Proposed Registration Decision PRD2017-14

Fluazinam and Secure Fungicide

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Overview

Proposed Registration Decision for Fluazinam

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Technical Fluazinam Fungicide and Secure Fungicide, containing the technical grade active ingredient fluazinam, to control fungal diseases on turf (golf courses and sod farms).

Fluazinam was previously registered in the end-use product Allegro 500F Agricultural Fungicide, granted full registration in 2008, to control various diseases on potatoes, soybeans, cruciferous vegetables, bushberries, edible-podded legume vegetables (except pea), dry shelled beans, ginseng, carrots, apples, cantaloupe, field peppers and bulb onions. For further details see the Proposed Registration Decision PRD2008-08, *Fluazinam*, the Regulatory Note REG2003-12, *Fluazinam,* and the Re-evaluation Note REV2016-12, *Special Review Decision: Fluazinam.*

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Technical Fluazinam Fungicide and Secure Fungicide, containing fluazinam.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and

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

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "… the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of the Canada.ca website at https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management.html.

Before making a final registration decision on fluazinam and Secure Fungicide, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on fluazinam and Secure Fungicide, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and the PMRA's response to these comments.

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

What Is Fluazinam?

Fluazinam is a conventional fungicide and the sole active ingredient in Secure Fungicide. This product is to be used as a foliar product for the control of dollar spot, anthracnose, Microdochium patch and brown patch in turf. Fluazinam works by interfering with respiration in susceptible pathogenic fungi. Fluazinam is already registered in Canada for use on agricultural crops.

Health Considerations

Can Approved Uses of Fluazinam Affect Human Health?

Secure Fungicide, containing fluazinam, is unlikely to affect your health when used according to label directions.

Potential exposure to fluazinam may occur through the diet (food and water), when handling and applying the products or when entering treated sites. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels

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

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

to which humans are normally exposed when pesticide-containing products are used according to label directions.

In laboratory animals, fluazinam was of low acute toxicity by the oral and dermal routes of exposure and of moderate toxicity by the inhalation route. It was corrosive to the eyes and slightly irritating to the skin. Fluazinam causes an allergic skin reaction.

Secure Fungicide, containing fluazinam, was of low acute toxicity by the oral, dermal, and inhalation routes of exposure. It was moderately irritating to the skin, minimally irritating to the eyes and caused an allergic skin reaction.

Registrant supplied short- and long-term (lifetime) animal toxicity studies were assessed for the potential of fluazinam to cause neurotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, genetic damage, and various other effects. The most sensitive endpoint used for risk assessment was liver toxicity. There was evidence that the young animal was more sensitive than the adult animal. The risk assessment protects against these findings as well as any other potential effects by ensuring that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and drinking water are not of health concern.

Aggregate chronic (cancer and non-cancer) dietary intake estimates (food plus drinking water) revealed that the general population and children 1-2 years old, the subpopulation which would ingest the most fluazinam relative to body weight, are expected to be exposed to less than 31% of the acceptable daily intake (ADI). Based on these estimates, the chronic dietary risk from fluazinam is not of health concern for all population subgroups.

Acute dietary (food plus drinking water) intake estimates for the general population and all population subgroups were less than 58% of the acute reference dose, and are not of health concern. The highest exposed subpopulation was adults 50+ years old.

Risks in Residential and Other Non-Occupational Environments

Residential and non-occupational risks are not of health concern when Secure Fungicide is used according to the label directions.

Adults, youth and children may be exposed to fluazinam while golfing on courses treated with Secure Fungicide. Based on the expected short- to intermediate-term duration of this activity, the health risk to children, youth and adults is not of concern. There are no residential turf uses of Secure Fungicide.

Occupational Risks From Handling Secure Fungicide

Occupational risks are not of health concern when Secure Fungicide is used according to the label directions, which include protective measures.

Workers who mix, load or apply Secure Fungicide, as well as field workers re-entering treated golf courses and sod farms, can come into direct contact with fluazinam residues on the skin. Therefore, the label specifies that workers, mixing/loading/applying Secure Fungicide and during clean up and repair, must wear coveralls over long-sleeved shirt, long pants, chemical-resistant gloves, socks and footwear. The label also requires that workers not enter treated sod farms for 12 hours after application, and that workers not enter treated golf courses "until sprays have dried". Taking into consideration these precautionary statements, the use directions and the exposure duration, the health risks to workers are not of concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens when Fluazinam is Introduced into the Environment?

When used according to label directions, fluazinam is not expected to pose risks of concern to the environment.

Fluazinam enters the environment when Secure Fungicide is applied to turf using field sprayers.

Fluazinam can enter terrestrial environments through spray drift resulting from the proposed use. Depending on the soil type, fluazinam breaks down slowly and can be present in the soil in the following crop season. Fluazinam has a low potential to move through the soil and is unlikely to reach groundwater.

Fluazinam can enter aquatic environments, such as streams, rivers, and lakes, through spray drift or overland runoff. In water, fluazinam breaks down rapidly and is non-persistent. Fluazinam is not expected to build-up in the tissues of organisms.

Fluazinam is not expected to be found in the air or to travel long distances in the atmosphere.

Fluazinam does not present a risk of concern to earthworms, sediment-dwelling organisms, pollinators, and birds. However, exposure to fluazinam can affect non-target terrestrial plants, wild mammals and freshwater and marine organisms. Therefore, to protect these organisms from spray drift, buffer zones are required. To protect these organisms from the effects of run-off, label statements informing users how to reduce run-off and precautionary label statements informing users of the toxicity are required.

Value Considerations

What Is the Value of Secure Fungicide?

Secure Fungicide will provide users with a new mode of action to control economically important diseases on golf courses and sod farms.

The addition of fluazinam to the rotation in a treatment program on turf will potentially delay fungicide resistance against products with different modes of action. The ability to tank mix Secure Fungicide with Banner Maxx (propiconazole) or Heritage Maxx (azoxystrobin) will provide users with a resistance management tool and a broad spectrum disease management strategy.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Secure Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

As users can come into direct contact with fluazinam on the skin or through inhalation of spray mists, anyone mixing, loading and applying fluazinam must wear coveralls over long-sleeved shirt, long pants, chemical-resistant gloves, socks and footwear during mixing, loading, application, clean up and repair. In addition, a standard label statement to protect against spray drift during application is required on the label.

The Secure Fungicide label requires that workers not enter treated sod farms for 12 hours after application. A separate statement specifying that workers and the general public are not to enter treated golf courses “until sprays have dried” was also added to the label.

Environment

The following risk reduction measures are required for Secure Fungicide to mitigate the identified risks:

- Precautionary label statements to inform the user that this product is toxic to aquatic organisms, small wild mammals and non-target terrestrial plants
- Spray drift buffer zones of 1 to 20 m to protect aquatic and terrestrial habitats will be required.

Next Steps

Before making a final registration decision on fluazinam and Secure Fungicide, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

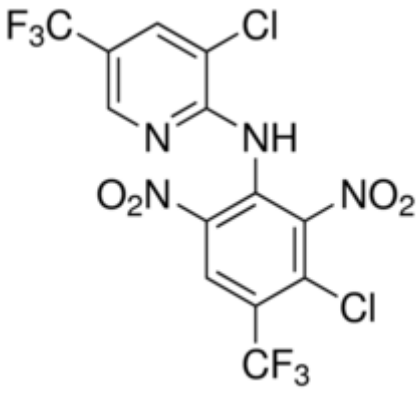
When the PMRA makes its registration decision, it will publish a Registration Decision on Fluazinam and Secure Fungicide (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Fluazinam

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Fluazinam
Function	Fungicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	3-chloro-*N*-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)pyridin-2-amine
2. Chemical Abstracts Service (CAS)	3-chloro-*N*-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine
CAS number	79622-59-6
Molecular formula	$C_{13}H_4Cl_2F_6N_4O_4$
Molecular weight	465.1 g/mol
Structural formula	
Purity of the active ingredient	97.47%

1.2 Physical and Chemical Properties of the Active Ingredient and End-use Product

Technical Product—Fluazinam Technical

Property	Result
Colour and physical state	Yellow granular powder
Odour	Strong musty
Melting range	Completely melted at 119ºC
Boiling point or range	Solid at room temperature
Density	1.74 g/mL
Vapour pressure at 20°C	2.3×10^{-5} Pa
Ultraviolet (UV)-visible spectrum	pH / λ_{max} (nm) / log γ <2 / 238 / 4.31 7 / 239, 342 / 4.27, 3.86 >10 / 260, 343, 482 / 4.22, 4.27, 3.54
Solubility in water at 25°C	pH / Solubility (mg/L) 5 / 0.131 7 / 0.157 9 / 3.384
Solubility in organic solvents at 25°C	Solvent / Solubility (mg/mL) acetone / 853 dichloromethane / 675 ethyl acetate / 722 ethyl ether / 231 hexane / 8 methanol / 192 octanol / 41 toluene / 451
n-Octanol-water partition coefficient (K_{ow})	log K_{ow} = 1.76
Dissociation constant (pK_a)	Average pK_a = 7.22 in 50% ethanol : water (v/v).
Stability (temperature, metal)	Thermogravimetric analysis showed no evidence of degradation at up to 150ºC. Differential Scanning Calorimetry showed no evidence of decomposition over the range of 25-150ºC in presence of Al, Fe and Sn powders.

End-Use Product—Secure Fungicide

Property	Result
Colour	Yellow
Odour	Pungent
Physical state	Liquid
Formulation type	Suspension
Guarantee	40.0%
Container material and description	1-100 L polyethylene containers
Density	1.24-1.26 g/mL
pH	5.9
Oxidizing or reducing action	Not an oxidizing or reducing agent.
Storage stability	Stable over 12 months at 25°C.
Corrosion characteristics	Corrosion was not observed after 91 days at 50°C.
Explodability	Not explosive

1.3 Directions for Use

Secure Fungicide is applied as a broadcast spray to turf at a rate of 16 ml product/100 m^2 or 1.6 L product per hectare. A minimum spray interval of 14 days is required. A maximum of four applications per year are permitted.

1.4 Mode of Action

Fluazinam, a contact fungicide, interferes with respiration in pathogenic fungi and is classified as a Group 29 fungicide by the Fungicide Resistance Action Committee (FRAC).

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and impurities in the technical product have been validated and assessed to be acceptable for the determinations.

2.2 Methods for Residue Analysis

Please refer to REG2003-12, *Fluazinam* for residue analytical methods for data generation and enforcement purposes.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicology database for fluazinam and the end-use product Allegro 500F Agricultural Fungicide, was conducted previously, and was used for the review of this product and is summarized in PRD2008-08, *Fluazinam* and in REG2003-12, *Fluazinam*. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. Overall, the studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to fluazinam.

Secure Fungicide, containing fluazinam, was of low acute toxicity by the oral and inhalation routes of exposure in rats and by the dermal route in rabbits. In rabbits, it was minimally irritating to the eyes and moderately irritating to the skin. Secure Fungicide was a dermal sensitizer in guinea pigs.

Results of the toxicology studies conducted on laboratory animals with fluazinam and Allegro 500F Agricultural Fungicide can be found in PRD2008-08, *Fluazinam* and REG2003-12, *Fluazinam*.

The toxicology reference values for use in human health risk assessment can be found in PRD2008-08, *Fluazinam*. The current assessment includes the establishment of an aggregate endpoint.

3.2 Toxicology Reference Value for Aggregate Risk Assessment

Short- and intermediate-term aggregate exposure to fluazinam may be comprised of food, drinking water and recreational post-application dermal exposure. The toxicology endpoint selected for aggregation for all populations was liver toxicity. For the oral component, the previously established ADI was used, which equates to a NOAEL of 1.1 mg/kg bw/day from the mouse chronic toxicity and oncogenicity study with a target margin of exposure (MOE) of 300. For the dermal component, the NOAEL of 100 mg/kg bw/day from the 21-day rat dermal toxicity study was selected with a target MOE of 100.

3.3 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. In addition, the general public, medical community, government and non-governmental organizations are able to report pesticide incidents directly to the PMRA. As of 26 May 2017, no human or domestic animal incident reports involving fluazinam have been submitted to the PMRA.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Occupational exposure to fluazinam is characterized as intermediate-term in duration, and is predominantly by the dermal and inhalation routes. Exposure to fluazinam when golfing on treated turf is characterized as short- to intermediate-term in duration, and is predominantly by the dermal route.

3.4.1.1 Dermal Absorption

As the short-term and intermediate-term NOAELs are based on oral toxicology studies, systemic exposure was calculated using a 9% dermal absorption value. Details are presented in Regulatory Note REG2003-12, *Fluazinam*.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/loader/applicator Exposure and Risk Assessment

Exposure estimates were derived for mixers/loaders/applicators applying Secure Fungicide at the maximum rate in golf courses and sod farms using groundboom or turf gun.

The exposure estimates are based on mixers/loaders/applicators with the following personal protective equipment (PPE):

- Cotton coveralls and chemical-resistant gloves for groundboom,
- Coveralls and gloves for turf gun.

As chemical-specific data for assessing human exposures were not submitted, dermal and inhalation exposures were estimated using the data from the Agricultural Handlers Exposure Task Force (AHETF) for workers involved in application using groundboom. Dermal and inhalation exposures for workers involved with low pressure handgun application were estimated using the data from the Outdoor Residential Exposure Task Force (ORETF).

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day and the dermal absorption value (9%). Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight. The dermal and inhalation exposure estimates were combined since they are both compared to the same toxicological endpoint of concern.

Calculated MOEs are above the target MOE of 100 for workers who wear the personal protective equipment stated on the product label, and are, therefore, not of concern.

Table 3.4.2.1.1 AHETF and ORETF unit exposure estimates for mixer/loader/applicators while handling Secure Fungicide

Unit Exposure Estimates for Mixer/Loaders and Applicators Handling Secure Fungicide (µg/kg a.i. handled)					
Scenario		**Dermal**	**Dermal absorbed[1]**	**Inhalation[2]**	**Total unit exposure[3]**
Mixer/loader AHETF estimates (cotton coveralls, CR gloves)					
A	Open mix/load liquids	31.32	2.82	0.63	3.45
Applicator AHETF estimates (cotton coveralls, CR gloves)					
B	Open cab groundboom liquid application	14.19	1.28	1.68	2.96
Mixer/loader + applicator estimates					
A+B	Open mixing/loading, groundboom application, open cab (liquids) (cotton coveralls, CR gloves)	45.51	4.10	2.31	6.41
C	Low pressure turf gun M/L/A (ORETF)[4] (coveralls, gloves)	301	27.1	4.0	31.1

[1] Adjusted with dermal absorption factor 9%
[2] Light inhalation rate
[3] Total unit exposure: Dermal absorbed + inhalation exposure
[4]Unit exposure for Turf Gun M/L/A taken from ORETF Summary Table (Liquid flowable; coveralls, gloves)

Table 3.4.2.1.2 Chemical handler assessment for Secure Fungicide

Mixer/Loader/Applicator Non-Cancer Risk Assessment for Chemical Handlers					
Exposure scenario	**Total unit exposure (µg/kg a.i. handled)[1]**	**ATPD (ha/day)[2]**	**Rate (kg ai/ha)**	**Daily exposure (mg/kg bw/day)[3]**	**MOE[4]**
PPE: Coveralls over single layer (and gloves when mixing/loading)					
Groundboom - Sod Farm	6.41	30	0.8	0.00192	988
Groundboom - Golf Course	6.41	16	0.8	0.00103	1853
Low Pressure Turf Gun[5]	31.1	2	0.8	0.000622	3055

[1] AHETF and ORETF total unit exposure from Table 3.4.2.1.1
[2] To convert L/day to ha/day, the minimum amount of spray volume/ha found on the proposed product label (in this case the following formula was used: L/day ÷ 200 L/ha = ha/day)
[3] Daily exposure = (AHETF or ORETF unit exposure × ATPD × Rate (0.8 kg ai/ha)) / (80 kg bw × 1000 µg/mg)
[4] Based on the intermediate-term dermal and inhalation NOAEL = 1.9 mg/kg bw/day, target MOE = 100
[5]Representative scenario for all handheld equipment and backpack

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers re-entering areas treated with Secure Fungicide when conducting various activities. The duration of exposure is considered to be intermediate-term for all re-entry activities. The primary route of exposure for workers re-entering treated areas is expected to be through the dermal route. Inhalation exposure is not considered to be a significant route of exposure for people entering treated areas compared to the dermal route since fluazinam is relatively non-volatile (2.3×10^{-5} Pa at 25°C), and as such, an inhalation risk assessment was not required.

Given that no chemical-specific Transferable Turf Residue (TTR) study was submitted, exposure calculations were performed using default TTR values which assume a peak transferable amount of 1% of the application rate with 10% dissipation per day. Exposure was estimated by coupling default TTR values after the fourth application with activity-specific transfer coefficients, the amount of time spent on the task per day, usually 8 hours, an average bodyweight of 80 kg, and a dermal absorption value of 9%.

Calculated MOEs for postapplication exposure to fluazinam were all above the target MOE of 100. Therefore, no risks to re-entry workers are expected.

Table 3.4.2.2.1 Postapplication exposure and risk estimates on the day of application for workers re-entering golf courses and sod farms treated with Secure Fungicide

Re-entry activity	RTI (days)	TTR Value (µg/cm²)*	Transfer coefficient (cm²/hr) †	Dermal exposure ‡ (mg/kg bw/day)	MOE	REI
Postapplication Workers – Sod Farms and Golf Courses						
Transplanting, planting	14	0.103	6700	0.0062	305	12◊ hours
Mowing, watering, cup changing, irrigation repair, miscellaneous grooming	14	0.103	3500	0.0033	583	Until sprays have dried

*Calculated using the default 1% turf transferable on the day of application and 10% dissipation per day.
†Transfer coefficients obtained from the PMRA Agricultural TCs table (2014-01-22) for worker exposure.
‡ Exposure = (Peak TTR [µg/cm²] × TC [cm²/hr] × Exposure Duration (8 hours for workers)) / (80 kg bw × 1000 µg/mg).
¶ Based on NOAEL of 1.9 mg/kg bw/day, target MOE = 100
◊ Minimum REI is 12 hours to allow residues to dry

3.4.3 Residential Exposure and Risk Assessment

3.4.3.1 Handler Exposure and Risk

Secure Fungicide is proposed as a commercial class product; therefore, a residential handler assessment was not required.

3.4.3.2 Postapplication Exposure and Risk

Since Secure Fungicide is for use in golf courses, there is potential for recreational postapplication exposure to the general population entering treated areas. The duration of exposure for golfing is considered to be short-term to intermediate-term. The primary route of exposure for these individuals would be through the dermal route.

Exposure was assessed according to equations and parameters stated in the 2012 United States Environmental Protection Agency Residential Standard Operating Procedures. Dermal exposure from golfing was assessed for adults (≥16 years), youth (11-<16 years) and children (6-<11 years). Default TTR values were used to assess postapplication exposure on the day of application.

Dermal postapplication risk was calculated using the dermal absorption value (9%) and the toxicological endpoint for short- to intermediate-term dermal exposure. The calculated MOEs are above the target MOE of 100, and therefore risks are not of concern for golfers re-entering treated golf courses after the sprays have dried.

Table 3.4.3.2.1 Dermal recreational postapplication exposure and risk from the use of Secure Fungicide on the day of last application

Re-entry activity	RTI (days)	TTR Value (µg/cm^2)*	Transfer coefficient (cm^2/hr) †	Dermal exposure ‡ (mg/kg bw/day)	MOE	REI
Recreational Users (Golfers) – Golf Courses						
Golfing – adults (16+)	14	0.103	5300	0.0025	770	Until sprays have dried
Golfing – youth (11-<16)	14	0.103	4400	0.0029	660	
Golfing – child (6-<11)	14	0.103	2900	0.0034	560	

*Calculated using the default 1% turf transferable on the day of application and 10% dissipation per day.
†Transfer coefficients obtained from the 2012 USEPA Residential SOP for golfer exposure.
‡ Exposure = (Peak TTR [µg/cm^2] × TC [cm^2/hr] × Exposure Duration (4 hours for golfers)) / (80 kg bw for adults, 57 kg bw for youths and 32 kg bw for children × 1000 µg/mg).
Based on NOAEL of 1.9 mg/kg bw/day, target MOE = 100

3.4.3.3 Aggregate Exposure and Risk

Fluazinam is proposed for use on golf courses and is currently registered for use on various crops. Therefore, there is a potential for co-occurrence from exposure to food and drinking water containing fluazinam residues as well as dermal exposure from golfing.

Table 3.4.3.3.1 presents the residential exposure (golfer) assessment using the aggregate endpoints to calculate MOEs.

Table 3.4.3.3.1 Residential (golfer) postapplication dermal exposure using aggregate endpoint

Age Group	RTI (days)	TTR Value (µg/cm^2)*	Transfer coefficient (cm^2/hr) †	Dermal exposure ‡ (mg/kg bw/day)	MOE
Golfer – adults (16+)	14	0.103	5300	0.0274	3600
Golfer – youth (11-<16)	14	0.103	4400	0.0319	3100
Golfer – child (6-<11)	14	0.103	2900	0.0375	2700

*Calculated using the default 1% turf transferable on the day of application and 10% dissipation per day.
†Transfer coefficients obtained from the 2012 USEPA Residential SOP for golfer exposure.
‡ Exposure = (Peak TTR [µg/cm^2] × TC [cm^2/hr] × Exposure Duration (4 hours)/ (80 kg bw for adults, 57 kg bw for youths and 32 kg bw for children × 1000 µg/mg).
Based on NOAEL of 100 mg/kg bw/day, target MOE of 100.

Table 3.4.3.3.2 presents the results of the aggregate risk assessment. The Aggregate Risk Index (ARI) method was chosen as it allows aggregation of MOEs that have dissimilar target MOEs (300 vs. 100). As all calculated ARIs for fluazinam are above 1, risks resulting from aggregate exposure to fluazinam are not expected.

Table 3.4.3.3.2 Aggregate risk from the use of Secure Fungicide

Aggregate risk assessment for Secure Fungicide				
Age group	Exposure (mg/kg bw/day)			ARI
	Dermal MOE[1] Golfer	Chronic Dietary + Drinking Water[2]	%RfD	
Adults (16+)	3600	0.000853	0.233	4
Youth (11-<16)	3100	0.000236	0.064	10
Children (6-<11)	2700	0.000437	0.119	6

[1] Dermal MOEs from Table 3.4.3.3.2
[2] Chronic dietary + drinking water exposure were derived from the DEEM calculator.
[3] Aggregate ARI = $\frac{1}{\%RfD + \frac{UF_D}{MOE_D}}$

Where %RfD= percent of Reference Dose for the oral route, UF_D = Dermal Uncertainty Factor (100) and MOE_D= Dermal MOE

3.4.3.4 Bystander Exposure and Risk

Bystander exposure should be negligible since the potential for drift is expected to be minimal.

3.5 Food Residues Exposure Assessment

3.5.1 Drinking Water Modelling Estimates

Application Information and Model Inputs

The Level 2 Estimated Environmental Concentrations (EECs) were calculated using the Pesticides in Water Calculator (PWC), for fluazinam in potential sources of drinking water from use on turf. Surface water modelling considered eleven regional scenarios for turf adjacent to a small reservoir. The surface water EEC provided in Table 3.5.1.3 is the highest EECs calculated resulting from the eleven scenarios. The EECs in groundwater were calculated by selecting the highest EEC from eleven turf scenarios representing different regions of Canada. All scenarios were run for 50 years, except BC north and Nova Scotia which were run for 100 years.). The major input parameters for the models are summarized in Table 3.5.1.1 and 3.5.1.2.

The turf use pattern was modelled with 4 applications of 800 g a.i./ha, 14 days apart, for a total yearly application of 3200 g a.i./ha. Modelling used initial application dates between early March and late July.

A previous assessment completed in 2012 for fluazinam for peppers and cantaloupe resulted in a higher estimated drinking water EEC. The value calculated in 2012 was used in the drinking water assessment which was estimated using six applications of 875 g a.i./ha at seven day intervals (total 5250 g a.i./ha).

EECs of fluazinam in potential drinking water sources are given in Table 3.5.1.3. The EECs resulting from this Level 2 assessment were calculated using conservative inputs with respect to application rate and timing.

Table 3.5.1.1 Summary of Use Pattern Modelled for the Level 2 Assessment of fluazinam

Item	Value	Value
Crops	Turf	Peppers and cantaloupes
Method of application	Ground	Ground
Yearly rate of application (g a.i./ha)	3200	5250
Rate per application (g a.i./ha), if multiple applications	800	875
Number of applications per year	4	6
Interval between applications (days)	14	7
Typical dates of first application	Early March through late July	Early May through mid-August

Table 3.5.1.2 Fate model input values

Parameter	Value
Molecular weight, g/mol	465.1
Vapour pressure, torr	$1.7e^{-7}$
Solubility, mg/L	0.157
Henry's law constant (unit less, calculated by PWC)	$2.7e^{-5}$
Photolysis (assumed at 40°N latitude), d	5
Hydrolysis (at pH 7), d	42
K_{oc} mL/g	5696
Aerobic soil $t_{1/2}$ (at 20°C), d	136
Total system aerobic aquatic $t_{1/2}$ (at 25°C), d	6.57
Total system anaerobic aquatic $t_{1/2}$ (at 25°C), d	1

Table 3.5.1.3 Level 2 EECs of fluazinam in potential sources of drinking water

Crop/use pattern	Groundwater (µg a.i./L)		Surface Water (µg a.i./L)	
	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]
Turf (4 × 800 g a.i./ha, at 14-day intervals), yearly total of 3200 g a.i./ha	0.0	0.0	13.5	0.73
Field peppers and cantaloupes (875 g a.i./ha × 6 @ 7 days, total of 5250 g a.i./ha)	0.0	0.0	24.0	1.2

[1] 90th percentile of daily average concentrations
[2] 90th percentile of 365-day moving average concentrations
[3] 90th percentile of the peak concentrations from each year
[4] 90th percentile of yearly average concentrations

3.5.2 Residues in Plant and Animal Foodstuffs

Please refer to REG2003-12, *Fluazinam* for previously reviewed data. The information captured herein relates only to the changes in dietary exposure due to the modification in the drinking water assessments to support the registration of fluazinam for use on turf in Canada.

3.5.3 Dietary Risk Assessment

Acute and chronic (cancer and non-cancer) dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™).

3.5.3.1 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the refined chronic cancer and non-cancer analysis for fluazinam: 100% crop treated, default and experimental processing factors (where available; or anticipated residues for apple juice), Canadian and/or American supervised trial median residues (STMdR) from field trials (where available) and anticipated residues for all animal commodities.

The refined chronic dietary exposure from all supported fluazinam food uses (alone) for the total population, including infants and children, and all representative population subgroups is less than 30.3% of the ADI. Aggregate exposure from food and drinking water is considered acceptable. The PMRA estimates that chronic dietary exposure to fluazinam from food and drinking water is 21.2% (0.000783 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for children 1-2 years old at 31.2% (0.001155 mg/kg bw/day) of the ADI.

3.5.3.2 Acute Dietary Exposure Results and Characterization

The following assumptions were applied in the refined acute analysis for fluazinam: 100% crop treated, default and experimental processing factors (where available), highest average field trial (HAFT) from Canadian and/or American field trials (where available) and anticipated residues for all animal commodities. The acute assessment was further refined by using the maximum observed residue value from 2011-2015 US monitoring data and by using all CDN and US apple trial data in a residue distribution file (RDF; probabilistic), since no Pesticide Data Program (PDP) monitoring data for apple were available. The refined acute dietary exposure from all supported fluazinam food uses (alone) for the total population, including infants and children, and all representative population subgroups is less than 54% of the acute reference dose (ARfD) (95^{th} percentile, probabilistic for apple and deterministic for all other crops). Aggregate exposure from food and drinking water is considered acceptable and is estimated at 40% (0.005204 mg/kg bw) for the total population (95^{th} percentile, probabilistic for apples and deterministic for all other crops). The highest exposure and risk estimate is for adults 50+ years old at 58% (0.007544 mg/kg bw).

3.5.4 Aggregate Exposure and Risk

Given that apples and blueberries can be treated with fluazinam, there is potential for aggregate exposure to fluazinam during pick-your-own activities. However, aggregation of acute dietary and dermal exposure to fluazinam from pick-your-own activities was not conducted, as the risk estimated for acute dietary exposure (for all registered crops) and dermal exposure (for re-entry workers) is below the level of concern and therefore protective of this scenario.

Given that fluazinam is registered for use on food crops and that turf and golf courses can also be treated with Secure Fungicide, there is potential for exposure to fluazinam through the diet, as well as activities related to golf. An aggregate risk assessment for fluazinam was conducted to include the dietary exposure from food and drinking water sources and the dermal exposure from the use on golf courses (refer to Table 3.4.3.3.2). The aggregate exposure for golfers, including the sum of the chronic dietary exposure and the dermal exposure incurred at the golf course for children, youth and adults are not of health concern.

3.5.5 Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

No food residue data are required to support the registration of fluazinam for use in/on turf on golf courses and sod farms in Canada. For the MRLs previously established for this active ingredient on various crop commodities, please refer to the Maximum Residue Limit Database in the Pesticides and Pest Management portion of the Canada.ca website.

The nature of the residues in animal and plant matrices, analytical methodology and residue trial data were assessed under REG2003-12, *Fluazinam*. The chronic dietary risk estimates are summarized in Appendix I.

4.0 Impact on the Environment

4.1 Fate and behaviour in the environment

The fate and behaviour of fluazinam in the environment was assessed previously, see REG2003-12, *Fluazinam*, PRD2008-08, *Fluazinam*, and REV2016-12, *Special Review Decision: Fluazinam*.

Fluazinam was determined to be of sparing to low solubility in water. The vapour pressure and Henry's Law constant indicate that fluazinam has a low potential for volatilization from water and moist soils. Fluazinam is relatively stable to hydrolysis at pH 5 and pH 7, but rapidly hydrolyses at pH 9. Phototransformation will not be an important route of transformation in soils. Fluazinam is slightly persistent to persistent under aerobic soil conditions and slightly persistent to moderately persistent under field conditions. Depending on site location, up to 52% of residues were carried to the following crop season. One major transformation product, HYPA (see Appendix I, Table 10 for chemical names), was detected under terrestrial field conditions. The adsorption Koc values indicate that fluazinam is of slight mobility in sandy soils and of low mobility in loamy sand, silty loam and clay soils. Field studies and water models indicate that fluazinam has a low potential to leach through the soil and reach groundwater.

Phototransformation is an important route of transformation for fluazinam in aquatic environment. Fluazinam transforms rapidly by biotransformation in aquatic systems and is non-persistent under aerobic and anaerobic conditions. Fluazinam formed transformation products of CAPA, DCPA, DAPA and AMPA under aerobic conditions and SDS-67200, DAPA and AMPA under anaerobic conditions. Appendix I, Table 10 provides the chemical names for the transformation products.

Fluazinam has a low potential for accumulation in organisms. The bioconcentration factors (BCFs) in bluegill sunfish were 5.8–273 µg/kg in fillet, 94-1410 µg/kg in viscera and 58–960 µg/kg in whole fish; however, the time required for 50% depuration was short (5 to 6 days).

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. 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 (i.e. protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or 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 (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC). 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 screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to terrestrial organisms

A summary of the effects of fluazinam on terrestrial organisms can be found in previously published documents, see REG2003-12, *Fluazinam*, PRD2008-08, *Fluazinam*, and REV2016-12, *Special Review Decision: Fluazinam*.

In summary, fluazinam is considered to be non-lethal to earthworms (28-d NOEC and LC_{50}: 100 and 500 mg a.i./kg soil, respectively). Fluazinam is non-toxic to bees on acute oral and contact basis. Fluazinam is moderately toxic to bobwhite quail on an acute oral basis, and practically

non-toxic to mallard ducks. Fluazinam caused adverse reproductive effects on bobwhite quail and mallard duck with a NOEC of 500 mg a.i./kg diet, based on hatching success, 14-d old survivorship, egg production and embryo viability. Fluazinam is of low acute oral toxicity in rats. A reproductive NOAEL of 10.6 mg a.i./kg/d was reported based on a decreased number of implantation sites and decreased litter sizes to day 4 postpartum for F1 females. An EC_{25} of 1500 g a.i./ha for fluazinam was observed for seed germination, seedling emergence and vegetative vigour of non-target plants .

Earthworms: The most sensitive acute LC_{50} for earthworm was 1000 mg a.i./kg substrate. The EEC, with a cumulative application rate of 2979.80 g a.i./ha and a half-life of 200 days, would be 1.32 mg a.i/kg soil. The risk quotient of 0.003 is below the LOC and, therefore, the proposed use of Secure Fungicide is not expected to pose risk of concern to earthworms.

Sediment-dwelling organisms: No data were submitted on toxicity of parent compound to sediment-dwelling organisms. However, two studies on toxicity of SDS-67200, a transformation product under anaerobic sediment-water conditions, to sediment dwelling species, *Chironomus tentans* and *Hyalella azteca* were submitted. The PMRA concluded that SDS-67200 is not expected to pose a risk of concern to sediment dwelling organisms (PRD2008-08, *Fluazinam*).

Pollinators: The acute contact and oral LD_{50}s for bees were >200 and >100 µg a.i./bee, respectively. The contact and oral exposures are estimated by multiplying the single maximum application rate with factors of 2.4 and 29, respectively. This procedure converts application rates (exposure) from kg a.i./ha to µg a.i./bee. The risk quotient values were then calculated with the exposure estimates and LD_{50} values in µg a.i./bee (exposure in EEC/toxicity end point) and then compared with level of concern of 0.4; a risk quotient value greater than 0.4 indicates risk to bees.

Using a single maximum application rate of 0.8 kg a.i./ha, the exposure estimates are 1.92 µg a.i./bee by contact exposure and 23.2 µg a.i./bee for oral exposure. The contact and oral risk quotient values of <0.01 and <0.23, respectively, are less than the level of concern (0.4) and therefore, the proposed use of Secure Fungicide is not expected to pose risks of concern to adult bees on an acute oral and contact basis.

Wild birds: A screening level risk to birds was assessed using the proposed application rates to turf. This assessment indicated that the acute risk quotient values were less than the LOC (Appendix I, Table 4 and 5). The on-field reproductive risk quotient values, however, slightly exceeded the LOC with exposure for small and medium birds. This risk assessment assumed that the diet consists of 100% treated food sources. The LOC for reproductive effects for off-field exposure were not exceeded for all sizes and feeding guilds of birds. Overall, the risk assessment indicated that the likelihood of observing adverse effects to birds following use of Secure Fungicide on turf is low given that (i) acute risk quotient values were less than LOC, (ii) the on-field reproductive risk quotients only slightly exceeds the LOC, and (iii) the LOC for off-field exposure was not exceeded. A label statement informing the user of potential risks to birds is not warranted for Secure Fungicide at this time.

Wild mammals: The acute oral and reproductive risk to small wild mammals was assessed using the proposed rates for turf (Appendix I, Table 4 and 5). The screening level assessment using the maximum EECs indicated that reproductive risk quotients with on-field exposures exceeded the level of concern for small, medium and large sized mammals. The LOC for reproduction was not exceeded when spray drift into non-target areas was considered. Further risk characterization which considered the mean EECs indicated that the on-field risk quotients exceeded LOC for the mean residue exposure to small, medium and large sized mammals. The on-field risk assessment assumed that the diet consists of 100% treated food from within the treated field. A hazard statement to indicate potential risk to wild mammals is required.

Terrestrial non-target plants: The most sensitive endpoint for effects of fluazinam on the vegetative vigour of terrestrial vascular plants was for cucumber (EC_{25}: 1500 g.a.i./ha). Using a cumulative application rate of 2979.80 g a.i./ha, the risk quotient is 1.99. This value exceeds the LOC and therefore, buffer zones and environmental hazard statements are required to protect the non-target terrestrial plants.

4.2.2 Risks to aquatic organisms

A summary of the effects of fluazinam on aquatic organisms can be found in previously published documents, see REG2003-12, *Fluazinam*, PRD2008-08, *Fluazinam*, and REV2016-12, *Special Review Decision: Fluazinam*.

In summary, fluazinam is toxic to freshwater invertebrates (*Daphnia* sp. acute LC_{50} and chronic NOEC: 220 and 68 µg a.i./L, respectively), fish (acute LC_{50} and chronic $NOEC_{F1\ generation\ hatching\ success}$: 36 and 0.69 µg a.i./L, respectively), algae (EC_{50}: 150 µg a.i./L, biomass) and non-target plants (>53.6 µg a.i./L, frond number and biomass). Fluazinam is also toxic to marine invertebrates (Eastern oyster EC_{50}: 4 µg a.i./L, shell deposition and Mysid shrimp LC_{50} (*Mysidopsis bahia*): 39 µg a.i./L) and fish (Sheepshead minnow LC_{50}: 120 µg a.i./L)

Risk to aquatic organisms was assessed using the proposed maximum application rate of 3.2 kg a.i./ha/year. The EECs were estimated using four applications of 800 g/ha each with an interval of 14 days and an aquatic half-life of 3.2 days. This assessment indicated that risk quotients for all the freshwater and marine aquatic organisms exceeded the level of concern (Appendix I, Table 6) and pose a risk to these organisms with the proposed use of Secure Fungicide on turf.

Amphibians: As no toxicity data on amphibians were submitted, acute risk to amphibians was assessed using the acute LC_{50} of the most sensitive fish species (rainbow trout, 36 µg a.i./L) with an uncertainty factor of 10. The chronic risk was assessed with a fish chronic NOEC (Fathead minnow, 0.69 µg a.i./L). The EEC was estimated for a water depth of 15 cm. Risk quotients (156 and 812 for acute and chronic, respectively) exceeded the LOC for both acute and chronic effects (Table 6) and therefore, risk was further characterized by estimating EECs in runoff water from treated areas into a receiving water body and by spray drift.

Refined risk assessment for aquatic organisms

Runoff: As the screening level risk assessment indicated that risk quotient exceeded LOC, risk was further characterized by estimating EECs in runoff water from treated areas into receiving water body. The Pesticides in Water Calculator (PWC) model (1.52) was run for eleven scenarios for 50 years. The values presented in Table 8 are the 90th percentiles for the highest yearly value of the peak concentration (highest value during each year), and 21-day moving averages through each year.

The risk quotient values with runoff EECs (Table 9) exceeded the LOC for freshwater fish (RQs = 3.9 and 3.2, acute and chronic respectively), marine fish (acute RQ = 1.2) and marine invertebrates (acute RQ = 6.9). The use of Secure Fungicide on turf may pose a risk of concern to these organisms if runoff from the treatment site occurs.

Acute and chronic risk quotients (20.08 and 3.71, respectively) for amphibians exceeded the LOC and, therefore, the proposed use may pose a risk to these organisms due to exposure to surface runoff water contaminated with fluazinam residues. Run-off is most likely to occur when heavy rain fall occurs immediately following application. Fluazinam has an affinity to bind to soil particles and, as such, if runoff did occur it is likely that exposure to amphibian in the aquatic stage would be limited as fluazinam will bind readily to sediments and particles in the water. Once in the water fluazinam dissipates quickly.

Because of the potential risks from run-off, label statements to help reduce surface runoff are required to protect the aquatic organisms.

Spraydrift: At the proposed single application of 800 g a.i./ha the deposition at a point 1 meter downwind of the site of application is 6% of the application rate (ground boom with medium droplets) and would result in a deposition of 48 g a.i./ha. Four applications with 14 day interval and an aquatic half-life of 3.2 days would result cumulative application of 50.4 g a.i./ha. The resulting EECs would be 0.034 and 0.006 mg a.i./L in 15 and 80 cm water depth, respectively.

Using the above aquatic EECs the acute and chronic risk quotients for fresh water fish and the acute risk quotient for amphibians exceed the LOC (Appendix I, Table 7). The acute risk quotient for marine invertebrate, Eastern oyster, also exceeded the LOC. The proposed use of Secure Fungicide on turf, therefore, poses risks of concern to freshwater fish, amphibians and marine invertebrates. Label statements and buffer zones to protect freshwater and estuarine marine environments are required.

4.3 Environmental Incident reports

As of May 26, 2017, no environment incident reports involving fluazinam have been submitted to the PMRA. There was also no incident data reported in the California or USEPA Ecological Incident information System (EIIS) databases.

5.0 Value

5.1 Consideration of Benefits

Several alternatives are registered for all four disease claims. However, Secure Fungicide will provide users with a new mode of action to control economically important diseases on golf courses and sod farms. This is beneficial from a resistance management perspective, as the addition of fluazinam to the rotation in a treatment program on turf will potentially delay fungicide resistance against products with different modes of action.

Using good cultural practices to improve soil drainage, increase air movement in the root zone and optimizing plant heath through proper fertilization is the first step in any IPM program. With good cultural practices, Secure Fungicide will fit in as a new option to provide healthy turfgrass in IPM based turf management programs.

The ability to tank mix Secure Fungicide with Banner Maxx (propiconazole) or Heritage Maxx (azoxystrobin) will provide users with a resistance management tool and a broad spectrum disease management strategy.

5.2 Effectiveness Against Pests

In support of the summer disease claims on turf, efficacy data from a total of 19 trials were provided. Based on the results of these trials, it was confirmed that Secure Fungicide is effective at providing control of dollar spot, anthracnose, Microdochium patch and brown patch at a rate of 16 ml of product/100 m^2. However, for anthracnose, the claim of control is restricted to conditions of low to moderate disease pressure only.

5.3 Non-Safety Adverse Effects

Efficacy trial reports showed negligible phytotoxicity (1.0% or less) for all treatments of Secure Fungicide.

5.4 Supported Uses

Based on the value information provided a claim of control of dollar spot (*Sclerotinia homoeocarpa*), anthracnose (*Colletotrichum cereale*), Microdochium patch (*Microdochium nivale*) and brown patch (*Rhizoctonia solani*), at an application rate of 16 ml/100 m^2 in a spray volume of 200-800 L/ha, is supported. Tank-mixes with Banner Maxx (propiconazole) or Heritage Maxx (azoxystrobin) were also supported.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances those that meet

all four criteria outlined in the policy, i.e. persistent (in air, soil, water and/or sediment), bioaccumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*.

During the previous review process, fluazinam and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03 and evaluated against the Track 1 criteria. The TSMP conclusions reached at that time apply to the current submission and refer to REG2003-12, *Fluazinam* for full details. According to this review,

> Fluazinam does not meet all Track 1 criteria, nor does it form any transformation products that meet all Track 1 criteria, and therefore, not considered as a Track 1 substance.

6.2 Formulants and Contaminants of Environmental Concern

During the current assessment, contaminants in the technical, and formulants and contaminants in the end-use product were compared against the List of Pest Control Product Formulants and Contaminants of Environmental Concern maintained in the *Canada Gazette*. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the Canadian Environmental Protection Act (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade fluazinam does not contain any formulants or contaminants of environmental concern identified in the Canada Gazette.
- The end-use product, Secure Fungicide, contains (as a component) the preservative 1,2-benzisothiazoline-3-one, which contains low levels of polychlorinated dibenzodioxins and furans (TSMP Track 1)). As the use of this preservative was recently re-evaluated by the PMRA in 2012 and found to be acceptable, and because the input of dioxins into the environment from pesticides is being managed as outlined in the PMRA Regulatory Directive DIR99-03 for the implementation of TSMP, the Agency position is that no further action is required.

The end-use product, Secure Fungicide, does not contain any other formulants or contaminants of of environmental concern identified in the *Canada Gazette*.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for fluazinam is adequate to define the majority of toxic effects that may result from exposure. The most sensitive endpoint used for risk assessment was liver toxicity. Fluazinam caused thyroid tumours in male rats and liver tumours in male mice, but was not genotoxic. Mode of action data were submitted that supported a threshold dose response. There was also no indication that fluazinam caused damage to the nervous system. Serious

effects in young animals occurred in the presence of maternal toxicity. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Please refer to REG2003-12, *Fluazinam* for previously reviewed data regarding food residue exposure assessment. The use of fluazinam on turf in golf courses and sod farms does not constitute a health risk of concern for acute or chronic dietary exposure (food and drinking water) to any segment of the population, including infants, children, adults and seniors.

Under the approved conditions of use, Secure Fungicide does not present an unacceptable risk to human health.

7.2 Environmental Risk

The vapour pressure and Henry's Law constant indicate that fluazinam has a low potential for volatilization from water and moist soils. Fluazinam is relatively stable to hydrolysis at pH 5 and pH 7, but rapidly hydrolyses at pH 9.

Fluazinam is slightly persistent to persistent under aerobic soil conditions and slightly persistent to moderately persistent under field conditions. Depending on site location, up to 52% of residues were carried to the following crop season. One major transformation product, HYPA, was detected under terrestrial field conditions. The adsorption Koc values indicate that fluazinam has slight mobility in sandy soils and low mobility in loamy sand, silty loam and clay soils. Field studies and water models indicate that fluazinam has a low potential to leach through the soil and reach groundwater.

Phototransformation is an important route of transformation for fluazinam in aquatic environment. Fluazinam transforms rapidly by biotransformation in aquatic systems and is non-persistent under aerobic and anaerobic conditions. Fluazinam formed transformation products of CAPA, DCPA, DAPA and AMPA under aerobic conditions and SDS-67200, DAPA and AMPA under anaerobic conditions.

Fluazinam has a low potential to bioaccumulate in organisms.

Potential risks to non-target terrestrial plants (RQ=1.99), small wild mammals (1.2-3.9) and aquatic organisms (spray drift RQ= 1.67 – 49.28 and runoff RQ=1.16-20.08) were identified for the proposed use on turf and therefore, risk mitigation measures are required.

7.2.1 Risk Mitigation

Environmental risks were identified (LOC exceeded) in small mammals, terrestrial plants and amphibians and aquatic organisms. To address these environmental concerns, the following mitigation measures, precautions and hazard warnings are required for Secure Fungicide.

Spray Drift

Fluazinam can enter aquatic habitats and adjacent terrestrial habitats through spray drift. The observance of buffer zones can effectively mitigate the risk of spray drift to aquatic and terrestrial organisms. Pesticide spray drift from field sprayers (ground boom) is predicted using a model that is based on the data of Wolf and Caldwell (2001). Buffer zones are required for broadcast applications of fluazinam to mitigate spray.

Persistence and residue carry-over

Fluazinam is persistent in soils and can carry-over to the following crop growing season. Precautionary statements recommending not to use the product in areas where it was used in the previous season must be included on the product label to minimize carry-over.

Runoff

Fluazinam runoff from treated areas can pose a risk to aquatic organisms. Precautionary statements identifying sites with characteristics that may be conducive to run-off and when heavy rain is forecasted are required. In addition, a vegetative strip between the treated area and the edge of a water body is recommended to reduce run-off of fluazinam to aquatic systems.

Environmental Toxicity

Fluazinam can pose a risk to small mammals present in treated areas. Hazard warnings must be included on the product label to minimize this risk.

7.3 Value

Secure Fungicide will provide users with a new mode of action to control economically important diseases on golf courses and sod farms. The addition of fluazinam to the rotation in a treatment program on turf will potentially delay fungicide resistance against products with different modes of action. The ability to tank mix Secure Fungicide with Banner Maxx (propiconazole) or Heritage Maxx (azoxystrobin) will provide users with a resistance management tool and a broad spectrum disease management strategy.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Technical Fluazinam Fungicide and Secure Fungicide, containing the technical grade active ingredient fluazinam, to control fungal diseases on turf (golf courses and sod farms).

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

°C	degrees Celsuis
µg	micrograms
λ	wavelength
a.i.	active ingredient
ADI	acceptable daily intake
AHETF	Agricultural Handler Exposure Task Force
ARfD	acute reference dose
ARI	aggregate risk index
ATPD	area treated per day
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstracts Service
CEPA	*Canadian Environmental Protection Act*
cm	centimetres
d	day(s)
DACO	data code
DEEM	Dietary Exposure Evaluation Model
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
EEC	estimated environmental concentration
EIIS	USEPA Ecological Incident information System
EP	end-use product
FRAC	Fungicide Resistance Action Committee
g	gram
ha	hectare(s)
HAFT	highest average field trial
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOC	level of concern
m	metre
mg	milligram
mL	millilitre
MAS	maximum average score
MOE	margin of exposure
MRL	maximum residue limit
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
ORETF	Outdoor Residential Exposure Task Force
Pa	Pascals
PDP	Pesticide Data Program

p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PWC	pesticides in water calculator
RDF	residue distribution file
REI	restricted-entry interval
RfD	reference dose
RQ	risk quotient
RTI	retreatment interval
STMdR	supervised trial median residue
$t_{1/2}$	half-life
TC	transfer coefficient
TGAI	technical grade active ingredient
TTR	transferable turf residue
TSMP	Toxic Substances Management Policy
UF_D	dermal uncertainty factor
US	United States
USEPA	United States Environmental Protection Agency
UV	ultraviolet
WDG	wettable dispersable granule
WG	water disperable granules
x	times
v/v	volume per volume

Appendix I Tables and Figures

Table 1 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

DIETARY RISK FROM FOOD AND WATER			
	POPULATION	**ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)**	
		Food Alone	**Food and Water**
Refined chronic cancer and non-cancer dietary exposure analysis **ADI = 0.0037 mg/kg bw/day** **Estimated chronic drinking water concentration = 1.2 Φg/L**	**All infants < 1 year**	17.6	20.1
	Children 1–2 years	30.3	31.2
	Children 3 to 5 years	19.0	19.7
	Children 6–12 years	9.8	10.3
	Youth 13–19 years	7.1	7.6
	Adults 20–49 years	21.3	21.9
	Adults 50+ years	26.5	27.1
	Females 13-49 years	22.9	23.6
	Total population	20.5	21.2
Refined acute dietary exposure analysis, 95th percentile (probabilistic for apple only; deterministic for all other crops) **ARfD = 0.013 mg/kg bw** **Estimated acute drinking water concentration = 24 Φg/L**	**POPULATION**	**ESTIMATED RISK % of ACUTE REFERENCE DOSE (ARfD)**	
		Food Alone	**Food and Water**
	All infants < 1 year	30.3	49.5
	Children 1–2 years	49.0	56.5
	Children 3 to 5 years	30.4	35.4

	Children 6–12 years	12.9	20.2
	Youth 13–19 years	7.0	13.5
	Adults 20–49 years	34.4	38.8
	Adults 50+ years	53.8	58.0
	Females 13-49 years	36.5	40.4
	Total population	35.3	40.0

Table 2 Risk assessment to bees

	Exposure	**Endpoint**	**EEC**	**RQ**	**Exceedance of LOC**
Adult bees	Acute contact	LD_{50}: >200 µg a.i./bee	1.92 µg a.i./bee*	<0.01	NO
	Acute oral	LD_{50}: >100 µg a.i./bee	23.2 µg a.i./bee**	<0.23	NO

*contact exposure estimated by multiplying single maximum application rate of 0.8 kg a.i./ha with a factor of 24
** oral exposure estimated by multiplying single maximum application rate of 0.8 kg a.i./ha with a factor 29

Table 3 Maximum and mean EECs (on field) in vegetation and insects

Environmental Compartment	**Fresh/dry weight ratios**	**Maximum residue concentration**		**Mean residue concentration**	
		Concentration fresh weight (mg a.i./kg)	**Concentration dry weight (mg a.i./kg)**	**Concentration fresh weight (mg a.i./kg)**	**Concentration dry weight (mg a.i./kg)**
Fluazinam on Turf: 4 × 800 g a.i./ha (14 d int. between app.) Ground Boom Sprayer Medium - assuming a foliar dissipation of 10 days					
short range grass	3.3	270	891.02	96	316.44
long grass	4.4	124	544.03	40	177.64
broadleaf plants	5.4	153	824.38	50	272.52
Insects	3.8	106	402.73	73	278.07
grain and seeds	3.8	16	62.33	8	29.73
fruit	7.6	16	124.65	8	59.45

Table 4 Screening level risk assessment to birds and mammals

	Toxicity (mg ai/kg bw/d)	Feeding Guild (food item)	On-field EDE (mg ai/kg bw)	On-field RQ	Off-field RQ (6% drift)
Fluazinam - data on Turf: 4 × 800 g a.i./ha (14 d int. between app.). Ground Boom Sprayer Medium - assuming a foliar dissipation of 10 days					
Birds					
Small Bird (0.02 kg)					
Acute	178.2	Insectivore	102.70	0.58	0.03
Reproduction	60.3	Insectivore	102.70	**1.70**	0.10
Medium Sized Bird (0.1 kg)					
Acute	178.2	Insectivore	80.14	0.45	0.03
Reproduction	60.3	Insectivore	80.14	**1.33**	0.08
Large Sized Bird (1 kg)					
Acute	178.2	Herbivore (short grass)	51.77	0.29	0.02
Reproduction	60.3	Herbivore (short grass)	51.77	0.86	0.05
Mammals					
Small Mammal (0.015 kg)					
Acute	419.0	Insectivore	59.07	0.14	0.01
Reproduction	10.6	Insectivore	59.07	**5.57**	0.33
Medium Sized Mammal (0.035 kg)					
Acute	419.0	Herbivore (short grass)	114.56	0.27	0.02
Reproduction	10.6	Herbivore (short grass)	114.56	**10.81**	0.65
Large Sized Mammal (1 kg)					
Acute	419.0	Herbivore (short grass)	61.21	0.15	0.01
Reproduction	10.6	Herbivore (short grass)	61.21	**5.77**	0.35

Table 5 Further characterization using same endpoints as screening level

Fluazinam - data on Turf: 4 × 800 g a.i./ha (14 d int. between app.). Ground Boom Sprayer Medium - assuming a foliar dissipation 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 (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ
Small Bird (0.02 kg)										
Reproduction	60.33	Insectivore	102.70	**1.7**	6.16	0.1	70.91	**1.18**	4.25	0.07
	60.33	Granivore (grain and seeds)	15.89	0.3	0.95	0.0	7.58	0.13	0.45	0.01
	60.33	Frugivore (fruit)	31.79	0.5	1.91	0.0	15.16	0.25	0.91	0.02
Medium Sized Bird (0.1 kg)										
Reproduction	60.33	Insectivore	80.14	**1.3**	4.81	0.1	55.34	0.92	3.32	0.06
	60.33	Granivore (grain and seeds)	12.40	0.2	0.74	0.0	5.92	0.10	0.35	0.01
	60.33	Frugivore (fruit)	24.81	0.4	1.49	0.0	11.83	0.20	0.71	0.01
Small Mammal (0.015 kg)										
Reproduction	10.6	Insectivore	59.07	**5.6**	3.54	0.3	40.78	**3.85**	2.45	0.23
	10.6	Granivore (grain and seeds)	9.14	0.9	0.55	0.1	4.36	0.41	0.26	0.02
	10.6	Frugivore (fruit)	18.28	**1.7**	1.10	0.1	8.72	0.82	0.52	0.05
Medium Sized Mammal (0.035 kg)										
Reproduction	10.6	Insectivore	51.78	**4.9**	3.11	0.3	35.75	**3.37**	2.15	0.20
	10.6	Granivore (grain and seeds)	8.01	0.8	0.48	0.0	3.82	0.36	0.23	0.02
	10.6	Frugivore (fruit)	16.03	**1.5**	0.96	0.1	7.64	0.72	0.46	0.04
	10.6	Herbivore (short grass)	114.56	**10.8**	6.87	0.6	40.68	**3.84**	2.44	0.23
	10.6	Herbivore (long grass)	69.95	**6.6**	4.20	0.4	22.84	**2.15**	1.37	0.13
	10.6	Herbivore (Broadleaf plants)	105.99	**10.0**	6.36	0.6	35.04	**3.31**	2.10	0.20

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 (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ
Large Sized Mammal (1 kg)										
Reproduction	10.6	Insectivore	27.67	**2.6**	1.66	0.2	19.10	**1.80**	1.15	0.11
	10.6	Granivore (grain and seeds)	4.28	0.4	0.26	0.0	2.04	0.19	0.12	0.01
	10.6	Frugivore (fruit)	8.56	0.8	0.51	0.0	4.08	0.39	0.25	0.02
	10.6	Herbivore (short grass)	61.21	**5.8**	3.67	0.3	21.74	**2.05**	1.30	0.12
	10.6	Herbivore (long grass)	37.38	**3.5**	2.24	0.2	12.20	**1.15**	0.73	0.07
	10.6	Herbivore (Broadleaf plants)	56.63	**5.3**	3.40	0.3	18.72	**1.77**	1.12	0.11

Table 6 Screening level risk assessment to aquatic organisms

Organism	Exposure	Endpoint value*	EEC (80 cm) µg a.i./L	Risk quotient	Exceedance of LOC
Freshwater					
Rainbow trout	acute	LC_{50}(1/10): 3.60 µg a.i./L	105	29.17	exceeds LOC
Fathead minnow	chronic	NOEC: 0.69 µg a.i./L	105	152	exceeds LOC
Daphnids	acute	LC_{50}((½): 110 µg a.i./L	105	0.95	No
	chronic	NOEC: 68 µg a.i./L	105	1.54	exceeds LOC
Amphibians	acute	Fish LC_{50}(1/10): 3.60 µg a.i./L	560**	156	exceeds LOC
	chronic	NOEC: 0.69 µg a.i./L	560**	812	exceeds LOC
Green algae	acute	EC_{50} (½):75 µg a.i./L	105	1.4	exceeds LOC
Duckweed	acute	EC_{50} (½): 26.8 µg a.i./L	105	3.92	exceeds LOC

Organism	Exposure	Endpoint value*	EEC (80 cm) µg a.i./L	Risk quotient	Exceedance of LOC
Marine					
Eastern oyster	acute	LC_{50}(½):2.0 µg a.i./L	105	52.5	exceeds LOC
Sheepshead minnow	acute	(1/10): 12 µg a.i./L	105	8.75	exceeds LOC

*for toxicity endpoints, refer to REG2003-12, *Fluazinam*
**15 cm water

Table 7 Refined risk assessment to aquatic organisms: spray drift

Organism	Exposure	Endpoint value*	EEC (80 cm) µg a.i./L***	Risk quotient	Exceedance of LOC
Freshwater					
Rainbow trout	acute	LC_{50}(1/10): 3.60 µg a.i./L	6.0	1.67	exceeds LOC
Fathead minnow	chronic	NOEC: 0.69 µg a.i./L	6.0	8.70	exceeds LOC
Daphnids	acute	LC_{50}((½): 110 µg a.i./L	6.0	0.05	No
	chronic	NOEC: 68 µg a.i./L	6.0	0.09	No
Amphibians	acute	Fish LC_{50}(1/10): 3.60 µg a.i./L	34.0	9.44	exceeds LOC
	chronic	NOEC: 0.69 µg a.i./L	34.0	49.28	exceeds LOC
Green algae	acute	EC_{50} (½):75 µg a.i./L	6.0	0.08	No
Duckweed	acute	EC_{50} (½): 26.8 µg a.i./L	6.0	0.22	No
Marine					
Eastern oyster	acute	LC_{50}(½):2.0 µg a.i./L	6.0	3.0	exceeds LOC
Sheepshead minnow	acute	(1/10): 12 µg a.i./L	6.0	0.5	No

*for toxicity endpoints, refer to REG2003-12, *Fluazinam*
**15 cm water
*** EECs were calculated with four applicatiojns of 800 g a.i./ha each, 6% spray drift and aquatic half-life of 3.2 days

Table 8 EECs in surface runoff water (µg a.i./L)

Depth	Peak	21 days
15 cm	72.3	2.56
80 cm	13.9	2.22

Table 9 Refined risk assessment to aquatic organisms: runoff

Organism	Exposure	Endpoint value*	EEC (80 cm) µg a.i./L*	Risk quotient	Exceedance of LOC
Freshwater					
Rainbow trout	acute	96 h LC_{50}(1/10): 3.60 µg a.i./L	13.9 (peak)	3.86	exceeds LOC
Fathead minnow	chronic	NOEC: 0.69 µg a.i./L	2.22 (21 day)	3.21	exceeds LOC
Daphnids	acute	48 h LC_{50}((½): 110 µg a.i./L	13.9 (peak)	0.13	No
	chronic	21 d NOEC: 68 µg a.i./L	2.22 (21 day)	0.03	No
Amphibians	acute	96 h Fish LC_{50}(1/10): 3.60 µg a.i./L	72.3 (peak) **	20.08	exceeds LOC
	chronic	NOEC: 0.69 µg a.i./L	2.56 (21 day) **	3.71	exceeds LOC
Green algae	acute	96 h EC_{50} (½):75 µg a.i./L	13.9 (peak)	0.18	No
Duckweed	acute	7 d EC_{50} (½): 26.8 µg a.i./L	13.9 (peak)	0.51	No
Marine					
Eastern oyster	acute	96 h LC_{50}(½):2.0 µg a.i./L	13.9 (peak)	6.95	exceeds LOC
Sheepshead minnow	acute	96 h (1/10): 12 µg a.i./L	13.9 (peak)	1.16	exceeds LOC

*for toxicity endpoints, refer to REG2003-12, *Fluazinam*
**15 cm water

Table 10 List of transformation products

Name	Chemical name
AMPA	4-Chloro-N2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]-3-nitro-5-(trifluoromethyl)-1,2-benzenediamine
CAPA	5-chloro-6-[3-chloro-2, 6-dinitro-4-trifluoromethylanilino) nicotinic acid
DAPA	3-chloro-2-(2,6-diamino-3-chloro-α,α,α-trifluoro-p-toluidino)-5-(trifluoromethyl) pyridine
HYPA	5-[(3-chloro-5-(trifluoromethyl)-2-pyridyl)amino]-α,α,α-trifluoro-4,6-dinitro-o-cresol
MAPA	3-Chloro-N1-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]-6-nitro-4-(trifluoromethyl)-1,2-benzenediamine
SDS-67200	2-chloro-6-[(3-chloro-5-(trifluoromethyl)-2-pyridyl)-α,α,α-trifluoro-5-nitro-m-cresol

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

None

2.0 Human and Animal Health

PMRA Document Number	Reference
707763	2001, Dermal Absorption of [14C]-Fluazinam in Two Formulations in the Rat, DACO: 5.8
2607545	2016, Use Description and Scenario (Mixer/Loader/Applicator and Post-application) for Secure Fungicide, DACO: 5.2,5.3

3.0 Environment

None

4.0 Value

PMRA Document Number	Reference
2607527	2016, Value Summary - Secure Fungicide, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.3.1, 10.3.2
2607529	2016, Comments on Trial GBAXOF9022010, DACO: 10.2.3.3
2607530	2016, Comments on Trial GBAXOF9042010, DACO: 10.2.3.3
2607531	2016, Comments on Trial GBAXOF9052010, DACO: 10.2.3.3
2607532	2016, Comments on Trial USNOF1242010, DACO: 10.2.3.3
2607533	2016, Comments on Trial CAONOF6102011, DACO: 10.2.3.3
2607534	2016, Comments on Trial CAONOF6132011, DACO: 10.2.3.3
2607535	2016, Efficacy: small-scale trials, DACO: 10.2.3.3

PMRA Document Number	Reference
2607536	2016, Comments on Trial USNIOF1202011, DACO: 10.2.3.3
2607537	2016, Efficacy: small-scale trials, DACO: 10.2.3.3
2607538	2016, Comments on Trial USEAOF1252001, DACO: 10.2.3.3
2607539	2016, Comments on Trial USEAOF1262001, DACO: 10.2.3.3
2607540	2016, Efficacy: small-scale trials, DACO: 10.2.3.3
2607541	2016, Comments on Trial USEAOF11172001, DACO: 10.2.3.3
2651680	2010, EXPP(FAPH30A4- 2010US)2, DACO: 10.2.3, CBI

B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

U.S. EPA Residential SOPs

PMRA Document Number	Reference
2409268	U.S. EPA (2012a). Standard Operating Procedures for Residential Pesticide Exposure Assessment. EPA: Washington, DC. Revised October 2012.

U.S. EPA Residential SOPs Task Force

PMRA Document Number	Reference
1563654	1999, Integrated Report for Evaluation of Potential Exposures to Homeowners and Professional Lawn Care Operators Mixing, Loading, and Applying Granular and Liquid Pesticides to Residential Lawns. Appendix 4 Exposure Of Professional Lawn Care Workers During The Mixing And Loading Of Dry And Liquid Formulations And The Liquid Application Of Turf Pesticides Utilizing A Surrogate Compound., DACO: 5.3,5.4

PMRA Document Number	Reference
1563664	1999, Integrated Report for Evaluation of Potential Exposures to Homeowners and Professional Lawn Care Operators Mixing, Loading, and Applying Granular and Liquid Pesticides to Residential Lawns. Appendix B Field Phase Report for Exposure of Professional Lawn Care Workers During the Mixing and Loading of Dry and Liquid Formulations and the Liquid Application of Turf Pesticides Utilizing a Surrogate Compound., DACO: 5.3,5.4
1913109	2009, Agricultural Handler Exposure Scenario Monograph: Open Cab Groundboom Application of Liquid Sprays, DACO 5.3, 5.4

2.0 Environment

Ganzelmeier, H; Rautmann, D; Spangenberg, R; Streloke, M; Herrmann, M; Wenzelburger, H-J; Walter, H-F 1995. Studies on the spray drift of plant protection n products: Results of a test program carried out throughout the Federal Republic of Germany. Report Number 305 from the Biologischen Bundesanstalt fhr Land- und Forstwirtschaft, Berlin-Dahlem. Blackwell Wissenschafts-Verlag GmbH, Berlin/Vienna.

USEPA, PMRA and California Department of Pesticide Regulation, 2014. Guidance for Assessing Pesticide Risks to Bees. https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

Wolf, T.M. and Caldwell, B.C., 2001. Development of a Canadian spray drift model for the determination of buffer zone distances. In Expert Committee on Weeds - Comité d'experts en malherbologie (ECWCEM), Proceedings of the 2001 National Meeting, Québec City. Sainte-Anne-de-Bellevue, Québec: ECW-CEM. Eds. D Bernier, D R A Campbell and D Cloutier, pp. 60.