

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2021-5100
Application: Changes TGAI 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: 3367945

Purpose of Application

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

Product Characterization and Analysis

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

Food and Feed Residue Analysis

The registrant submitted sufficient data to address the concerns regarding the content of secondary metabolites contained in the TGAI resulting from the new manufacturing site and new manufacturing methods. The data demonstrated that risks to human health are acceptable from the dietary exposure to *Beauveria bassiana* strain ANT-03 when applied to food crops as a microbial pest control agent (MPCA).

Human Health and Safety Testing

There is no change to the toxicological profile of *Beauveria bassiana* strain ANT-03.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and has found it sufficient to support the registration of a new manufacturing site for *Beauveria bassiana* strain ANT-03.

References

PMRA Document Number	References
3270802	2021, DACO M2.8 Manufacturing methods and quality assurance, DACO: M2.8
3270804	2021, Manufacturing process of B. bassiana powder in technical material, DACO: M2.8 CBI
3270805	2020, Manufacturing process of B. bassiana granule, DACO: M2.8 CBI
3270806	2021, DACO M2.9.2 Potency estimation and product guarantee, DACO: M2.9.2
3270807	2020, Germination assessment of Beauveria bassiana conidia, DACO: M2.9.2 CBI
3270809	2021, DACO M2.10.2 Analysis of Microbial Contaminants, DACO: M2.10.2
3270810	2021, Total bacterial, yeasts and molds count in technical grade of Beauveria bassiana, DACO: M2.10.2 CBI
3325771	2022, Analysis for microbial contaminant, DACO: M2.10.2
3325772	2022, Analysis for other unintentional ingredient, DACO: M2.10.3
3325773	2022, Name and address for manufacturing plant, DACO: M2.3
3325774	2022, RDI-2.2.4_V3_ manufacturing process of B. bassiana powder technical, DACO: M2.8 CBI

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