

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2022-1679

Application: Changes to TGAI Product Chemistry - New Source Same

Registrant

Product: Metarhizium brunneum Strain F52 Technical

Registration Number: 29146

Active ingredient (a.i.): Metarhizium brunneum strain F52

PMRA Document Number: 3444240

Purpose of Application

The purpose of this application was to add a new manufacturing site and change the guarantee to a minimum for the microbial technical product, Metarhizium brunneum Strain F52 Technical.

Product Characterization and Analysis

The information submitted to support a new source of *Metarhizium brunneum* strain F52 and change the guarantee of Metarhizium brunneum Strain F52 Technical from a nominal guarantee to a minimum guarantee is acceptable. Potency and microbial contaminant analysis data on a sufficient number of batches of technical grade active ingredient (TGAI) produced at a newly proposed site of manufacturing were also submitted and found to be acceptable.

The secondary metabolites cytochloasins, destruxins and swainsonine were associated with *M. anisopliae* and were assessed at the time of original registration. No additional secondary metabolites were found to be associated with *M. brunneum* or are expected as a result of the minor changes to the manufacturing methods used at the new site.

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 add a new manufacturing site and change the guarantee to a minimum for Metarhizium brunneum Strain F52 Technical.

References

PMRA Reference

Document



3393464 2022, QC-LPS-38 Determination of Molds for Patos, DACO: M2.10.2 3393465 2022, QC-LPC-47 Determination of Viability for Patos, DACO: M2.10.2 2022, QC-LPC-41 Enumeration of Metarhizium brunneum strain F52 for Wismar, 3393466 DACO: M2.10.2 3393467 2022, QC-LPC-80 Enumeration of non-target fungi in Metarhizium products for Wismar, DACO: M2.10.2 3427710 2023, QC-LPC-82-PAT Determination of bacteria content in products based on Metarhizium, DACO: M2.10.2 3427712 2023, QC-LPC-80-1 - Determination of bacterial contaminants in Metarhizium products (Wismar), DACO: M2.10.2 2023, QC-LPC-80-2 - Determination of non-target fungi in Metarhizium products 3427713 (Wismar), DACO: M2.10.2 2022, Product Chemistry for Metarhizium brunneum Strain F52 Technical, 3345019 DACO: M2.9.2

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