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Proposed Registration Decision

Fludioxonil
Scholar 50WP Fungicide

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Overview

Proposed Registration Decision for Scholar 50WP Fungicide

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 Scholar 50WP Fungicide, containing the technical grade active ingredient fludioxonil, to control fungal diseases on stone and pome fruit after harvest.

Scholar 50WP Fungicide (Registration Number 28568) is currently conditionally registered in Canada. The detailed review of this product can be found in Evaluation Report ERC2007-04, *Fludioxonil Scholar 50WP Fungicide*. The purpose of the current application is to convert Scholar 50WP Fungicide from conditional 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 Scholar 50WP 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 the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (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 Health Canada's website at healthcanada.gc.ca/pmra.

[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."

Before making a final registration decision on Scholar 50WP Fungicide, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on Scholar 50WP 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 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 diet (food and water) or when Scholar 50WP Fungicide is applied. 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 the 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 that the fetus was not any 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

[3] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.
[4] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

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.

Residues in Water and Food

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 the *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 the 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 properly disposed.

Value Considerations

What Is the Value of Scholar 50WP Fungicide

A single application of Scholar 50WP Fungicide effectively 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 to develop resistance to current products.

During the initial value assessment as presented in ERC2007-04, *Fludioxonil Scholar 50WP Fungicide*, it was determined that additional data were required to support the claim of mucor rot on pome fruit and rhizopus rot on stone fruit.

The confirmatory data submitted have been determined to be adequate to satisfy the condition of registration for the claim of rhizopus rot on stone fruit.

No confirmatory data were submitted for the claim of mucor rot on pome fruit. The claim of Mucor Rot on pome fruit has been removed from the Scholar 50WP Fungicide label.

Measures to Minimize Risk

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

The key risk-reduction measures being proposed on the label of Scholar 50WP Fungicide 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.”

Next Steps

Before making a final registration decision on Scholar 50WP Fungicide, 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. 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 Scholar 50WP Fungicide (based on the Science Evaluation of this consultation document and ERC2007-04, *Fludioxonil Scholar 50WP Fungicide*). 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

1.0 The Active Ingredient, Its Properties and Uses

Please refer to ERC2007-04 *Fludioxonil Scholar 50WP Fungicide* for a detailed evaluation of the properties and uses of Scholar 50WP Fungicide.

2.0 Methods of Analysis

Please refer to ERC2007-04 for a detailed evaluation of the methods of analysis for Scholar 50WP Fungicide.

3.0 Impact on Human and Animal Health

Please refer to ERC2007-04 for a detailed evaluation of the impact on human and animal health of Scholar 50WP Fungicide.

4.0 Impact on the Environment

Please refer to ERC2007-04 for a detailed evaluation of the impact on the environment of Scholar 50WP Fungicide.

5.0 Value

Please refer to ERC2007-04 for a detailed evaluation of the value of Scholar 50WP Fungicide.

5.1 Effectiveness Against Pests

5.1.1 Acceptable Efficacy Claims

5.1.1.1 Pome Fruit

During the initial value assessment, as presented in ERC2007-04, it was determined that additional data were required to support the claim of mucor rot on pome fruit.

No confirmatory data were submitted for the claim of mucor rot on pome fruit. The claim of mucor rot on pome fruit has been removed from the Scholar 50WP Fungicide label.

5.1.1.2 Stone Fruit

During the initial value assessment, as presented in ERC2007-04, it was determined that additional data were required to support the claim of rhizopus rot on stone fruit.

Two trials conducted in the United States were submitted to confirm the efficacy of Scholar 50WP on rhizopus rot on peaches at 227 g product/378 L water. The data demonstrated acceptable control which varied from 77–94% control.

The confirmatory data submitted have been determined to be adequate to satisfy the condition of registration for the claim of rhizopus rot on stone fruit.

6.0 Pest Control Product Policy Considerations

Please refer to ERC2007-04 for information on the Pest Control Product Policy considerations of Scholar 50WP Fungicide.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted is adequate to define the majority of toxic effects that may result from human exposure to fludioxonil. In subchronic and chronic studies on laboratory animals, target organs included the liver, kidneys and bile duct. There was no evidence of any carcinogenicity and no evidence of increased susceptibility of the young in teratology studies. Fludioxonil is not considered to be a neurotoxicant.

The nature of the residue in plants is adequately understood for the purposes of this registration. The residue definition is fludioxonil. The proposed postharvest use of fludioxonil on pome fruit and stone fruit does not constitute an unacceptable chronic dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed to recommend maximum residue limits to protect human health. The PMRA recommends that the following maximum residue limits be specified under the authority of the *Pest Control Products Act*:

- residues of fludioxonil in and on pome fruit (5 ppm)
- residues of fludioxonil in and on stone fruit (5 ppm)

Mixer, loader, applicators and workers handling treated fruit are not expected to be exposed to levels of fludioxonil that will result in unacceptable risk when Scholar 50WP Fungicide is used according to label directions. The personal protective equipment on the product label is adequate to protect workers and no additional personal protective equipment is required.

7.2 Environmental Risk

Only negligible release of fludioxonil to the environment is expected to occur with the indoor pome and stone fruit processing use of Scholar 50WP Fungicide. A label statement has been added to mitigate potential release of fludioxonil through effluent disposal.

7.3 Value

The rate of 0.6 g Scholar 50WP Fungicide/L (227 g Scholar WP Fungicide/378 L) is supported for control of blue mold and gray mold on apples and pears. This rate is also supported for control of brown rot, blue mold, gray mold and rhizopus rot on peaches, nectarine, plums and cherries.

The dip and drench application methods are supported for use on pome fruit and stone fruit.

The accepted use is extended to include the other commodities listed in the pome fruit crop group (apples, crabapple, loquat, mayhaw pear, oriental pear and quince) and stone fruit crop group (apricot, nectarine, peach, plum, plum (chickasaw), plum (damson), plum (japanese), plumcot, prune (fresh) as well as other cultivars of prunes, cherry (sweet), cherry (tart as well as cultivars and hybrids of cherries)).

The confirmatory data submitted have been determined to be adequate to satisfy the condition of registration for the claim of rhizopus rot on stone fruit

No confirmatory data were submitted for the claim of Mucor Rot on pome fruit. The claim of mucor rot on pome fruit has been removed from the Scholar 50WP Fungicide label.

8.0 Proposed Regulatory Decision

Health Canada's Pest Management Regulatory Agency, under the authority of the *Pest Control Products Act* and Regulations, is proposing 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.

References

A. List of Studies/Information Submitted by Registrant

1.0 Value

PMRA Document Number: 1479951
Reference: 2003, Evaluate effect of water volume on efficacy of Scholar on stonefruit, USW20F0472003, DACO: 10.2.3.2

PMRA Document Number: 1479952
Reference: 2001, Scholar as a post-harvest fungicide dip treatment for Loring peaches, 2001, STF21, DACO: 10.2.3.2