

Evaluation Report for Category B, Subcategory 2.4 Application

Application Number: 2021-3416
Application: Changes EP Chemistry – Proportion of Formulants
Product: SERENADE ASO
Registration Number: 28628
Active ingredient (a.i.): *Bacillus subtilis* (strain QST 713)
PMRA Document Number: 3333094

Purpose of Application

The purpose of this application was to add an alternate formulation and to make minor amendments to the formulation process for SERENADE ASO.

Product Characterization and Analysis

Sufficient batch analysis data for potency estimation, microbial contamination, storage stability, and physical and chemical properties were submitted to support the registration of a minor amendment to the formulation process and an alternate formulation for SERENADE ASO.

Health Assessments

SERENADE ASO produced using the amended formulation process and the alternate formulation are considered to be biologically equivalent to the existing registered end-use product. As the human health and safety database for the active ingredient, *Bacillus subtilis* strain QST 713, and SERENADE ASO is considered complete, no additional information is required.

Environmental Assessment

SERENADE ASO produced using the amended formulation process and the alternate formulation are considered to be biologically equivalent to the existing registered end-use product. As the environmental toxicology database for the active ingredient, *Bacillus subtilis* strain QST 713, and SERENADE ASO is considered complete, no additional information is required.

Value Assessment

Based on the available information, the formulation differences between the alternate formulation and the registered formulation of SERENADE ASO are unlikely to result in differences in product performance. Therefore, the registration of an alternate formulation is supported from a value perspective.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and has found it sufficient to support the addition of an alternate formulation and minor amendments to the formulation process for SERENADE ASO.

References

PMRA Document Number	References
3319093	2020, Manufacturing process for Serenade ASO for Canada, DACO: M2.8 CBI
3319094	2020, Material accountability study - 5 batch analysis of Serenade ASO, DACO: M2.9.2 CBI
3319092	2020, Serenade ASO: Accelerated storage stability, DACO: M2.11 CBI

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