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Proposed Registration Decision

PRD2010-29

# Fludioxonil

*(publié aussi en français)*

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# Overview

## Proposed Registration Decision for Fludioxonil

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 Fludioxonil Technical Fungicide and Instrata™ Fungicide, containing the technical grade active ingredient fludioxonil, to control snow moulds on golf course tees, greens and fairways. Fludioxonil Technical Fungicide (Registration Number 24731) and Instrata™ Fungicide (Registration Number 28861) are conditionally registered in Canada. The detailed review for Fludioxonil Technical Fungicide and Instrata™ Fungicide can be found in Regulatory Note REG2006-08, *Switch 62.5 WG Fungicide* and Evaluation Report ERC2008-02, *Fludioxonil Instrata™ Fungicide*. Subsequent to the original applications, an application to register Fludioxonil Technical Fungicide (Registration Number 24731) for turf was reviewed and conditionally approved. The current applications were submitted to convert Fludioxonil Technical Fungicide and Instrata™ Fungicide for the use on turf from conditional registration to full registration.

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 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<sup>1</sup> 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<sup>2</sup> when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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

<sup>2</sup> "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."

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 environmental contaminants). These methods and 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 Health Canada's website at [healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra).

Before making a final registration decision on Fludioxonil Technical Fungicide, the PMRA will consider all comments received from the public in response to this consultation document.<sup>3</sup> The PMRA will then publish a Registration Decision<sup>4</sup> on Fludioxonil Technical Fungicide, which will include the decision, the reasons for it, a summary of comments received on the proposed final 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 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, chlorothalonil and propiconazole.

## **Health Considerations**

### **Can Approved Uses of Fludioxonil Affect Human Health?**

**Instrata™ Fungicide is unlikely to affect your health when used according to the 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 health effects occur and the levels to which people may be exposed. The dose used to assess risks is 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.

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<sup>3</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>4</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

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 the 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 also 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 not any more sensitive to fludioxonil than the adult animal.

### **Risks in Residential and Other Non-Occupational Environments**

**Non-occupational risks are not of concern when Instrata™ Fungicide is used according to label directions.**

Adults and youth may be exposed to fludioxonil while golfing on treated courses. Based on the expected short-term duration of this activity, risk to golfers is not a concern.

### **Occupational Risks From Handling Instrata™ Fungicide**

**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 on the skin. Therefore, the label specifies 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 in 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 and has a low potential for leaching. Fludioxonil is persistent in soil and is expected to carry over to the following growing season. In aquatic systems, fludioxonil will rapidly move from the water column into the sediment phase where it will persist. 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 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. In addition, re-entry into treated areas is restricted until sprays have dried.

### **Environment**

Currently, spray buffer zones of one metre are required to protect sensitive aquatic habitats from fludioxonil spray drift. Spray buffer zones will be amended at a later date to reflect the upcoming re-evaluation decisions for chlorothalonil and propiconazole.

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.

### **Next Steps**

Before making a final registration decision on Fludioxonil, the PMRA will consider all 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 Fludioxonil (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

## Fludioxonil

### 1.0 The Active Ingredient, Its Properties and Uses

Refer to Evaluation Report ERC2008-02 for the summary of the chemistry evaluation of fludioxonil and Instrata™ Fungicide.

### 2.0 Methods of Analysis

Refer to Evaluation Report ERC2008-02 for the summary of the analytical methods of fludioxonil and Instrata™ Fungicide.

### 3.0 Impact on Human and Animal Health

#### 3.1 Toxicology Summary

Please refer to Evaluation Report ERC2007-04 for a summary of the database for fludioxonil. Propiconazole and chlorothalonil are currently registered for the control of gray and pink snow mould on turf. The end-use product Instrata™ exhibits slight acute oral and inhalation toxicity but a 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.

##### 3.1.1 PCPA Hazard Characterization

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

With respect to the completeness of the toxicity database, no additional studies are required at this time since extensive data are available on fludioxonil. The potential pre- and post-natal toxicity in rats and potential developmental toxicity in rabbits provided no indication of increased susceptibility of the rat or rabbit fetuses to in utero exposure to fludioxonil. There was no indication of increased susceptibility in the offspring compared to parental animals in the reproductive toxicity study. On the basis of this information, the 10-fold PCPA factor can be reduced to 1.

#### 3.2 Determination of Acute Reference Dose and Acceptable Daily Intake

An ADI and ARfD are not required as no food uses were requested.

### **3.3 Occupational and Residential Risk Assessment**

#### **3.3.1 Toxicological Endpoints**

Please refer to Evaluation Report ERC2007-04, pages 11- 12 for the endpoints for fludioxonil.

##### **3.3.1.1 Dermal Absorption**

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

#### **3.3.2 Occupational Exposure and Risk**

##### **3.3.2.1 Mixer/loader/applicator Exposure and Risk Assessment**

Individuals have potential for exposure to fludioxonil during mixing, loading and application of Instrata™ Fungicide. Exposure is expected to be short- to intermediate- term in duration and to occur through both the dermal and inhalation routes. Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted. Dermal and inhalation exposure estimates for workers mixing, loading and applying by groundboom equipment were generated from the Pesticide Handlers Exposure Database (PHED), Version 1.1. Risk assessments were performed for workers wearing a single layer and gloves during mixing/loading and a single layer and no gloves during application.

The maximum application rate is 300 mL product/100 m<sup>2</sup> turf to treat fairways, greens and tees once per season (before snowfall). This is the equivalent of 4.36 g fludioxonil/100m<sup>2</sup> or 0.436 kg a.i./ha. PMRA assumes a default area treated per day value for golf courses of 16 ha and this is considered representative of the use pattern.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day and the dermal absorption value. 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 using 70 kg body weight for adults.

Exposure estimates were compared to the toxicological end points or no observed adverse effects levels (NOAELs) to obtain the margin of exposure (MOE); the target MOE is 100. The MOEs for mixers/loaders and applicators were above the target of 100 for dermal exposure and for inhalation exposure, and thus occupational risk associated with mixing/loading and applying Instrata™ Fungicide is considered acceptable with the protective equipment specified on the label.

**Table 1 Mixer/Loader/Applicator Exposure Estimates and MOEs for Fludioxonil**

Route of Exposure	PPE Scenario	Application Method	Total Unit Exposure (µg/kg a.i. handled)	Rate (kg a.i./ha)	Default, Area Treated Per Day (ha)	Exposure Estimate (µg/kg bw/day) <sup>a</sup>	MOE <sup>b</sup>	Combined MOE <sup>c</sup>
<b>Dermal</b>	Mixer/loader: single layer + gloves Applicator: open cab, single layer	Groundboom	84.12	0.436	16	8.38	2387	2315
<b>Inhalation</b>			2.56			0.255	78 431	

<sup>a</sup> Exposure Estimate:  $\frac{\text{PHED Exposure } (\mu\text{g/kg a.i. handled}) \times \text{ATPD (ha/day)} \times \text{Rate (kg a.i./ha)} \times \text{Dermal Absorption (100\%)}}{\text{Body Weight (70 kg)}}$

<sup>b</sup> MOE:  $\frac{\text{NOAEL (20 mg/kg bw/day)}}{\text{Exposure Estimate (mg/kg bw/day)}}$

<sup>c</sup> Combined MOE:  $\frac{1}{(1/\text{Dermal MOE}) + (1/\text{Inhalation MOE})}$

Target MOE = 100

### 3.3.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers re-entering areas treated with Instrata™ Fungicide when performing activities such as scouting and mowing. Dermal exposure is the predominant route of exposure for workers re-entering treated golf courses. Inhalation exposure is assumed to be negligible, and given the nature of activities performed, dermal contact with treated surfaces would be short-term in duration.

Dermal exposure to workers entering treated areas is estimated by coupling the turf transferable residue values with activity-specific transfer coefficients. Activity transfer coefficients are based on Agricultural Re-entry Task Force (ARTF) data. Syngenta Crop Protection Canada Inc. is a member of ARTF. Chemical-specific dislodgeable foliar residue data were not submitted, so a default turf transferable residue (TTR) value (expressed as 5% of the applied rate on the day of application) was used in the exposure assessment.

Exposure estimates were compared to the toxicological end point to obtain the margin of exposure (MOE); the target MOE is 100. The MOEs for golf course workers re-entering treated turf for maintenance activities are above the target of 100.

**Table 2 Worker Postapplication Margin of Exposure on Golf Courses**

Activity	Transfer coefficient <sup>a</sup>	Exposure (mg a.i./kg bw/day) <sup>b</sup>	MOE <sup>c</sup>
Mowing, watering, grooming, cup changing, irrigation repair	3500	0.0872	229
Scouting, aerating, fertilizing, hand pruning, mechanical weeding, seeding	500	0.0125	1606

<sup>a</sup> Transfer coefficient based on Agricultural Re-entry Task Force (ARTF) data. Syngenta Crop Protection Inc. is a member of ARTF.

<sup>b</sup> Exposure:  $\text{TTR } (\mu\text{g}/\text{cm}^2) \times \text{Transfer Coefficient } (\text{cm}^2/\text{hr}) \times \text{Workday } (8 \text{ hr}) \times \text{Dermal Absorption } (100\%)$   
Body Weight (70 kg)

<sup>c</sup> MOE:  $\frac{\text{NOAEL } (20 \text{ mg}/\text{kg bw}/\text{day})}{\text{Exposure } (\text{mg}/\text{kg bw}/\text{day})}$

Target MOE = 100

### 3.3.3 Residential Exposure and Risk Assessment

#### 3.3.3.1 Handler Exposure and Risk

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

#### 3.3.3.2 Postapplication Exposure and Risk

The predominant route of exposure for golfers (adults and youths) entering treated golf courses is through 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.

**Table 3 Golfer Margin of Exposure on Golf Courses**

Activity	Transfer coefficient <sup>a</sup>	Exposure (mg a.i./kg bw/day) <sup>b</sup>	MOE <sup>c</sup>
Golfing, youth	344	0.011	2600
Golfing, adult	500	0.006	3211

<sup>a</sup> Transfer coefficient based on Agricultural Re-entry Task Force (ARTF) data. Syngenta Crop Protection Inc. is a member of ARTF. Youth transfer coefficients are scaled based on the smaller surface area of the body.

<sup>b</sup> Exposure:  $\text{TTR } (\mu\text{g}/\text{cm}^2) \times \text{Transfer Coefficient } (\text{cm}^2/\text{hr}) \times \text{Duration of Exposure } (4 \text{ hr}) \times \text{Dermal Absorption } (100\%)$   
Body Weight (39 kg for youth, 70 kg for adult)

<sup>c</sup> MOE:  $\frac{\text{NOAEL } (20 \text{ mg}/\text{kg bw}/\text{day})}{\text{Exposure } (\text{mg}/\text{kg bw}/\text{day})}$

Target MOE = 100

#### 3.3.3.3 Bystander Exposure and Risk

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 Evaluation Report for fludioxonil and Instrata™ Fungicide (ERC2008-02) for a detailed assessment of the environmental impacts of fludioxonil.

Previously outstanding data requirements for fludioxonil were related to the biotransformation of the active ingredient in an aerobic water/sediment system and the phototransformation of the active ingredient on soil and in water (ERC2008-02). Information to address the outstanding requirements was submitted to the PMRA and reviewed.

### 4.1 Fate and Behaviour in the Environment

The fate and behaviour of fludioxonil has previously been evaluated. For details, please refer to the PMRA Evaluation Report for fludioxonil and Instrata™ Fungicide (ERC2008-02).

New information on the biotransformation of fludioxonil in an aerobic water/sediment system and the phototransformation of fludioxonil on soil and in water were submitted to the PMRA and were reviewed. Below is an overview of recent findings:

#### *Biotransformation in water/sediment systems*

In a study on the aerobic biotransformation of fludioxonil in water/sediment systems, fludioxonil rapidly moved from the water column (half-life in the water phase was 0.6 day and 2.6 days in pond and river systems, respectively) into the sediment phase where it remained strongly bound. When considering the whole system (both sediment and water), fludioxonil was found to be persistent (half-life of 737 and 643 days in pond and river systems, respectively). No major transformation products were formed.

#### *Phototransformation*

Previous information on the phototransformation of fludioxonil showed that phototransformation is an important route of dissipation on soil and in water. However, the identity of the transformation products on soil and in water could not be confirmed at the time. On soil, it was thought that CGA 192155 and CGA 265378 were major phototransformation products; CGA 339833 was thought to be a minor transformation product on soil. In water, it was thought that CGA 339833 was a major phototransformation product and that CGA 344623, CGA 308565 and SYN 545245 were minor phototransformation products. The chemical name and structure of transformation products are presented in Appendix I Table 1.

Recent information confirmed that phototransformation is an important route of dissipation for fludioxonil. Results indicate that SYN 545245 and CGA 339833 are major phototransformation products and that CGA 265378 is a minor transformation product on soil. In water, numerous minor transformation products were formed which are shown in Appendix I, Table 1.

When comparing new and previously submitted information:

- On soil, CGA 265378 and CGA 339833 are common to both experiments, but are found in different proportions, whereas SYN 545245 was not previously identified (but is possibly a precursor to CGA 192155).
- In water, all previously identified transformation products were observed in the new study, but in different proportions.

Differences between new and previous results on soil and in water are likely due to variations in irradiation intensity between the two experiments. In the more recent phototransformation studies, irradiation intensity in the 300-400 nm region was approximately double, which may have caused some products to react at a different rate, thus affecting the pathway. Differences in soil properties (soil type, moisture content, microbial activity, pH, etc) may also have subtly impacted the overall degradation pathway on soil.

## **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 (LOC = 1) 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.

A risk assessment has previously been carried out for fludioxonil uses on turf. For details, please refer to the PMRA Evaluation Report for fludioxonil and Instrata™ Fungicide (ERC2008-02). At the screening level, potential for concern was identified for some freshwater organisms (chronic risk to invertebrates, acute and chronic risk to fish and amphibians, acute risk to algae). While it was possible to further characterize the risk to these organisms from spray drift, the risk from runoff could not be characterized due to the absence of data on the aerobic aquatic biotransformation of fludioxonil. Using information recently submitted to the PMRA, the expected environmental concentrations from run-off were determined and the risk from run-off was characterized (Appendix I, Table 2). The calculated risk quotients did not exceed the level of concern, indicating that the risk to aquatic organisms from runoff is minimal.

## 5.0 Value

### 5.1 Contribution to Risk Reduction and Sustainability

Please refer to the PMRA Evaluation Report for fludioxonil and Instrata™ Fungicide (ERC2008-02).

## 6.0 Pest Control Product 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:

- It was previously determined that the fludioxonil active ingredient does not meet all TSMP Track 1 criteria (ERC2008-02). While fludioxonil is persistent, this compound is not bioaccumulative.
- Major transformation products of fludioxonil identified from recently submitted information [SYN 545245 (3-Cyano-2-(2,2-difluoro-benzo[1,3]dioxol-4-yl)-propionic acid) and CGA 338933 (3-Carbamoyl-2-cyano-3-(2,2-difluorobenzo[1,3]dioxol-4-yl)-oxirane-2-carboxylic acid)], are not expected to meet TSMP criteria for bioaccumulation.
- Technical grade fludioxonil does not contain any contaminants of health or 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 end-use product Instrata™ Fungicide does not contain any formulants of health or 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*.

Therefore, the use of fludioxonil is not expected to result in the entry of Track 1 substances into the environment.

## **7.0 Summary**

### **7.1 Human Health and Safety**

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

### **7.2 Environmental Risk**

Additional information on the fate of fludioxonil in the environment has been submitted and was found to adequately address previously identified data gaps for this active ingredient. Using this information, the risk to aquatic organisms from runoff was assessed and showed no potential for concern.

### **7.3 Value**

Please refer to the PMRA Evaluation Report for fludioxonil and Instrata™ Fungicide (ERC2008-02).

## **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 Fludioxonil Technical Fungicide and Instrata™ Fungicide, containing the technical grade active ingredient Fludioxonil, to control moulds on golf course tees, greens and fairways.

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.

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**List of Abbreviations**

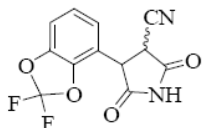
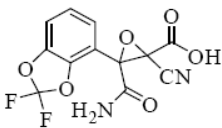
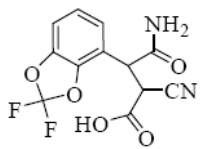
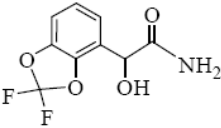
µg	micrograms
1/n	exponent for the Freundlich isotherm
a.i.	active ingredient
ADI	acceptable daily intake
ALS	acetolactate synthase
ARfD	acute reference dose
ARTF	Agricultural Re-entry Task Force
atm	atmosphere
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetres
d	day(s)
DF	dry flowable
DNA	deoxyribonucleic acid
DT <sub>50</sub>	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT <sub>75</sub>	dissipation time 75% (the dose required to observe a 75% decline in concentration)
EC <sub>10</sub>	effective concentration on 10% of the population
EC <sub>25</sub>	effective concentration on 25% of the population
EEC	Estimated environmental concentration
ER <sub>25</sub>	effective rate for 25% of the population
g	gram
ha	hectare(s)
HDT	highest dose tested
Hg	mercury
hr	hour(s)
HPLC	high performance liquid chromatography
IC <sub>50</sub>	inhibitory concentration 50%
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K <sub>d</sub>	soil-water partition coefficient
K <sub>F</sub>	Freundlich adsorption coefficient
km	kilometre
K <sub>oc</sub>	organic-carbon partition coefficient
K <sub>ow</sub>	<i>n</i> -octanol-water partition coefficient
L	litre
LC <sub>50</sub>	lethal concentration 50%
LD <sub>50</sub>	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOEC	low observed effect concentration
LOQ	limit of quantitation
LR <sub>50</sub>	lethal rate 50%
mg	milligram
mL	millilitre

MAS	maximum average score
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
N/A	not applicable
nm	nanometre
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
N/R	not required
NZW	New Zealand white
OC	organic carbon content
OM	organic matter content
PBI	plantback interval
PHED	Pesticide Handler Exposure Database
PHI	preharvest interval
pKa	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
RSD	relative standard deviation
SC	soluble concentrate
t <sub>1/2</sub>	half-life
T3	tri-iodothyronine
T4	thyroxine
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
TTR	Turf Transferable Residue
UAN	urea ammonium nitrate
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution

## Appendix I Tables and Figures

**Table 1 Summary of recent and previously submitted information on the phototransformation products formed on soil and in water**

Common name	Chemical name	Chemical structure	Comment
<b>Soil</b>			
CGA 339833	3-Carbamoyl-2-cyano-3-(2,2-difluorobenzo[1,3]dioxol-4-yl)-oxirane-2-carboxylic acid		<ul style="list-style-type: none"> <li>Major transformation product based on recent information</li> <li>Minor transformation product based on previous information</li> </ul>
SYN 545245	3-Cyano-2-(2,2-difluorobenzo[1,3]dioxol-4-yl)-propionic acid		<ul style="list-style-type: none"> <li>Major transformation product based on recent information</li> </ul>
CGA 265378	4-(2,2-Difluoro-benzo[1,3]dioxol-4-yl)-2,5-dioxopyrrole-3-carbonitrile		<ul style="list-style-type: none"> <li>Minor transformation product based on recent information</li> <li>Major transformation product based on previous information</li> </ul>
CGA 192155	2,2-Difluoro-benzo[1,3]dioxole-4-carboxylic acid		<ul style="list-style-type: none"> <li>Major transformation product based on previous information</li> </ul>
<b>Water</b>			
CGA 192155	2,2-Difluoro-benzo[1,3]dioxole-4-carboxylic acid		<ul style="list-style-type: none"> <li>Minor transformation product based on recent information <sup>a</sup></li> </ul>
SYN 545245	3-Cyano-2-(2,2-difluorobenzo[1,3]dioxol-4-yl)-propionic acid		<ul style="list-style-type: none"> <li>Minor transformation product based on recent information <sup>a</sup></li> <li>Minor transformation product based on previous information</li> </ul>
CGA 265378	4-(2,2-Difluoro-benzo[1,3]dioxol-4-yl)-2,5-dioxopyrrole-3-carbonitrile		<ul style="list-style-type: none"> <li>Minor transformation product based on recent information <sup>a</sup></li> </ul>

Common name	Chemical name	Chemical structure	Comment
CGA 308565	4-(2,2-Difluoro-benzo[1,3]dioxol-4-yl)-2,5-dioxopyrrolidine-3-carbonitrile		<ul style="list-style-type: none"> <li>Minor transformation product based on recent information <sup>a</sup></li> <li>Minor transformation product based on previous information</li> </ul>
CGA 339833	3-Carbamoyl-2-cyano-3-(2,2-difluorobenzo[1,3]dioxol-4-yl)-oxirane-2-carboxylic acid		<ul style="list-style-type: none"> <li>Minor transformation product based on recent information <sup>a</sup></li> <li>Major transformation product based on previous information</li> </ul>
CGA 344623	2-Cyano-3-(2,2-difluoro-benzo[1,3]dioxol-4-yl)-succinamic acid		<ul style="list-style-type: none"> <li>Minor transformation product based on recent information <sup>a</sup></li> <li>Minor transformation product based on previous information</li> </ul>
CGA 308103	2-(2,2-Difluoro-benzo[1,3]dioxol-4-yl)-2-hydroxy-acetamide		<ul style="list-style-type: none"> <li>Minor transformation product based on recent information <sup>a</sup></li> </ul>

<sup>a</sup> Other unidentified minor transformation products were also observed but are not shown in Table.

**Table 2 Risk to Non-Target Species from Runoff**

Organism <sup>a</sup>	Exposure <sup>a</sup>	Toxicity <sup>b</sup> (mg a.i./L)	EEC <sup>c</sup> (mg a.i./L)	RQ <sup>d</sup>
<b>Freshwater species</b>				
Invertebrates	Chronic	NOEC: 0.019	21-d, 80 cm: 0.0044	0.2
Fish	Acute	1/10 LC <sub>50</sub> : 0.023	96-h, 80 cm: 0.0049	0.2
	Chronic	NOEC: 0.019	21-d, 80 cm: 0.0044	0.2
Amphibians	Acute	1/10 LC <sub>50</sub> : 0.023	96-h, 15 cm: 0.0087	0.4
	Chronic	NOEC: 0.019	21-d, 15 cm: 0.0054	0.3
Algae	Acute	1/2 IC <sub>50</sub> : 0.044	96-h, 80 cm: 0.0049	0.1

<sup>a</sup> Organism/exposure for which the level of concern was exceeded at the screening level (ERC2008-02).

<sup>b</sup> Refer to ERC2008-02 for description of effects.

<sup>c</sup> EECs resulting from fludioxonil run-off in a one hectare receiving water body, as predicted by PRZM-EXAMS; these are 90<sup>th</sup> percentile concentrations of the yearly peaks determined for 15 cm and 80 cm deep water bodies at a number of time-frames.

<sup>d</sup> Risk Quotient = EEC/Toxicity

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## References

### A. List of Studies/Information Submitted by Registrant

#### 1.0 Environment

PMRA Number	Reference
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1806304	2009, Photo-transformation of [Phenyl-U-14C]-CGA173506 in Sterile Buffered Aqueous Solution Under Artificial Sunlight. Ricerca Biosciences, LLC. Report Number: 023916-1. Report Date: 1-September-2009. 172 pages. DACO: 8.2.3.3.2
1806301	2009, Photo-transformation of [Phenyl-U-14C]CGA173506 in or on Soil Under Artificial Sunlight. Ricerca Biosciences, LLC. Report Number: 023917-1. Report Date: 20-August-2009. 125 pages. DACO: 8.2.3.3.1
1761658	2009, Rationale for use of existing water/sediment study to support full registration of the active ingredient fludioxonil including foliar uses. Syngenta Crop Protection Canada Inc. Report Number: CER 04172-08. Report date: 27-February-2009. 14 pages. DACO: 8.2.3.5.4
1266648	1992, Metabolism of CGA 173506 Under Aerobic Conditions in Aquatic Systems. Ciba-Geigy Limited. Report Number: 21/92. Report date: 25-November-1992. 46 pages. DACO: 8.2.3.5.4
1927082	Response to clarification request, 2-July-2010, 2 pages.
1931590	Response to clarification request, 13-July-2010, 1 page.
1931593	EPISuite results for SYN 545245