

Evaluation Report for Category B, Subcategory 2.5 Application

Application Number: 2023-0472
Application: Changes End-use Product: Product Chemistry - Formulation Type
Product: MINUET
Registration Number: 33651
Active ingredient (a.i.): *Bacillus subtilis* (strain QST 713)
PMRA Document Number: 3495290

Purpose of Application

The purpose of this application was to change the formulating process for the registered end-use product MINUET.

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 for MINUET.

Health Assessments

MINUET produced using the amended formulation process is 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 MINUET is considered complete, no additional information is required.

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

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

A value assessment was 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 support the change in the formulating process of MINUET.

References

PMRA Document Number	Reference
3495033	2023, 33651- Trade Name -31Jan2023, DACO: M2.4 CBI
3432819	2018, Manufacturing process overview for QST 713 FS end use product for USA, DACO: M2.8 CBI

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