



Evaluation Report for Category B, Subcategory 4.6 Application

Application Number: 2017-3883
Application: B.4.6: Fulfill Requirements of Registration
Product: Bioprotec Lawn Herbicide Ready to Use
Registration Number: 30883
Active ingredients (a.i.): Citric Acid and Lactic Acid
PMRA Document Number : 3001352

Purpose of Application

The purpose of this application was to address the requirements of registration for Bioprotec Lawn Herbicide Ready to Use. These requirements were 1) microbial contamination and potency estimation data from 5 production-scale batches of the end use product and 2) confirmatory storage stability data.

Chemistry Assessment

Bioprotec Lawn Herbicide Ready to Use contains the active ingredients lactic acid and citric acid (present as fermentation products of *Lactobacillus casei* strain LPT-111, *Lb. rhamnosus* strain LPT-21, *Lactococcus lactis* spp. *lactis* strain LL64/CSL, *Lc. lactis* spp. *lactis* strain LL102/CSL, and *Lc. lactis* spp. *cremoris* strain M11/CSL) at nominal concentrations of 4.24 and 4.75 g/L respectively.

Potency data from 5 production-scale batches were submitted which indicate that the product meets the potency specifications. Analysis for microbial contamination was conducted on 5 production scale batches of the product and the results demonstrate below threshold levels of contaminating microorganisms.

Storage stability data also show that the product is stable for one year, when stored away from direct sunlight at 20 - 22°C.

No additional data are required to complete the product characterization and analysis database.

Health, Environmental and Value Assessment

Health, environmental and value assessments were not required for this application.

Conclusion

The PMRA has reviewed the information provided to address the requirements of registration. Based on the results of this review, all of the requirements of registration have been satisfied.

References

2911816 M2.9.2 Potency estimation
2911817 M2.10.2 Analysis of Microbial contaminants
2924597 Updated DACO M2.11 storage stability

ISSN: 1911-8082

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