Health Canada Santé Canada

Evaluation Report for Category B, Subcategories 3.12 and 3.13 Application

Application Number: 2015-1275
Application: Changes to product labels -new site and precautions
Product: Trianum P Biological Fungicide
Registration Number: 31502
Active ingredients (a.i.): *Trichoderma harzianum* Rifai strain T-22
PMRA Document Number : 2566809

Background

Trianum P Biological Fungicide is a commercial-class fungicide containing the microbial pest control agent (MPCA), *Trichoderma harzianum* Rifai strain T-22. Trianum P Biological Fungicide is a biological fungicide used to suppress various phytopathogenic fungi on carrots, cucumbers, lettuce, tomatoes, ornamentals and turf; including *Pythium violae*, *Pythium ultimatum*, *Pythium aphanidermatum*, *Rhizoctonia solani*, *Fusarium oxysporum*, *Sclerotinia homoecarpa* and *Microdochium nivale*. Trianum P Biological Fungicide is registered for use as drench application or as a spray at sowing

Purpose of Application

The purpose of this application was to change the net contents (from 0.50–20 kg to 0.25–20 kg), to include suppression of root rot on the new crop, ginseng, and to change the format of the "Directions for Use" section of the label.

Chemistry Assessment

No changes were made to the formulation of Trianum P Biological Fungicide.

Health Assessments

No new toxicology data were submitted in support of this submission. Based on previously submitted information, *Trichoderma harzianum* Rifai strain T-22 is of low toxicity and not infective or pathogenic to rats via the oral, pulmonary, and intravenous routes. Trianum P Biological Fungicide is also not irritating to skin of rabbits and slightly/minimally irritating to the eyes of rabbits. A search in PubMed using the keyword "(trichoderma harzianum) AND ("2014-06/01"[Date - Publication] : "3000"[Date - Publication])" found no new reports of adverse effects. The database for this product is considered complete.

The change in the use of Trianum P Biological Fungicide is consistent with existing registered uses for this product. The treatment of additional crop species is not expected to significantly increase exposure to workers and bystanders if the directions for use on the label are followed.

The recommended protective equipment, precautions and decontamination procedures to follow in the event of product exposure and/or spills are the same as those currently found on the registered label for this product. Label warnings, restrictions and risk mitigation measures are adequate to protect users of Trianum P Biological Fungicide, and no significant occupational or bystander risks are anticipated for this product.

Also, the addition of ginseng to the product's use pattern is not expected to significantly alter the dietary risk to *T. harzianum* Rifai strain T-22. As previously noted, the MPCA is of low toxicity and not infective or pathogenic to rats via the oral, pulmonary, and intravenous routes. Based on all the available data, negligible to no risk is expected for the general population, including infants and children, or animals.

No additional studies are required to support the amendments to the registration of Trianum P Biological Fungicide.

Environmental Assessment

No new environmental information or data were submitted in support of this submission. Based on previously submitted information, *Trichoderma harzianum* is a fungal pathogen and many isolates reportedly produce enzymes and metabolites which could adversely affect non-target microorganisms. It is not generally considered a pathogen of birds, mammals, fish, arthropods, non-arthropod invertebrates or plants. Previous searches through PubMed using the various keywords have yielded no reports of adverse effects to birds, wild mammals, fish, arthropods and non-arthropod invertebrates. A single report concluding that the culture filtrate of an isolate of *T. harzianum* reduced various parameters of root and shoot growth in wheat seedlings was found. No new reports of adverse effects were found in PubMed using the keyword "(trichoderma harzianum) AND ("2014-06/01"[Date - Publication] : "3000"[Date - Publication])".

The change in the use of Trianum P Biological Fungicide is consistent with existing registered uses for this microbial pest control agent. The treatment of an additional crop is not expected to significantly increase environmental risk to non-target organisms if the directions for use on the label are followed. No additional information or studies are required to support the use to suppress root rot on ginseng.

Value Assessment

Value information was submitted in the form of a scientific rationale. This rationale addressed the registration for precedent products with similar claims, current claims on the Trianum P Biological Fungicide label and the generalist nature of the pathogens. Based on the value information provided, a claim of suppression of root root (*Pythium* spp., *Rhizoctonia* spp. and *Fusarium* spp.) in ginseng was supported.

Conclusion

The addition of ginseng to the Trianum P Biological Fungicide label and associated claims, suppression of root rot (*Pythium* spp., *Rhizoctonia* spp. and *Fusarium* spp.), and amendments to the use directions were approved.

References

PMRA Document Number	Reference
2518781	2015, Value Summary for Trianum P Biological Fungicide, DACO: 10.1,10.2.2,10.2.3.1,10.3

.

ISSN: 1911-8082