

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2019-2363
Application: B.1.1: New Source (site): Same Registrant
Product: T34 Biocontrol Technical
Registration Number: 30228
Active ingredients (a.i.): *Trichoderma asperellum* strain T34
PMRA Document Number: 3099530

Purpose of Application

The purpose of this application was to add two new manufacturing sites for T34 Biocontrol Technical.

Product Characterization and Analysis

The new manufacturing and formulating processes and the quality assurance associated with the production of T34 Biocontrol Technical at the new manufacturing sites were described in sufficient detail and determined to be acceptable. Acceptable representative potency and microbial contaminant screening data were also submitted to demonstrate that all batches of T34 Biocontrol Technical meet the required acceptance criteria for potency and microbial contamination. All batches of T34 Biocontrol Technical must conform to the limits outlined in the OECD Issue Paper on Microbial Contaminants for Microbial Pest Control Products.

The potential production of secondary metabolites was adequately addressed in a scientific rationale.

Storage stability data support the current storage conditions of up to 2 years at 4°C.

Health Assessments

A rationale was accepted to address human health and safety. The site-specific batch data for potency and microbial contaminant analyses (under Characterization and Analysis section) and the lack of toxicity in non-target organism studies conducted with T34 Biocontrol Technical manufactured at the new sites (under Environmental Assessment) demonstrate that the toxicity profiles of T34 Biocontrol Technical has not changed. The existing toxicological database indicates that the MPCA is of low toxicity and infectivity.

Environmental Assessment

Environmental toxicology studies submitted demonstrated the toxicological equivalence of T34 Biocontrol Technical produced by the new manufacturing methods at the new manufacturing and formulating sites. Comparison of non-target organism test results (in honeybees and freshwater fish) using T34 Biocontrol Technical produced at the registered sites as well as at the new manufacturing sites indicate that the toxicity profiles are equivalent.

Value Assessment

A value assessment was not required for this application.

Conclusion

The PMRA has reviewed the information provided in support of the new manufacturing sites. Based on the results of this review, the two new manufacturing sites are acceptable.

References

None

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