

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2015-6043
Application: Changes to technical grade active ingredient product chemistry-Specifications
Product: *Bacillus amyloliquefaciens* Strain MBI 600 Technical
Registration Number: 29452
Active ingredients (a.i.): *Bacillus amyloliquefaciens* strain MBI 600
PMRA Document Number: 2697962

Background

The technical grade active ingredient product, *Bacillus subtilis* Strain MBI 600 Technical (Registration Number 29452), was first registered for use in Canada in 2010.

Purpose of Application

The purpose of this application was to change the microbial pest control agent (MPCA) for the technical grade active ingredient, *Bacillus amyloliquefaciens* Strain MBI 600 Technical (previously known as *Bacillus subtilis* Strain MBI 600 Technical). In addition, a new manufacturing site was requested for the technical.

Product Characterization and Analysis

Data and information were submitted to change the species of the MPCA from *Bacillus subtilis* strain MBI 600 to *Bacillus amyloliquefaciens* strain MBI 600 and to support a new manufacturing site. The data and information supported the change in the taxonomic designation of the MPCA and confirmed that new manufacturing site maintained acceptable quality control standards. No additional information or data are required to complete the product characterization and analysis database for *Bacillus amyloliquefaciens* Strain MBI 600 Technical.

Health, Environmental and Value Assessments

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

Conclusion

The PMRA has completed a review of all available information in support of *Bacillus amyloliquefaciens* Strain MBI 600 Technical and found it sufficient to approve the change in the taxonomic designation of the MPCA as well as the new manufacturing site.

References

PMRA Document Number	Reference
2581436	2012, Biochemical, Morphological and Molecular Characterization of <i>Bacillus amyloliquefaciens</i> subsp. plantarum Strain MBI600, DACO: M2.7.1
2581437	2012, Genetic Characterization of Strain MBI600, DACO: M2.7.1
2581445	2015, Hypersensitivity Incidence with <i>Bacillus amyloliquefaciens</i> Strain MBI600, DACO: M4.6
2637563	2016, Confirmation of the Completion of Genome Sequencing of <i>Bacillus amyloliquefaciens</i> Strain MBI600, DACO: M2.7.1 CBI
2684944	2016, Routine Quality Control Analysis of <i>Bacillus amyloliquefaciens</i> strain MBI600 in Technical Grade Material, DACO: M2.9.2 CBI
2684945	2016, <i>Bacillus amyloliquefaciens</i> strain MBI 600 Technical Group A Product Analysis, DACO: M2.10.2, M2.8, M2.9.2 CBI

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