



Evaluation Report for Category B, Subcategory 1.1, 2.1, 2.3 Application

Application Number: 2022-1680
Application: Changes to EP Product Chemistry - New Source Same Registrant, Guarantee and Identity of Formulants
Product: LALGUARD M52 OD
Registration Number: 30829
Active ingredient (a.i.): *Metarhizium brunneum* strain F52
PMRA Document Number: 3444248

Purpose of Application

The purpose of this application was to amend the microbial end-use product, LALGUARD M52 OD, to add an additional formulating site, to change the guarantee to a minimum, to amend the formulation and change the format of disclosing the active ingredient on the label.

Product Characterization and Analysis

The information submitted to support an alternate formulating site for LALGUARD M52 OD, to change the guarantee from a nominal guarantee to a minimum guarantee and amend the formulation is acceptable. Potency and microbial contaminant analysis data on a sufficient number of batches of end-use product (EP) produced at a newly proposed site of formulating 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 and Environmental Assessments

Health, environmental and value assessments were not required for this application.

Value Assessment

There is no issue with the change to how the guarantee appears on the label, as the amount of active ingredient in the end-use product remains the same.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information acceptable to add an additional formulating site, to change the guarantee to a minimum, to amend the formulation and change the format of disclosing the active ingredient on LALGUARD M52 OD.

References

PMRA Document Number	Reference
3345032	2022, <i>Metarhizium brunneum</i> F52 / Enumeration Procedure, DACO: M2.10.1
3345030	2022, MANUFACTURING PROCESS AND QUALITY CONTROL <i>Metarhizium brunneum</i> (also known as <i>Metarhizium anisopliae</i>) F52, DACO: M2.8
3345031	2022, Certificates of Analysis for 5 batches, DACO: M2.9.2, M2.9.3

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