



Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2023-3119
Application: Changes to TGAI (Product Chemistry) - New source (site), same registrant
Applicant: Anatis Bioprotection Inc.
Product: Beauveria bassiana strain ANT-03
Registration Number: 31230
Active ingredient (a.i.): *Beauveria bassiana* strain ANT 03
PMRA Document Number: 3566647

Purpose of Application

The purpose of this application was to register a new manufacturing site for the technical grade active ingredient product, *Beauveria bassiana* strain ANT-03.

Product Characterization and Analysis

The data submitted to assess the new manufacturing site are acceptable. Analysis for the secondary metabolite, beauvericin, will be required for every batch of technical grade active ingredient produced as part of the standard quality control procedures.

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 register the new manufacturing site for *Beauveria bassiana* strain ANT-03.

References

PMRA Document Number	Reference
3479956	2023, DACO M2.10.2 Analysis for Microbial Contaminants, DACO: M2.10.2 CBI
3479957	2023, DACO M2.10.3 Analysis for Other Unintentional Ingredients, DACO: M2.10.3 CBI
3479959	2023, DACO M2.8. Manufacturing methods and quality assurance, DACO: M2.8 CBI
3479960	2023, DACO M2.9.2 Potency estimation and product guarantee, DACO: M2.9.2 CBI
3479961	2023, Results of 5 lots of TGAI of b. bassiana ANT-03 manufactured by BIOFARM , DACO: M2.10.2,M2.9.2 CBI
3507336	2023, SOP Procedure for BioCeres GR Manufacturing, DACO: M2.10.2 CBI
3507337	2023, SOP Procedure for Production and Harvesting of Technical Grade Active Ingredient-TGAI Material, DACO: M2.10.2 CBI

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