

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number: 2020-5776
Application: Changes to Technical Grade Active Ingredient - New Source (site) same registrant; Specifications
Product: Bacillus subtilis strain BU1814 Technical
Registration Number: 33254
Active ingredient (a.i.): *Bacillus subtilis* strain BU 1814
PMRA Document Number: 3238692

Purpose of Application

The purpose of this application was to add a new manufacturing site for the technical grade active ingredient product, Bacillus subtilis strain BU1814 Technical, and to revise its storage stability.

Product Characterization and Analysis

The information and data provided in support of the new source of Bacillus subtilis strain BU1814 Technical were reviewed and found to be acceptable.

Data were provided from an acceptable number of batches to support the product specifications of a minimum of 5.0×10^{10} viable spores/g. All batches of Bacillus subtilis strain BU1814 Technical conform to the limits set out in the Organisation for Economic Co-operation and Development (OECD) issue paper on microbial contaminants for microbial pest control products [ENV/JM/MONO(2011)43].

Data supports stability of Bacillus subtilis strain BU1814 Technical for 12 months at 20°C to 25°C.

Health, Environmental and Value Assessments

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

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and has found it sufficient to support the new manufacturing site and to update the storage stability for Bacillus subtilis strain BU1814 Technical.

References

PMRA

Document

Number	Reference
3178870	2020, Product Characterization Table Bacillus subtilis BU1814 Technical Grade, DACO: M2.1,M2.2,M2.4,M2.5,M2.6 CBI
3178871	2017, Bacillus subtilis Strain BU1814 Technical Group A - Product Identity, Composition and Analysis, DACO: M2.10.1,M2.10.3,M2.7.1,M2.7.2,M2.8,M2.9.1,M2.9.2,M2.9.3 CBI
3178872	2020, Bacillus subtilis Strain BU1814 Technical Product Identity, Composition and Analysis - Attestation for second source, DACO: M2.10.1,M2.10.3,M2.7.1,M2.7.2,M2.8,M2.9.1,M2.9.2,M2.9.3 CBI
3178873	2017, 5-Batch Analysis Enumeration of Active Ingredient and Microbial impurities profile of BAS 100 U, DACO: M2.10.2,M2.9.2 CBI
3178874	2017, Storage Stability on BAS 100 U, DACO: M2.11 CBI
3208678	2021, Response to Request for Clarification on Submission No. 2020-5776, part M2.8, DACO: M2.8 CBI
3208680	2021, Response to Request for Clarification on Submission No. 2020-5776, Part 2.10.1, DACO: M2.10.1 CBI
3208681	2021, Response to Request for Clarification on Submission No. 2020-5776, Part M 2.11, DACO: M2.11 CBI
3208682	2021, Response to Request for Clarification on Submission No. 2020-5776, DACO: M2.9.2 CBI
3208683	2016, Stability to Elevated Temperatures According to OPPTS 830.6313 on BAS 100 U, DACO: M2.11 CBI
3208684	2021, 5-Batch Analysis Enumeration of Active Ingredient and Microbial impurities profile of BAS 100 U Replacement Certificates, DACO: M2.9.2 CBI

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