

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2020-5899
Application: Changes to 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 : 3295975

Purpose of Application

The purpose of this application was to add a new alternate manufacturing site and a new manufacturing method for *Beauveria bassiana* strain ANT-03.

Product Characterization and Analysis

The registrant has submitted sufficient data to assess the proposed new manufacturing site and new manufacturing methods. 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.

Health Assessments

The registrant has submitted sufficient data to address the concerns regarding the content of secondary metabolites contained in the TGAI resulting from the proposed 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).

Toxicology and occupational exposure assessments were not required for this application.

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 information provided and has found it sufficient to support the addition of a new manufacturing site and manufacturing method for *Beauveria bassiana* strain ANT-03.

References

| PMRA Document Number | References |
|----------------------------|--|
| 3182334 | 2020, Manufacturing method and quality assurance, DACO: M2.8 |
| 3182335 | 2020, Manufacturing method protocol <i>Beauveria bassiana</i> TGA1 ANT-03, DACO: M2.8 CBI |
| 3182336 | 2020, Potency estimation and production guarantee, DACO: M2.9.2 |
| 3182337 | 2020, Germination assessment of <i>Beauveria bassiana</i> conidia, DACO: M2.9.2 CBI |
| 3182338 | 2020, Conidia concentration of <i>Beauveria bassiana</i> , DACO: M2.9.2 CBI |
| 3182339 | 2020, Analysis of microbial contaminant, DACO: M2.10.2 |
| 3182340 | 2020, Total bacterial, yeasts and molds count in technical grade of <i>B. bassiana</i> , DACO: M2.10.2 CBI |
| 3287918 | 2021, Manufacturing protocol <i>B. bassiana</i> strain ANT-03 revised, DACO: M2.8 CBI |
| 3287919 | 2016, Liquid nitrogen procedure, DACO: M2.8 CBI |
| 3287920 | 2021, Analysis for other unintentional ingredients, DACO: M2.10.3 |
| 3287921 | 2013, Analysis of beauvericin in the fungus <i>B. bassiana</i> ANT-03, DACO: M2.10.3 CBI |
| 2552721 | European Food Safety Authority, 2014, Scientific Opinion on the risks to human and animal health related to the presence of beauvericin and enniatins in food and feed, DACO M7.0. |

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