

Evaluation Report for Category B, Subcategory 2.1, 2.5, 3.1, 3.14 Application

Application Number: 2019-3661
Application: New End-use Product (Product Chemistry) – Guarantee, Formulation Type; New Product Label - Application Rate Increase or Decrease, Classifications
Product: Rootshield Plus G Biological Fungicide
Registration Number: 33781
Active ingredients (a.i.): *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41
PMRA Document Number : 3114138

Purpose of Application

The purpose of this application was to register the new end-use product (EP) Rootshield Plus G Biological Fungicide for the suppression of root rot and damping-off caused by *Pythium* spp., *Rhizoctonia* spp., *Fusarium* spp., and *Phytophthora* spp. in greenhouse crops, greenhouse vegetable transplants, cannabis (marihuana) produced commercially indoors, and outdoor nursery plants.

Product Characterization Assessment

Rootshield Plus G Biological Fungicide is considered equivalent to the registered manufacturing concentrate (MA). Since the product characterization and analysis database for the precedent MA is considered complete, no additional information is required for the new EP.

Health Assessments

Rootshield Plus G Biological Fungicide is considered equivalent to the registered manufacturing concentrate (MA). Since the human health and safety database for the precedent MA is considered complete, no additional toxicological information is required for the new EP and its technical grade active ingredients (TGAI).

Overall, the PMRA does not expect that residential and bystander exposures will pose a health risk of concern on the basis of the low toxicity profile for Rootshield Plus G Biological Fungicide, the low infectivity/pathogenicity profiles for *T. harzianum* Rifai strain KRL-AG2 and *T. virens* strain G-41, and the expectation that precautionary label statements will be followed by commercial applicators in the use of the EP.

Label warnings, restrictions and risk mitigation measures are adequate to protect users of Rootshield Plus G Biological Fungicide, and no significant occupational risks are anticipated for these products.

The potential for dietary and occupational exposure from Rootshield Plus G Biological Fungicide is not expected to increase, and therefore, no additional exposure information is required. The available information is sufficient to support the use of Rootshield Plus G Biological Fungicide in greenhouse crops, greenhouse vegetable transplants, cannabis (marihuana) produced commercially indoors, and outdoor nursery plants.

Maximum Residue Limit (MRL)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that 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 an MRL under the *Pest Control Products Act* (PCPA) for the purposes of adulteration provision of the *Food and Drugs Act* (FDA). Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

PMRA has not specified a maximum residue limit (MRL) for *Trichoderma harzianum* Rifai strain KRL-AG2 or *Trichoderma virens* strain G-41. The available information is sufficient to support the uses of Rootshield Plus G Biological Fungicide.

Environmental Assessment

The formulation of Rootshield Plus G Biological Fungicide is considered equivalent to the registered manufacturing concentrate (MA). Since the environmental fate and toxicology database for the precedent MA is considered complete, no additional environmental information is required for the new EP and its technical grade active ingredients (TGAI).

The use sites for Rootshield Plus G Biological Fungicide are within those currently registered for the microbial pest control agents (MPCA) *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41.

Soil incorporated applications of Rootshield Plus G Biological Fungicide at rates up to 1200 g/m³ are not expected to result in soil concentrations that are above naturally occurring background levels of *Trichoderma*. Exposure in marine or estuarine environments resulting from runoff is expected to be similar to that which would occur as a result of natural soil concentrations of *Trichoderma* species.

Soil surface applications of Rootshield Plus G Biological Insecticide are consistent with registered use patterns and rates of these two MPCAs.

The available information is sufficient to support the use of Rootshield Plus G Biological Fungicide in greenhouse crops, greenhouse vegetable transplants, cannabis (marihuana) produced commercially indoors, and outdoor nursery plants.

Value Assessment

Four bridging trials and a rationale supported the extrapolation of claims from a precedent

product to Rootshield Plus G Biological Fungicide. This new product is expected to suppress root rot and damping-off caused by *Pythium* spp., *Rhizoctonia* spp., *Fusarium* spp., and *Phytophthora* spp. on greenhouse crops, greenhouse transplants, indoor cannabis and outdoor nursery crops. The registration of Rootshield Plus G Biological Fungicide will provide growers with an alternative biological product for root rot and damping-off management.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to register Rootshield Plus G Biological Fungicide.

References

PMRA Document Number	Reference
3018162	2019, Value Summary for Rootshield Plus G Biological Fungicide, containing <i>Trichoderma harzianum</i> Rifai strain KRL-AG2 and <i>Trichoderma virens</i> strain G-41, for Root Rot caused by <i>Pythium</i> spp., <i>Rhizoctonia</i> spp., <i>Fusarium</i> spp., and <i>Phytophthora</i> spp. in Greenhouse Crops, Greenhouse Vegetable Transplants, Cannabis (marihuana) produced commercially indoors, Outdoor Nursery Plants and Ginseng, DACO: M10.1, M10.2.1, M10.2.2, M10.3.1, M10.3.2, M10.4.1, M10.4.2, M10.4.4
3018164	2019, Efficacy of different rates of RootShield Plus WP and RootShield Plus G against Pythium Damping-Off of Cucumber., DACO: M10.2.1, M10.2.2
3018165	2019, Efficacy of different rates of RootShield Plus WP and RootShield Plus G against Pythium Damping-Off of Cucumber., DACO: M10.2.1, M10.2.2
3018166	2019, Efficacy of different rates of RootShield Plus WP and RootShield Plus G against Rhizoctonia Damping-Off of Broccoli seedlings., DACO: M10.2.1, M10.2.2
3018167	2019, Efficacy of RootShield Plus WP and G formulations and the chemical standard fungicide Previcur Flex against Fusarium Wilt and Root Rot <i>Fusarium oxysporium</i> infesting Tomato under greenhouse conditions, DACO: M10.2.1, M10.2.2
3018168	2019, Supplement - Efficacy of RootShield Plus WP and G formulations and the chemical standard fungicide Previcur Flex against Fusarium Wilt and Root Rot <i>Fusarium oxysporium</i> infesting Tomato under greenhouse conditions, DACO: M10.2.1, M10.2.2

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