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Proposed Re-evaluation Decision

PRVD2017-20

Trichoderma harzianum **Rifai strain KRL-AG2** **and Its Associated End- use Products**

Consultation Document

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Proposed Re-evaluation Decision

Under the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies. The PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Trichoderma harzianum Rifai strain KRL-AG2 is a fungus that protects plants from disease-causing fungal pathogens. *Trichoderma harzianum* Rifai strain KRL-AG2 is a biological fungicide registered for the suppression of root and foliar diseases on greenhouse crops, outdoor nursery plants and agricultural field crops. It can be applied as a soil drench, bulb dip, seed treatment, and as a ground foliar spray.

This document presents the proposed regulatory decision for the re-evaluation of *Trichoderma harzianum* Rifai strain KRL-AG2 including the proposed risk mitigation measures to further protect human health and the environment, as well as the science evaluation on which the proposed decision was based. All products containing *Trichoderma harzianum* Rifai strain KRL-AG2 registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period, during which the public including the pesticide manufacturers and stakeholders may submit written comments and additional information to the PMRA Publications Section. The final re-evaluation decision will be published taking into consideration the comments and information received.

Outcome of Science Evaluation

Trichoderma harzianum Rifai strain KRL-AG2 represents an additional disease management tool that can reduce the reliance on chemical fungicides for greenhouse, nursery and agricultural field crops. Due to its broad mode of action, *Trichoderma harzianum* Rifai strain KRL-AG2 is not prone to the development of resistance and, thus, can be used as a resistance management tool in a disease management program.

Potential exposure to *Trichoderma harzianum* Rifai strain KRL-AG2 may occur when handling and applying, or when ingesting treated produce. When spores of *Trichoderma harzianum* Rifai strain KRL-AG2 were tested on laboratory animals, there were no signs that it caused any significant toxicity or disease. While secondary metabolites of toxicological significance (peptaibols) have been shown to be produced by certain naturally occurring strains of *Trichoderma harzianum* (including strain KRL-AG2), its use is not expected to result in a sustained increase in levels of these peptaibols beyond the naturally occurring background levels of those produced by native *Trichoderma harzianum* strains. These metabolites are expected to be short-lived in the environment once produced. As well, the likelihood of residues of *Trichoderma harzianum* Rifai strain KRL-AG2 contaminating drinking water supplies resulting from applications as a pesticide is considered to be low. Based on the above, dietary risks from food and water are not of concern under the current conditions of use.

There are no domestic-class products containing *Trichoderma harzianum* Rifai strain KRL-AG2, nor is it expected that the commercial products would be applied in residential areas. Even in the event of exposure, no risks of concern to bystanders are expected when the products are applied according to label directions since there were no signs of disease or toxicity noted with this microorganism.

Occupational exposures of workers mixing, loading and applying the end-use products, as well as to workers re-entering treated sites, are not expected to result in risks of concern when *Trichoderma harzianum* Rifai strain KRL-AG2 is used according to the label directions. However, to meet the current standard, updates to the restricted-entry interval section of the labels are proposed.

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

Trichoderma species are ubiquitous soil-dwellers, inhabiting soil, rotting wood and vegetable matter in virtually all terrestrial environments. *Trichoderma harzianum* Rifai strain KRL-AG2 and its metabolites (peptaibols) are not expected to pose risks of concern to the environment when used according to the label directions.

Proposed Regulatory Decision for *Trichoderma harzianum* Rifai strain KRL-AG2

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, Health Canada is proposing that products containing *Trichoderma harzianum* Rifai strain KRL-AG2 are considered acceptable for continued registration for the sale and use in Canada.

Registered pesticide product labels include specific instructions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. As a result of the re-evaluation of *Trichoderma harzianum* Rifai strain KRL-AG2, no additional risk mitigation measures are proposed by the PMRA.

To meet the current labelling standard the following label updates are proposed (Refer to the details in Appendix I):

- Restricted-entry intervals
- Precautionary label statement to minimize the potential for spray drift.
- Environmental label statements

International Context

Trichoderma harzianum Rifai strain KRL-AG2 is currently acceptable for use in other Organisation for Economic Co-operation and Development (OECD) member countries, including Australia, the European Union, and the United States. As of 21 July 2017, no decision by an OECD member country to prohibit all uses of this microbial for health or environmental reasons has been identified.

Next Steps

The public including the registrants and stakeholders are encouraged to submit comments during the 90-day public consultation period¹ upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of re-evaluation decision document. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with the PMRA's responses.

Additional Scientific Information

No additional data are required.

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

Science Evaluation

1.0 Introduction

Trichoderma harzianum Rifai strain KRL-AG2 is a biological fungicide used on greenhouse and field crops. This beneficial microbe grows on the outside of the plant root to provide prolonged protection against soil-borne fungi such as *Pythium*, *Rhizoctonia*, *Fusarium*, *Cylindrocladium* and *Thielaviopsis*. *Trichoderma harzianum* is a ubiquitous species in the environment and the specific strain KRL-AG2 is a novel strain created from the fusion of two naturally occurring isolates.

Following the re-evaluation announcement for *Trichoderma harzianum* Rifai strain KRL-AG2, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the label of end-use products in Canada.

As of 30 August 2017, one technical grade active ingredient (TGAI), one manufacturing concentrate (MC) and seven commercial end-use products (EP) containing *Trichoderma harzianum* Rifai strain KRL-AG2 are registered in Canada (Appendix II).

2.0 Use Description of *Trichoderma harzianum* Rifai strain KRL-AG2

Trichoderma harzianum Rifai strain KRL-AG2 is registered for the suppression of root and foliar diseases on greenhouse crops including ornamentals, vegetable transplants and *Cannabis* (marijuana), outdoor nursery plants and agricultural field crops. It can be applied as a soil drench, bulb dip, seed treatment, and as a ground foliar spray. End-use products are applied using hand-held backpack or ground spray equipment.

3.0 The Active Ingredient, Its Properties and Uses

3.1 Identity of the Active Ingredient.

Active microorganism	<i>Trichoderma harzianum</i> Rifai strain KRL-AG2
Function	Biological Fungicide
Binomial name	<i>Trichoderma harzianum</i> Rifai strain KRL-AG2
Taxonomic designation	
Kingdom	Fungi
Phylum	Deuteromycotina
Order	Hyphomycetes (syn. Moniliales)
Genus	<i>Trichoderma</i>
Species	<i>harzianum</i>
Strain	KRL-AG2

Trichoderma harzianum Rifai strain KRL-AG2 was derived from the fusion of two auxotrophic strains of *T. harzianum*, strain T12m-2 hisG and strain T95-1 lysG.

4.0 Human Health

Potential exposure to *Trichoderma harzianum* Rifai strain KRL-AG2 may occur when handling and applying, or when ingesting treated produce. When assessing health risks of microorganisms, several key factors are considered:

- the microorganism's biological properties (for example, production of toxic byproducts);
- reports of any adverse incidents;
- its potential to cause disease or toxicity as determined in toxicological studies; and
- the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses that are determined as having no health risks of concern are considered acceptable for registration.

Studies in laboratory animals describe potential health effects from large doses of exposure to a microorganism and identify any potential pathogenicity, infectivity, and toxicity concerns.

4.1 Toxicity and Infectivity Summary

The database for *Trichoderma harzianum* Rifai strain KRL-AG2 consists of laboratory animal (in vivo) toxicity/pathogenicity studies (acute oral toxicity/pathogenicity, acute pulmonary toxicity/ infectivity, acute intravenous injection infectivity) and primary irritation studies. Acceptable waivers were submitted for the acute dermal toxicity and primary dermal irritation studies. No data deficiencies have been identified by the PMRA.

Trichoderma harzianum Rifai strain KRL-AG2 is not known to be a human pathogen. The submitted toxicity/infectivity studies in the rodent indicate that, following oral, pulmonary and intravenous injection routes of exposure, the immune system is still intact and able to process and clear the microbial.

Trichoderma species, including *Trichoderma harzianum* Rifai strain KRL-AG2, are known to produce secondary metabolites called peptaibols. Based on the information available, the PMRA concluded that the level of peptaibols produced by *Trichoderma harzianum* Rifai strain KRL-AG2 is not expected to be greater than the level produced by naturally occurring *Trichoderma* strains, for which there have been no reports of adverse effects to humans. On this basis, the potential presence of peptaibols is not expected to pose a concern for human health.

No endpoints of toxicological concern for quantitative risk assessment were established for *Trichoderma harzianum* Rifai strain KRL-AG2. As a result, the PMRA has used a qualitative approach to assess the potential risks of *Trichoderma harzianum* Rifai strain KRL-AG2 to human health.

4.2 Occupational Exposure and Risk

Workers can be exposed to *Trichoderma harzianum* Rifai strain KRL-AG2 through mixing, loading or applying the product as a soil drench, dip, seed treatment and spray or when entering a treated site to conduct activities such as scouting and/or handling treated crops.

4.2.1 Mixer/Loader/Applicator Exposure and Risk

The potential for dermal, inhalation exposure for applicators, mixer/loaders, handlers and early-entry workers is expected to be low under current conditions of use. The current labels require workers to wear personal protective equipment (PPE) consisting of long-sleeved shirt, long pants, water proof gloves, socks with shoes, eye goggles and a NIOSH-approved dust/mist filtering respirator/mask when handling, mixing/loading or applying the product and during all clean-up/repair activities.

Since unbroken skin is a natural barrier to microbial invasion of the human body, dermal absorption could occur only if the skin were cut, if the microbe were a pathogen equipped with mechanisms for entry through or infection of the skin, or if metabolites were produced that could be dermally absorbed. This microbe has not been identified as a wound pathogen and there is no indication that it could penetrate intact skin of healthy individuals. The personal protective equipment currently required on the end-use product labels further reduces potential dermal exposure of workers.

The potential risk from inhalation exposure to *Trichoderma harzianum* Rifai strain KRL-AG2 is also considered to be not of concern under current conditions of use. The use of a respirator is expected to address any concerns for potential inhalation risk.

A pure powder preparation of strain KRL-AG2, was shown to be minimally irritating to the eye, however the end use products contain formulants that are eye irritants. Handlers, applicators as well as workers involved in post-application activities, are required to wear goggles to minimize potential eye irritation.

Consequently, the PMRA does not expect that occupational exposures is of concern given the low toxicity/pathogenicity profile for *Trichoderma harzianum* Rifai strain KRL-AG2 and the use of the required personal protective equipment. No additional mitigation measures are proposed.

4.2.2 Post-application Exposure and Risk

Potential postapplication exposure of workers entering treated sites is not expected to be of concern given the toxicity/pathogenicity profile of this active ingredient and current conditions of use. To meet the current labelling standard, updates to re-entry interval statements are proposed.

4.3 Non-occupational Exposure

4.3.1 Residential Exposure and Risk

There are no domestic-class products containing *Trichoderma harzianum* Rifai strain KRL-AG2 nor is it expected that the commercial products would be applied in residential areas.

An advisory label statement to limit the potential for spray drift to residential areas such as houses, cottages, schools and recreational areas is proposed. The proposed label statements are listed in Appendix I.

4.3.2 Bystander Exposure and Risk

There is a potential for bystander exposure to spray drift from applications to outdoor field crops or ornamental nursery stocks. For bystanders, inhalation exposure is expected to be much less than that of handlers and mixer/loaders and is considered to be of no concern. Overall, the PMRA does not expect that bystander exposures will pose a risk of concern on the basis of the low toxicity/pathogenicity profile for *Trichoderma harzianum* Rifai strain KRL-AG2, and a limited potential for exposure. Therefore, the health risk to bystanders is expected to be low.

No additional risk mitigation measures are proposed.

4.3.3 Dietary Exposure and Risk

Even though *Trichoderma harzianum* is ubiquitous in most terrestrial environments, *Trichoderma* species are rarely reported to occur on living plants.

The use of *Trichoderma harzianum* Rifai strain KRL-AG2 is not expected to result in a significant level of residues of this active ingredient and/or the secondary metabolites (peptaibols) on food commodities at the time of harvest. The secondary metabolites are proteinaceous in nature and are expected to have a short residency time due to a rapid denaturation under environmental conditions. As such, the level of anticipated exposure to the parent or the metabolites is extremely low. In addition, the active ingredient and/or metabolite residues may be further removed by washing, peeling, or processing of commodities, further minimizing the potential for exposure.

The risk to the general population, including children and infants, from exposure to *Trichoderma harzianum* Rifai strain KRL-AG2 and/or metabolite residues on food commodities is not expected to be of concern based on the toxicity profile and a limited potential for exposure. No additional risk mitigation measures are proposed.

4.3.4 Drinking Water

There is a potential for *Trichoderma harzianum* Rifai strain KRL-AG2 to enter aquatic environments via spray drift or surface water runoff from treated field. *Trichoderma harzianum* is not generally recognized as an aquatic microorganism and, therefore, is not expected to

proliferate in aquatic habitats following direct or indirect application to bodies of water. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of significant transfer of residues to drinking water sources.

Trichoderma harzianum Rifai strain KRL-AG2 is not registered for the control of pests in aquatic systems.

Overall, potential exposure via drinking water is likely to be minimal for this microbial. On this basis, the potential risk from exposure to drinking water is not of concern under current conditions of use.

4.4 Maximum Residue Limits

As part of the assessment, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally specified as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

Minimal residues of *Trichoderma harzianum* Rifai strain KRL-AG2 are anticipated on treated food crops, at the time of harvest. Consequently, the PMRA has applied a hazard-based approach for determining whether an MRL is required for this microorganism. Based on the lack of toxicity and pathogenicity effects observed in the acute oral toxicity and infectivity study, the risks anticipated for dietary exposure are considered low. In addition and as described in Section 4.3.4, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Therefore, the PMRA has determined that an MRL does not need to be specified for *Trichoderma harzianum* Rifai strain KRL-AG2.

4.5 Cumulative Exposure and Risk

The PMRA has considered available information on the cumulative effects of residues of *Trichoderma harzianum* Rifai strain KRL-AG2 and other substances that share a common mechanism of toxicity with *Trichoderma harzianum* strain KRL-AG2 (other than its synonym, strain T-22). Besides naturally occurring strains of *Trichoderma harzianum* in the environment, no cumulative effects are anticipated if the residues of *Trichoderma harzianum* strain KRL-AG2 interact with related strains of this microbial species.

5.0 Environment

5.1 Environmental Fate

Trichoderma species are ubiquitous soil-dwellers, inhabiting soil, rotting wood and vegetable matter in virtually all terrestrial environments. Environment fate of *Trichoderma harzianum* Rifai strain KRL-AG2 has been described in PRD2009-13.

Trichoderma harzianum Rifai strain KRL-AG2 does not persist when applied to foliage or fruit. Information on the environmental fate of *Trichoderma harzianum* Rifai strain KRL-AG2 suggests that, as a soil microorganism, it is likely that *Trichoderma harzianum* Rifai strain KRL-AG2 survive in outdoor soil under suitable environmental conditions (in other words, type of soil, moisture, acidity levels, and temperature) but that over time the populations of *Trichoderma harzianum* Rifai strain KRL-AG2 should return to naturally occurring levels.

Trichoderma harzianum Rifai strain KRL-AG2 secondary metabolites, peptaibols, are not expected to persist in the environment, as they are easily denatured by ultraviolet light, heat and various microbial processes in the environment.

5.2 Environment Exposure and Risk Assessment

5.2.1 Terrestrial Organisms

Although there is a potential for exposure of terrestrial species to this active ingredient following application to agricultural fields and outdoor nurseries, the overall potential risk is not expected to be of concern. *Trichoderma* species are ubiquitous in terrestrial environments. Adverse effects in non-target terrestrial species (including birds, mammals, invertebrates, soil dwelling organism, and non-target plants) from exposure to this microorganism are not expected. There is no evidence of adverse effects in terrestrial species following exposure to *Trichoderma harzianum* Rifai strain KRL-AG2 in the available animal toxicity studies. It is not known to be a pathogen in birds.

Trichoderma harzianum Rifai strain KRL-AG2 is a ubiquitous fungus, but it is rarely reported to occur on living plants and is not an endophyte. Despite the potent cellulolytic enzyme systems and secondary metabolites with plant growth regulating properties, the ability of *Trichoderma harzianum* Rifai strain KRL-AG2 to attack living wood or plants is considered weak.

The potential risk to terrestrial organisms following exposure to the secondary metabolites (peptaibols) of *Trichoderma harzianum* Rifai strain KRL-AG2 is also not expected to be of concern given that they are not expected to persist under environmental conditions due to a rapid degradation.

Based on the available information on the effects of *Trichoderma harzianum* Rifai strain KRL-AG2 to terrestrial organisms, there is reasonable certainty no harm will come to terrestrial species.

5.2.2 Aquatic Organisms

There is a potential for contamination of aquatic habits with *Trichoderma harzianum* Rifai strain KRL-AG2 as a result of spray drift or runoff from treated fields. However, *Trichoderma harzianum* Rifai strain KRL-AG2 is not recognized as an aquatic microorganism. Based on the lack of evidence on its natural occurrence in freshwater or salt water, *Trichoderma harzianum* Rifai strain KRL-AG2 is not expected to establish itself in aquatic environments in the event of runoff or spray drift from treated fields.

Therefore, sustained levels of *Trichoderma harzianum*, beyond that of naturally occurring *Trichoderma* strains, are not expected. Consequently, potential risks to aquatic organisms are not expected to be of concern based on the available information.

To meet the current labelling standard, updates to the environmental label statements are proposed (Appendix I).

6.0 Value

Trichoderma harzianum Rifai strain KRL-AG2 represents an additional disease management tool which can reduce the reliance on chemical fungicides for greenhouse, nursery and agricultural field crops. Due to its broad mode of action, *Trichoderma harzianum* Rifai strain KRL-AG2 is not prone to the development of resistance and thus, can be used as a resistance management tool in a disease management program.

7.0 Pest Control Product Policy Considerations

7.1 Toxic Substances Management Policy Considerations

In accordance with the PMRA Regulatory Directive DIR99-03², the assessment of *Trichoderma harzianum* Rifai strain KRL-AG2 against Track 1 criteria of Toxic Substances Management Policy (TSMP) under *Canadian Environmental Protection Act* was conducted. It determined that:

- *Trichoderma harzianum* Rifai strain KRL-AG2 does not meet the TSMP Track 1 criteria.

7.2 Contaminants of Health or Environmental Concern

During the re-evaluation of *Trichoderma harzianum* Rifai strain KRL-AG2, contaminants in the technical were compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

- *Trichoderma harzianum* Rifai strain KRL-AG2 and does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*.

² DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

8.0 Incident Reports

Starting 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame.

As of 30 August 2017, the PMRA has not received any incident reports associated with *Trichoderma harzianum* Rifai strain KRL-AG2.

9.0 Conclusion

The PMRA has determined that products containing *Trichoderma harzianum* Rifai strain KRL-AG2 for sale and use in Canada are acceptable for continued registration.

Trichoderma harzianum Rifai strain KRL-AG2 represents an additional disease management tool which can reduce the reliance on chemical fungicides for greenhouse, nursery and agricultural field crops. Due to its broad mode of action, *Trichoderma harzianum* Rifai strain KRL-AG2 is not prone to the development of resistance and thus, can be used as a resistance management tool in a disease management program.

With respect to human health, *Trichoderma harzianum* Rifai strain KRL-AG2 is unlikely to affect your health when used according to the label directions. Occupational risks are not of concern when *Trichoderma harzianum* Rifai strain KRL-AG2 is used according to label directions, which include protective measures. Estimated risk for residential and other non-occupational exposure, as well as dietary risk is not of concern, when the label directions are followed.

The potential risk to terrestrial and aquatic organisms from exposure to *Trichoderma harzianum* Rifai strain KRL-AG2 is not expected to be of concern when used according to the label directions.

Label updates to meet the current labelling standard are proposed (Appendix I).

List of Abbreviations

EP	end-use product
C	commercial
FTR	<i>Trichoderma harzianum</i> Rifai strain KRL-AG2
ha	hectare
L	litre(s)
MC	manufacturing concentrate
mg	milligram(s)
MRL	maximum Residue limit
OECD	Organization for Economic Co-operation and Development
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
REI	restricted-entry interval
T	technical
TDG	<i>Trichoderma Virens</i> Strain G-41
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
µg	microgram(s)
USEPA	United States Environmental Protection Agency

Appendix I Label Amendments for Products Containing *Trichoderma harzianum* Rafai strain KRL-AG2

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

The following label statements are required:

- I) The following statement must be included under the **RE-ENTRY INTERVAL section for end-use products with indoor and outdoor foliar applications** (excluding granular formulations):
 - “DO NOT re-enter or allow re-entry into treated areas for 4 hours or until sprays have dried, unless wearing appropriate personal protective equipment including long-sleeved shirt, long pants, shoes plus socks, and waterproof gloves.”
- II) The following statement must be included under the **PRECAUTIONS section for all end-use product labels with outdoor uses**:
 - “Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.”
- III) The following statements must be included under the **ENVIRONMENTAL PRECAUTIONS section for all end-use products**:
 - “To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil, or clay.”
 - “Avoid application when heavy rain is forecast.”
 - “Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.”
- IV) The following statements must be included under the **DIRECTIONS FOR USE section for all end-use products**:
 - “DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.”

V) The following statement must be included under the **DIRECTIONS FOR USE** section for **all end-use products with greenhouse uses**:

- “DO NOT allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.”

Appendix II Registered *Trichoderma harzianum* Rifai strain KRL-AG2 Products in Canada as of 30 August 2017

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
31054	MC	Bioworks Inc	Rootshield plus granules biological fungicide	Granular	TDG: 5.3×10^6 FTR: 1×10^7
27115	C		Rootshield HC biological fungicide wettable powder	Live Organism	FTR: 1×10^7
27116	C		Rootshield granules biological fungicide		FTR: 1×10^7
29890	C		Rootshield WP - biological fungicide		FTR: 1×10^7
30539	C		Rootshield plus WP biological fungicide		TDG: 5.3×10^6 FTR: 1×10^7
31989	C		BW240 WP biological fungicide		TDG: 5.3×10^6 FTR: 1×10^7
37114	T		Rootshield technical biological fungicide		FTR: 5×10^8
31103	C		AEF Global Inc		Bora HC
31104	C	Bora WP		FTR: 1×10^7	

References

Published Information

PMRA Number	Reference
650066	Regulatory Note REG2002-01, Rootshield Biological Fungicide <i>Trichoderma harzianum</i> Rifai strain KRL-AG2. Pest Management Regulatory Agency. 4 June 2002.
1862477	Proposed Regulatory Decision Document, PRDD2007-01, RootShield Biological Fungicide <i>Trichoderma harzianum</i> Rifai strain KRL-AG2. Pest Management Regulatory Agency. 9 January 2007.
1643808	Registration Decision, RD2008-14, RootShield Biological Fungicide <i>Trichoderma harzianum</i> Rifai strain KRL-AG2. Pest Management Regulatory Agency. 29=7 November 2008.
1864174	Proposed Registration Decision, PRD2009-13 <i>Trichoderma harzianum</i> Rifai strain KRL-AG2. Pest Management Regulatory Agency. 23 October 2009.
1864176	Registration Decision, RD2010-02, <i>RootShield Biological Fungicide, Trichoderma harzianum</i> Rifai strain KRL-AG2. Pest Management Regulatory Agency. 8 February 2010.