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Evaluation Report

Fludioxonil

Instrata™ Fungicide

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Overview

Registration Decision for Instrata™ Fungicide

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, has granted conditional registration for the sale and use of Fludioxonil Technical Fungicide and Instrata™ Fungicide containing the technical grade active ingredient fludioxonil to control pink snow mould and grey snow mould on golf course turf.

Current scientific data from the applicant and scientific reports were evaluated to determine if, under the proposed conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This report summarizes the information that was evaluated and provides the results of the evaluation as well as the reasons for the registration decision, with an outline of the additional scientific information required from the applicant. It also describes the conditions of registration that the applicant must meet to ensure that the health and environmental risks as well as the value of these pest control products are acceptable for their intended use.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of Fludioxonil Technical Fungicide and Instrata™ Fungicide.

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 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 (e.g. children) as well as organisms in the environment (e.g. those most sensitive to

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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".

environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What Is Fludioxonil?

Fludioxonil is one of the active ingredients in the product Instrata™ Fungicide, which controls grey snow mould and pink snow mould on turf grass. Instrata™ Fungicide is a coformulation of fludioxonil, chorothalonil and propiconazole.

Health Considerations

Can Approved Uses of Fludioxonil Affect Human Health?

Fludioxonil is unlikely to affect your health when Instrata™ Fungicide is used according to label directions.

Exposure to fludioxonil may occur when handling and applying Instrata™ Fungicide. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only the 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 at which no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when products containing fludioxonil are used according to label directions.

The technical grade active ingredient fludioxonil caused mild eye irritation in animals. Consequently, the statement "Caution—Eye Irritant" is required on the label. Fludioxonil did not cause cancer in animals and was not genotoxic. There was no indication that fludioxonil caused damage to the nervous system, and there were no effects on reproduction. The first signs of toxicity in animals given daily doses of fludioxonil over longer periods of time were effects on the liver. 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.

When fludioxonil was given to pregnant animals, effects on the developing fetus were observed at doses that were toxic to the mother, indicating that the fetus was no more sensitive to fludioxonil than the adult animal.

Occupational Risks From Handling Fludioxonil

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

Workers mixing, loading or applying Instrata™ Fungicide, as well as workers exposed to freshly treated turf can come in direct contact with fludioxonil, chlorothalonil and propiconazole on the skin. Therefore, the label will specify that anyone mixing, loading or applying Instrata™ Fungicide or involved in clean-up or repair activities must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear. In addition, during mixing and loading a chemical-resistant apron must be worn. Taking into consideration these label requirements and the expectation that occupational exposure will be of short- to intermediate-term duration, risk to applicators or workers is not a concern.

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

Environmental Considerations

What Happens When Fludioxonil Is Introduced Into the Environment?

Fludioxonil is toxic to aquatic organisms; therefore, buffer zones are required during application.

Fludioxonil enters the environment when used as a fungicide on golf courses. Once in the terrestrial environment, fludioxonil strongly binds to soil particles. Fludioxonil has a low potential for leaching but may still be found in subsurface soil. This may be related to the movement of surface soil down preferential flow channels in the soil rather than actual leaching of the compound. Fludioxonil is persistent in soil and is expected to carry over to the following growing season. The persistence of fludioxonil in water and the persistence of major fludioxonil transformation products both on soil and in water could not be characterized. Residues of fludioxonil are not expected to be found in air due to low volatility.

Value Considerations

What Is the Value of Instrata™ Fungicide?

Instrata™ Fungicide controls pink and grey snow mould on turf.

A single application of Instrata™ Fungicide applied prior to the development of a permanent snow cover provides effective control of pink and grey snow mould diseases on turf. A fungicide spray in late fall is necessary to maintain a high level of snow mould disease control.

There are currently seven active ingredients registered for control of pink and grey snow mould, two of which are components of Instrata™ Fungicide (chlorothalonil, propiconazole). The third component, fludioxonil, is a new active ingredient for snow mould control. A blended product that combines several active ingredients, such as Instrata™ Fungicide, allows the use of lower rates and thereby results in a net reduction in fungicide load.

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 on the label of Instrata™ Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

- **Human Health**

  As there is a concern with users coming into direct contact with fludioxonil, chlorothalonil and propiconazole on the skin, anyone mixing, loading or applying Instrata™ Fungicide must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear. A chemical-resistant apron must also be worn during mixing and loading.

- **Environment**

  Fludioxonil is toxic to aquatic organisms. Therefore, a one-metre buffer zone must be respected to protect aquatic habitats.

  In addition, as fludioxonil is persistent and will carry over, it is recommended that any products containing fludioxonil not be used in areas treated with this product during the previous season.

What Additional Scientific Information Is Required?

Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation section of this Evaluation Report and in the Section 12 Notice associated with these conditional registrations. The applicant must submit the following information within the time frames indicated.

- Environment

  Data on the phototransformation of fludioxonil on soil and in water as well as data on the biotransformation of fludioxonil in an aerobic water/sediment system must be submitted to the PMRA by 30 September 2009.

Other Information

As these conditional registrations relate to a decision on which the public must be consulted,[3] the PMRA will publish a consultation document when there is a proposed decision on applications to convert the conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

The test data cited in this Evaluation Report (i.e. the test data relevant in supporting the registration decision) will be made available for public inspection when the decision is made to convert the conditional registrations to full registrations or to renew the conditional registrations (following public consultation). If more information is required, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

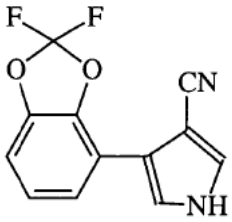
[3] As per subsection 28(1) of the *Pest Control Products Act.*

Science Evaluation

Fludioxonil Technical Fungicide

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Fludioxonil
Function	Fungicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	4-(2,2-difluoro-1,3-benzodioxol-4-yl) pyrrole-3-carbonitrile
2. Chemical Abstracts Service (CAS)	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile
CAS number	131341-86-1
Molecular formula	$C_{12}H_6F_2N_2O_2$
Molecular weight	248.2
Structural formula	
Purity of the active ingredient	97.6% nominal

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product—Fludioxonil Technical Fungicide

Property	Result
Colour and physical state	Light olive green powder
Odour	None

Property	Result
Melting point	199.8 °C
Boiling point	Not applicable
Density	1.54 g/mL
Vapour pressure at 25 °C	3.87 x 10^{-7} Pa
Henry's law constant at 20 °C	5.4 × 10^{-5} Pa m^3/mol (1/H = 4.56 × 10^7)
Ultraviolet (UV)-visible spectrum	λ_{max} = 207 nm
Solubility in water at 25 °C	1.8 ppm
Solubility in organic solvents at 25 °C (g/100 g)	**Solvent** — **Solubility** acetone — 19 ethanol — 4.4 *n*-octanol — 2.0 toluene — 0.27 *n*-hexane — 0.00078
n-Octanol-water partition coefficient (K_{ow}) at 25 °C	log K_{ow} = 4.12, pH-independent between pH 4 and 9
Dissociation constant (p*K*a)	pKa_1 < 0 pKa_2 ~ 14.1 (calculated)
Stability (temperature, metal)	Stable to metals and sunlight

End-Use Product—Instrata™ Fungicide

Property	Result
Colour	Grey
Odour	Aromatic
Physical state	Liquid
Formulation type	Suspension
Guarantee	Propiconazole 57 g/L Fludioxonil 14.5 g/L Chlorothalonil 362 g/L
Container material and description	3.78, 9.46 or 37.85 L fluorinated or non-fluorinated high-density polyethylene (HDPE)

Property	Result
Density	1.21 g/mL
pH of 1% dispersion in water	4–7
Oxidizing or reducing action	Not an oxidizing substance
Storage stability	Stable over two years
Explodability	Not explosive

1.3 Directions for Use

Instrata™ Fungicide controls pink snow mould (*Microdochium nivale*) and grey snow mould (*Typhula incarnata, T. ishikariensis*) on turf grass at 300 mL of product per 100 m^2. A single application should be made by ground sprayer only in late fall prior to the development of a permanent snow cover in a spray volume of 400 to 800 L of water per 100 m^2.

1.4 Mode of Action

Instrata™ Fungicide is a suspension emulsion formulation containing three active ingredients together in a premix form (56.87 grams propiconazole per litre, 361.79 grams chlorothalonil per litre and 14.52 grams fludioxonil per litre). This is a broad-spectrum fungicide with both systemic and curative properties.

Fludioxonil blocks a protein kinase that catalyzes phosphorylation of a regulatory enzyme of glycerol synthesis. This active ingredient acts prior to plant penetration to inhibit spore germination and growth of germination tubes and mycelia before penetration of plant tissues. In fungi, the most sensitive development stages are spore germination and germ tube growth. Chlorothalonil and propiconazole function via different modes of action. Chlorothalonil binds glutathione, which inhibits glutathione-dependent enzymes, and propiconazole interferes with ergosterol biosynthesis, which is essential for building fungal cell walls.

2.0 Methods of Analysis

2.1 Methods for Analysis of Fludioxonil Technical Fungicide

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

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredients in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

Not required for environmental monitoring purposes at this time.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Please refer to Evaluation Report ERC2007-04, *Fludioxonil, Scholar 50WP Fungicide,* for a summary of the toxicology database for fludioxonil.

The end-use product Instrata™ Fungicide exhibits slight acute oral and inhalation toxicity and low dermal toxicity in the rat. It is moderately irritating to the eye and mildly irritating to the skin of the rabbit. It is a dermal sensitizer in the guinea pig (Appendix I, Table 1).

3.2 Determination of Acceptable Daily Intake

An acceptable daily intake is not required as no food uses were requested.

3.3 Determination of Acute Reference Dose

An acute reference dose is not required as no food uses were requested.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Please refer to Evaluation Report ERC2007-04, *Fludioxonil, Scholar 50WP Fungicide,* for the toxicological endpoints for fludioxonil.

Dermal Absorption
No dermal absorption study was submitted for the application. Therefore, the dermal absorption is considered to be 100%.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/Loader/Applicator Exposure and Risk Assessment

Workers are expected to be exposed to fludioxonil for short- to intermediate-term duration through the dermal and inhalation routes while mixing, loading and applying Instrata™ Fungicide.

Exposure to Instrata™ Fungicide during mixing/loading and applying by groundboom equipment was estimated using the Pesticide Handlers Exposure Database (PHED), Version 1.1. The maximum application rate is 300 mL product/100 m^2 turf to treat fairways, greens and tees once per season (before snowfall). This is the equivalent of 4.36 g a.i./100m^2 or 0.436 kg a.i./ha. The PMRA assumes a default area treated per day value for golf courses of 16 ha and this is considered representative of the use pattern. The MOEs for mixers/loaders and applicators are above the target of 100 for dermal exposure and for inhalation exposure with the protective equipment specified on the label.

3.4.2.2 Postapplication Worker Exposure and Risk

Dermal exposure would be the predominant route of exposure for workers re-entering treated golf courses. The default turf transferable residue (expressed as 5% of the applied rate on the first day of application) was used for the exposure calculation. The MOEs for golf course workers re-entering treated turf for maintenance activities are above the target of 100.

3.4.3 Residential Exposure and Risk Assessment

3.4.3.1 Handler Exposure and Risk

There are no domestic class products. Therefore, a residential handler assessment was not required.

3.4.3.2 Postapplication Exposure and Risk

The predominant route of exposure for golfers (adults and youths) entering treated golf courses is dermal exposure. The MOEs for adults and youths exposed to fludioxonil residues on turf as a consequence of golfing are above the target of 100 for dermal exposure.

3.4.4 Bystander Exposure and Risk Assessment

Risk to bystanders is considered negligible as exposure to spray drift is not expected to exceed the exposure for mixers/loaders and applicators.

4.0 Impact on the Environment

Please refer to the PMRA Regulatory Note REG2006-08, *Switch 62.5 WG Fungicide,* for a detailed assessment of the environmental impacts of fludioxonil.

Previously outstanding data requirements for fludioxonil were related to the phototransformation of the active ingredient on soil and in water, the biotransformation of the active ingredient in an aerobic water/sediment system and the acute toxicity of the active ingredient to earthworms and chironomids (REG2006-08, *Switch 62.5 WG Fungicide*).

Information to address the outstanding requirements as well as additional ecotoxicity data were submitted to the PMRA and were reviewed. Data on the phototransformation of the active ingredient on soil and in water and on the aquatic biotransformation of the active ingredient were not adequate; therefore, further data are required.

The following is the environmental assessment for the use of fludioxonil on turf.

4.1 Fate and Behaviour in the Environment

Once fludioxonil enters the terrestrial environment, it is expected to be adsorbed to soil particles. Due to this adsorption and the low solubility of fludioxonil, this compound has a low potential for leaching. Laboratory studies on mobility indicated that fludioxonil is immobile in soils. Despite the results of the laboratory studies, field dissipation trials have shown that fludioxonil may move through the soil profile. However, this may be related to the movement of surface soil down preferential flow channels in the soil rather than actual leaching of the compound. Fludioxonil will persist in soil and is expected to carry over to the following growing season. Fludioxonil's half-life ranges from 143 to 494 days under aerobic soil conditions. Based on these values, biotransformation is not expected to be a major route of transformation of fludioxonil in the terrestrial environment. Phototransformation is an important route of transformation of fludioxonil, and it is thought that CGA 192155 (2,2 difluoro-l,3-benzodioxole 4-carboxylic acid) and CGA 265378 (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-2,5-dihydro-2,5-dioxo 1H-pyrrole-3-carbonitrile) are major phototransformation products of fludioxonil in soil (Appendix I, Table 2). However, due to limited data, the identity of phototransformation products could not be adequately confirmed and their persistence could not be characterized.

Fludioxonil could enter the aquatic environment through spray drift or runoff through the movement of soil particles to which fludioxonil is strongly bound. Once in water, fludioxonil is not expected to hydrolyse. The fate of fludioxonil in a water/sediment system is not fully characterized, as the submitted studies on the aerobic biotransformation of fludioxonil were not adequate. Nonetheless, results from the submitted studies showed that this compound dissipated slowly from the whole system and that most of the fludioxonil applied to the test system partitioned into the sediment. Phototransformation is an important route of transformation of fludioxonil, and CGA 339833 (cis-3-cyano-2-(2,2-difluoro-1,3-benzodioxol-4-yl)-oxiranecarboxylic acid amide) is thought to be a major phototransformation product of fludioxonil in water (Appendix I, Table 3). However, due to limited data, the identity of phototransformation products could not be adequately confirmed and their persistence could not be characterized.

Based on the vapour pressure and Henry's law constant, fludioxonil has a low potential of volatilisation.

4.2 Effects on Non-Target Species

The environmental risk assessment integrates environmental exposure and ecotoxicology data to estimate the potential for adverse ecological effects. Risk characterization is based on the risk quotient (RQ), which is the ratio of the expected environmental concentration (EEC) to a relevant toxicity endpoint.

A screening level risk assessment is initially performed. For this assessment, conservative exposure estimates are used, such as those obtained from a direct overspray of the compound on soil or over a body of water. At the screening level, a risk quotient of less than one is considered to be below the level of concern and no further assessment is done. If the screening level risk assessment results in a risk quotient above the level of concern of one, then refinements may be performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats and runoff to water bodies) and might consider different toxicity endpoints.

4.2.1 Effects on Terrestrial Organisms

The toxicity of fludioxonil to many terrestrial organisms has previously been evaluated; please refer to the PMRA Regulatory Note REG2006-08, *Switch 62.5 WG Fungicide*. Below is an overview of recent findings.

Earthworms were not affected by an acute exposure to fludioxonil. No earthworm mortality was observed at concentrations lower than 333 mg of fludioxonil per kg of dry substrate. Therefore, the lethal dose 50% (LD_{50}) was greater than 1000 mg a.i./kg dry substrate. Also, the LD_{50} for CGA 192155 and CGA 265378, which are thought to be major phototransformation products of fludioxonil on soil, was 794 and greater than 1000 mg a.i./kg dry soil, respectively. Screening level risk quotients for all tested compounds were below the level of concern of one.

For terrestrial plants, there were no effects (i.e. less than 25% reduction) on seedling emergence in three species of plants (wheat, lettuce and radish) at concentrations up to 0.25 mg fludioxonil per kg of soil. For seedling emergence, the screening level risk quotient did not exceed the level of concern of one. No data on vegetative vigour were submitted; therefore, it was not possible to characterize the risk to emerged plants. However, as is typical of fungicides, it is not expected that the use on turf will affect emerged plants.

All the data related to the toxicity of fludioxonil and the potential major phototransformation products to terrestrial non-target organisms are presented in Appendix I, Table 3. Screening level risk quotients calculated under a realistic worst-case scenario are presented in Appendix I, Table 4.

4.2.2 Effects on Aquatic Organisms

The toxicity of fludioxonil to many aquatic organisms has previously been evaluated. Please refer to the PMRA Regulatory Note for Switch 62.5 WG Fungicide (REG2006-08). Below is an overview of recent findings.

It was found that CGA 339833, which is thought to be a major phototransformation product of fludioxonil in water, is less toxic to *Daphnia magna* than the parent compound, fludioxonil. No adverse effects were observed following acute 48-hour exposure at (mean measured) concentrations of up to 100.1 mg of CGA 339833 per litre. The screening level risk quotient did not exceed the level of concern of one for this phototransformation product.

Previously submitted data on the toxicity of fludioxonil to *Daphnia magna* were used to calculate screening level risk quotients. It was found that the level of concern was not exceeded on an acute basis for this species, but was exceeded on a chronic basis.

In a chronic study performed with chironomids, fludioxonil affected the survival of emerged midges at the two highest test concentrations of 80 and 160 mg fludioxonil per kg of dry sediment. Based on this toxicity information and also the screening level exposure estimate, the screening level risk quotient did not exceed the level of concern of one.

It was found that CGA 339833 is less toxic to rainbow trout than fludioxonil. No adverse effects were observed following an acute 96-hour exposure at a nominal concentration of 100 mg CGA339833 per litre. The screening level risk quotient did not exceed the level of concern of one for this phototransformation product.

Previously submitted data on the acute toxicity of fludioxonil to fish was used to calculate screening level risk quotients. It was found that the level of concern was exceeded for the rainbow trout but not for the bluegill sunfish. Screening level risk quotients calculated with results from early life stage toxicity studies performed with the fathead minnow exceeded the level of concern of one.

Fludioxonil is toxic to freshwater algae, with an IC_{50} of 0.0876 mg a.i./L for *Selenastum capricornutum*. The CGA 339833 transformation product is less toxic than the parent compound, with an IC_{50} of 95.8 mg/L for *S. capricornutum*. The screening level risk quotient exceeded the level of concern for fludioxonil but did not exceed the level of concern for CGA 339833.

No studies to assess the toxicity of fludioxonil to amphibians were submitted. In order to assess the risk to amphibians for acute and chronic exposure, the endpoint values for the most sensitive fish species was used as surrogate data. Using such data, the screening level risk quotient exceeded the level of concern on both an acute and chronic basis.

Previously submitted data on the toxicity of fludioxonil to saltwater species (mysid shrimp, Eastern oyster and sheepshead minnow) were used to calculate screening level quotients. The level of concern was not exceeded for any of the saltwater species.

All the data related to the toxicity of fludioxonil and the potential major phototransformation products to aquatic non-target organisms are presented in Appendix I, Table 3. Screening level risk quotients calculated under a realistic worst-case scenario are presented in Appendix I, Table 4.

A refined assessment (Appendix I, Table 5) was conducted to characterize the risk from spray drift for all aquatic organisms for which the risk quotients were exceeded at the screening level. For this assessment, the percent drift associated with the use of a groundboom sprayer with a medium spray droplet size (as would typically be the case for fungicide applications on golf courses) was estimated to be 6%. After adjusting the expected concentration of fludioxonil accordingly, the calculated risk quotients did not exceed the level of concern of one for any of the aquatic organisms. Due to insufficient information on the fate of fludioxonil in aquatic systems, it was not possible to characterize the risk associated with runoff for this compound.

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Control of Pink Snow Mould (*Michrodochium nivale*) on Golf Course Turf

Eight efficacy trials conducted in Ontario and Quebec were reviewed for the claim of pink snow mould control on turf. Instrata™ Fungicide was applied at three rates: 148 mL, 222 mL and 296 mL product per 100 m^2. Instrata™ Fungicide applications were compared to each active ingredient applied alone. Chlorothalonil and propiconazole were applied at the rates registered for end-use products containing these active ingredients and fludioxonil was applied to turf at two rates using a product registered in the U.S. The higher rates of Instrata™ Fungicide provided consistently greater disease severity control. The mean percent control value from the eight trials at 296 mL/100 m^2 was 87.1%. An application rate of 350 mL product/100 m^2 was tested in four trials but did not provide significantly better control. Comparison to commercial standards for pink snow mould control revealed that there is a benefit to applying the three active ingredients together, as it provided the greatest disease severity control. Fludioxonil applied alone (not registered for pink snow mould control) provided good disease control that was comparable to or better than the other two active ingredients that are registered for pink snow mould control. However, the coformulated product containing the three actives was consistently better. The claim of control of pink snow mould at a product rate of 300 mL/100 m^2 was supported.

5.1.2 Control of Grey Snow Mould (*Typhula incarnata, T. ishikariensis*) on Golf Course Turf

A total of eight efficacy trials were reviewed for grey snow mould control on turf; five studies were conducted on *Typhula incarnata* and three were conducted on *T. ishikariensis*. Studies were conducted under high disease pressure except for one of the *T. ishikariensis* studies, where disease pressure was low to moderate. One trial conducted on *T. ishikariensis* was not reviewed as the disease pressure was too low. Three rates of Instrata™ Fungicide were tested; 148 mL, 222 mL, and 300 or 296 mL of product per 100 m^2. Commercial standards included

chlorothalonil and propiconazole applied alone at the registered rates and fludioxonil applied alone at two different rates. Under high disease pressure, the higher application rates provided the best control. A rate of 350 mL/100 m^2 tested in the *T. incarnata* study did not provide significantly better control than the 300 mL/100 m^2 rate. Instrata™ Fungicide provided significantly better disease control than the commercial standards under high disease pressure. Fludioxonil had low levels of activity on these fungi when applied alone under high disease pressure. However, its activity against the pink snow mould pathogen warrants its inclusion in the Instrata™ Fungicide formulation. The claim of control of grey snow mould at a product rate of 300 mL/100 m^2 is supported.

5.2 Phytotoxicity to Host Plants

No phytotoxicity was noted in any of the studies on golf course turf when tested at the proposed rate. Higher rates (350 mL/ha) also resulted in no observable phytotoxic effect on golf course turf.

5.3 Impact on Succeeding Crops

Not applicable to turf.

5.4 Impact on Adjacent Crops

No data were submitted to assess the impact on adjacent crops.

5.5 Economics

No data were submitted to assess the economic impact of Instrata™ Fungicide.

5.6 Sustainability

5.6.1 Survey of Alternatives

Non-chemical control methods involve limiting conditions for infection in winter and hastening recovery in spring. The use of cultural practices will reduce disease severity but will not prevent occurrence.

The chemical fungicide products listed in Table 5.5.1.1 are registered for the control of pink and grey snow mould on turf.

Table 5.6.1.1 Alternative Fungicides for Control of Pink and Grey Snow Mould on Golf Course Turf

Technical Grade Active Ingredient	Disease Claim	Fungicide Classification Group
Thiophanate-methyl	Pink snow mould	1
Chlorothalonil	Pink and grey snow mould	M
Iprodione	Pink and grey snow mould	2
Azoxystrobin	Pink and grey snow mould	11
Propiconazole	Pink and grey snow mould	3
Quintozene	Pink and grey snow mould	14
Chloroneb	Grey snow mould	14

5.6.2 Compatibility with Current Management Practices Including Integrated Pest Management

Integrated pest management (IPM) practices will help reduce the severity of these two winter diseases and aid in regrowth in spring via various cultural practices. Another aspect of IPM is to combine or alternate the use of fungicide chemical groups. Currently, there are seven different active ingredients registered for pink and/or grey snow mould control with six different modes of action. These products may be alternated or tank-mixed, where permitted, to avoid the development of resistance by a particular pathogen.

Instrata™ Fungicide combines three active ingredients with different modes of action to aid in resistance management and should, therefore, complement current management practices.

5.6.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

The Fungicide Resistance Action Committee (FRAC) has not reported specific recommendations for turf pathogens; however, general principles of resistance management are included on the Instrata™ Fungicide label, as per Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action*.

5.6.4 Contribution to Risk Reduction and Sustainability

Instrata™ Fungicide is a coformulated product containing propiconazole, chlorothalonil and fludioxonil, and is produced to prevent resistance to single mode of action fungicides. The rates of the individual fungicide components of propiconazole and chlorothalonil in Instrata™ Fungicide are lower than the currently registered rates for these actives alone. Thus, the net reduction in the fungicide load would contribute to sustainability.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, fludioxonil was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of fludioxonil were also considered, including major transformation products formed in the environment, microcontaminants in the technical product and formulants in the end-use product, Instrata™ Fungicide. The PMRA has reached the following conclusions.

- Fludioxonil meets the criteria for persistence. Its value for half-life in soil is 494 days. The value for soil is above the TSMP Track 1 cut-off criteria for soil (≥182 days). The persistence of fludioxonil in water and sediment is not characterized.

- Fludioxonil is not bioaccumulative. Studies have shown that the bioconcentration factor is 366, which is below the TSMP Track 1 cut-off criterion of ≥5000.

- CGA 192155 (2,2difluoro-l,3-benzodioxole4-carboxylic acid), CGA 265378 (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-2,5-dihydro-2,5-dioxo 1H-pyrrole-3-carbonitrile) and CGA 339833 (cis-3-cyano-2-(2,2-difluoro-1,3-benzodioxol-4-yl)-oxiranecarboxylic acid amide), which are thought to be the major transformation products of fludioxonil (Appendix I, Table 2), are not expected to meet TSMP Track 1 criteria for bioaccumulation.

6.2 Formulants and Contaminants of Health or Environmental Concern

Fludioxonil (technical grade) does not contain microcontaminants of environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

The Instrata™ Fungicide does not contain any formulants of environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*. However, the chlorothalonil technical grade active ingredient (TGAI) has been shown to be contaminated with hexachlorobenzene (HCB) and decachlorobiphenyl, which have been identified as TSMP Track 1 substances. The PMRA is continuing to pursue its efforts to implement the Agency's strategy to manage Track 1 contaminants in pest control products (DIR99-03). Following a PMRA request, data from the analysis of recent production batches of the chlorothalonil TGAI using sensitive and readily available analytical methods have been submitted. In an ongoing effort, the PMRA will use this data to evaluate the progress made towards the virtual elimination of HCB and decachlorobiphenyl from chlorothalonil and whether additional measures are warranted.

7.0 Summary

7.1 Human Health and Safety

Instrata™ Fungicide exhibits slight acute oral and inhalation toxicity and low dermal toxicity in the rat. It is moderately irritating to the eye and mildly irritating to the skin of the rabbit. It is a dermal sensitizer in the guinea pig.

Mixers, loaders, applicators and workers entering treated areas are not expected to be exposed to levels of fludioxonil that will result in unacceptable risk when Instrata™ Fungicide is used according to label directions.

7.2 Environmental Risk

The screening level risk assessment showed that the level of concern was not exceeded for terrestrial non-target organisms but was exceeded for some aquatic non-target organisms. On an acute basis, the level of concern was exceeded for fish, amphibians and algae. On a chronic basis, the level of concern was exceeded for daphnids, fish and amphibians. A refined assessment to characterize the risk associated with spray drift was conducted and it was found that the risk from spray drift is minimal and can be mitigated with a one-metre aquatic buffer zone. It was not possible to perform a refined assessment to characterize the risk associated with runoff because the aquatic biotransformation studies for fludioxonil were not adequate to provide the appropriate modelling inputs.

7.3 Value

A single application of 300 mL Instrata™ Fungicide/100 m^2 is supported to control pink and grey snow mould on turf. As a coformulation, this product will contribute to sustainability by reducing the overall fungicide load.

8.0 Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and in accordance with the Pest Control Products Regulations, has granted conditional registration for the sale and use of the technical grade active ingredient fludioxonil and end-use product Instrata™ Fungicide.

An evaluation of current scientific data from the applicant has resulted in the determination that, under the approved conditions of use, the end-use product has value and does not present an unacceptable risk to human health or the environment.

Although the risks and value have been determined to be acceptable when all risk-reduction measures are followed, as a condition of these registrations, additional scientific information (listed below) is being requested from the applicant as a result of this evaluation. (For more details, refer to the Section 12 Notice associated with these conditional registrations.)

Environment

- study on the phototransformation of the active ingredient on soil
- study on the phototransformation of the active ingredient in water
- study on the aerobic biotransformation of the active ingredient in a water/sediment system

NOTE: The PMRA will publish a consultation document at the time when there is a proposed decision on applications to convert these conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

List of Abbreviations

°C	degree(s) Celsius
µg	microgram(s)
1/H	
a.i.	active ingredient
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetre(s)
d	day(s)
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
EEC	expected environmental concentration
g	gram(s)
ha	hectare(s)
HCB	hexachlorobenzene
IC_{50}	concentration causing 50% inhibition
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
mg	milligram(s)
mL	millilitre(s)
MAS	maximum average score
MIS	maximum irritation score
MOE	margin of exposure
nm	nanometre(s)
NOEC	no observed effect concentration
NOEL	no observed effect level
NZW	New Zealand white
Pa	Pascal(s)
PHED	Pesticide Handler Exposure Database
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
RQ	risk quotient
SD	Sprague Dawley
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Summary of Acute Toxicity of Instrata™ Fungicide

Study	Species Strain and Doses	Results	Target Organ, Significant Effects, Comments	Reference
Acute oral	10 Female SD rats Up and Down method 175, 550, 1750 or 5000 mg/kg	Oral LD_{50}: >1750 and <5000 mg/kg bw	5000 mg/kg bw: All animals died. 1750 mg/kg bw: Soft feces, hypoactivity, pilo-erection, diarrhea and reduced fecal volume, recovering by day 4 **Slightly acutely toxic** CAUTION—POISON	1266638
Acute dermal	10 SD rats (5/sex) Limit dose: 5000 mg/kg	Dermal LD_{50}: >5000 mg/kg bw	No mortality, no lesions on test sites, no systemic toxic effects. **Low toxicity**	1266639
Acute inhalation	10 SD rats (5/sex) Test atmosphere concentration = 0.5 and 2.01 mg/L	LC_{50}: (Males) >0.5 and <2.01 mg/L (Females) >2.01 mg/L (Combined) >0.5 and <2.03 mg/L	Eight animals died at 2.01 mg/L. Surviving females recovered by day 7. The low dose showed minimal signs and lesions. **Slightly acutely toxic** CAUTION—POISON	1266640
Eye irritation	3 NZW Rabbits 0.1 ml of Instrata	MAS (24–72 hours) = 33/110 MIS (24 hours) = 36.3/110	The test substance caused ocular irritation (corneal opacity, iritis and conjunctivitis) in all 3 rabbits, which subsided by day 7. **Moderately irritating** WARNING—EYE IRRITANT	1266641
Skin irritation	3 young adult NZW Rabbits 0.5 ml Instrata (Buehler method)	MAS (24-72 hours) = 2.7/8.0 MIS (1 and 24 hours) = 3.0/8.0	Instrata produced a mild irritation in all 3 rabbits. Irritation subsided by day 10. **Mildly irritating** CAUTION—SKIN IRRITANT	1266642
Dermal sensitization (Buehler method)	Hartley albino guinea pigs 20 test animals 10 naive controls Topical induction: 100% test substance. Topical challenge: 100% test substance.	Very faint to moderate erythema in 13 of 20, and 11 of 20 animals (at 24 and 48 hours, respectively, following challenge).	**Potential skin sensitizer**	1266643

Table 2 Identity of Major Phototransformation Products

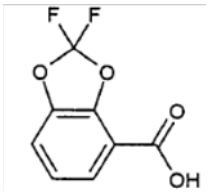
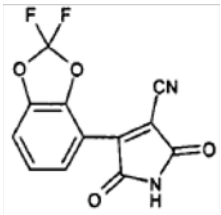
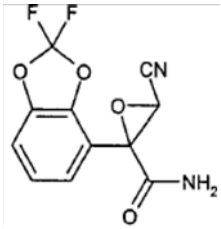
Common Name	Chemical Name	CAS No.	Chemical Structure	Mol. Wt.	Occurrence
CGA 192155	**CAS**: 2.2difluoro-l,3-benzodioxole4-carboxylic acid **IUPAC**: 2,2-difluorobenzo[l,3]dioxol-4-carboxylic acid	126120-85-2		202.12	Soil
CGA 265378	**CAS**: 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-2,5-dihydro-2,5-dioxo 1H-pyrrole-3-carbonitrile **IUPAC**: 4-(2,2-difluorobenzo[l,3]dioxol-4-yl)-2,5-dioxo-2,5-dihydro-lH-pyrrole-3-carbonitrile	Not issued		265.15	Soil
CGA 339833	**CAS**: cis-3-cyano-2-(2,2-difluoro-1,3-benzodioxol-4-yl)-oxiranecarboxylic acid amide **IUPAC:** 3-Cyano-2-(2,2-difluorobenzo[l,3]dioxol-4-yl)-oxirane-2-carboxylic acid amide	Not issued		312.19	Water

Table 3 Toxicity to Non-Target Species

Organism	Exposure	Test Substance	Toxicity Data	Reference
Terrestrial Organisms				
Invertebrates				
Earthworm	Acute	fludioxonil	LC_{50} > 1000 mg a.i./kg dry artificial substrate	1266652
		CGA 192155	LC_{50} = 794 mg/kg dry soil	1266654
		CGA 265378	LC_{50} > 1000 mg/kg dry soil	1266655

Organism	Exposure	Test Substance	Toxicity Data	Reference
Bee	Oral	fludioxonil	LD_{50} > 100 µg a.i./bee (estimated as >112 kg a.i./ha) NOEC = 100 µg a.i./bee	Refer to REG2006-08
	Contact	fludioxonil	LD_{50} > 100 µg a.i./bee NOEC = 100 µg a.i./bee	Refer to REG2006-08
Birds				
Bobwhite quail	Acute	fludioxonil	LD_{50} > 2000 mg a.i./kg bw	Refer to REG2006-08
	Dietary	fludioxonil	LC_{50} > 5200 mg a.i./kg diet	Refer to REG2006-08
	Reproduction	fludioxonil	NOEC = 125 mg a.i./kg diet	Refer to REG2006-08
Mallard duck	Dietary	fludioxonil	LC_{50} > 5200 mg a.i./kg diet	Refer to REG2006-08
	Reproduction	fludioxonil	NOEC = 700 mg a.i./kg diet	Refer to REG2006-08
Mammals				
Rat	Acute	fludioxonil	LD_{50} > 5000 mg/kg bw	Refer to REG2006-08
	Dietary (90-day)	fludioxonil	NOEL: 64 mg/kg bw/day	Refer to REG2006-08
	Reproduction (multigeneration dietary)	fludioxonil	Maternal NOEL = 300 ppm Reproduction NOEL = 300 ppm (20 mg/kg bw/day)	Refer to REG2006-08
Mouse	Dietary (90-day)	fludioxonil	NOEL = 445 mg/kg bw/day	Refer to REG2006-08
Vascular Plants				
Vascular plant	14-day seedling emergence	Fludioxonil formulation: CGA 173506 025 FS	EC_{25} > 0.25 mg a.i./kg soil dw	1266661
Freshwater Organisms				
Daphnia magna	Acute	fludioxonil	EC_{50} = 0.9 mg a.i./L NOEC < 0.5 mg a.i./L	Refer to REG2006-08
		CGA 339833	EC_{50} > 100.1mg/L NOEC = 100.1mg /L	1266657
	Chronic	fludioxonil	NOEC (survival) = 86 µg a.i./L NOEC (reproduction) = 19 µg a.i./L NOEC (weight) = 34 µg a.i./L	Refer to REG2006-08

Organism	Exposure	Test Substance	Toxicity Data	Reference
Chironomus riparius	Chronic	fludioxonil	NOEC (survival) = 40 mg a.i./kg sediment	1266656
Rainbow trout *Oncorhynchus mykiss*	Acute	fludioxonil	LC_{50} = 0.23 mg a.i./L NOEC = 0.066 mg a.i./L	Refer to REG2006-08
		CGA 339833	LC_{50} > 100 mg/L NOEC = 100 mg/L	1266658
Bluegill sunfish *Lepomis macrochirus*	Acute	fludioxonil	LC_{50} = 0.74 mg a.i./L NOEC = 0.14 mg a.i./L	Refer to REG2006-08
Fathead minnow *Pimephales promelas*	Chronic	fludioxonil	NOEC = 0.019 mg a.i./L	Refer to REG2006-08
			NOEC = 0.039 mg a.i./L	1266660
Freshwater alga *Scenedesmus subspicatus*	Acute	fludioxonil	IC_{50} = 0.83 mg a.i./L	Refer to REG2006-08
Freshwater alga *Selenastrum capricornutum*	Acute	fludioxonil	IC_{50} = 0.088 mg a.i./L	1266663
		CGA 339833	IC_{50} = 0.088 mg a.i./L (biomass)	1266662
Estuarine/Marine Organisms				
Saltwater mysid *Mysidopsis bahia*	Acute	fludioxonil	LC_{50} = 0.27mg a.i./L NOEC = 0.075 mg a.i./L	Refer to REG2006-08
Eastern oyster *Crassostrea virginica*	Acute	fludioxonil	EC_{50} = 0.37 mg a.i./L	Refer to REG2006-08
Sheepshead minnow *Cyprinodon variegatus*	Acute	fludioxonil	LC_{50} = 1.2 mg a.i./L NOEC = 0.93 mg a.i./L	Refer to REG2006-08

Table 4 Screening Level Risk Assessment on Non-Target Species

Organism	Exposure: Test Substance	Toxicity	Exposure	Units	RQ[a]
Terrestrial Invertebrates—exposure to treated soil (for earthworms) and contact exposure to treated surfaces or ingestion of a treated sucrose solution (for bees)					
Earthworms	Acute: fludioxonil	1/2 LC_{50}: >500	0.193	mg a.i./kg soil	<0.0004
	Acute: CGA 192155	1/2 LC_{50}: 397	0.173	mg/kg soil	0
	Acute: CGA 265378	1/2 LC_{50}: >500	0.227	mg/kg soil	<0.0005
Bees	Oral and contact: fludioxonil	LD_{50}: >112	0.435	kg a.i./ha	<0.004
Terrestrial Vertebrates—exposure to treated food items without dissipation of active substance					
Birds	Acute oral: fludioxonil	1/10 LD_{50}: >200	6.25[b, c]	mg a.i./kg bw	<0.031
	Short-term dietary: fludioxonil	1/10 LC_{50}: >520	76.2[b, c]	mg a.i./kg diet	<0.146
	Reproduction: fludioxonil	NOEC: 125	76.2[b, c]	mg a.i./kg diet	0.609
Mammals	Acute oral: fludioxonil	1/10 LD_{50}: >500	17.89[b, d]	mg a.i./kg bw	<0.0358
	Short-term dietary: fludioxonil	NOEL: 1000	219.5[b, d]	mg a.i./kg diet	0.22
	Reproduction: fludioxonil	NOEL: 300	219.5[b, d]	mg a.i./kg diet	0.732
Terrestrial Vascular Plants—exposure from direct overspray					
Vascular Plants	Seedling emergence: fludioxonil formulation	EC_{25}: >0.25	0.193	mg a.i./kg soil	0.785
Freshwater Organisms—exposure to a directly oversprayed water body (80-cm depth, except for amphibians where a 15-cm depth is used)					
Invertebrates	Acute: fludioxonil	1/2 EC_{50}: 0.45	0.054	mg a.i./L	0.12
	Acute: CGA 339833	1/2 EC_{50}: >50.1	0.075	mg/L	0.0015
	Chronic: fludioxonil	NOEC: 0.019	0.054	mg a.i./L	2.86

Organism	Exposure: Test Substance	Toxicity	Exposure	Units	RQ[a]
Fish	Acute: Fludioxonil	1/10 LC_{50}: 0.023	0.054	mg a.i./L	2.37
	Acute: CGA 339833	1/10 LC_{50}: >10	0.075	mg/L	<0.0075
	Chronic: fludioxonil	NOEC: 0.019	0.054	mg a.i./L	2.86
Amphibians	Acute: fludioxonil	1/10 LC_{50} (fish): 0.023	0.29	mg a.i./L	12.6
	Chronic: fludioxonil	NOEC (fish): 0.019	0.29	mg a.i./L	15.3
Algae	Acute: fludioxonil	1/2 EC_{50}: 0.0438	0.054	mg a.i./L	1.24
	Acute: CGA 339833	1/2 EC_{50}: 4.79	0.075	mg/L	0.0016
Estuarine/Marine Organisms—exposure to a directly oversprayed water body (80-cm depth)					
Invertebrates	Acute: fludioxonil	1/2 EC_{50}: 0.135	0.054	mg a.i./L	0.403
Fish	Acute: fludioxonil	1/10 LC_{50}: 0.12	0.054	mg a.i./L	0.453

[a] Risk quotient = exposure/toxicity

[b] For terrestrial vertebrates, exposure is estimated according to a nomogram developed by the USEPA (1986) and modified according to Fletcher et al. (1994).

[c] Calculated using daily food intake of 0.016 kg/day and body weight of 0.195 kg; these values were drawn from previously submitted studies on the toxicity of fludioxonil to the bobwhite quail.

[d] Calculated using daily food intake of 0.015 kg/day and body weight of 0.184 kg; these values were drawn from previously submitted studies on the toxicity of fludioxonil to the rat.

Shading indicates that the screening level risk quotients exceeds the level of concern of one.

Table 5 Refined Risk Assessment on Non-Target Species

Organism	Exposure: Test Substance	Toxicity	Exposure[a]	Units	RQ
Freshwater Organisms					
Invertebrates	Chronic: Fludioxonil	NOEC: 0.019	0.003	mg a.i./L	0.17
Fish	Acute: Fludioxonil	1/10 LC_{50}: 0.023	0.003	mg a.i./L	0.14
	Chronic: Fludioxonil	NOEC: 0.019	0.003	mg a.i./L	0.17

Organism	Exposure: Test Substance	Toxicity	Exposure[a]	Units	RQ
Amphibians	Acute: Fludioxonil	1/10 LC_{50}: 0.023	0.017	mg a.i./L	0.76
	Chronic: Fludioxonil	NOEC: 0.019	0.017	mg a.i./L	0.92
Algae	Acute: Fludioxonil	½ EC_{50}: 0.0438	0.003	mg a.i./L	0.07

[a] Only the risk associated with drift was assessed. For this assessment, the maximum drift deposition from the use of a groundboom sprayer and a medium spray droplet size was estimated to be 6% and expected environmental concentrations were adjusted accordingly. It was not possible to assess the risk associated with runoff due to limited data.

Table 6 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Proposed		Recommendation (based on value assessment)
Diseases on turf	Pink snow mould (*Microdochium nivale*) Grey snow mould (*Typhula incarnata, T. ishikariensis*)	Supported
Rate	300 mL product/100 m^2	Supported
Spray volume	800 L water/100 m^2	400–800 L water/100 m^2
Application method	Ground application only	Supported
Timing of application	Apply in late fall prior to development of permanent snow cover.	Supported

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

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4.0 Value

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B. ADDITIONAL INFORMATION CONSIDERED

i) Published Information

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