

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2022-6684
Application: Changes to Technical Grade Active Ingredient Product Chemistry-
New Source (site) same registrant
Product: BioTitan GR
Registration Number: 33924
Active ingredient (a.i.): *Beauveria bassiana* strain ANT 03
PMRA Document Number: 3499584

Purpose of Application

The purpose of this application was to add three new formulating sites for the end-use product, BioTitan GR.

Product Characterization and Analysis

The data submitted to assess the three new formulating sites are acceptable.

Health, Environmental and Value Assessments

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

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the addition of three new formulating sites for the end-use product, BioTitan GR.

References

PMRA

Document

Number

Reference

3232289	2021, manufacturing method and quality assurance, DACO: M2.8
3232290	2020, manufacturing process of b. bassiana granular, DACO: M2.8 CBI
3232291	2020, manufacturing process of bioceres GR, DACO: M2.8 CBI
3232293	2020, ana-01 germination assessment of beauveria bassiana conidia, DACO: M2.9.2 CBI
3232294	2020, ana-002 conidia concentraion of beauveria bassiana, DACO: M2.9.2 CBI
3232296	2020, ana-008 total bacterial , yeasts and molds count in technical grade of b. bassiana, DACO: M2.10.2 CBI
3243150	2021, potency estimation and product guarantee, DACO: M2.9.2
3243151	2021, analysis of microbial contaminant, DACO: M2.10.2
3299204	2018, blending of boiceres WP, DACO: M2.8 CBI
3299205	2021, certificate of analysis, DACO: M2.8
3299206	2021, analysis of unintentional ingredient, DACO: M2.10.3
3299207	2021, manufacturing of b bassiana granule, DACO: M2.8 CBI
3299208	2021, manufacturing process of bioceres GR, DACO: M2.8 CBI
3299209	2013, analysis of beauvericin in the fungus b. bassiana, DACO: M2.10.3 CBI
3318344	2022, analysis of other unintentional ingredients, DACO: M2.10.3
3347979	2022, analysis for the other unintentional ingredients, DACO: M2.10.3
3347980	2022, limit of beauvericin, DACO: M2.10.3 CBI
3350796	2022, statement method validation, DACO: M2.10.3 CBI
3364301	2022, Conidia concentration of Beauveria bassiana, DACO: M2.9.2 CBI
3364302	2022, Germination assessment of Beauveria bassiana conidia, DACO: M2.9.2 CBI
3364304	2020, Total bacterial, yeasts and molds count in technical grade of Beauveria bassiana, DACO: M2.10.2 CBI
3364306	2022, Limit of beauvericin by LC-MSMS, DACO: M2.10.3 CBI
3400492	2022, Procedure for BioCeres GR manufacturing - AAC/SOP/SSF/Granules/01 V1, DACO: M2.8 CBI
3400493	2022, Potency estimation and product guarantee, DACO: M2.9.2
3400494	2022, Analysis for microbial contaminants, DACO: M2.10.2
3400495	2022, Analysis for other unintentional ingredients, DACO: M2.10.3
3411830	2022, PROCEDURE FOR "BioCeres GR" MANUFACTURING for Multiplex Bio-Tech Pvt Ltd, DACO: M2.8 CBI
3411832	2022, DACO M2.10.2 Analysis for Microbial Contaminants for Multiplex Bio-Tech Pvt Ltd, DACO: M2.10.2 CBI

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