

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2022-5629
Application: Changes to Technical Grade Active ingredient (TGAI) Product Chemistry - New Source (site), same registrant
Product: Beauveria bassiana Technical
Registration Number: 29319
Active ingredient (a.i.): *Beauveria bassiana* strain GHA
PMRA Document Number: 3576154

Purpose of Application

The purpose of this application was to add a new manufacturing site for the product, *Beauveria bassiana* Technical.

Product Characterization and Analysis

Information was provided on a new manufacturing site for the TGAI, *Beauveria bassiana* Technical. The information included details on the manufacturing process at the new site, as well as information on quality control and product specifications. The information database also included representative potency and quality control data for up to five batches of the TGAI.

Sufficient information and data were provided by the applicant to demonstrate that the TGAI manufactured at the new manufacturing site will be equivalent to the existing TGAI.

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* Technical.

References

PMRA Document Number	Reference
3400397	2021, Beauveria bassiana strain GHA Technical: Alternate Production Site Manufacturing Process and Quality Control Procedures, DACO: M2.2, M2.8, M2.9, M2.9.1, M2.9.2, M2.9.3 CBI
3400398	2021, Beauveria bassiana strain GHA Technical: Alternate Production Site Manufacturing Process and Quality Control Procedures Addendum to MRID 514284-01, DACO: M2.2, M2.8, M2.9, M2.9.1, M2.9.2, M2.9.3 CBI
3481033	2023, Deficiency Response Beauveria bassiana strain GHA, TGAI Submission Number: 2022-5629, DACO: M2.10.2, M2.8, M2.9.3 CBI
3526518	2023, Certificate of Analysis for Beauveria bassiana, DACO: M2.10.2 CBI

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