

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.13 Application

Application Number: 2023-7287
Application: Changes to End-Use Product Chemistry – Guarantee, Identity of Formulants, Proportion of Formulants
Changes to Product Labels - Precautions
Applicant: Danstar Ferment AG
Product: LALGUARD M52 GR
Registration Number: 29147
Active ingredient (a.i.): *Metarhizium brunneum* strain F52
PMRA Document Number: 3660986

Purpose of Application

The purpose of this application was to correct the guarantee, amend the formulation, and amend the storage stability and expiration date statements on the label of LALGUARD M52 GR.

Product Characterization and Analysis

The data and information, including manufacturing process and microbial contamination analysis batch data, submitted to support the correction of the guarantee of the product, amend the formulation, and amend the storage stability and expiration date statements were acceptable.

Health and Environmental Assessments

Health and environmental assessments were not required for this application.

Value Assessment

The new formulation of LALGUARD M52 GR is expected to perform similarly to the original formulation in terms of efficacy and crop tolerance. The change in guarantee to a minimum 9 x 10⁸ CFU/g was supported as the amount of active ingredient being applied remains the same.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the correction to the guarantee, amend the formulation, and amend the storage stability and expiration date statements on the label of LALGUARD M52 GR.

References

PMRA Document Number	Reference
3538589	2023, Updated Manufacturing Process and Quality Control, DACO: M2.8 CBI
3647872	2024, Lallemand Biologicals GmbH E 2024100257-61, DACO: M2.10.2 CBI

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