

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number: 2020-1211
Application: New TGAI - New Source (site) same registrant; Specifications
Product: QST 713 Technical 1
Registration Number: 33990
Active ingredient (a.i.): *Bacillus subtilis* (strain QST 713)
PMRA Document Number : 3167286

Purpose of Application

The purpose of this application is to register QST 713 Technical 1 as the new technical grade active ingredient (TGAI) for *Bacillus subtilis* (strain QST 713), based on a precedent product.

Product Characterization and Analysis

The manufacturing process for QST 713 Technical 1 was adequately described and sufficient batch analysis data for microbial contamination and potency estimation were submitted to support its registration. All batches of TGAI must conform to the limits outlined in the OECD Issue Paper on Microbial Contaminants for Microbial Pest Control Products [ENV/JM/MONO(2011)43].

Value, Health and Environmental Assessments

Value, health and environmental 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 sufficient to register QST 713 Technical 1.

References

PMRA Document Number	Reference
3106626	2004, Methods for determination of aerobic colony forming units utilizing spiral plater, DACO: M2.10.1 CBI
3106627	2014, Method for determination of aerobic colony forming units per gram of fermentation product, DACO: M2.10.1 CBI
3106631	2020, Manufacturing process overview for <i>Bacillus subtilis</i> QST 713 whole broth (syn. QST 713 Technical 1) for Canada, DACO: M2.8 CBI

**PMRA Document Reference
Number**

3106632

2020, Analysis of *Bacillus subtilis* QST 713 whole broth (syn. QST 713 Technical 1) batches, DACO: M2.10.1, M2.10.2, M2.9.2 CBI

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