

Evaluation Report for Category B, Subcategory 2.1, 2.3 and 2.4 Application

Application Number: 2017-2351
Application: B.2.1: Change Guarantee
B.2.3: Change in Identity of Formulants
B.2.4: Change in Proportion of Formulants
Product: Bio-Ceres G WP
Registration Number: 31231
Active ingredients (a.i.): *Beauveria bassiana* strain ANT-03
PMRA Document Number : 2821911

Purpose of Application

The purpose of this application was to change the formulation of the end use product, BioCeres G WP.

Chemistry Assessment

Information and data were provided on the formulation and quality control of the new formulation of BioCeres G WP. The described formulation and quality control processes, and representative batch data were adequate to demonstrate that the end use product is equivalent to the currently registered product. All information or data requirements are complete the Product Characterization and Analysis for BioCeres G WP.

Health Assessments

The health assessment is acceptable given that the information on the formulation process and quality assurance associated with the production of the new formulation of BioCeres G WP were adequate to demonstrate that the new formulation is equivalent in terms of health assessment to the currently registered product.

Environmental Assessment

No environmental assessment was required.

Value Assessment

Based on positive results of a laboratory bioassay, efficacy of the BioCeres G WP is expected to be comparable to the currently registered formulation.

Conclusion

The PMRA has reviewed information in support of the new formulation of BioCeres G WP. Based on the results of this review, the new formulation of BioCeres G WP is acceptable.

References

- 2760880 2017, Value Summary, DACO: 10.1
2760884 2017, Efficacy: Laboratory Trial, DACO: 10.2.3.2
- 2760888 2017, name and address, DACO: M2.1
2760889 2017, manufacturing methods and quality assurance, DACO: M2.8 CBI
2760890 2016, conidia concentration of *beauveria bassiana*, DACO: M2.8
2760891 2017, viability assessment of *beauveria bassiana* conidia, DACO: M2.8
2760892 2017, product specifications, DACO: M2.9.1
2760893 2017, potency estimation and product guaranty, DACO: M2.9.2
2760894 2017, unintentional ingredients, DACO: M2.9.3
2760895 2017, active ingredient / MPCA, DACO: M2.10.1
2760896 2017, analysis for microbial contaminants, DACO: M2.10.2
2760897 2017, analysis for other unintentional ingredients, DACO: M2.10.3
- 2760898 2017, acute dermal toxicity, DACO: M4.4
2760899 2017, dermal irritation study, DACO: M4.5.2 CBI

ISSN: 1911-8082

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