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Registration Decision

RootShield Biological Fungicide

Trichoderma harzianum Rifai strain KRL-AG2

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Overview

Registration Decision for *Trichoderma harzianum* Rifai Strain KRL-AG2

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 RootShield Technical Biological Fungicide and the end-use products RootShield Drench Biological Fungicide Wettable Powder and RootShield Granules Biological Fungicide containing *Trichoderma harzianum* Rifai strain KRL-AG2 for the suppression of root pathogens in greenhouse tomatoes, cucumbers and ornamentals.

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[1]: Proposed Registration Decision PRDD2007-01, *RootShield Biological Fungicide Trichoderma harzianum Rifai strain KRL-AG2*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for RootShield Biological Fungicide and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRDD2007-01. This decision is consistent with the proposed registration decision stated in PRDD2007-01.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRDD2007-01, *RootShield Biological Fungicide Trichoderma harzianum Rifai strain KRL-AG2* that 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[3] 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

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

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

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

conditions of registration. The Act also requires that products have value[4] 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 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 PMRA's website at www.pmra-arla.gc.ca.

What Is *Trichoderma harzianum* Rifai Strain KRL-AG2?

Trichoderma harzianum Rifai strain KRL-AG2 is a fungus that protects plants from disease-causing fungal pathogens by secreting cell degrading enzymes and antibiotics and by invading and growing within pathogenic fungi to suppress their growth.

Health Considerations

Can Approved Uses of *T. harzianum* Rifai Strain KRL-AG2 Affect Human Health?

***Trichoderma harzianum* Rifai strain KRL-AG2 is unlikely to affect your health when used according to the label directions.**

Exposure to *T. harzianum* Rifai strain KRL-AG2 may occur when handling of RootShield Drench Biological Fungicide Wettable Powder or RootShield Granules Biological Fungicide. When assessing health risks, several key factors are considered: the microorganism's biological properties (e.g. production of toxic by-products), reports of any adverse incidents, its potential to cause disease or toxicity as determined in toxicological studies and the likely levels to which people may be exposed relative to exposures already encountered in nature to other strains of the microorganism.

Toxicology studies in laboratory animals describe potential health effects from large doses in the hope of identifying any potential to cause disease or toxicity. No significant toxicity and no signs of causing diseases were observed when *T. harzianum* Rifai strain KRL-AG2 was tested on laboratory animals.

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[4] "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."

Residues in Water and Food

Dietary risks from food and water are not of concern.

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

Trichoderma harzianum is common in most terrestrial environments, and the use of RootShield Drench Biological Fungicide Wettable Powder and RootShield Granules Biological Fungicide is not expected to significantly increase the natural environmental background levels of this microorganism. Furthermore, *Trichoderma* species are rarely reported to occur on living plants. Based on the use pattern for RootShield Drench Biological Fungicide and RootShield Granules Biological Fungicide, minimal dietary exposure to residues of *T. harzianum* Rifai strain KRL-AG2 and its secondary metabolites are expected. No adverse effects have been reported for this microbial pest control agent in the United States where it has been registered for use since 1990. In addition, no significant toxicity or signs of causing disease were observed when *T. harzianum* Rifai strain KRL-AG2 was administered orally to rats. Therefore, establishment of an MRL is not required for *T. harzianum* Rifai strain KRL-AG2. The likelihood of residues of *T. harzianum* Rifai strain KRL-AG2 contaminating drinking water supplies is negligible to non-existent. Consequently, dietary exposure and risk are minimal to non-existent.

Occupational Risks From Handling RootShield Drench Biological Fungicide Wettable Powder or RootShield Granules Biological Fungicide

Occupational risks are not of concern when RootShield Drench Biological Fungicide Wettable Powder or RootShield Granules Biological Fungicide are used according to the label directions, which include protective measures.

Growers handling or applying RootShield Drench Biological Fungicide Wettable Powder or RootShield Granules Biological Fungicide as well as growers working with treated crops can be exposed to *T. harzianum* Rifai strain KRL-AG2 via the skin, eyes or by inhalation. For this reason, the label will specify that applicators and other handlers of RootShield Drench Biological Fungicide Wettable Powder or RootShield Granules Biological Fungicide must wear personal protective equipment including water proof gloves, long-sleeved shirts, long pants, shoes and socks and a National Institute for Safety and Health (NIOSH) approved respirator. In addition, early entry workers will be restricted from entering greenhouses for up to four hours following treatment of crops with RootShield Drench Biological Fungicide Wettable Powder or RootShield Granules Biological Fungicide.

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

Environmental Considerations

What Happens When *T. harzianum* Rifai Strain KRL-AG2 Is Introduced Into the Environment?

Environmental risks are not of concern.

Field studies suggest that *T. harzianum* Rifai strain KRL-AG2 will likely disperse and persist in the environment. Published reports indicate that there may be potential negative effects on non-target plants and beneficial soil microorganisms. However, application of RootShield Drench Biological Fungicide Wettable Powder or RootShield Granules Biological Fungicide is limited to specific food and non-food crops grown in greenhouses. Therefore, release to the environment and exposure and risk to non-target terrestrial and aquatic organisms is negligible.

A few adverse effect reports have identified *T. harzianum* as the causal agent of "green mould disease." Although the active ingredient's potential to cause this disease is unknown, a label statement preventing greenhouse operators from distributing treated plant matter to mushroom growers for use as substrate is required.

Value Considerations

What Is the Value of *T. harzianum* Rifai Strain KRL-AG2?

The end-use products RootShield Drench Biological Fungicide Wettable Powder and RootShield Granules Biological Fungicide are biofungicides that contain the active ingredient *T. harzianum* Rifai strain KRL-AG2 for the suppression of fungal root diseases on tomato, cucumber and ornamental crops. The registration of these two products will provide the Canadian greenhouse industry with an additional non-chemical fungicide. The active ingredient *T. harzianum* Rifai strain KRL-AG2 employs multiple modes of action for the suppression of fungal pathogens and, therefore, can be used as a resistance-management tool.

Measures to Minimize Risk

Registered pesticide product labels 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 RootShield Drench Biological Fungicide Wettable Powder and RootShield Granules Biological Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

As a standard precaution anyone handling or applying RootShield Drench Biological Fungicide Wettable Powder or RootShield Granules Biological Fungicide must wear waterproof gloves, a long-sleeved shirt, long pants and shoes plus socks. In addition, a NIOSH approved respirator must be worn by applicators and early-entry (postapplication) workers. Early-entry workers will also be restricted from entering greenhouses for up to four hours following treatment of the crops with RootShield Drench Biological Fungicide Wettable Powder or RootShield Granules Biological Fungicide.

Environment

As a general precaution, handlers are advised not to contaminate irrigation or drinking water, or aquatic habitats while cleaning equipment or disposing of waste. In addition, the following label statement is required: “The treated plant material must not be used as substrate for mushroom farms.”

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 at 1-800-267-6315) or by e-mail at pmra_infoserv@hc-sc.gc.ca.

Any person may file a notice of objection[5] 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 PMRA's website (Requesting a Reconsideration of Decision, http://www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html) or contact the PMRA's Pest Management Information Service by phone at 1-800-267-6315 or by e-mail at pmra_infoserv@hc-sc.gc.ca.

[5] As per subsection 35(1) of the *Pest Control Products Act.*

References

A. List of Studies/Information Submitted by Registrant

1.0 Product Characterization and Analysis

PMRA 1260502 2003.On the detection of the presence of peptaibols in cultures of *Trichoderma harzainum*, Qualitative comparison among three strains. DACO: M2.7.2.

4.0 Value

PMRA 818731 Tests of the Efficacy of Rootshield against Pythium in Greenhouse Tomatoes in Quebec. DACO M10.2.2.

PMRA 818732 Efficacy of Biological and Chemical Treatments for Control of Fusarium Root and Stem Rot on Greenhouse Cucumber. Plant Dis. 87: 1462–1470. DACO M10.2.2.

B. Additional Information Considered

Published Information

1.0 Product Characterization and Analysis

PMRA 1617452 Sivan, A., and Harman, G. E. 1990. Improved rhizosphere competence in a protoplast fusion progeny of *Trichoderma harzianum*. DACO: M2.7.2.

PMRA 1617456 Rebuffat, S., Goulard, C., and Bodo, B. 1995. Antibiotic peptides from *Trichoderma harzianum*: harzianins HC, proline-rich 14-residue peptaibols. DACO: M2.7.2.

PMRA 1617463 Rebuffat, S., El Hajji, M., Hennig, P., Davoust, D., and Bodo, B. 1989. Isolation, sequence, and conformation of seven trichorzianines B from *Trichoderma harzianum*. DACO: M2.7.2.

PMRA 1617465 Goulard, C., Hlimi, S., Rebuffat, S., and Bodo, B. 1995. Trichorzins HA and MA, Antibiotic Peptides from *Trichoderma harzianum*. DACO: M2.7.2.

PMRA 1617469 El Hajji, M., Rebuffat, S., Lecommandeur, D. and Bodo, B. 1986. Isolation and sequence determination of trichorzianines A antifungal peptides from *Trichoderma harzianum*. DACO: M2.7.2.

PMRA 1617471 Bodo, B., Rebuffat, S., El Hajji, M., and Davoust, D. 1985. Structure of Trichorzianine A IIIc, an Antifungal Peptide from *Trichoderma harzianum*. DACO: M2.7.2.

PMRA 1617473 Augeven-Bour, I., Rebuffat, S., Auvin, C., Goulard, C., and Bodo, B. 1997. Harzianin HB I, an 11-residue peptaibol from *Trichoderma harzianum*: isolation, sequence, solution synthesis and membrane activity. DACO: M2.7.2.