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RD2009-15

Registration Decision

# Fludioxonil Scholar 50WP Fungicide

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## Registration Decision for Scholar 50 WP Fungicide

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Scholar 50WP Fungicide, containing the technical grade active ingredient fludioxonil, to control fungal diseases on stone and pome fruit after harvest.

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.

These products were first proposed for registration in the consultation document<sup>1</sup> Proposed Registration Decision PRD2009-07, *Fludioxonil Scholar 50WP Fungicide*. This Registration Decision<sup>2</sup> describes this stage of the PMRA's regulatory process for Scholar 50WP Fungicide and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2009-07. This decision is consistent with the proposed registration decision stated in PRD2009-07.

For more details on the information presented in this Registration Decision, please refer to Proposed Registration Decision PRD2009-07, which contains a detailed evaluation of the information submitted in support of this registration.

### 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>3</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 conditions of registration. The Act also requires that products have value<sup>4</sup> 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 human subpopulations (such as children) as well as organisms in the environment (those most sensitive to environmental contaminants, for example). These methods and policies also consider the nature

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

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

<sup>3</sup> "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

<sup>4</sup> "Value" as defined by subsection 2(1) of *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."

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 Pesticide and Pest Management section of Health Canada's website at [healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra).

## **What Is Scholar 50WP Fungicide?**

Scholar 50WP Fungicide, which contains the active ingredient fludioxonil, is used to control fungal diseases on pome and stone fruit after harvest.

## **Health Considerations**

### **Can Approved Uses of Scholar 50WP Fungicide Affect Human Health?**

**Scholar 50WP is unlikely to affect your health when used according to the label directions.**

People could be exposed to fludioxonil through consumption of food or water, or when handling and applying the product. 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 (such as 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. Animals show health effects at doses more than 100-times higher (and often much higher) than normal exposure levels for humans when they use products containing fludioxonil according to label directions.

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

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. Liver effects were the first signs of toxicity in animals given daily doses of fludioxonil over longer periods of time. 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.

## **Residues in Food and Water**

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

There is no acute reference dose or cancer potency factor established for fludioxonil. Chronic aggregate dietary intake estimates (food plus water) revealed that the general population will typically consume less than 14% of the acceptable daily intake for fludioxonil. Children from one to two years old, the subpopulation most sensitive to fludioxonil relative to body weight, are expected to be exposed to less than 40% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from fludioxonil is not of concern for all population subgroups.

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

Residue trials conducted in the United States on pome fruit and stone fruit treated with fludioxonil after harvest were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of Evaluation Report ERC2007-04, *Fludioxonil Scholar 50WP Fungicide*.

### **Occupational Risks from Handling Scholar 50WP Fungicide**

#### **Occupational risks are not of concern when Scholar 50WP Fungicide is used according to label directions, which include protective measures.**

Direct skin contact can occur when workers mix, load or apply Scholar 50WP Fungicide or handle freshly treated fruit. Therefore, the label will specify that applicators and other handlers of Scholar 50WP Fungicide must wear a long-sleeved shirt, pants and chemical resistant gloves. Taking into consideration these label requirements and that occupational exposure is expected to be of short- to intermediate-term, risk to applicators or workers is not a concern.

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

## **Environmental Considerations**

### **What Happens When Scholar 50WP Fungicide Is Introduced Into the Environment?**

**Only negligible amounts of fludioxonil are expected to be released into the environment because Scholar 50WP Fungicide is applied indoors.**

The PMRA has added a label statement to Scholar 50WP Fungicide to reduce any potential risk by ensuring waste water contaminated with fludioxonil is disposed of properly.

## **Value Considerations**

### **What Is the Value of Scholar 50WP Fungicide?**

**A single application of Scholar 50WP Fungicide controls a wide range of fungal diseases on pome and stone fruit after harvest.**

The number of fungicides available for controlling fungal diseases in pome and stone fruit after the fruit is harvested is limited. The active ingredient in Scholar 50WP Fungicide, fludioxonil, represents a new class of chemistry (phenylpyrrole) for this use. The addition of fludioxonil to manage fungal diseases which occur after harvest could help reduce the reliance on other products, thereby lowering the potential for pome and stone fruit fungal diseases to develop resistance to other currently registered products.

## **Measures to Minimize Risk**

Registered pesticide product labels include specific, legally enforced instructions for use. Directions include risk-reduction measures to protect human and environmental health. The key risk-reduction measures on the label of Scholar 50WP to address the potential risks identified in this assessment are as follows:

### **Key Risk-Reduction Measures**

#### **Human Health**

Anyone mixing, loading or applying Scholar 50WP Fungicide must wear a long-sleeved shirt, pants and chemical-resistant gloves to protect their skin.

#### **Environment**

The following statement has been added to the label:

“DO NOT allow fludioxonil contaminated waste water from processing plants to enter lakes, streams, ponds or other waters.”

## Other Information

The relevant test data on which the decision is based, as referenced in this document, are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, 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](mailto:pmra.infoserv@hc-sc.gc.ca)).

Any person may file a notice of objection<sup>5</sup> regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website, Request a Reconsideration of Decision (<http://www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd>), or contact the PMRA's Pest Management Information Service.

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<sup>5</sup> As per subsection 35(1) of the *Pest Control Products Act*.





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## References

### A. LIST OF STUDIES/INFORMATION SUBMITTED BY APPLICANT

#### 1.0 Product Characterization and Analysis

PMRA Document Number: 1036107

Reference: 2005, Scholar 50WP (A7850D) - Starting Materials, Data  
Numbering Code: 3.2.1 Confidential Business Information

PMRA Document Number: 1036108

Reference: 2005, Scholar 50WP (A7850D) - Manufacturing Process, Data  
Numbering Code: 3.2.2 Confidential Business Information

PMRA Document Number: 1036109

Reference: 2005, Scholar 50WP (A7850D) - Discussion Of Formation Of  
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PMRA Document Number: 1036110

Reference: 2005, Scholar 50WP (A7850D) - Certification Of Limits, Data  
Numbering Code: 3.3.1 Confidential Business Information

PMRA Document Number: 1036112

Reference: 1993, Determination Of Cga 173506 In Cga 173506 50WP By  
Capillary Gas Chromatography, Data Numbering Code: 3.4.1 Confidential Business Information

PMRA Document Number: 1036113

Reference: 1993, Validation Of Analytical Method ASM-290-R For The  
Determination Of CGA 173506 In 50WP Formulation By Capillary Gas Chromatography, Data  
Numbering Code: 3.4.1 Confidential Business Information

PMRA Document Number: 1036114

Reference: 2005, Scholar 50WP (A7850D) - Chemical And Physical Properties,  
Data Numbering Code: 3.5 Confidential Business Information

PMRA Document Number: 1036126

Reference: 2005, Scholar 50WP (A7850D) - Product Identification, Data  
Numbering Code: 3.1 Confidential Business Information

PMRA Document Number: 1036359

Reference: 2005, Scholar 50WP (A7850D) - Specification Sheet Final  
Product, Data Numbering Code: 3.3.2 Confidential Business Information

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## 2.0 Impact on Humans and Animal Health

PMRA Document Number: 1036116

Reference: 1993, CGA 173506 50W: Acute Oral Toxicity Study In Rats, Data Numbering Code: 4.6.1

PMRA Document Number: 1036117

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PMRA Document Number: 1036118

Reference: 1993, CGA-173506 50W, FL-922033: Acute Dermal Toxicity Study In Rabbits, Data Numbering Code: 4.6.2

PMRA Document Number: 1036119

Reference: 1993, CGA-173506 50W, FL-922033: Acute Dermal Toxicity Study In Rabbits; Amendment To Final Report, Data Numbering Code: 4.6.2

PMRA Document Number: 1036120

Reference: 1993, CGA-173506 50W: Acute Inhalation Toxicity Study In Rats, Data Numbering Code: 4.6.3

PMRA Document Number: 1036121

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PMRA Document Number: 1036122

Reference: 1993, CGA-173506 50W, FL-922033: Primary Dermal Irritation Study In Rabbits, Data Numbering Code: 4.6.5

PMRA Document Number: 1036123

Reference: 1993, Skin Sensitisation Test In The Guinea Pig: Maximization Test, Data Numbering Code: 4.6.6

PMRA Document Number: 1163380

Reference: 1992, Metabolism Of [14C-pyrrole]-CGA-173506 In Goats (f-00088;43470601)(fludioxonil), Data Numbering Code: 6.2

PMRA Document Number: 1163381

Reference: 1992, Metabolism Of [14C-pyrrole]-CGA 173506 In Goats Amendment 1 To Final Report F-00088 (april 15 1992)(fludioxonil), Data Numbering Code: 6.2

PMRA Document Number: 1163391

Reference: 1992, Metabolism Of [14C-pyrrole]-CGA-173506 In Chickens (f-00089;43470602)(fludioxonil), Data Numbering Code: 6.2

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PMRA Document Number: 1036130

Reference: 2003, Fludioxonil: Magnitude Of The Residue On Apple Following Post Harvest Treatment, Data Numbering Code: 7.4.1

PMRA Document Number: 1036131

Reference: 2003, Fludioxonil: Magnitude Of The Residue On Pear Following Post Harvest Treatment, Data Numbering Code: 7.4.1

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Reference: 2001, Fludioxonil: Magnitude Of The Residue On Pear Following Post-harvest Treatment, Data Numbering Code: 7.4.1

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Reference: 1999, Fludioxonil: Magnitude Of The Residue On Peach Following Post-harvest Treatment, Data Numbering Code: 7.4.1

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Reference: 1999, Fludioxonil: Magnitude Of The Residue On Plum Following Post-harvest Treatment, Data Numbering Code: 7.4.1

PMRA Document Number: 1103805

Reference: 2005, Summary Of Additional Residue Data Being Submitted To Address The Deficiency Notice, Data Numbering Code: 7.4.1

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Reference: 2005, Fludioxonil-magnitude Of The Residues In Or On Peach And Plum Following Post-harvest Applications., Data Numbering Code: 7.4.1

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PMRA Document Number: 1163343

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Reference: 1996, Analytical Method For The Determination Of Residues Of Difenconazole, Fludioxonil, Fluxofenim, Mefanoxam, And Metalaxyl In Seed By Capillary Gas Chromatography, Data Numbering Code: 7.2.1.

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PMRA Document Number: 1045908

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PMRA Document Number: 1103804

Reference: 2005, Scholar 50WP Fungicide Occupational Exposure Risk Assessment For Commercial Application On Stone And Pome Fruits. Data Numbering Code: 5.4

### **3.0 Value**

PMRA Document Number: 1036142

Reference: 2005, Agriculture And Agri-food Canada, Scholar Fungicide: Efficacy - Small-scale Trials, Data Numbering Code: 10.2.3.3

PMRA Document Number: 1479951

Reference: 2003, Evaluate Effect Of Water Volume On Efficacy Of Scholar On Stonefruit, Data Numbering Code: 10.2.3.2

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Reference: 2001, Scholar As A Post-harvest Fungicide Dip Treatment For Loring Peaches, 2001, Data Numbering Code: 10.2.3.2