

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2022-2656

Application: Changes to Technical Grade Active Ingredient (Product

Chemistry) – New Source (Site) Same Registrant

Product: Beauveria bassiana strain ANT-03

Registration Number: 31230

Active ingredient (a.i.): Beauveria bassiana strain ANT-03

PMRA Document Number: 3439583

Purpose of Application

The purpose of this application was to register a new manufacturing site for Beauveria bassiana strain ANT-03.

Product Characterization and Analysis

The data submitted to assess the new manufacturing site and new manufacturing method is 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 support the addition of the new manufacturing site for Beauveria bassiana strain ANT-03.



References

PMRA Document Number	Reference
3364299	2022, Beauveria bassiana ANT-03 TGAI Production SOP, DACO: M2.8 CBI
3364300	2022, Potency Estimation and Product Guarantee, DACO: M2.9.2
3364301	2022, Conidia Concentration of Beauveria bassiana, DACO: M2.9.2 CBI
3364302	2022, Germination Assessment of <i>Beauveria bassiana</i> Conidia, DACO: M2.9.2 CBI
3364303	2022, Analysis for Microbial Contaminants, DACO: M2.10.2
3364304	2020, Total Bacterial, Yeasts and Molds Count in Technical Grade of <i>Beauveria bassiana</i> , DACO: M2.10.2 CBI
3364305	2022, Analysis for Other Unintentional Ingredients, DACO: M2.10.3
3364306	2022, Limit of Beauvericin by LC-MSMS, DACO: M2.10.3 CBI
3406630	2022, Safer Agrobiólogicos – <i>Beauveria bassiana</i> ANT-03 TGAI Production SOP, DACO: M2.8 CBI

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