

Evaluation Report for Category B, Subcategory 3.13 Application

Application Number: 2009-0969
Application: B.2.3 Changes to EP Chemistry-Identity and Formulants
B.2.4 Changes to EP Chemistry-Proportion of Formulants
B.3.13 Changes to Product Labels-Precautions
Product: Mycostop Biofungicide
Registration Number: 26265
Active ingredients (a.i.): *Streptomyces Griseovirdis* Strain K61
PMRA Document Number English PDF: 2009627

Purpose of Application

The purpose of this submission is to amend the formulation and precautions statement of Mycostop Biofungicide (Reg. No. 26265). The active ingredient, manufacturing procedure, and use pattern have not changed. Mycostop Biofungicide is a commercial-class biological fungicide that is to be applied by spraying or drenching the surface of growing media, or by using drip irrigation.

Chemistry Assessment

Mycostop Biofungicide is a registered end-use product. The amendments to the formulation are minimal and are not expected to result in an unacceptable risk. The product characterization and analysis database for Mycostop Biofungicide is complete.

Health Assessments

The amendments to the formulation are not of toxicological concern. Given the directions of use, pulmonary exposure to workers entering the area post-application is minimal. Therefore, a re-interval entry is not required. The human health and safety database for Mycostop Biofungicide is complete.

Environmental Assessment

The amendments to the formulation do not pose a concern to terrestrial or aquatic environments. The environmental database for Mycostop Biofungicide is complete.

Value Assessment

The effect of formulation change on the efficacy of Mycostop Biofungicide was evaluated. Concentration of the active ingredient is now slightly higher (+2%) in the product. The overall formulation change is only 4%, which is not considered a significant modification. These changes are not expected to modify the efficacy of the product.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided to amend the formulation and precautions statement in support for the product, Mycostop Biofungicide, and has found the information sufficient to support the registration of this application.

References

PMRA No.	Title
1772943	Anonymous, 2008, Finnfix 150 Safety Data Sheet, DACO: 0.9.1 (OECD)
1772947	2008, Statement for Producing Finnfix 150, DACO: 11.1, Document I CBI
1734157	2008, Five batch analysis of Mycostop, DACO: M2.9 CBI
1772941	2009, Clarification of the registration of Mycostop - Covering letter, DACO: 0.1.6000 (OECD)
1772943	Anonymous, 2008, Finnfix 150 Safety Data Sheet, DACO: 0.9.1 (OECD)
1772946	2005, Finnfix 150 Product Data Sheet, DACO: 11.1, Document I CBI
1772947	2008, Statement for Producing Finnfix 150, DACO: 11.1, Document I CBI

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