b>Reproductive toxicity</b></p> <p><b>NOAEL: 54.7 mg/kg bw/day</b></p> <p><b>387 mg/kg bw/day:</b> ↓ fertility and mating indices F1, ↓ birth wt F2, ↑ ovary wt, ↑ vacuolization of the ovary F1, ↓ litter size F1, ↑ number of still births P/F1, ↓ live birth index (P / F1)</p> <p><b>Offspring toxicity</b></p> <p><b>NOAEL: 54.7 mg/kg bw/day</b></p> <p><b>387 mg/kg bw/day:</b> ↓ viability index P / F1), ↓ pup bw (after PND 4 for F1/ F2 generations)</p>
<p>Reverse gene mutation assay in S.typhimurium strains: TA 98, TA 100, TA 1535, TA 1537, TA 1538</p> <p>PMRA# 1180270</p>	<p>Negative (± metabolic activation)</p>
<p>Mammalian cell gene mutation assay in Chinese hamster ovary (CHO) cells</p> <p>PMRA# 1180272</p>	<p>Negative (± metabolic activation)</p>
<p>Chromosomal aberration assay in human lymphocytes (in vitro)</p> <p>PMRA# 1180274</p>	<p>Negative (± metabolic activation)</p>

Study type/ Animal/PMRA#	Study results
Chromosome Aberrations in Cultured Human Peripheral Blood Lymphocytes (California summary)  PMRA# 3172244	Negative (+ metabolic activation)  Positive (- metabolic activation)
Mouse bone marrow micronucleus assay (in vivo)  CD-1 mice  PMRA# 1180275	Negative
Unscheduled DNA synthesis in primary rat hepatocytes (in vitro)  Wistar rats  PMRA# 1180273	Negative
Impurity  Reverse gene mutation assay in <i>S.typhimurium</i> and <i>E. coli</i>  Strains : TA 98, TA 100, TA 1535, TA 1537, TA1538 of <i>S.</i> <i>typhimurium</i>  PMRA# 1180271	Negative ( $\pm$ metabolic activation)
Metabolite RPA 406203. Reverse gene mutation assay in <i>S.typhimurium</i> (TA98, TA 100, TA1535, and TA1537) and <i>E. coli</i> (WP2uvrA)  PMRA #2801214	Negative ( $\pm$ metabolic activation)
Metabolite RPA 406341. Reverse gene mutation assay in <i>S.typhimurium</i> and <i>E. coli</i> WP2uvrA  PMRA# 2801215	Negative ( $\pm$ metabolic activation)
<b>Immunotoxicity Studies</b>	
28-day dietary Immunotoxicity study (TDAR)  Female Rat	<b>NOAEL: 162 mg/kg bw/day</b>  <b>462 mg/kg bw/day:</b> ↓ bw (9% day 14), ↓ bwg (32% day 14), ↑ liver wt (17% abs and 28% rel), enlarged liver (2/8)

Study type/ Animal/PMRA#	Study results
PMRA# 2801215	<b>Positive control group:</b> 2 deaths, ↓ SRBC IgM antibody titres, ↓ spleen and thymus weights.  <b>No evidence of immunotoxicity</b>
<b>Neurotoxicity Studies</b>	
Acute gavage (range-finding)  Rat  PMRA# 1180266	<b>Supplemental</b>  <b>≥ 1000 mg/kg bw/day:</b> ↑ motor activity (♂);  <b>2000 mg/kg bw/day:</b> The time-to-peak effect for motor activity was determined to be 3 hr after dosing
Acute gavage (main) neurotoxicity  Rat  PMRA# 1180265	<b>NOAEL: 2000 mg/kg bw/day (♂)</b> <b>NOAEL: 400 mg/kg bw/day (♀)</b>  <b>≥ 2000 mg/kg bw/day:</b> ↑ motor activity at day 1 (♀)  <b>No evidence of selective neurotoxicity</b>
90-day dietary neurotoxicity  Rat  PMRA# 1180267, 1180268	<b>NOAEL: 170/200 mg/kg bw/day</b>  <b>≥ 695/820 mg/kg bw/day:</b> ↓bw, ↓bwg ↓ fc;  <b>No evidence of selective neurotoxicity</b>

**Table 3 Toxicology reference values for use in health risk assessment for triticonazole**

Exposure scenario	Study	Point of departure and endpoint	CAF <sup>1</sup> or Target MOE
Acute dietary	Rabbit developmental toxicity (gavage)	NOAEL = 5 mg/kg bw/day maternal bw loss in first few days following initiation of dosing; developmental skeletal variations in pups	100
ARfD = 0.05 mg/kg bw			
Repeated dietary	1-year dog toxicity (oral)	NOAEL = 2.5 mg/kg bw/day ↑ vacuolation of adrenal cortical cells and clinical chemistry findings (♂/♀) and ↓ bw/bwg and fc in (♀)	100
ADI = 0.03 mg/kg bw/day			
Short-/Intermediate-term dermal <sup>2</sup>  Occupational and residential adult + residential youth	Rabbit developmental toxicity (gavage)	NOAEL = 5 mg/kg bw/day maternal bw loss in first few days following initiation of dosing; developmental skeletal variations in pups	100
Short-/Intermediate-term dermal  Residential children	23-day rat dermal toxicity study	NOAEL = 1000 mg/kg bw/day	100
Short-/Intermediate term inhalation <sup>3</sup>  Occupational and residential adult + residential children and youth	1-year dog toxicity (oral)  Supported by 90-day toxicity (dietary)	NOAEL = 2.5 mg/kg bw/day ↑ vacuolation of adrenal cortical cells and clinical chemistry findings (♂/♀) and ↓ bw/bwg and fc in (♀)	100
Aggregate Short-/intermediate-term  Adults, or youth  Children	Inhalation exposure- not expected for adult, youth and children  Oral/dermal: Rabbit developmental toxicity (gavage)  No common endpoint for oral /dermal aggregate	NOAEL = 5 mg/kg bw/day maternal bw loss in first few days following initiation of dosing; developmental skeletal variations in pups	100
Cancer	There was no indication of treatment-related oncogenic effects, and therefore, no cancer risk assessment is necessary.		

<sup>1</sup>CAF (composite assessment factor) refers to a total of uncertainty and PCPA factors for dietary assessments; MOE refers to a target MOE for occupational and residential assessments.

<sup>2</sup>Since an oral NOAEL was selected, a dermal absorption factor of 36% was used in a route-to-route extrapolation.

<sup>3</sup> Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

## Appendix IV Dietary exposure and risk assessment

**Table 1 Summary of dietary exposure and risk from triticonazole using EECs from modelling of turf use at the current maximum label seasonal rate**

Population	Acute Dietary (95 <sup>th</sup> percentile) <sup>1</sup>				Chronic Dietary <sup>2</sup>			
	Food Only		Food + Water Turf maximum seasonal rate (3 × 648 g a.i./ha)		Food Only		Food + Water Turf maximum seasonal rate (3 × 648 g a.i./ha)	
	Exposure (mg/kg bw)	%ARfD	Exposure (mg/kg bw)	%ARfD	Exposure (mg/kg bw/day)	%ADI	Exposure (mg/kg bw/day)	%ADI
General Population	0.000588	1.18	0.085920	171.84	0.000217	0.7	0.032645	108.8
All Infants (<1 year old)	0.000977	1.95	0.293868	587.74	0.000253	0.8	0.121386	404.6
Children 1–2 years old	0.001453	2.91	0.124368	248.74	0.000775	2.6	0.045373	151.2
Children 3–5 years old	0.001030	2.06	0.098429	196.86	0.000554	1.8	0.036843	122.8
Children 6–12 years old	0.000697	1.39	0.076786	153.57	0.000349	1.2	0.027331	91.1
Youth 13–19 years old	0.000446	0.89	0.071901	143.80	0.000207	0.7	0.023067	76.9
Adults 20–49 years old	0.000366	0.73	0.084068	168.14	0.000171	0.6	0.032389	108.0
Adults 50–99 years old	0.000295	0.59	0.073109	146.22	0.000143	0.5	0.031476	104.9
Females 13–49 years old	0.000339	0.68	0.084830	169.66	0.000157	0.5	0.031829	106.1
<sup>1</sup> Acute Reference Dose (ARfD) of 0.05 mg/kg bw applies to the general population and all population subgroups;								
<sup>2</sup> Acceptable Daily Intake (ADI) of 0.03 mg/kg bw/day applies to the general population and all population subgroups.								

**Table 2 Summary of dietary exposure and risk from triticonazole using EECs from modelling of turf use at the typical seasonal rate**

Population	Food + Water Turf typical rate with 2 applications/season (2 × 420 g a.i./ha)				Food + Water Turf typical rate with 1 application/season (1 × 420 g a.i./ha)			
	Acute Dietary (95 <sup>th</sup> percentile) <sup>1</sup>		Chronic Dietary <sup>2</sup>		Acute Dietary (95 <sup>th</sup> percentile) <sup>1</sup>		Chronic Dietary <sup>2</sup>	
	Exposure (mg/kg bw)	%ARfD	Exposure (mg/kg bw/day)	%ADI	Exposure (mg/kg bw)	%ARfD	Exposure (mg/kg bw/day)	%ADI
General Population	0.017179	34.36	0.006622	22.1	0.008744	17.49	0.003429	11.4
All Infants (<1 year old)	0.058310	116.62	0.024178	80.6	0.029208	58.42	0.012253	40.8
Children 1–2 years old	0.025320	50.64	0.009584	31.9	0.013089	26.18	0.005194	17.3
Children 3–5 years old	0.019967	39.93	0.007722	25.7	0.010252	20.50	0.004149	13.8
Children 6–12 years old	0.015508	31.02	0.005678	18.9	0.007950	15.90	0.003022	10.1
Youth 13–19 years old	0.014438	28.88	0.004722	15.7	0.007413	14.83	0.002471	8.2
Adults 20–49 years old	0.016774	33.55	0.006535	21.8	0.008481	16.96	0.003363	11.2
Adults 50–99 years old	0.014562	29.12	0.006332	21.1	0.007363	14.73	0.003247	10.8
Females 13–49 years old	0.016943	33.89	0.006412	21.4	0.008568	17.14	0.003294	11.0
<sup>1</sup> Acute Reference Dose (ARfD) of 0.05 mg/kg bw applies to the general population and all population subgroups;								
<sup>2</sup> Acceptable Daily Intake (ADI) of 0.03 mg/kg bw/day applies to the general population and all population subgroups.								

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## Appendix V Food residue chemistry summary

The currently registered food use of triticonazole in Canada is seed treatment on wheat, barley, oats, rye, triticale, corn and annual canarygrass (for human consumption) at rates of 5–5.1 g a.i./100 kg seed. A higher rate of 50 g a.i./100 kg seed is permitted on corn for the control of head smut (*Sporisorium reilianum*) only. Treated seeds are not to be used for food, feed or oil processing.

The first comprehensive dietary risk assessment for triticonazole was conducted in support of the Proposed Regulatory Decision Document PRDD2004-06, *Triticonazole*, published on 29 December 2004 for use as a seed treatment on wheat, barley and oats. The registration was extended to rye and triticale in 2012 and corn in 2013. Canadian MRLs were established for residues of triticonazole, from the treatment of seed prior to planting, in/on the registered cereal grains and milk at the limit of quantitation (LOQ) of 0.01 ppm and in eggs, meat and meat byproducts of livestock at the LOQ of 0.05 ppm.

The residue chemistry database for triticonazole is complete and up-to-date for the registered uses (that is, cereal seed treatment prior to planting). The residue definition (RD) in plant and animal commodities was previously determined to be triticonazole per se for enforcement and risk assessment purposes. No change is being proposed as a result of this re-evaluation. This RD is aligned with current residue definitions established by the USEPA and the European Food Safety Authority (EFSA). There are no JMPR evaluations and, therefore, no Codex MRLs established for residues of triticonazole.

All triazole-based fungicides share common metabolites resulting from the release of the triazole ring (1,2,4-triazole) from the parent compound and its subsequent conjugation to produce triazolylacetic acid (TAA) and triazolylalanine (TA). Due to their intrinsic toxicological properties, residue chemistry and human health risks associated with these metabolites (resulting from the use of all registered triazole-based fungicides) will be assessed separately and not as part of the re-evaluation of triticonazole.

The RD in drinking water (for risk assessment) is proposed to be expressed as parent triticonazole (an alcohol derivative) and its major transformation products (also alcohol derivatives) since the transformation products have physicochemical properties similar to the parent and, thus, are expected to be similar to the parent in persistence and toxicity. The proposed RD is in line with the RD for drinking water risk assessment used by USEPA and EFSA.

In a confined crop rotation study applying triticonazole to soil at 25-times the registered application rate, uptake of triticonazole residues into representative rotational crops at 1-, 5- and 12-month plantback intervals was low (<0.01 ppm). It was concluded that application of triticonazole at normal seed dressing rate would result in insignificant (<LOQ) uptake in rotational crops. Parent triticonazole was the predominant extractable residue. A 30-day plantback interval (the shortest plantback trial interval) is recommended as per current practice.

Liquid chromatography-mass spectrometry (LC-MS) and liquid chromatography-tandem mass spectrometry (LC-MS/MS) analytical methods were provided in previous petitions for the enforcement of triticonazole MRLs in plant commodities. The LOQs for LC-MS were 0.01 ppm

for grain and 0.04 ppm for forage and straw; the LOQ for LC-MS/MS was 0.005 ppm for grain, forage and straw. The average recoveries of triticonazole ranged from 77 to 122% for all plant matrices when samples were spiked at levels ranging from 0.02 to 0.5 ppm (LC-MS) and from 0.002 to 0.5 ppm (LC-MS/MS). Inter laboratory validation (ILV) of the methods using wheat forage was successfully completed. A gas chromatographic method using an electron capture detector (GC-ECD) was provided for the enforcement of triticonazole MRLs in animal commodities. The LOQs were 0.05 ppm (eggs, beef and poultry tissues and fat) and 0.01 ppm (milk). Average recoveries in beef and poultry tissues, milk and eggs spiked at 0.01 and 0.05 ppm, ranged from 85 to 97%.

Triticonazole residues in foods are monitored by the USDA PDP but not by the CFIA monitoring program. Practically all samples in the PDP data for triticonazole showed non-detect residue values in the last 10-year time frame.

## Appendix VI Residential postapplication exposure and risk assessment

**Table 1 Residential postapplication dermal exposure and risk assessment**

Form.	TTR <sup>a</sup>	Lifestage	TC <sup>b</sup> (cm <sup>2</sup> /hr)	Dermal Exposure (mg/kg bw/day) <sup>c</sup>	Dermal MOE
Golfing on treated greens, tees, and fairways					Target MOE = 100
Liquid	2%	Adult	5300	$1.32 \times 10^{-2}$	380 <sup>d</sup>
		Youth (11<16 years)	4400	$1.52 \times 10^{-2}$	330 <sup>d</sup>
		Children (6<11 years)	2900	$5.01 \times 10^{-2}$	20000 <sup>e</sup>

Form. = formulation; TTR = turf transferable residue; TC = transfer coefficient; MOE = margin of exposure; NOAEL = no observed adverse effect level.

<sup>a</sup> TTR values are determined using 2% of the application rate for the peak TTR and a dissipation rate of 18% per day based on chemical-specific data. (Tew, 2001).

<sup>b</sup> Standard TCs from the USEPA Residential SOP (USEPA, 2012) were used.

<sup>c</sup> Exposure(mg/kg bw/day) = TTR (ug/cm<sup>2</sup>) × TC (cm<sup>2</sup>/hr) × duration (hr) × dermal absorption factor/Body Weight (kg). Duration was 4 hours. Body weights were 80, 57 and 32 kg for adults, youth (11<16 years), and children (6<11 years), respectively. Dermal absorption was 36% for adult and youth. A dermal absorption factor was not applicable to children as the toxicology reference value was based on a route-specific study.

<sup>d</sup> Short-term NOAEL of 5 mg/kg bw/day from an oral developmental rabbit study and target MOE of 100.

<sup>e</sup> Short-term NOAEL 1000 mg/kg bw/day from a rat dermal toxicity study and target MOE of 100.

## Appendix VII Occupational handler and postapplication exposure and risk estimates for turf uses

**Table 1 Mixer, loader, applicator turf risk assessment**

Crop	Appl. Equip.	Eng. Controls	ATPD <sup>a</sup> (ha/day)	Rate <sup>b</sup> (kg/ha)	Exposure (µg/kg bw/day)		MOE	
					Dermal <sup>c</sup>	Inhalation <sub>d</sub>	Dermal <sub>e</sub>	Inhalation <sub>f</sub>
Assessed with baseline PPE								
Golf Course - Turf	Groundboom – Open Cab	Open M/L <sub>g</sub>	16	0.648	3.914	0.299	1280	8350
	Turf Gun Sprayer	Open Pour <sub>g h</sub>	2		4.578	0.065	1090	38600
	Backpack				31.760	1.006	157	2490

SC = Suspension Concentrate; Appl. = application; Equip. = Equipment; Eng. = Engineering; M/L = mix/load; ATPD = area treated per day; MOE = margin of exposure; PPE = personal protective equipment; Baseline PPE = long-sleeved shirt, long pants, chemical resistant gloves; NOAEL = no observed adverse effect level.

<sup>a</sup>Based on standard assumptions.

<sup>b</sup>Maximum listed label application rate.

<sup>c</sup>Dermal exposure (µg/kg bw/day) = (dermal unit exposure × ATPD × application rate × dermal absorption)/80 kg body weight (BW). Dermal absorption of triticonazole = 36%.

<sup>d</sup>Inhalation exposure (µg/kg bw/day) = (inhalation unit exposure × ATPD × application rate)/80 kg body weight.

<sup>e</sup>Based on a short- to intermediate-term NOAEL of 5 mg/kg bw/day from an oral rabbit developmental study, target MOE of 100.

<sup>f</sup>Based on a short- to intermediate-term NOAEL of 2.5 mg/kg bw/day from an oral dog toxicity study, target MOE of 100.

<sup>g</sup>Liquid formulation was used as a surrogate for suspension concentrates (SC).

<sup>h</sup>Input is for mixer, loader, and applicator.

**Table 2 Postapplication dermal exposure and risk assessment<sup>a</sup>**

Crop	Rate (g ai/ha) <sup>a</sup>	Postapplication Activity	TC (cm <sup>2</sup> /hr)	Dermal Exposure <sup>b</sup> (mg/kg bw/day)	Day 0 MOE <sup>c</sup> (T= 100)	REI <sup>d,e</sup>
Turf - 3 applications, 14 day interval - Turf TTR study (Georgia Site)						
Golf course	648	Transplanting/planting	6700	33.32	150	12 hours
		Mowing, watering, cup changing, irrigation repair, miscellaneous grooming	3500	17.41	287	
		Aerating, fertilizing, hand pruning, scouting, mechanical weeding	1000	4.97	1010	

TC = transfer coefficient; MOE = margin of exposure; T = target MOE; REI = restricted-entry interval; TTR = turf transferable residue; DA = dermal absorption; BW = body weight; NOAEL = no observed adverse effect level

<sup>a</sup>Maximum registered application rate for turf.

<sup>b</sup>Dermal exposure (mg/kg bw/day) = (TTR × TC × Duration × DA) / BW. A dermal absorption of 36% was used (Auger, 1996). The duration is for 8 hours. A TTR value of 2% of the application rate and an 18% dissipation rate per day was used in the risk assessment. This was based on chemical-specific data from the Georgia site (Tew, 2001).

<sup>c</sup>MOE = NOAEL/exposure. A NOAEL of 5 mg/kg bw/day from an oral rabbit developmental study, with a target MOE of 100 was used.

<sup>d</sup>The REI is the length of time that it takes for the residues to dissipate to reach the target TTR, which is calculated using the following equation:

$$TTR_i = \frac{NOAEL (\mu g/kg) \times BW (kg)}{TC (cm^2/hr) \times Exposure Time (8 hrs) \times Target MOE (unitless) \times DA factor (36\%)}$$

<sup>e</sup>For golf courses, entry is allowed once sprays have dried.

**Table 3 Summary of REIs for triticonazole**

<b>Crop</b>	<b>Activity</b>	<b>Triticonazole REI <sup>a</sup></b>	<b>REI</b>
<b>Established Turf</b>			
Golf courses	All	Risks acceptable on peak residue day (Day 0).	Until sprays have dried <sup>b</sup>

REI = restricted-entry interval.

<sup>a</sup> Day at which risks were shown to be acceptable for triticonazole for postapplication workers entering treated areas to conduct activities.

<sup>b</sup> This REI is applicable for golf courses where other essential activities in the treated area are required as soon as residues have dried and residues in the air have dissipated.

## Appendix VIII Seed treatment exposure and risk assessment

**Table 1 Commercial seed treatment exposure and risk assessment<sup>a</sup>**

Crop	Activity <sup>b</sup>	Application Rate (g a.i./ kg seed) <sup>c</sup>	Throughput (kg seed/day) <sup>d</sup>	MOE	
				Dermal <sup>e</sup>	Inhalation <sup>f</sup>
Commercial Seed Treatment					
PPE: Single layer; Open mixing/loading (Kroski, 2006 – AH803)					
Wheat and Cereals	Treating	0.051	9 2000	891	17 260
PPE: Single layer (Wilson, 2009)					
Wheat and Cereals	Bagging/Sewing/Stacking	0.051	92 000	13 400	47 900
PPE: CR coveralls over single layer (Wilson, 2009 – AH817)					
Wheat and Cereals	Clean-up and repair	0.051	-	12 000	61 300
PPE: Coveralls over single layer; Closed mixing/loading (Krolski, 2010 – AH806)					
Corn	Treating	0.50	125 000	105	860
PPE: Single layer (Krolski, 2010 – AH806)					
Corn	Bagging/Sewing/Stacking	0.50	125 000	156	171
	Clean-up and repair		-	175	166

MOE = margin of exposure; NOAEL = No observed adverse effects level; PPE = personal protective equipment; BW = body weight; Single layer = long-sleeved shirt, long pants, shoes, socks and CR gloves; CR = chemical-resistant; cereals = triticale, oat, rye, barley and canaryseed/canarygrass.

<sup>a</sup> All registered products are formulated as suspension concentrates.

<sup>b</sup> Activities are based on what was monitored in the surrogate exposure study. Cleaning activities were normalized to the application rate rather than the amount handled.

<sup>c</sup> Maximum application rates were used in the assessment. The maximum application rate for canaryseed/canarygrass is 0.050 g a.i./kg seed; however, it was assessed using the maximum rate for all other cereal crops as indicated in the table.

<sup>d</sup> Standard commercial throughput data was used for all crops. The value for wheat and cereals is based on wheat but was used to assess all cereal crops.

<sup>e</sup> Where: MOE = NOAEL/Exposure, based on the short- to intermediate-term NOAEL of 5 mg/kg bw/day. Exposure (mg/kg bw/day) = (Unit exposure (µg/kg a.i.) × Application Rate (g a.i./kg seed) × Throughput (kg seed/day) × (dermal absorption factor 36%) × 0.001 mg/µg × 0.001 kg/g) / BW (80 kg). Target MOE = 100.

<sup>f</sup> Where: MOE = NOAEL/Exposure, based on the short- to intermediate-term NOAEL of 2.5 mg/kg bw/day. Exposure (mg/kg bw/day) = (Unit exposure (µg/kg a.i.) × Application Rate (kg a.i./kg seed) × Throughput (kg seed/day) × 0.001 mg/µg) / BW (80 kg). Target MOE = 100.

**Table 2 On-farm seed treatment and planting exposure and risk assessment**

Crop	Formulation <sup>a</sup>	Activity	Application Rate (g a.i./ kg seed) <sup>b</sup>	Throughput (kg seed/day) <sup>c</sup>	MOE	
					Dermal <sup>d</sup>	Inhalation <sup>e</sup>
On-Farm Seed Treatment						
PPE: Single layer; Open mixing/loading, Closed cab planter (Krolski, 2006)						
Wheat	Liquid	All Tasks	0.051	28 350	5290	18 200
Oats				9120	16 500	56 500
Barley				19 600	7650	26 300
Rye				5380	27 890	96 000
Triticale				16 800	8930	30 700
Canaryseed / Canarygrass				7290	20 600	71 000

MOE = margin of exposure; PPE = personal protection equipment; NOAEL = no observed adverse effect level; BW = body weight; CR = chemical-resistant; Single layer = long-sleeved shirt, long pants, shoes, socks and CR gloves.

<sup>a</sup> Liquid formulation includes suspensions.

<sup>b</sup> Maximum application rates were used in the assessment. The maximum application rate for canaryseed/canarygrass is 0.050 g a.i./kg seed; however, it was assessed using the maximum rate for all other cereal crops as indicated in the table.

<sup>c</sup> Farm throughput data are upper bound estimates for amount of seeds treated per day based on seeding rate and area planted per day.

<sup>d</sup> Where: MOE = NOAEL/Exposure, based on the short- to intermediate-term NOAEL of 5 mg/kg bw/day. Exposure (mg/kg bw/day) = (Unit exposure (µg/kg a.i.) × Application Rate (g a.i./kg seed) × Throughput (kg seed/day) × (dermal absorption factor 36%) × 0.001 mg/µg × 0.001 kg/g) / BW (80 kg). Target MOE = 100.

<sup>e</sup> Where: MOE = NOAEL/Exposure, based on the short- to intermediate-term NOAEL of 2.5 mg/kg bw/day. Exposure (mg/kg bw/day) = (Unit exposure (µg/kg a.i.) × Application Rate (kg a.i./kg seed) × Throughput (kg seed/day) × 0.001 mg/µg) / BW (80 kg). Target MOE = 100.

**Table 3 Exposure and risk assessment for planting treated seed**

Crop	Formulation <sup>a</sup>	Application Rate (g a.i./ kg seed) <sup>b</sup>	Planting Rate (kg seed/day) <sup>c</sup>	MOE	
				Dermal <sup>d</sup>	Inhalation <sup>e</sup>
PPE: Single layer; Closed cab planter (Zeitz, 2007 – AH825)					
Corn (sweet) <sup>f</sup>	Liquid	0.50	1520	965	3180
Corn (field)			3150	466	1530
PPE: Coveralls over single layer; Closed cab planter (Krainz, 2013 – AH823)					
Wheat	Liquid	0.051	28 350	659	384
Oat			9120	2050	1190
Barley			19 600	953	550
Rye			5380	3470	2020
Triticale			16 800	1110	650
Canaryseed			7290	2610	1520

PPE = personal protective equipment; MOE = margin of exposure; NOAEL = no observed adverse effect level; BW = body weight; CR = chemical-resistant; Single layer = long-sleeved shirt, long pants, shoes, socks and CR gloves.

<sup>a</sup> Liquid formulation includes suspensions.

<sup>b</sup> Maximum application rates were used in the assessment. The maximum application rate for canaryseed/canarygrass is 0.050 g a.i./kg seed; however, it was assessed using the maximum rate for all other cereal crops as indicated in the table.

<sup>c</sup> Based on standard seeding rates and area planted per day.

<sup>d</sup> MOE = NOAEL/Exposure, based on the short- to intermediate-term NOAEL of 5 mg/kg bw/day.

Exposure (mg/kg bw/day) = (Unit exposure (µg/kg a.i.) × Application Rate (g a.i./kg seed) × Planting rate (kg seed/day) × (dermal absorption factor 36%) × 0.001 mg/µg × 0.001 kg/g) / BW (80 kg). Target MOE = 100.

<sup>e</sup> MOE = NOAEL/Exposure, based on the short- to intermediate-term NOAEL of 2.5 mg/kg bw/ day. Exposure (mg/kg bw/day) = (Unit exposure (µg/kg a.i.) × Application Rate (kg a.i./kg seed) × Planting rate (kg seed/day) × 0.001 mg/µg) / BW (80 kg). Target MOE = 100.

<sup>f</sup> Pop corn seed is included in the assessment for sweet corn seed.

## Appendix IX Aggregate risk assessment

**Table 1 Residential aggregate exposure and risk assessment for triticonazole**

Lifestage <sup>a</sup>	Dermal Exposure <sup>b</sup> (mg/kg bw/day)	Chronic Dietary Exposure <sup>c</sup> (mg/kg bw/day)	Total Exposure <sup>d</sup> (mg/kg bw/day)	Aggregate MOE <sup>e</sup>
Target MOE = 100				
Adult	$1.32 \times 10^{-2}$	$3.28 \times 10^{-3}$	$1.65 \times 10^{-2}$	304
Youth (11<16 years)	$1.54 \times 10^{-2}$	$2.37 \times 10^{-3}$	$1.77 \times 10^{-2}$	282

MOE = margin of exposure; NOAEL = no observed adverse effect level; TTR = turf transferable residue; TC = transfer coefficient.

<sup>a</sup> An aggregate risk assessment was not conducted for children (6 <11 years) as a common toxicological effect and reference value was not identified for this lifestage.

<sup>b</sup> Dermal Exposure (golfing) = TTR (ug/cm<sup>2</sup>) × TC × duration × dermal absorption factor/Body Weight. Duration was 4 hours. Body weights were 80 and 57 kg for adults and youth (11<16 years), respectively. Based on the maximum application rate of 648 g a.i./ha, maximum number of applications and minimum re-treatment interval. The application rate was not refined for residential exposure because mitigation was not necessary.

<sup>c</sup> Chronic Dietary Exposure is based on the refined application rate of 420 g a.i./ha and a single application as required to mitigate drinking water exposure.

<sup>d</sup> Dermal exposure + chronic dietary exposure (mg/kg bw/day).

<sup>e</sup> Aggregate MOE = NOAEL (mg/kg bw/day) / Total Exposure (mg/kg bw/day). Target MOE = 100 and NOAEL of 5 mg/kg bw/day based on developmental rabbit study.

## Appendix X Environmental risk assessment – Fate and behaviour

**Table 1 Fate and behaviour of triticonazole and transformation products in terrestrial and aquatic environments**

Type of study	Medium	Temp (°C)	pH <sup>4</sup>	Rep. DT <sub>50</sub> (day)	Calculated DT <sub>50</sub> by PMRA (days)	Kinetic model used	t <sub>R</sub> (days) adjusted to 25°C <sup>2</sup>	Comments <sup>5, 6, 7</sup>	PMRA #
TRT Hydrolysis	3.87 mg/L (98.9% TRT)	25	5	Stable	3214.0	SFO	N/A	Not an important route of transformation	1180298
	3.87 mg/L (98.9% TRT)		7	Stable	Stable	SFO	N/A		
	3.87 mg/L (98.9% TRT)		9	Stable	Stable	SFO	N/A		
1,2,4-triazole hydrolysis	Acetate buffer	25	5	303.0	N/A	DFOP	N/A	Not an important route of transformation	3143748, MRID 00133373 (supplemental)
	Phosphate buffer		7	421.0	N/A	DFOP	N/A		
	Borate buffer		9	98.7	N/A	SFO	N/A		
TRT Phototransformation on soil	Manningtree sandy loam (97.3% TRT), at 400 g a.i./kg; irradiated	20	6.0	65.0	65.2	SFO	N/A	Not an important route of transformation	619492
	Manningtree sandy loam (97.3% TRT), at 400 g a.i./kg; dark			NR	216.0	SFO	N/A		
	Net half-life <sup>2</sup>				93.4				
TRT Phototransformation in water	4µg/mL (98.5% TRT, without acetone), irradiated	25	5.0	3.2	7.4	DFOP	7.4	An important route of dissipation	619493
	4µg/mL (98.5% TRT, without acetone), irradiated	25	5.0	3.2	19.5	SFO	19.5	An important route of dissipation	
	5.5 mg/L (99.3% TRT), continuous irradiation	22	5.0	9.3	32.9	SFO	N/A		
	5.5 mg/L (93.3% TRT), dark			NR	425.0	SFO	N/A		
	Net half-life <sup>2</sup>				29.0				
	90 <sup>th</sup> percentile confidence bound of the mean half-life				25.2				
1,2,4-triazole Phototransformation in water	Distilled water	NR	7	Stable	N/A	N/A	N/A	Not an important route of transformation	3143748, MRID 45284026

Type of study	Medium	Temp (°C)	pH <sup>4</sup>	Rep. DT <sub>50</sub> (day)	Calculated DT <sub>50</sub> by PMRA (days)	Kinetic model used	t <sub>R</sub> (days) adjusted to 25°C <sup>2</sup>	Comments <sup>5, 6, 7</sup>	PMRA #
TRT Phototransformation in air	12 hours of sunlight	NA	NA	0.114	NR	NA	NR	Rapid atmospheric photo-oxidation breakdown of TRT	USEPA EPI Suite™, version 2012
TRT aerobic soil biotransformation (combined residues)	Clay loam (UK)	22	6.18	NR	311.6	SFO	253.0	Persistent	1180301
	Sandy loam (UK)	22	6.42	NR	564.0	SFO	458.0		
	Clay soil (94/33, Mississippi, United States)	25	6.5	NR	3307.0	SFO	3307.0	Persistent	1180303
	Sand (California, United States)	20	8.1	NR	517.6	SFO	366.0	Persistent	2801226
	Loam (New Jersey, United States)	20	6.8	NR	395.8	DFOP	280.0		
	Loamy sand (Wisconsin, United States)	20	6.0	NR	387.7	DFOP	274.0		
	Sandy loam (Idaho, United States)	25	7.0	NR	832.7	IORE	833.0	Persistent	2801223 2883790
	Clay loam (Minnesota, United States)	25	7.9	NR	711.8	IORE	712.0		
	Sandy loam (Manningtree, UK) low rate	25	6.7	NR	592.0	SFO	592.0		
	<b>90<sup>th</sup> percentile confidence bound of the mean half-life at 25°C</b>						<b>1236.0</b>	Moderately persistent	-
RPA 406780 <sup>2</sup>	Clay loam (UK)	22	6.18	NR	316.0	SFO	N/A	Persistent	1180301
	UK high organic loamy sand	22	6.42	NR	<b>1100.0</b>	DFOP	N/A	Persistent	
RPA 406341 <sup>1</sup>	Clay loam (UK)	22	6.18	NR	739.0	SFO	600.0	Persistent	1180301
	Sandy loam (UK)	22	6.42	NR	711.0	SFO	577.0	Persistent	
	Clay loam (Herts, UK)	20	7.6	165.0	165.0	SFO	117.0	Moderately persistent	1049882 80866
	Sandy loam (Suffolk, UK)	20	6.0	195.0	197.0	SFO	139.0	Persistent	
	Clay loam (Essex, UK)	20	6.9	330.0	346.0	SFO	245.0	Persistent	
	<b>90<sup>th</sup> percentile confidence bound of the mean half-life at 25°C</b>						<b>497.0</b>	Persistent	-

Type of study	Medium	Temp (°C)	pH <sup>4</sup>	Rep. DT <sub>50</sub> (day)	Calculated DT <sub>50</sub> by PMRA (days)	Kinetic model used	t <sub>R</sub> (days) adjusted to 25°C <sup>2</sup>	Comments <sup>5, 6, 7</sup>	PMRA #
RPA 404766 <sup>1</sup>	Three unknown soils	20	NR	21–46	N/A	N/A	N/A	Slightly to moderately persistent	3143747
RPA 407922 <sup>1</sup>	Clay loam 1 (Herts, UK)	20	7.8	3.7	0.4	SFO	N/A	Non-persistent	1049883 286858
	Clay loam 2 (Essex, UK)	20	7.9	5.1	2.0	IORE	N/A	Non-persistent	
	Loamy sand (Suffolk, UK)	20	6.8	4.8	1.1	SFO	N/A	Non-persistent	
	<b>90<sup>th</sup> percentile confidence bound of the mean half-life</b>						<b>2.0</b>	Non-persistent	-
1,2,4-triazole aerobic soil biotransformation	Les Barges (Swiss) silty loam, 1 ppm applied	25	7.6	378.0	N/A	DFOP	N/A	Persistent	3143748 MRID 45284027
	Laacher Hof AXXa (German) sandy loam, ~0.06 ppm applied	20	6.9	70.1	N/A	IORE	N/A	Moderately persistent	3143748 MRID 45284032
	BBA 2.2 (German) loamy sand ~0.06 ppm applied	20	6.19	319.0	N/A	DFOP	N/A	Persistent	
	Laacher Hof A III (German) silt loam, ~0.06 ppm applied	20	7.88	20.3	N/A	IORE	N/A	Slightly persistent	
	Standard Soil 2.2, 50 ppm applied	22	6.0	1530.0	N/A	DFOP	N/A	Persistent	3143748 MRID 45297203
	Standard Soil 2.3, 50 ppm applied	22	5.5	1550.0	N/A	DFOP	N/A	Persistent	
	<b>90<sup>th</sup> percentile confidence bound of the mean half-life</b>			<b>1070.7</b>				Persistent	-
TRT anaerobic soil biotransformation (combined residues)	Sandy loam (Manningtree, UK)	25	7.65	NR	626.0	SFO	626.0	Persistent	619499
1,2,4-triazole anaerobic soil biotransformation	Les Barges (Swiss) silt loam	20	7.31	81.2	N/A	SFO	N/A	Moderately persistent	3143748 MRID 45930701
TRT aerobic aquatic biotransformation	Rhine river loamy sand whole system (Switzerland)	20	8.5 (w), 6.9 (s)	NR	397.2	SFO	397.2	Persistent	619497
	Anwil clay loam pond whole system (Switzerland)	20	8.3 (w), 6.9 (s)	NR	225.2	SFO	225.2	Persistent	

Type of study	Medium	Temp (°C)	pH <sup>4</sup>	Rep. DT <sub>50</sub> (day)	Calculated DT <sub>50</sub> by PMRA (days)	Kinetic model used	t <sub>R</sub> (days) adjusted to 25°C <sup>2</sup>	Comments <sup>5, 6, 7</sup>	PMRA #
	Wabasha silt loam pond (Minnesota, United States)	25	7.1 (w), 6.4 (s)	210.0	-	SFO	297.1	Persistent	2801229
	80 <sup>th</sup> percentile half-life at 20°C						357.2	-	-
TRT anaerobic aquatic biotransformation	River Roding clay sediment water system	20	7.4 (s)	0.27	4.8	IORE	4.8	Non-persistent	2895393
	River Roding clay sediment whole system	20	7.4 (s)	NR	-	SFO	3719.0	Persistent	
TRT Foliar dissipation	PMRA Default half-life based on Willis and McDowell (1987)	N/A	N/A	N/A	10.0	N/A	N/A	-	1930629
Type of study	Medium	OC (%)	pH	CEC (meq/100 g)		PMRA K <sub>d</sub> value	PMRA K <sub>oc</sub> value	Comments	PMRA#
TRT soil adsorption/desorption	Silt loam (96/19)	0.50	6.20	5.70		3.6	716.8	Low mobility	1161955
	Sandy loam (96/44)	1.20	6.70	6.50		4.8	401.5	Medium mobility	
	Loam (96/50)	2.20	7.00	15.00		8.0	361.8	Medium mobility	
	Sand (97/14)	2.40	6.90	13.20		12.9	536.5	Low mobility	
	Clay sediment (97/17)	3.40	7.40	62.30		10.8	316.8	Medium mobility	
	UK Manningtree sandy loam	0.83	6.30	5.99		3.2	382.2	Medium mobility	1180305
	UK Ongar clay loam	3.19	6.08	28.50		12.0	376.9	Medium mobility	
	UK Bury-St-Edmund Loamy sand	16.96	6.24	51.12		32.5	191.9	Medium mobility	
	UK Mildenhall sand	0.53	6.23	2.30		1.7	314.1	Medium mobility	
	Germany Speyer 2.1 sand	0.77	6.12	2.95		4.0	524.1	Low mobility	
	Grignon silty clay loam	1.04	8.20	NR		4.4	418.0	Medium mobility	3143753
	20 <sup>th</sup> percentile					3.6	316.8	Medium mobility	
RPA 407922 <sup>1</sup> soil adsorption/desorption	United States Leland silt loam (97/11)	0.50	6.50	6.30		2.4	482.5	Medium mobility	1049885
	United States Iola sandy loam (98/15)	1.30	5.80	5.00		14.4	1105.1	Slight mobility	
	UK Ongar loam (98/26)	1.90	7.00	10.00		7.4	390.9	Medium mobility	
	UK Royston clay loam (99/26)	4.10	7.80	51.90		14.3	348.9	Medium mobility	
	UK Essex sdy-clay loam sediment (00/03)	2.60	8.20	43.80		9.0	344.7	Medium mobility	
	20 <sup>th</sup> percentile					6.4	348.1	Medium mobility	

Type of study	Medium	Temp (°C)	pH <sup>4</sup>	Rep. DT <sub>50</sub> (day)	Calculated DT <sub>50</sub> by PMRA (days)	Kinetic model used	t <sub>R</sub> (days) adjusted to 25°C <sup>2</sup>	Comments <sup>5, 6, 7</sup>	PMRA #	
RPA 406341 <sup>1</sup> soil adsorption/desorption	US Leland Silt loam (97/11)	0.50	6.50	6.30		0.7	135.7	High mobility	1049884	
	US Iola sandy loam (98/15)	1.30	5.80	5.00		1.4	106.1	High mobility		
	UK Ongar loam (98/26)	1.90	7.00	10.00		2.3	123.3	High mobility		
	UK Royston clay loam (99/26)	4.10	7.80	51.90		2.2	52.8	High mobility		
	UK Essex sdy clay loam sediment (00/03)	2.60	8.20	43.80		2.9	112.2	High mobility		
	20 <sup>th</sup> percentile					1.2	95.4	High mobility		
1,2,4-triazole soil adsorption/desorption	Alpaugh Silty Clay	0.65	8.8	30.5		0.83	120	High mobility	3143748	
	Hollister Clay Loam	1.74	6.9	16.9		NR	43	Very high mobility		
	Lakeland Sand	0.12	4.8	1.2		0.23	202	Medium mobility		
	Lawrenceville Silty Clay Loam	0.70	7.0	6.6		NR	104	High mobility		
	Pachappa Sandy Loam	0.81	6.9	11.1		NR	89	High mobility		
	20 <sup>th</sup> percentile						79.8	High mobility		
Type of study	Medium	Average percentage applied radioactivity recovered in soil sections (cm)							Comments	PMRA#
		0–5.1	5.2– 10.3	10.4– 15.5	15.6– 20.7	20.8– 25.9	30–35.1	Leachate		
TRT unaged soil column leaching	UK Manningtree sandy loam	39.5	43.0	8.3	0.4	0.3	0.2	0.39	Low leaching (91% above 15.5-cm depth)	1180306
	UK Ongar clay loam	49.4	46.0	2.2	0.8	0.5	0.4	0.3	Low leaching (95% above 10-cm depth)	
	UK Bury-St-Edmund loamy sand	101.3	1.0	0.3	0.2	0.1	0.1	0.1	Low leaching (100% above 11-cm depth)	
	UK Midenhall sand	3.1	2.4	3.4	4.9	6.6	10.0	70.6	High leaching (71% in leachate)	
	German Speyer 2.1 sand	30.6	40.5	29.5	0.8	0.4	0.3	1.2	Low leaching (about 100% above 15.5 cm)	
TRT aged soil column leaching	UK Manningtree sandy loam	38.2	38.5	12.4	1.7	1.0	0.5	1.4	Low leaching (89% above 15.5 cm depth)	
	UK Ongar clay loam	79.8	14.0	2.5	1.2	0.6	0.3	0.6	Low leaching (94% above 10-cm depth)	

Type of study	Medium	Temp (°C)	pH <sup>4</sup>	Rep. DT <sub>50</sub> (day)		Calculated DT <sub>50</sub> by PMRA (days)	Kinetic model used	t <sub>R</sub> (days) adjusted to 25° C <sup>2</sup>	Comments <sup>5, 6, 7</sup>	PMRA #
	UK Bury-St-Edmund loamy sand	89.1	3.1	0.5	0.1	0.1	0.05	0.4	Low leaching (89% above 5-cm depth)	
	UK Midenhall sand	19.0	5.2	7.5	11.4	15.3	14.6	27.0	Significant leaching below 30-cm depth (42%)	
	German Speyer 2.1 sand	51.3	37.4	7.4	0.9	0.8	0.6	1.8	Low leaching (89% above 10-cm depth)	
Type of study	Properties	Criteria of Cohen <i>et al.</i> , (1984) indicating a potential for leaching				TRT	RPA 406341 <sub>1</sub>	RPA 407922 <sup>1</sup>	Criteria met	
TRT Criteria of Cohen (1984)	Solubility in water (mg/L)	> 30				8.4	NR	NR	No for TRT, unknown for others	
	K <sub>d</sub> (mL/g)	< 5 and usually < 1 or 2				3.6	1.2	6.4	No for TRT and RPA 407922, yes for RPA 406341	
	K <sub>oc</sub> (mL/g)	< 300				316.8	95.4	348.1	No for TRT and RPA 407922, yes for RPA 406341	
	Henry's law constant (atm.m <sup>3</sup> /mole)	< 0.01				3.75 × 10 <sup>-10</sup>	NR	NR	Yes for TRT, unknown for RPA 406341 and RPA 407922	
	pKa	Negatively charged (either fully or partially) at ambient pH				No dissociation	NR	NR	No for TRT, unknown for others	
	Hydrolysis half-life (days)	> 140 d (> 20 weeks)				> 3213	Assumed stable	Assumed stable	Yes for all residues	
	Soil phototransformation half-life (days)	> 7				93.4	Not a major TP	Not a major TP	Yes for TRT and also assumed to be > 7 days for RPA 406341 and RPA 407922	
	Soil biotransformation half-life (days)	> 14 to 21				480	497	2.04	Yes for TRT and RPA 406341 and no for RPA 407922	
	PMRA Interpretation for leaching potential using Cohen criteria					TRT: Only 4 out of 8 criteria were met suggesting TRT has limited potential for leaching. RPA 406341: 4 out of 8 criteria (no information for 3 criteria) were met suggesting may have potential to leach RPA 407922 : 1 out of 8 criteria (no information for 3 criteria) were met suggesting negligible potential for leaching				
GUS Score	Triticonazole at 25°C					4.02	TRT is expected to be leacher			
	Triticonazole at 10°C					4.53	TRT is expected to be leacher			
	RPA 406341 <sup>1</sup> at 25°C					5.45	RPA 406341 is expected to be leacher			
	RPA 407922 <sup>1</sup> at 22°C					0.44	RPA 407922 is not expected to be leacher			
TRT volatilization	Vapour pressure (Pa at 25°C)					1 × 10 <sup>-3</sup>	Overall, triticonazole is not considered to be volatile and is not expected to undergo long-range atmospheric			
	Henry's law constant (atm m <sup>3</sup> /mole)					1.43 × 10 <sup>-12</sup>				

Type of study	Medium	Temp (°C)	pH <sup>4</sup>	Rep. DT <sub>50</sub> (day)	Calculated DT <sub>50</sub> by PMRA (days)	Kinetic model used	t <sub>R</sub> (days) adjusted to 25°C <sup>2</sup>	Comments <sup>5, 6, 7</sup>	PMRA #	
	Long range transport atmospheric half-life	OECD threshold: > 2 days			0.114		transport.			
Type of study	Location/Medium	Treatment	pH	OM (%)	Max soil depth detection (cm)	Report ed DT <sub>50</sub> (day)	PMRA t <sub>R</sub> (day)	PMRA reporte d kinetics	Carry over (%)	PMRA#
TRT Terrestrial Field Dissipation (Canadian equivalent ecoregion)	Fort Qu’Appelle, Saskatchewan; Loamy sand ecoregion 9.2	Single application of 10 g a.i./ha. Four months of dissipation.	7.8–8.2	0.7–2.0	0–15	144.0	159.0	IORE	16.6	714171 775285
	Ephrata, WA, United States; Fallow (bare) Quincy loamy fine sand; ecoregion 10.1 <sup>2</sup>	6 broadcast foliar applications (636 g a.i./ha each). Four months of dissipation	7.1–8.2	0.1–0.4	15	133.0	154.0	SFO	N/A	775186 491643
	Ephrata, WA, United States; Turf covered Quincy loamy fine sand; ecoregion 10.1 <sup>2</sup>	6 broadcast foliar applications (636 g a.i./ha each). Four months of dissipation	7.5–8.5	0.1–1.5	15–30	247.0	243.0	SFO	N/A	
	Ephrata, WA, United States; Fallow Quincy loamy fine sand; ecoregion 10.1 <sup>2</sup>	6 broadcast foliar applications (636 g a.i./ha each). 4 to 18 months of dissipation	7.1–8.2	0.1–0.4	60–75	154.0	143.0	SFO	11.8	1062857 2883580
	Ephrata, WA, United States; Coarse sandy loam-sand; ecoregion 10.1 <sup>2</sup>	Foliar Pre-plant incorporation (187 g a.i./ha). 0 to 4 months of dissipation	7.4–8.5	0.3–1.3	0–10	62.0	69.0	SFO	N/A	1034711 (Part 1), 80996 <sup>3</sup>
	Ephrata, WA, United States; Coarse sandy loam-sand; ecoregion 10.1 <sup>2</sup>	Soil column seed treatment to wheat (189 g a.i./ha). 0 to 4 months of dissipation	7.4–8.5	0.3–1.3	20 (95)	124.0	ND	N/A	N/A	
	Ephrata, WA, United States; Coarse sandy loam-sand; ecoregion 10.1 <sup>2</sup>	Foliar Pre-plant incorporation (187 g a.i./ha).4 to 18 months of dissipation	7.4–8.5	0.3–1.3	0–10	173.0	163.0	SFO	19.6	1034713 (Part 1), 367953
	Bologna, Italy loam; ecoregion NA0414 – Southern Great Lakes forest (83% similarity)	240 g a.i./ha; Pre-plant incorporation	8.3–8.4	1.5–1.7	NR	105.0	163.0	SFO	6.3	1062858 1180400

Type of study	Medium	Temp (°C)	pH <sup>4</sup>	Rep. DT <sub>50</sub> (day)	Calculated DT <sub>50</sub> by PMRA (days)	Kinetic model used	t <sub>R</sub> (days) adjusted to 25°C <sup>2</sup>	Comments <sup>5, 6, 7</sup>		PMRA #
	Goch, Germany sandy loam; ecoregion NA0416 – Western Great Lakes forests (83% similarity)	240 g a.i./ha; Pre-plant incorporation		6.2–6.8	0.4–2.1	NR	178.0	181.0	SFO	17.0–19.8
	Manningtree, UK sandy loam; ecoregion NA0522 – Okanagan dry forests (82%)	240 g a.i./ha; Pre-plant incorporation		5.3–7.3	0.2–1.6	NR	104.0	199.0	IORE	8.6
	Manningtree, UK sandy loam; ecoregion NA0522 – Okanagan dry forests (82%)	240 g a.i./ha; seed treatment		5.3–7.3	0.2–1.6	NR	139.0	217.0	SFO	36.0–51.2
	<b>90<sup>th</sup> percentile confidence bound of the mean half-life</b>						<b>190.0</b>	-	<b>16.9</b>	-
1,2,4-triazole terrestrial field dissipation	Newtown, Pennsylvania Silty Loam, 0-3' depth (study sampled to 36" depth)			NR	15–30	445.0	N/A	IORE	N/A	3143748, MRID
	Newtown, Pennsylvania Silty Loam, 0-3' depth			NR	15–30	391.0	N/A	SFO	N/A	45284025
	Cleveland, Mississippi Loam, 0-3' depth			NR	15–30	525.0	N/A	SFO	N/A	3143748, MRID 00164564
	Newtown, Pennsylvania Silty Loam, 0-3' depth (study sampled to 36" depth)			NR	15–30	445.0	N/A	IORE	N/A	3143748, MRID 45284025
TRT Bioaccumulation	Octanol/water partition coefficient			Log K <sub>ow</sub> = 3.29				Some potential for bioaccumulation		PRDD2004-06
	Bluegill sunfish ( <i>Lepomis macrochirus</i> ) exposed to 89 µg/L of triticonazole for 28 d.			BCF edible tissue = 9.2 (14) <sup>9</sup> ; BCF inedible tissue = 114.9 (157) <sup>9</sup> ; BCF whole fish = 72.6 (94) <sup>9</sup> ; Depuration half-life = 0.86 day				Low potential for bioaccumulation		2801259 1049886 103843
	Rainbow trout ( <i>Oncorhynchus mykiss</i> ) exposed to 0.09 and 0.16 mg/L of triticonazole for 28 d.			BCF edible tissue = 9.2 (14) <sup>9</sup> ; BCF inedible tissue = 114.9 (157) <sup>9</sup> ; BCF whole fish = 72.6 (94) <sup>9</sup> ; Depuration half-life = < 1 day				Low potential for bioaccumulation		2801262

OM = organic matter; CEC = cation exchange capacity; UK = United Kingdom, TRT = triticonazole; Rep. = reported; Temp = temperature; SFO = single first order kinetics; DFOP = double first order in parallel kinetic; IORE = Indeterminate order rate equivalent kinetic; ND = Not determined; NR = not reported; N/A = not applicable; **Bold** and shaded values are to be used in the environmental risk assessment of triticonazole.

<sup>1</sup>Major transformation product;

<sup>2</sup>Minor transformation product;

<sup>3</sup>DT<sub>50</sub> from SFO values, then adjusted for the dark sample using the equation: DT<sub>50</sub> = 1/((1/DT<sub>50</sub>, irr.) - (1/DT<sub>50</sub>, dark));

<sup>4</sup>for pH, (w) = water phase; (s) = sediment phase;

<sup>5</sup> = Based on classification of Goring et al. 1975 for soils;

<sup>6</sup>Classification of McEwen and Stephenson and based on reported and PMRA DT<sub>50</sub> values for water;

<sup>7</sup>Adsorption/desorption classification of McCall et al. 1981;

<sup>8</sup>Equivalent ecoregion generated using OECD ENASGIPS v3, 2014 for experimentation site but the seed treatment use in Canada is normally for wheat, barley and oats produced in Canadian ecoregions 9.1, 9.2 and 9.3;

<sup>9</sup> BCF = bioconcentration factor calculated by the USEPA, 2015;

## Appendix XI Terrestrial ecotoxicological data

**Table 1 Terrestrial toxicity data of triticonazole and related transformation products**

Organism	Compound	Endpoint Type	Reported Endpoint	Value	Comment	Reference
<b>Earthworm</b>						
Earthworm, <i>Eisenia fetida</i>	Triticonazole (95.9% purity)	Acute	14d-LC <sub>50</sub>	>1000 mg a.i./kg soil	No effect at highest test concentration	1122425
	RPA 406341		14d-LC <sub>50</sub>	>1000 mg a.i./kg soil	No effect at highest test concentration	3143763
	RPA 407922		14d-LC <sub>50</sub>	>1000 mg a.i./kg soil	No effect at highest test concentration	3143763
	Triticonazole	Chronic	56d-NOEC	500 mg a.i./kg soil	No effect on reproduction at highest test concentration	3143763
<b>Pollinators</b>						
Honey bee, <i>Apis mellifera</i> L.	Triticonazole Technical (90.5% purity)	Adult Acute Contact	48h-LD <sub>50</sub> NOED	> 24 µg a.i./bee (HDT) 24 µg a.i./bee (HDT)	Relatively non-toxic	1122426 2883582
	Triticonazole Technical (96.5% purity)		48h-LD <sub>50</sub>	> 100 µg a.i./bee (HDT)	Relatively non-toxic	2801233 3143747
	Triticonazole Technical (96.5% purity)	Adult Acute Oral	48h-LD <sub>50</sub>	> 155.5 µg a.i./bee (HDT)	Relatively non-toxic	2801233 3143747
	BAS 595 F	Larvae Chronic Test	96h-LD <sub>50</sub> 96h-NOED	37 µg a.i./bee 10 µg a.i./bee	N/A	2875337
	BAS 595 F Triticonazole Technical, (90.3% purity)	Chronic Test (adult emergence)	22d-ED <sub>50</sub> 22d-NOED	19 µg a.i./bee 10 µg a.i./bee	N/A	
	Triticonazole Technical, (91.3% purity)	Adult Chronic Test	10d-LC <sub>50</sub> 10d-LDD <sub>50</sub> NOEC NOEDD	>627 mg a.i./kg >18.4 µg a.i./bee/day (HDT)  627 mg a.i./kg 18.4 µg a.i./bee/day	N/A	2875338

Organism	Compound	Endpoint Type	Reported Endpoint	Value	Comment	Reference
Beneficial arthropods						
Predators, Predatory mite <i>T. pyri</i>	EXP80523A (2.5% TRT seed treatment)	Acute exposure	48h-LR <sub>50</sub>	> 100.0 g a.i./ha(HTR)	No effect on mortality and fecundity	3143763
	EXP80472B or Premis 25 FS (25.5 g TRT/L)	Acute exposure	48h-LR <sub>50</sub>	> 50.0 g a.i./ha (HTR)	No effect on mortality and fecundity	
Parasitoid, Parasitic wasp <i>Aphidius Rhopalosiphi</i>	EXP80523A	Acute exposure	48h-LR <sub>50</sub>	>11.5 and < 100.0 g a.i./ha	0% mortality and <30% reduction in fecundity. 86% mortality.	3143763
	EXP80472B	Acute exposure	48h-LR <sub>50</sub>	>50.0 g a.i./ha (HTR)	0% mortality and 22.9% reduction in fecundity	
Soil-dwelling arthropod <i>P. cupreus</i>	EXP80560B + guazatine	Acute exposure	LR <sub>50</sub> and food consumption	>120.0 g a.i./ha (HTR)	0% mortality and 11% reduction in consumption	3143747
	EXP80527B TRT+ iprodione			>192.0 g a.i./ha (HTR)	0% mortality and 14% reduction in consumption	
Soil-dwelling arthropod <i>A.bilineata</i>	EXP80560B + guazatine	Acute exposure	LR <sub>50</sub> and reduction in parasitatic capacity	>48.0 g a.i./ha (HTR)	-12% (increased parasitisation)	
	EXP80527B TRT + iprodione			>120.0 g a.i./ha (HTR)	-4% (increased parasitation)	
Birds						
Bobwhite quail ( <i>Colinus virginianus</i> )	TRT or RPA 400727 (95.9% purity)	Acute oral	14d-LD <sub>50</sub> NOEL	>2000 mg a.i./kg bw 2000 mg a.i./kg bw	Practically non-toxic	1180318
Mallard duck ( <i>Anas platyrhynchos</i> )	TRT or RPA 400727 (95.9% purity)		14d-LD <sub>50</sub> NOEL	>2000 mg /kg bw 1000 mg a.i./kg bw	Practically non-toxic	1180319
Ring-necked pheasant ( <i>Phasianus colchicus</i> )	TRT or RPA 400727 (98-100% purity)		14d-LD <sub>50</sub> NOEL	>2000 mg /kg bw 2000 mg a.i./kg bw	Practically non-toxic	1180321
Pigeon ( <i>Columbia liva</i> )	TRT or RPA 400727 (98-100% purity)		14d-LD <sub>50</sub> NOEL	>2000 mg /kg bw 2000 mg a.i./kg bw	Practically non-toxic	1180320
Red-legged partridge ( <i>Alectoris rufa</i> )	TRT or RPA 400727 (95.9% purity)		14d-LD <sub>50</sub>	>2000 mg/kg bw	Practically non-toxic	1180323
Grey partridge ( <i>Perdrix perdrix</i> )	TRT or RPA 400727 (95.9% purity)		14d-LD <sub>50</sub> NOEL	>2000 mg/kg bw 2000 mg a.i./kg bw	Practically non-toxic	1180322
Bobwhite quail ( <i>Colinus virginianus</i> )	TRT or RPA 400727 (95.9% purity)	Acute dietary	5d-LC <sub>50</sub> 5d-LD <sub>50</sub> NOEC	>5200 mg a.i./kg diet >693 mg a.i./kg bw 1300 mg a.i./kg diet	Practically non-toxic	1180324 3143763 3143747

Organism	Compound	Endpoint Type	Reported Endpoint	Value	Comment	Reference
Mallard duck ( <i>Anas platyrhynchos</i> )	TRT or RPA 400727 (95.9% purity)		5d-LC <sub>50</sub> NOEC	>5200 mg a.i./kg diet 1300 mg a.i./kg diet	Practically non-toxic	1180326
Bobwhite quail ( <i>Colinus virginianus</i> )	TRT or RPA 400727 (97.5% purity)	Chronic (Reproduction)	21W- NOAEC 21W- LOAEC 21W- NOAEC 21W- NOAEL 21W- LOAEL	250 mg a.i/kg diet 500 mg a.i/kg diet <172 mg a.i./kg diet <b>19.5 mg a.i./kg bw/d</b> 39.4 mg a.i./kg bw/d	-	1180332 1180332 3143747 3143748
Mallard duck ( <i>Anas platyrhynchos</i> )	TRT or RPA 400727 (90.52% purity)		21W- NOAEC 21W- NOAEC	1000 mg a.i./kg diet 905.2 mg a.i./kg diet <sup>2</sup>	-	1049887 1052806
Coturnix quail ( <i>Coturnix japonica</i> )	1,2,4-triazole	Acute oral	14d-LD <sub>50</sub>	>316 mg a.i./kg bw	Moderately toxic	3143748
Bobwhite quail ( <i>Colinus virginianus</i> )			14d-LD <sub>50</sub>	<b>770 mg a.i./kg bw</b>	Slightly toxic	
Mammals						
Rat <i>Rattus norvegicus</i>	TRT	Acute Oral (gavage) CD rats	LD <sub>50</sub>	<b>&gt; 2000 mg a.i./kg bw</b>	↓ motor activity and ataxia in one ♂ and all ♀ on Day1. No effects in bw or necropsy. <b>Low acute toxicity</b>	1180232
			LD <sub>50</sub>	> 2000 mg a.i./kg bw	No treatment related clinical signs <b>Low acute toxicity</b>	1180233
		Developmental/Repr oductive Toxicity Studies – dietary reproductive 2- generation type	NOAEL LOAEL	<b>49.4/54.7 mg a.i./kg/day 307/387mg a.i./kg/day</b>	<b>307/387mg/kg bw/day:</b> ↓fertility and mating indices F1, ↑ovary wt (45%), ↑ vacuolization of the ovary F1, ↓ litter size F1, ↑ number of still births P/F1, ↓ livebirth index (82 vs. 93% P and 85 vs. 99 F1)	1180173 1180261

Organism	Compound	Endpoint Type	Reported Endpoint	Value	Comment	Reference
Terrestrial plants						
Cabbage <i>Brassica o. capitata</i>	TRT	Seedling Emergence Test (shoot length)	EC <sub>25</sub>	941 g a.i./ha	-	619554 491643 3143748
Lettuce <i>Lactuca sativa</i>				59 g a.i./ha	17 g a.i./ha according to the USEPA, 2015	
Soybean <i>Glycine max</i>				818 g a.i./ha	-	
Turnip <i>Brassica rapa</i>				2690 g a.i./ha	-	
Cucumber <i>Cucumis sativus</i>		Vegetative Vigor Test (plant weight)		4483 g a.i./ha	-	
Lettuce <i>Lactuca sativa</i>				2466 g.a.i./ha	-	
Soybean <i>Glycine max</i>				3475 g a.i/ha	-	
Turnip <i>Brassica rapa</i>				1345 g a.i./ha	1457 g a.i./ha according to the USEPA 2015	

HTR = Highest tested rate; HTD = Highest dose tested; NR = not reported; Shaded and **bold** values are to be used in the environmental risk assessment.

**Table 2 Aquatic ecotoxicological data of triticonazole and related transformation products**

Compound-Code	Purity (%)	System/Medium	Organism	Species	Toxicity type	Duration (d)	Endpoint	Symbol	Value <sup>1</sup> (mg a.i./L)	Comment (classification) <sup>2</sup>	PMRA #
<b>Freshwater organisms</b>											
<b>Freshwater invertebrates acute exposure</b>											
Triticonazole technical (TRT)	99.5	Static	Water flea	<i>Daphnia magna</i>	Acute	2	EC <sub>50</sub>	=	<b>9.0</b>	Moderately toxic	1122428
EXP 10642A (Formulation)	NR	Static	Water flea	<i>Daphnia magna</i>	Acute	2	EC <sub>50</sub>	=	0.8	Highly toxic	3143763
RPA 406203	99.8	Flow-through	Water flea	<i>Daphnia magna</i>	Acute	2	EC <sub>50</sub>	=	<b>3.4</b>	Moderately toxic	2801234
RPA 404766	96.9	Semi-static	Water flea	<i>Daphnia magna</i>	Acute	2	EC <sub>50</sub>	>	<b>100.0 (HCT)</b>	Practically non-toxic	3143763
RPA 407922	99.5	Semi-static	Water flea	<i>Daphnia magna</i>	Acute	2	EC <sub>50</sub>	>	<b>100.0 (HCT)</b>	Practically non-toxic	3143763
RPA 406341	94.7	Semi-static	Water flea	<i>Daphnia magna</i>	Acute	2	EC <sub>50</sub>	=	<b>50.0</b>	Slightly toxic	3143763
1,2,4-triazole	NR	NR	Water flea	<i>Daphnia magna</i>	Acute	2	EC <sub>50</sub>	>	98.1 (HCT)	Slightly toxic	3143748
<b>Freshwater invertebrates chronic exposure</b>											

Compound-Code	Purity (%)	System/Medium	Organism	Species	Toxicity type	Duration (d)	Endpoint	Symbol	Value <sup>1</sup> (mg a.i./L)	Comment (classification) <sup>2</sup>	PMRA #
Triticonazole	97.2	Static renewal	Water flea	<i>Daphnia magna</i>	Chronic	21	NOEC	=	1.3	N/A	1122429
RPA 400727 (Triticonazole)	95.9	Semi-static	Water flea	<i>Daphnia magna</i>	Chronic	21	NOEC	=	0.092	N/A	3143763
BAS 595 F (Triticonazole)	90.3	Static renewal	Water flea	<i>Daphnia magna</i>	Chronic	21	NOEC	=	1.5	N/A	2801238
BAS 595 F (Triticonazole)	91.3	Static renewal	Water flea	<i>Daphnia magna</i>	Chronic	21	NOEC	=	0.11	N/A	2801239 3143748
Triticonazole	96.5	Static	Midge larvae	<i>Chironomus riparius</i>	Chronic	26	NOEC	=	<b>0.078 (HCT)</b>	N/A	1508614 3143763
<b>Freshwater fish acute exposure</b>											
Triticonazole	97.2	Flow-through	Rainbow trout	<i>Onchorhynchus mykiss</i>	Acute	4	LC <sub>50</sub> NOEC	> =	<b>3.6 (HCT)</b> 1.4	Moderately toxic Erratic swimming	1122434
BAS 671 01 F (8.8% TRT + 0.8% PYA + 17.2% TPM)	0.88	Static	Rainbow trout	<i>Onchorhynchus mykiss</i>	Acute	4 4	LC <sub>50</sub> NOEC	= =	0.98 [ 0.086] <sup>3,4</sup> 0.66 [ 0.058] <sup>3,4</sup>	Highly toxic	2489880
Triticonazole	97.1	Flow-through	Bluegill sunfish	<i>Lepomis macrochirus</i>	Acute	4	LC <sub>50</sub>	>	8.9 (HCT)	Moderately toxic	1122435 2801246
1,2,4-triazole	NR	NR	Rainbow trout	<i>Onchorhynchus mykiss</i>	Acute	4	LC <sub>50</sub>	=	<b>498.0</b>	Practically non-toxic	3143748
1,2,4-triazole	NR	NR	Rainbow trout	<i>Onchorhynchus mykiss</i>	Acute	4	LC <sub>50</sub>	=	506.0	Practically non-toxic	3143748
<b>Freshwater fish chronic exposure</b>											
Triticonazole technical	90.5	Flow-through	Fathead minnow	<i>Pimephales promelas</i>	Chronic ELS	34	NOEC	=	<b>0.021</b>	N/A	1122437 2801241
BAS 595 F (TRT)	91.3	Flow-through	Fathead minnow	<i>Pimephales promelas</i>	Chronic Life cycle	257	NOEC LOEC	= =	0.047 0.094	N/A	2801255
1,2,4-triazole	NR	NR	Rainbow trout	<i>Onchorhynchus mykiss</i>	Chronic	28	NOAEC	=	<b>3.2</b>	N/A	3143748
<b>Freshwater amphibian exposure (based on surrogate fish)</b>											
Triticonazole	97.2	Flow-through	Rainbow trout	<i>Onchorhynchus mykiss</i>	Acute	4	LC <sub>50</sub>	>	<b>3.6</b>	N/A	1122434
Triticonazole	97.2	Flow-through	Fathead minnow	<i>Pimephales promelas</i>	Chronic ELS	34	NOEC	=	<b>0.021</b>	N/A	1122437 2801241
<b>Freshwater algae and vascular plant exposure</b>											
Triticonazole	90.5	Static	Green algae	<i>Selenastrum capricornutum</i>	Acute	5	ErC <sub>50</sub>	>	2.5	N/A	619550
Triticonazole	96.8	Static	Green algae	<i>Selenastrum capricornutum</i>	Acute	4	EbC <sub>50</sub>	>	1.0	N/A	3143763
Triticonazole	90.5	Static	Green algae	<i>Anabaena flos</i>	Acute	5	ErC <sub>50</sub>	>	2.6	N/A	619551

Compound-Code	Purity (%)	System/Medium	Organism	Species	Toxicity type	Duration (d)	Endpoint	Symbol	Value <sup>1</sup> (mg a.i./L)	Comment (classification) <sup>2</sup>	PMRA #
				<i>aquae</i>							
Triticonazole	90.5	Static	Freshwater diatom	<i>Navicula pelliculosa</i>	Acute	5	ErC <sub>50</sub>	=	<b>0.95</b>	N/A	619552
1,2,4-triazole	NR	NR	Green algae	<i>P. subcapitata</i>	Acute	4	EbC <sub>50</sub>	=	<b>14.0</b>	N/A	3143748
1,2,4-triazole	NR	NR	Green algae	<i>Scenedesmus subspicatus</i>	Acute	4	EbC <sub>50</sub>	=	6.3	N/A	3143748
Triticonazole	90.5	Semi static	Freshwater vascular plant	<i>Lemna gibba</i>	Acute	14	EbC <sub>50</sub>	=	<b>1.1</b>	N/A	619550
<b>Saltwater organisms</b>											
<b>Estuarine/Marine invertebrates acute exposure</b>											
RPA 400727 (TRT)	90.5	Flow-through	Mysid shrimp	<i>Americamysis bahia</i>	Acute	4	EC <sub>50</sub>	=	<b>1.9</b>	Moderately toxic	1122431
RPA 400727 (TRT)	90.5	Flow-through	Atlantic oyster (shell deposition)	<i>Crassostrea virginica</i>	Acute	4	EC <sub>50</sub>	=	8.9	Moderately toxic	1122432
<b>Estuarine/Marine invertebrates chronic exposure</b>											
BAS 595 F (TRT)	90.3	Flow-through	Mysid shrimp	<i>Americamysis bahia</i>	Chronic	28	NOEC	=	<b>0.025</b>	N/A	2801243 3143748
<b>Estuarine/Marine fish acute exposure</b>											
Triticonazole technical	90.5	Flow-through	Sheepshead minnow	<i>Cyprinodon variegatus</i>	Acute	4	LC <sub>50</sub>	>	<b>9.1 (HCT)</b>	Moderately toxic	1122436
<b>Estuarine/Marine fish chronic exposure</b>											
BAS 595 F (TRT)	90.3	Flow-through	Sheepshead minnow	<i>Cyprinodon variegatus</i>	Chronic ELS	34	NOEC	=	<b>0.12 (HCT)</b>	N/A	2801249
<b>Estuarine/Marine algae acute exposure</b>											
Triticonazole	90.5	Static	Marine diatom	<i>Skeletonema costatum</i>	Acute	5	ErC <sub>50</sub>	=	<b>0.31</b>	N/A	2801263

<sup>1</sup> All data were transformed into mg a.i./L;<sup>2</sup> Toxicity classification according to USEPA, 2017 (PMRA# 3193618);<sup>3</sup> Value given for TRT content;<sup>4</sup> Qualitative information only;N/A = Not Applicable; TRT = triticonazole; TPM = Thiophanate methyl; PYA = pyraclostrobin; (TP) = transformation product; HCT = highest concentration tested; **bold** and shaded values are to be used in the environmental risk assessment.

## Appendix XII Estimated environmental concentration

**Table 1 The estimated environmental concentration (EEC) of triticonazole**

Crop	Application equipment	Number. of applications	Droplet size	Maximum single rate of application (g a.i./ha)	Interval between application (day)	Maximum cumulative rate of applications (g a.i./ha)	Soil EEC, 15-cm depth (mg a.i./kg soil)	Refined drift (%)	Refined Soil EEC, 15-cm depth with drift (mg a.i./kg soil)
<b>Triticonazole</b>									
Turf (golf course)	Groundboom	3	Medium	648	14	1944 (1928.84) <sup>1</sup>	0.86	6	0.052
Barley	Seed treatment	1	N/A	6.2	N/A	6.2	0.003	N/A	0.003
Field corn (field, pop, field corn for seed production)	Seed treatment	1	N/A	15.8 (field) 7.6 (sweet)	N/A	15.8 (field) 7.6 (sweet)	0.007 0.003	N/A	0.007 0.003
Oats	Seed treatment	1	N/A	5.8	N/A	5.8	0.003	N/A	0.003
Rye	Seed treatment	1	N/A	3.4	N/A	3.4	0.002	N/A	0.002
Triticale	Seed treatment	1	N/A	10.7	N/A	10.7	0.005	N/A	0.005
Wheat (all types)	Seed treatment	1	N/A	8.9	N/A	8.9	0.004	N/A	0.004
Canaryseed and Canarygrass (grown for human consumption)	Seed treatment	1	N/A	2.3	N/A	2.3	0.001	N/A	0.001

<sup>1</sup> Value in parentheses represents the true cumulative rate taking into account the dissipation of TRT in soils between applications; N/A = Not applicable.

**Table 2 The estimated environmental concentration of triticonazole in freshwater and estuarine/marine habitats (mg a.i./l) at 15 and 80 cm depth as a result of foliar direct application**

Habitat	Crop	Application equipment	Number of applications	Maximum single rate of application (g a.i./ha)	Interval between applications (day)	Cumulative rate of applications (g a.i./ha)	EEC, 15 cm water depth (mg a.i./L)	EEC, 80 cm water depth (mg a.i./L)	EEC, 15 cm water depth with 6% drift (mg a.i./L)	EEC, 80 cm water depth with 6% drift (mg a.i./L)
<b>Triticonazole</b>										
Freshwater	Turf (golf course)	Groundboom	3	648	14	1892	1.26	0.24	0.076	0.014
Estuarine/marine			1	648	N/A	648	N/A	0.081	N/A	0.005

N/A = Not applicable.

## Appendix XIII Risk assessment for non-target organisms

**Table 1 Screening level risk assessment of earthworms (*Eisenia fetida*) exposed to triticonazole and its major transformation products**

Formulation Type	Reported Endpoint	Value <sup>1</sup> (mg a.i./kg soil)	Crop scenario	EEC (mg a.e./kg soil)	RQ	LOC exceeded
Acute Toxicity						
Triticonazole						
RPA 400727 (95.9 % purity)	½ 14d-LC <sub>50</sub>	>500	Turf (golf course)	0.86	< 0.002	No
			Seed treatment	0.007	< 0.00001	No
Major transformation products						
RPA 406341	½ 14d-LC <sub>50</sub>	>500	Turf (golf course)	0.86	< 0.002	No
			Seed treatment	0.007	< 0.00001	No
RPA 404766	½ 14d-LC <sub>50</sub>	>500	Turf (golf course)	0.86	< 0.002	No
			Seed treatment	0.007	< 0.00001	No
RPA 407922	½ 14d-LC <sub>50</sub>	>500	Turf (golf course)	0.86	< 0.002	No
			Seed treatment	0.007	< 0.00001	No
Reproduction Toxicity						
Triticonazole						
Unknown source and purity	56 d-NOEC	500	Turf (golf course)	0.86	0.002	No
			Seed treatment	0.007	0.00001	No

<sup>1</sup>Endpoint value taking into account the uncertainty factor. Risk quotient (RQ) = EEC / endpoint.

**Table 2 Screening level risk assessment of honey bees (*Apis mellifera*) exposed to triticonazole**

Application method	Application rate		Bee stage	Exposure		Exposure to bee (µg a.i./bee/day) <sup>1</sup>	Toxicity Endpoint (µg a.i./bee/day)		RQs <sup>2</sup>
Foliar (turf: golf course scenario)	0.648	kg a.i./ha	Adults	Contact	Acute	1.555	LD <sub>50</sub> >	100.0	< 0.02
				Oral	Acute	18.543	LD <sub>50</sub> >	155.5	< 0.12
					Chronic	18.543	NOEDD =	18.4	<b>1.01</b>
			Larvae	Oral	Acute	7.874	LD <sub>50</sub> =	37.0	0.21
					Chronic	7.874	NOED =	10.0	0.79
Seed Treatment	0.0158	kg a.i./ha	Adults	Oral	Acute	0.292	LD <sub>50</sub> >	155.5	< 0.002
					Chronic	0.292	NOEDD =	18.4	0.016
			Larvae	Oral	Acute	0.124	LD <sub>50</sub> =	37.0	0.003
					Chronic	0.124	NOED =	10.0	0.012

<sup>1</sup>Exposure estimate for bees (µg a.i./bee): For contact exposure route: Application rate (kg a.i./ha) × 2.4 µg a.i./bee per kg a.i./ha; For oral exposure route using foliar application: Application rate (kg a.i./ha) × 98 µg a.i./g × consumption rate (0.292 g/day for adult bee, 0.124 g/day for larvae); For oral exposure using seed treatment: (default residue level of 1 µg a.i./g) × consumption rate (0.292 g/day for adult bee, 0.124 g/day for larvae);

<sup>2</sup> RQ = Exposure estimate for bees / Toxicity endpoint; LOC for bees is set at 0.4 for acute exposure and 1 for chronic exposure. **Bold** and shaded values indicates RQ ≥ LOC.

**Table 3 Refined risk assessment of beneficial arthropods exposed to triticonazole**

Organism	Scenario	Endpoint	Value (g a.i./ha)	On-field EEC (g a.i./ha) <sup>1</sup>	RQ <sup>2</sup>	Off-field EEC (g a.i./ha) <sup>3</sup>	RQ <sup>2</sup>
<b>Triticonazole</b>							
<i>Aphidius rhopalosiphi</i> (foliar dwelling)	Turf (golf course)	Acute, mortality, LR <sub>50</sub>	< 100.0	394.7	<b>&gt; 3.9</b>	2.37	0.02
			> 11.5	394.7	<b>&lt; 34.3</b>	2.37	0.2
<i>Aleochara bilineata</i> (soil dwelling)	Turf (golf course)	Acute, mortality, LR <sub>50</sub>	>48.0 (>0.021mg a.i./kg)	0.516 mg a.i./kg	<b>&lt; 24.6</b>	0.003 mg a.i./kg	< 0.15

<sup>1</sup> On-field EEC is based on the foliar deposition fraction of 0.4 related to the "Grass I – all phases crop type and to the soil deposition fraction of 0.6, <sup>2</sup>LOC threshold = 2 for beneficials., <sup>3</sup> Off-field vegetation distribution factor of 0.1 is applied to the off-field EEC. Bold and shaded values indicate RQ ≥ LOC.

**Table 4 Screening level risk assessment for triticonazole technical to wild birds in turf (golf course) scenario based on foliar application scenario (3 × 648 g triticonazole/ha at 14 days interval between applications and foliar half-life of 10 days) and maximum nomogram residues**

Bird size and exposure	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	On-field EDE <sup>1</sup> (mg a.i./kg bw)	On-field RQ <sup>2</sup>	Off-field RQ (6% drift)
<b>Triticonazole</b>					
<b>Small Bird (0.02 kg)</b>					
Acute	>200.0	Insectivore	80.31	<0.40	0.02
Reproduction	19.5	Insectivore	80.31	<b>4.12</b>	0.25
<b>Medium Sized Bird (0.1 kg)</b>					
Acute	>200.0	Insectivore	62.67	<0.31	0.02
Reproduction	19.5	Insectivore	62.67	<b>3.21</b>	0.19
<b>Large Sized Bird (1 kg)</b>					
Acute	>200.0	Herbivore (short grass)	40.48	<0.20	0.01
Reproduction	19.5	Herbivore (short grass)	40.48	<b>2.08</b>	0.12

<sup>1</sup>EDE = Estimated Daily Exposure, <sup>2</sup>RQ = Risk quotient, Bold and shaded values indicate RQ ≥ LOC.

**Table 5 Tier 1 - Expanded characterization for reproductive risk to wild birds exposed to triticonazole using the LOAEL value of 39.4 mg a.i./kg bw/day in turf (golf course) scenario based on foliar application scenario, foliar half-life of 10 days**

Toxicity (mg ai/kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (6% drift)		On-field		Off-field (6% drift)	
			EDE <sup>1</sup> (mg a.i./kg bw)	RQ <sup>2</sup>	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)										
Reproduction	19.50	Insectivore	80.31	4.1	4.82	0.2	55.45	2.84	3.33	0.17
		Granivore (grain and seeds)	12.43	0.6	0.75	< 0.1	5.93	0.30	0.36	< 0.1
		Frugivore (fruit)	24.86	1.3	1.49	< 0.1	11.86	0.61	0.71	< 0.1
21 wk-LOAEL	39.40	Insectivore	80.31	2.0	4.82	0.1	55.45	1.41	3.33	< 0.1
		Granivore (grain and seeds)	12.43	0.3	0.75	< 0.1	5.93	0.15	0.36	< 0.1
		Frugivore (fruit)	24.86	0.6	1.49	< 0.1	11.86	0.30	0.71	< 0.1
Medium Sized Bird (0.1 kg)										
Reproduction	19.50	Insectivore	62.67	3.2	3.76	0.2	43.28	2.22	2.60	0.13
		Granivore (grain and seeds)	9.70	0.5	0.58	< 0.1	4.63	0.24	0.28	< 0.1
		Frugivore (fruit)	19.40	1.0	1.16	< 0.1	9.25	0.47	0.56	< 0.1
21 wk-LOAEL	39.40	Insectivore	62.67	1.6	3.76	< 0.1	43.28	1.10	2.60	< 0.1
		Granivore (grain and seeds)	9.70	0.2	0.58	< 0.1	4.63	0.12	0.28	< 0.1
		Frugivore (fruit)	19.40	0.5	1.16	< 0.1	9.25	0.23	0.56	< 0.1
Large Sized Bird (1 kg)										
Reproduction	19.50	Insectivore	18.30	0.9	1.10	< 0.1	12.63	0.65	0.76	< 0.1
		Granivore (grain and seeds)	2.83	0.1	0.17	< 0.1	1.35	< 0.1	0.08	< 0.1
		Frugivore (fruit)	5.66	0.3	0.34	< 0.1	2.70	0.14	0.16	< 0.1
		Herbivore (short grass)	40.48	2.1	2.43	0.1	14.38	0.74	0.86	< 0.1
		Herbivore (long grass)	24.72	1.3	1.48	< 0.1	8.07	0.41	0.48	< 0.1
		Herbivore (Broadleaf plants)	37.46	1.9	2.25	0.1	12.38	0.63	0.74	< 0.1
21 wk-LOAEL	39.40	Insectivore	18.30	0.5	1.10	< 0.1	12.63	0.32	0.76	< 0.1
		Granivore (grain and seeds)	2.83	< 0.1	0.17	< 0.1	1.35	< 0.1	0.08	< 0.1
		Frugivore (fruit)	5.66	0.1	0.34	< 0.1	2.70	< 0.1	0.16	< 0.1
		Herbivore (short grass)	40.48	1.0	2.43	< 0.1	14.38	0.36	0.86	< 0.1
		Herbivore (long grass)	24.72	0.6	1.48	< 0.1	8.07	0.20	0.48	< 0.1
		Herbivore (Broadleaf plants)	37.46	1.0	2.25	< 0.1	12.38	0.31	0.74	< 0.1

<sup>1</sup>EDE = Estimated Daily Exposure, <sup>2</sup>RQ = Risk quotient, **Bold** and shaded values indicate RQ ≥ LOC.

**Table 6 Refined level risk assessment for triticonazole technical exposed to wild birds in field corn production based on seed treatment scenario and a reproduction LOAEL of 39.4 mg a.i./kg bw/day/UF**

Bird size and exposure	Study Endpoint (mg a.i./kg bw/day / UF)	EDE <sup>1</sup> (mg a.i./kg bw/day)	RQ <sup>2</sup>
<b>Small bird (0.02 kg)</b>			
Acute	>200.00	126.969	<0.6
Reproduction LOAEL	39.40	126.969	<b>3.2</b>
<b>Medium bird (0.10 kg)</b>			
Acute	>200.00	99.736	<0.5
Reproduction LOAEL	39.40	99.736	<b>2.5</b>
<b>Large bird (1.00 kg)</b>			
Acute	>200.00	29.077	<0.1
Reproduction LOAEL	39.40	29.077	0.7

<sup>1</sup>EDE = Estimated Daily Exposure, <sup>2</sup>RQ = Risk quotient, **Bold** and shaded values indicate RQ ≥ LOC.

**Table 7 Screening level risk assessment for triticonazole technical to mammals in turf production based on foliar application scenario (3 × 648 g Triticonazole/ha at 14-day interval)**

Mammal size and exposure	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE (mg a.i./kg bw) <sup>1</sup>	RQ <sup>2</sup>
<b>Triticonazole</b>				
<b>Small Mammal (0.015 kg)</b>				
Acute	>200.00	Insectivore	46.19	<0.23
Reproduction	>49.40	Insectivore	46.19	<0.94
<b>Medium Sized Mammal (0.035 kg)</b>		Insectivore		
Acute	>200.00	Herbivore (short grass)	89.59	<0.45
Reproduction	>49.40	Herbivore (short grass)	89.59	<b>&lt;1.81</b>
<b>Large Sized Mammal (1 kg)</b>				
Acute	>200.00	Herbivore (short grass)	47.87	<0.24
Reproduction	>49.40	Herbivore (short grass)	47.87	<0.97

<sup>1</sup>EDE = Estimated Daily Exposure, <sup>2</sup>RQ = Risk quotient, **Bold** and shaded values indicate RQ ≥ LOC

**Table 8 Screening level risk assessment for triticonazole exposed to wild mammals in field corn production based on seed treatment scenario**

Mammal size and exposure	Toxicity (mg a.i./kg bw/day)	EDE (mg a.i./kg bw/day) <sup>1</sup>	RQ <sup>2</sup>
<b>Triticonazole</b>			
<b>Small mammals (0.015 kg)</b>			
Acute	>200.00	72.559	<0.4
Reproduction	>49.40	72.559	<b>&lt;1.5</b>
<b>Medium mammals (0.035 kg)</b>			
Acute	>200.00	62.401	<0.3
Reproduction	>49.40	62.401	<b>&lt;1.3</b>
<b>Large mammals (1.00 kg)</b>			
Acute	>200.00	34.359	<0.2
Reproduction	>49.40	34.359	<0.7

<sup>1</sup>EDE = Estimated Daily Exposure, <sup>2</sup>RQ = Risk quotient, **Bold** and shaded values indicate RQ ≥ LOC.

**Table 9 Seedling emergence and vegetative vigour risk assessments (on-field and off-field) for terrestrial vascular plants exposed to triticonazole**

Organism	Exposure	Endpoint value	Crop	Exposure	EEC (g a.i./ha)	RQ <sup>3</sup>
<b>Terrestrial Vascular plants</b>	Seedling emergence	Lettuce ( <i>Lactuca sativa</i> ), EC <sub>25</sub> value: 17 g a.i./ha	Turf (Golf Course)	On-field	1928.8 <sup>1</sup>	<b>113.0</b>
				Off-field (GB, 6% drift):	115.7	<b>6.8</b>
			Field corn seed treatment	On-field	15.8	0.9
	Vegetative vigour	Turnip: <i>Brassica napus</i> EC <sub>25</sub> value: 1457 g a.i./ha	Turf (Golf Course)	On-field	1944.0 <sup>2</sup>	<b>1.3</b>
				Off-field (GB, 6% drift):	116.6	0.1

GB = groundboom; <sup>1</sup>value obtained by taking into account the rate of dissipation of TRT in soil following multiple applications; Value obtained assuming application of 3 × 648 g a.i./ha directly on foliage with 100% interception for vegetative vigor risk assessment. **Bold** and shaded values indicate RQ ≥ LOC.

**Table 10 Triticonazole aquatic organisms risk characterization for drift (turf)**

Organism	Species	Exposure	Endpoint	Value (mg a.i./L)	Applic. Rate (g a.i./ha) <sup>1</sup>	Water depth (cm)	Drift	EEC (mg a.i./L)	RQ <sup>2</sup>	Exceed LOC?
<b>Freshwater invertebrates exposure</b>										
Midge larvae	<i>Chironomus riparius</i>	Chronic	NOEC	0.078	3 × 648	80	0.06	0.014	0.18	No
<b>Amphibian (surrogate) exposure</b>										
Rainbow trout	<i>Onchorhynchus mykiss</i>	Acute	1/10 LC <sub>50</sub>	> 0.36	3 × 648	15	0.06	0.0756	< 0.11	No
Fathead minnow	<i>Pimephales promelas</i>	Chronic	NOEC	0.021	3 × 648	15	0.06	0.0756	<b>3.6</b>	<b>Yes</b>

Organism	Species	Exposure	Endpoint	Value (mg a.i./L)	Applic. Rate (g a.i./ha) <sup>1</sup>	Water depth (cm)	Drift	EEC (mg a.i./L)	RQ <sup>2</sup>	Exceed LOC?
<b>Freshwater fish exposure</b>										
Rainbow trout	<i>Onchorhynchus mykiss</i>	Acute	1/10 LC <sub>50</sub>	0.36	3 × 648	80	0.06	0.014	0.04	No
Fathead minnow	<i>(Pimephales promelas)</i>	Chronic	NOEC	0.021	3 × 648	80	0.06	0.014	0.68	No
<b>Freshwater algae exposure</b>										
Diatom	<i>Navicula pelliculosa</i>	Acute	½ EC <sub>50</sub>	0.048	3 × 648	80	0.06	0.014	0.30	No
<b>Marine/estuarine invertebrates exposure</b>										
Mysid shrimp	<i>Americamysis bahia</i>	Chronic	NOEC	0.025	648	80	0.06	0.005	0.19	No
<b>Marine/estuarine algae exposure</b>										
Marine diatom	<i>Skeletonema costatum</i>	Chronic	NOEC	< 0.031	648	80	0.06	0.005	> 0.16	No

<sup>1</sup> Only a single application is considered in marine/estuarine drift RQ calculations; <sup>2</sup> **Bold** and shaded cells indicate that the level of concern is exceeded (RQ > 1)

**Table 11 Triticonazole aquatic organism risk characterization for run-off (turf and seed treatment)**

Organisms	Species	Exposure	Endpoint value (mg a.i./L)	EEC <sup>1</sup> (mg a.i./L)	Water depth (cm)	RQ	LOC exceeded?
<b>Turf Scenario</b>							
<b>Freshwater invertebrate</b>							
Midge larvae	<i>Chironomus riparius</i>	Chronic NOEC	0.078	0.0436	80	0.56	No
<b>Amphibian (surrogate)</b>							
Rainbow trout	<i>Onchorhynchus mykiss</i>	Acute 1/10 LC <sub>50</sub>	<0.36	0.164	15	>0.46	No
Fathead minnow	<i>(Pimephales promelas)</i>	Chronic NOEC	0.021	0.144	15	<b>6.86</b>	<b>Yes</b>
<b>Freshwater fish</b>							
Rainbow trout	<i>Onchorhynchus mykiss</i>	Acute 1/10 LC <sub>50</sub>	>0.36	0.0476	80	<0.13	No
Fathead minnow	<i>(Pimephales promelas)</i>	Chronic NOEC	0.021	0.0465	80	<b>2.21</b>	<b>Yes</b>
<b>Freshwater algae</b>							
Diatom	<i>Navicula pelliculosa</i>	Acute ½ EC <sub>50</sub>	0.048	0.0476	80	0.99	No
<b>Marine/estuarine invertebrates</b>							
Mysid shrimp	<i>Americamysis bahia</i>	Chronic NOEC	0.025	0.0465	80	<b>1.86</b>	<b>Yes</b>
<b>Marine/estuarine algae</b>							
Marine diatom	<i>Skeletonema costatum</i>	Chronic NOEC	<0.031	0.0476	80	<b>&gt; 1.54</b>	<b>Yes</b>
<b>Seed treatment scenario</b>							
<b>Freshwater invertebrate</b>							
Midge larvae	<i>Chironomus riparius</i>	Chronic NOEC	0.078	0.0006	80	0.01	No
<b>Amphibian (surrogate)</b>							
Rainbow trout	<i>Onchorhynchus mykiss</i>	Acute 1/10 LC <sub>50</sub>	0.36	0.0197	15	0.06	No
Fathead minnow	<i>(Pimephales promelas)</i>	Chronic NOEC	0.021	0.0177	15	0.85	No
<b>Freshwater fish</b>							
Rainbow trout	<i>Onchorhynchus mykiss</i>	Acute 1/10 LC <sub>50</sub>	0.36	0.0006	80	0.002	No

Organisms	Species	Exposure	Endpoint value (mg a.i./L)	EEC <sup>1</sup> (mg a.i./L)	Water depth (cm)	RQ	LOC exceeded?
Fathead minnow	<i>Pimephales promelas</i>	Chronic NOEC	0.021	0.0006	80	0.03	No
<b>Freshwater algae</b>							
Diatom	<i>Navicula pelliculosa</i>	Acute ½ EC <sub>50</sub>	0.048	0.0006	80	0.01	No
<b>Marine/estuarine invertebrates</b>							
Mysid shrimp	<i>Americamysis bahia</i>	Chronic NOEC	0.025	0.0006	80	0.24	No
<b>Marine/estuarine algae</b>							
Marine diatom	<i>Skeletonema costatum</i>	Chronic NOEC	< 0.031	0.0006	80	> 0.19	No

<sup>1</sup>EEC values were obtained from Level 1 aquatic ecoscenario of the simulation model PRZM/EXAMS. **Bold** and shaded cells indicate that the level of concern is exceeded (RQ > 1).

## Appendix XIV Toxic substances management policy considerations

**Table 1 Toxic substances management policy considerations for triticonazole - comparison to TSMP track 1 criteria**

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Triticonazole Endpoints
CEPA toxic or CEPA toxic equivalent <sup>1</sup>	Yes		Yes
Predominantly anthropogenic <sup>2</sup>	Yes		Yes
Persistence <sup>3</sup>	Soil	Half-life ≥ 182 days	Yes; tR = 1236 days
	Water	Half-life ≥ 182 days	Yes; 357 d (longest of two tR)
	Sediment	Half-life ≥ 365 days	Not applicable
	Air	Half-life ≥ 2 days	No; Long range transport not expected
Bioaccumulation <sup>4</sup>	Log K <sub>ow</sub> ≥ 5		Log K <sub>ow</sub> = 3.29; not expected to bioaccumulate
	BCF ≥ 5000		No
	BAF ≥ 5000		No data available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No

<sup>1</sup> All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (in other words, all other TSMP criteria are met).

<sup>2</sup> The policy considers a substance “predominantly anthropogenic” if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

<sup>3</sup> If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) then the criterion for persistence is considered to be met.

<sup>4</sup> Field data (for example, BAFs) are preferred over laboratory data (for example, BCFs) which, in turn, are preferred over chemical properties (for example, log  $K_{ow}$ ).

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## Appendix XV Proposed label amendments for products containing triticonazole

Information on approved labels of currently registered products should not be removed unless it contradicts the label statements provided below.

### *1.0 General label amendments for all products containing triticonazole*

- Replace “guarantee” with “active ingredient”.
- The Minor Use Liability statement must be updated to the following:

The DIRECTIONS FOR USE for the uses described in this section of the label were developed by persons other than [registrant name], under the User Requested Minor Use Label Expansion program. For these uses, [registrant name] has not fully assessed performance (efficacy) and/or crop tolerance (phytotoxicity) under all environmental conditions or for all crop varieties when used in accordance with the label. The user should test the product on a small area first, under local conditions and using standard practices, to confirm the product is suitable for widespread application.

### *2.0 Label amendments relating to the health risk assessment*

#### **Label amendments for commercial class products containing triticonazole**

##### **1. Label amendments for end-use products for turf:**

###### **Update statement under PRECAUTIONS / RESTRICTED-ENTRY INTERVAL (REI):**

**DO NOT** enter or allow entry into treated areas of the golf course until sprays have dried.

###### **Update application rates under DIRECTIONS FOR USE:**

- Remove all label directions related to the maximum seasonal turf rate ( $3 \times 648$  g a.i./ha).
- Modify label directions so that the typical application rate of 420 g a.i./ha becomes the maximum application rate with only 1 application per season.

###### **Update statement under PRECAUTIONS:**

Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. Gloves are not required during application within a closed cab.

**Add to the following statements under PRECAUTIONS:**

When applied as a tank-mix combination, read and observe all label directions, including rates, personal protective equipment, restrictions and precautions for each product used in the tank-mix. Always use in accordance with the most restrictive label restrictions and precautions.

Apply only when the potential for drift to areas of human habitation or other areas of human activity (other than golf courses), such as parks, school grounds, and playing fields, is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

For use on established golf course turf.

**DO NOT** use beyond the course boundary.

**2. Label amendments for end-use products for seed treatment:****Add to PRECAUTIONS:**

Apply only in a way that this product will not contact workers or other persons, either directly or through drift. Only workers wearing personal protective equipment may be in the area when seed is being treated or bagged.

**Add to DIRECTIONS FOR USE:**

- Create a new sub-header: CROP ROTATION

**Add to CROP ROTATION:**

A rotational plantback interval of 30 days must be observed for crops not listed on the label.

**2a. On the principal panel****For labels with corn seed treatment applications:****Add the following statement:**

For use in commercial seed treatment facilities (and mobile treaters) with closed transfer including closed mixing, loading, calibrating, and closed treatment equipment only. No open transfer is permitted.

**Maintain the following statement:**

No on-farm seed treatment is permitted.

**For Labels with Use on Wheat, Oat, Barley, Rye, Triticale, Canary Seed and  
Canary Grass (PCP# 30685 and 33210):**

Update the closed-transfer restriction for commercial seed treatment with the following statement:

For use in commercial seed treatment facilities (and mobile treaters) with closed transfer including closed mixing, loading, calibrating, and closed treatment equipment only. No open transfer in commercial facilities is permitted.

**2b. For labelled treated seed (seed tags):**

**For All Seed Tags, add the following statements:**

Keep treated seed out of reach of children and animals.

A rotational plantback interval of 30 days must be observed for crops not listed on the label.

**For seed tags with corn seed treatment applications, add the following statement:**

When handling and planting treated seed, wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during handling and planting treated seeds. Use a closed-cab tractor when planting treated seed. Gloves are not required within a closed cab.

**For seed tags with use on wheats and other cereals:**

The following statement must be added to the seed tag unless the current statement is equivalent or more restrictive:

When handling and planting treated seed, wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during handling and planting treated seeds. Use a closed-cab tractor when planting treated seed. Gloves are not required within a closed cab.

### 3. Updates to personal protective equipment (PPE) statements for seed treatment end-use products

Reference table of updated PPE and engineering control statements for seed treatment products are provided in Table 1. Label statements must be amended (or added to) according the statements found in Table 1.

**Table 1 Proposed label modifications based on the occupational risk assessment for currently registered triticonazole seed treatment end-use products**

Seed Types	Tasks	PPE/Engineering Controls
<b>For Commercial Seed Treatment</b>		
Corn	Treating (Closed M/L)	Wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading and application.  For use with closed transfer including closed mixing, loading, calibrating, and closed treatment equipment only. No open transfer is permitted.
	Bagging/Sewing/Stacking, clean-up and repair activities	Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes when handling treated seeds and during clean-up and repair activities.
Wheat, Barley, Oat, Rye, Triticale, Canary seed and Canary grass	Treating (Open or Closed M/L), Bagging/Sewing/Stacking	Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, and any other activities involving handling treated seeds.
	Clean-up and repair activities <sup>a</sup>	Wear chemical-resistant coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during clean-up and repair activities.
<b>For On-Farm Seed Treatment</b>		
Wheat, Barley, Oat, Rye, Triticale, Canary seed and Canary grass	Treating + Handling (Open or Closed M/L)	Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up, repair and any other activities involving handling treated seeds.
<b>For Planting Treated Seeds (also include on seed tags)</b>		
Corn	Handling + Planting <sup>b</sup>	Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during loading and planting treated seeds.  Use a closed-cab tractor when planting treated seed. Gloves are not required within a closed cab
Wheat, Barley, Oat, Rye, Triticale, Canary seed and Canary grass	Handling + Planting <sup>c</sup>	Wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during loading and planting treated seeds.  Use a closed-cab tractor when planting treated seed. Gloves are not required within a closed cab.

<sup>a</sup> The PPE required from the risk assessment is more restrictive than what is currently on the labels. The labels are proposed to be updated to reflect this change.

<sup>b</sup> The current label does not contain a PPE statement/engineering control for planting treated seed. This direction is proposed to be added to the label.

<sup>c</sup> The PPE and engineering control required from the risk assessment are more restrictive than what is currently on the labels. The labels are proposed to be updated to reflect this change.

### 3.0 Label amendments relating to the environmental risk assessment

**1. Label amendments for technical grade active ingredient and manufacturing concentrates**

**Add to ENVIRONMENTAL HAZARDS/PRECAUTIONS:**

Toxic to aquatic organisms.

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

**Add to 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

**2. Label amendments for commercial class products**

**2a. For Labels Related to Seed Treatment (except corn) Applications:**

**Add to ENVIRONMENTAL PRECAUTIONS:**

Toxic to birds. Any spilled or exposed seeds must be incorporated into the soil or otherwise cleaned-up from the soil surface.

This product demonstrates the properties and characteristics associated with chemicals detected in groundwater. The use of this product in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

**Add to LABELLING OF TREATED SEED or USE RESTRICTIONS:**

All containers or packages containing treated seed (except corn) for sale or use in Canada must be labeled or tagged as follows:

Toxic to birds. Any spilled or exposed seeds must be incorporated into the soil or otherwise cleaned-up from the soil surface.

**2b. For labels related to corn seed treatment applications:**

**Add to ENVIRONMENTAL PRECAUTIONS:**

Toxic to birds and small wild mammals. Any spilled or exposed seeds must be incorporated into the soil or otherwise cleaned-up from the soil surface.

This product demonstrates the properties and characteristics associated with

chemicals detected in groundwater. The use of this product in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

**Add to LABELLING OF TREATED SEED or USE RESTRICTIONS:**

All containers or packages containing corn treated seed for sale or use in Canada must be labeled or tagged as follows:

Toxic to birds and small wild mammals. Any spilled or exposed seeds must be incorporated into the soil or otherwise cleaned-up from the soil surface.

**3. For labels related to foliar application on established golf course:**

**Add to ENVIRONMENTAL PRECAUTIONS:**

Toxic to birds and non-target terrestrial plants. Observe spray buffer zones specified under DIRECTIONS FOR USE.

Toxic to certain beneficial arthropods (soil dwelling beneficials). Minimize spray drift to reduce harmful effects on beneficial arthropods in habitats next to the application site such as hedgerows and woodland.

Toxic to aquatic organisms. Observe spray buffer zones specified under DIRECTIONS FOR USE.

To reduce runoff from foliar 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.

This product demonstrates the properties and characteristics associated with chemicals detected in groundwater. The use of this product in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

**Add to GENERAL DIRECTIONS FOR USE:**

The following statement is required for all end-use products:

**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.**

**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 S572.1) medium classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply using aerial application equipment.

#### Add to SPRAY BUFFER ZONES:

Spot treatments using hand-held equipment do not require a spray buffer zone. Use of low-clearance hooded or shielded sprayers that prevent spray contact with foliage.

The spray 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) and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

Method of application	Crop	Spray Buffer Zones (metres) Required for the Protection of:		
		Freshwater Habitat of Depths:		Terrestrial Habitat:
		Less than 1 m	Greater than 1 m	
Field sprayer (groundboom)	Established golf course (turf)	3	1	4

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) spray 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.

The spray buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the [Spray Buffer Zone Calculator](#) on the Pesticides section of Canada.ca.

#### Add to DISPOSAL:

The following statements should be used for commercial and restricted class products other than agriculture and non-crop land, where non-recyclable, non-returnable or non-refillable containers are used:

1. Triple- or pressure-rinse the empty container. Add the rinsings to the spray mixture in the tank.
2. Follow provincial instruction for any required additional cleaning of the

container prior to its disposal.

3. Make the empty container unsuitable for further use.
4. Dispose of the container in accordance with provincial requirements.
5. For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.

#### ***4.0 Label amendments relating to the value assessment***

##### **1. Label amendments for commercial class products**

###### **General label statement revisions:**

- Update the resistance management statements on each end-use product label as per Regulatory Directive DIR2013-04, *Pesticide Resistance Management Labelling Based on Target Site / Mode of Action*.

###### **2. For labels of specific end-use products (PCP# 28387 and 29109):**

- As the maximum application rate on turf has been reduced to 420 g a.i./ha, this will have an impact on the supported disease claims.

###### **3. Label amendments for end-use products for turf:**

- Tank mix partners must be registered and clearly indicated by product name on triticonazole product labels. Tank mix partners that are no longer registered (i.e., Rovral Green; Rovral Green GT) must be removed.

## References

### A. Information considered in the chemistry risk assessment

#### List of studies/information submitted by registrant

PMRA document number	Title
1241775	Impurities of Toxicological Concern, DACO: 2.13.4 CBI
1241776	Colour, DACO: 2.14.1 CBI
1241777	Physical State, DACO: 2.14.2 CBI
1241778	Odour, DACO: 2.14.3 CBI
1241779	1993, Stability of RFA 4727 Active Ingredient Above Its Melting Point, DACO: 2.14.4,2.14.5 CBI
1241780	Boiling Point/Boiling Range, DACO: 2.14.5 CBI
1241781	Density or Specific Gravity, DACO: 2.14.6 CBI
1241782	1991, RFA 400727 Water Solubility, Product Chemistry Series 63, DACO: 2.14.7 CBI
1241783	1991, RPA 400727 Technical Grade, Solubility in Organic Solvents. Product Chemistry Series 63,
1241784	DACO: 2.14.8 CBI
1241785	1992, RPA 400727 Fat Solubility, DACO: 2.14.8 CBI
	1992, RPA 400727 - Constant De Henry, DACO: 2.14.9 CBI
1241786	1992, RPA 400727 Technical Grade. Vapour Pressure Curve, Product Chemistry Series 63, DACO: 2.14.9 CBI
1241787	1994, RPA 400727 Active Ingredient, Assessment for Ionization Constant Determination, DACO: 2.14.10 CBI
1241788	1991, RPA 400727 Octanol/Water Partition Coefficient at 20°C, Product Chemistry Series 63, DACO: 2.14.11 CBI
1241789	1992, RPA 400727 Technical Grade, Physical Properties and pH Determination, Product Chemistry Series 63, DACO: 2.14.12,2.14.3,2.14.6 CBI
1241790	1992, RPA 400727 - NMR, IR and MS Spectra, DACO: 2.14.13 CBI
1241791	1993, RPA 400727 Technical Grade Active Ingredient, Physical and Chemical Characteristics, Storage Stability, Two Years Stability Data, DACO: 2.14.14 CBI
1241792	1995, Triticonazole Active Ingredient, Suitability for use as an Analytical Standard Reference Material, DACO: 2.16 CBI
1241794	1992, RPA 400727. Lot EA3010SD7 - Suitability for use as an Analytical Standard, DACO: 2.16 CBI
1241797	1993, RPA 400727: UV-Visible Characteristics, DACO: 2.14.13 CBI
1241798	1992, RPA 400727 Technical Grade Stability Study, DACO: 2.14.14 CBI
2783332	2014, Analytical Profile of Five Batches of Triticonazole Technical Grade Active Substance, DACO: 2.13.3 CBI
2783333	2017, Product Identity and Composition of BAS 595 F Triticonazole, DACO: 2.11.1,2.11.2, 2.11.3, 2.11.4 CBI
2860313	2018, BASF response to PMRA questions, DACO: 2.13.1,2.13.3,2.13.4 CBI
2860314	1994, Technical RPA 400727 – [CBI Removed] determination of active ingredient, DACO: 2.13.1 CBI
2860315	1994, Technical RPA 400727 –[CBI Removed] determination of [CBI Removed], DACO: 2.13.1 CBI
2860316	2002, Validation of the analytical method AL010/01-0 for the determination of organic impurities in

	Triticonazole - AE C632720 (Triticonazole) technical grade active ingredient, DACO: 2.13.1 CBI
2860317	[CBI Removed], 1999, Miscellaneous techniques – [CBI Removed] method using pyridine-free reagents, DACO: 2.13.1 CBI
2860318	[CBI Removed], 2017, Determination of the content of [CBI Removed] in Triticonazole, DACO: 2.13.4 CBI
2860319	[CBI Removed], 2017, Development and validation of an analytical method for content determination of [CBI Removed] in Triticonazole, DACO: 2.13.4 CBI
2860320	[CBI Removed], 2017, Amendment No 1. Development and validation of an analytical method for content determination of [CBI Removed] in Triticonazole, DACO: 2.13.4 CBI 3060439

## B. Information considered in the toxicological risk assessment

### Studies/information provided by registrant

PMRA document number	Title
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1180263	1993, Mass spectrometry. Metabolism study in rat. Analysis of fecal extracts and urinary samples. DACO 4.5.9
1180232	1990, RPA 400727. Acute oral toxicity in rats. DACO 4.2.1
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1180243	1992, RPA 400727. Delayed contact hypersensitivity study in guinea pigs. DACO 4.2.6
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1180236	1992, RPA 402570 - Acute dermal limit test in rats. DACO 4.2.2
2801212	1992, An acute oral toxicity study in rats with RPA 406203. DACO 4.2.1
1180244	1991, RPA400727: Preliminary toxicity study by dietary administration to CD- 1 mice for six weeks. DACO 4.3.1
1180245	1991, RPA400727: Preliminary toxicity study by dietary administration to CD- 1 mice for 13 weeks. DACO 4.3.1
1180300	1993, RPA 400727 RPA 402570: Fourteen Day Comparative Oral Toxicity Study in the rat. DACO 4.3.1
1180247	1991, RPA400727: Preliminary toxicity study by dietary administration to F-344 rats for four weeks DACO 4.3.1
1049910, 1049911, 1180246	1991, RPA400727: Toxicity study by dietary administration to CD rats for 13 weeks DACO 4.3.1

1180249	1991, Determination of MTD in Beagle dogs. DACO 4.3.2
1049889	1991, Preliminary toxicity study by oral capsule. Administration to beagle dogs for four weeks. DACO 4.3.2
1180250,1049913,1049914	1991, Triconazole: 1 year oral (capsule) study in Beagle dogs. DACO 4.3.2
1180312	1997, 3-Week dermal toxicity study with Triconazole in Rats DACO 4.3.3
1180254,1180170	1994, Oncogenicity study by dietary administration to CD-1 mice for 78 weeks. DACO 4.4.2
1180171,1180172	1994, Combined oncogenicity and toxicity study by dietary administration to CD rats. DACO 4.4.1 and 4.4.4
1180268	1991, Dose range finding summary. Oral developmental (gavage). DACO 4.5.2
1180268,1049916	1991, RPA400727: Teratology study in the rat. DACO 4.5.2
1180269,1049917	1991, RPA400727: Teratology study in the rabbit. DACO 4.5.3
1180173,1180261	1993, Dietary 2- generation reproduction study in rat.
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1180274	1991, In vitro assessment of the clastogenic activity of RPA 400727 in cultured human lymphocytes. DACO 4.5.6
1180275	1992, Clastogenic action on bone marrow erythrocytes in the micronucleus test. DACO 4.5.8
1180273	1992, RPA 400727 Induction of unscheduled DNA synthesis (UDS) in rat hepatocytes in vitro. DACO 4.8
1180271	1993, RPA402570. S.typhimurium reverse mutation assay (Ames test). DACO 4.5.4
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1180266	1997, Benchmark and time-to-peak effect neurotoxicity study with triconazole in rats. DACO 4.5.12
1180265	1997, Acute neurotoxicity study with triconazole in rats. DACO 4.5.13

### Additional information considered

### Published information

PMRA document number	Title
3172244	California EPA Summary of toxicology data. DACO 12.5.4

## C. Information considered in the dietary risk assessment

### Additional information considered

#### Published information

PMRA document number	Title
	Proposed Registration Decision Document PRDD2004-06, Triticonazole, December 29, 2004.
	USEPA Memo: Triticonazole Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for a Section 3 Registration Action for Seed Treatment of Cereals, DP# 366041, June 10, 2009.
	USEPA Memo: Tier II Drinking Water Assessment for Triticonazole Proposed Section 3 Registration for Use on Crop Group 15 (Cereal Grains, Except Rice) and Crop Group 16 (Forage Fodder and Hay of the Cereal Grains, Except Rice), DP# D358615; March 24, 2009.
	EFSA Scientific Report (2009) 277, 1-23: Review of the Existing MRLs for Triticonazole (Reasoned opinion).
	EFSA Scientific Report (2005) 33, 1-69: Conclusion Regarding the Peer Review of the Pesticide Risk Assessment of the Active Substance Triticonazole.

## D. Information considered in the occupational and non-occupational risk assessment

### Studies/information provided by registrant

PMRA document number	Title
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## Studies/information provided by task force

PMRA document number	Title
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2572745	AHETF, 2015. Agricultural Handler Exposure Scenario Monograph: Open Pour Mixing and Loading of Liquid Formulations. Report Number AHE1003-1. March 31, 2015.
2313627	Krainz, A. 2013. Determination of Dermal and Inhalation Exposure to Operators During Loading and Sowing Seed Treated with Austral® Plus Net Using Conventional or Pneumatic Sowing Machines. AHETF, AH823. Macon, Missouri.
2313618	Krolski, ME. 2010. Observational Study to Determine Dermal and Inhalation Exposure to Workers in a Commercial Seed Treatment Facilities: Mixing/Treating with a Liquid Pesticide Product and Equipment Clean-out. AHETF, AH806.
2313625	Krolski, M.E. November 20, 2006, GAUCHO 480 SC – Worker Exposure During On-farm and Commercial Seed Treatment of Cereals, Bayer CropScience Environmental Research Bayer Research Park 17745 South Metcalf Avenue Stilwell, KS 66085-9104 & Grayson Research, LLC 1040 Grayson Farm Road Creedmoor, NC 27522. RANTY012. Unpublished. AHETF, AH803.
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## Additional information considered

### USEPA residential SOPs

PMRA document number	Title
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### USEPA residential SOPs task force information

PMRA document number	Title
2476396	Cowell, J. and Johnson, D. (1999). Evaluation of Transferable Turf Residue Techniques: Evaluation Study of Transferable Residue Techniques (OMD001) and Transferable Residue Technique Modification Study: An Evaluation of Three Turf Sampling Techniques (OMD002). October 7, 1999. Outdoor Residential Exposure Task Force. EPA MRID 44972203.
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1619682	Klonne, D. and Johnson, D. (2004) Determination of Potential Dermal Exposure to Adults and Children Reentering a Pesticide-Treated Turf Area Study Number: ORFO3O. Unpublished study prepared by Outdoor Residential Exposure Task Force, LLC. 56 p. (MRID 47292001).
1560575	Merricks, D.L. (1997a). Carbaryl Mixer/Loader/Applicator Exposure Study during Application of RP-2 Liquid (21%), Sevin Ready to Use Insect Spray or Sevin 10 Dust to Home Garden Vegetables. ORETF OMA006. EPA MRID # 44459801
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## D. Information considered in the environmental risk assessment

### List of studies/information submitted by registrant

PMRA document number	Title
80866	PMRA Data Evaluation Report of McGhee, I. 2000. <sup>14</sup> C-RPA 406341 Rate of Degradation in Three Soils at 20°C. Aventis CropScience UK Ltd, Fyfield Road, Ongar, Essex, UK. Laboratory Report Number: 16713. Sponsored by Aventis CropScience UK Ltd. Study Date: November 30, 2000. Unpublished. Pest Management Regulatory Agency, Health Canada, Ottawa, Canada. 15 p.
80996	PMRA Data Evaluation Report of Norris, F.A. 1998. Terrestrial Soil Dissipation After Preplant Application or Seed Treatment on Wheat. Rhône-Poulenc Ag Company, North Carolina. Rhône-Poulenc Ag Company Laboratory Report Number 97Z13032B. Completed July 29, 1998. Unpublished. Pest Management Regulatory Agency, Health Canada, Ottawa, Canada. 15 p.
103843	Toy, L. and Glaser, J. 2003. Category A Review of the Technical Grade Active Ingredient, Triticonazole, and its Associated End-Use Product, Triton Fungicide, for Use on Turf (USC 30), From the Viewpoint of Environmental Protection. Pest Management Regulatory Agency, Health Canada, Ottawa, Canada. Submission No: 1999-0637 and 1999-0638. 80 p.
491643	Glaser, J. 2003. Level D/Category A.2.0 Submission /USC 30/ Triticonazole monograph (memorandum). Pest Management Regulatory Agency, Health Canada, Ottawa, Canada. Submission 1999-0637 and 1999-0638. 57 p.
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1049882	McGhee, I. 2000. <sup>14</sup> C-RPA 406341 Rate of Degradation in Three Soils at 20°C. Aventis CropScience UK Ltd, Fyfield Road, Ongar, Essex, UK. Laboratory Report Number: 16713. Sponsored by Aventis CropScience UK Ltd. Study Date: November 30, 2000. Unpublished. 15 p.
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## Additional information considered

### Published information

PMRA document number	Title
PRDD2004-06	PMRA 2004. Proposed Regulatory Decision Document of Triticonazole. Alternatives Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency, Health Canada, Ottawa, Ontario, Canada. ISBN: 0-662-39023-7. 79 p.