Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2021-5642
Application: Changes TGAI Product Chemistry-Specifications
Product: Bacillus amyloliquefaciens strain MBI 600 Technical
Registration Number: 29452
Active ingredient (a.i.): *Bacillus amyloliquefaciens* strain MBI 600
PMRA Document Number: 33811331

Purpose of Application

The purpose of this application was to add an alternative post-production processing site for the manufacture of the registered microbial technical product Bacillus amyloliquefaciens strain MBI 600 Technical (Reg. No. 29452).

Chemistry Assessment

The alternative manufacturing site for Bacillus amyloliquefaciens strain MBI 600 Technical is acceptable. There are no changes to the manufacturing or quality assurance processes. Potency, microbial contaminant analysis and physical and chemical properties data submitted on five batches of Bacillus amyloliquefaciens strain MBI 600 Technical manufactured at this new site demonstrate that it is capable of producing technical –grade product that meets the established release standards.

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 information provided, and has found it sufficient to support the alternative post-production processing site for the manufacture of Bacillus amyloliquefaciens strain MBI 600 Technical.

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References

PMRA Document Number	Reference
3272016	2021, Product Characterization Table - Registered pesticides containing *Bacillus amyloliquefaciens*, Strain MBI 600 Technical, DACO: M2.2, M2.3, M2.4, M2.5, M2.6 CBI
3272030	2021, Analysis from 5 batches, DACO: M2.9.2,M2.9.3 CBI
3338785	2022, Company Split with [CBI removed], DACO: M2.2 CBI
3338786	2020, Re: Certificate of Manufacture, DACO: M2.2 CBI
3338787	2022, Name and address of manufacturing plant *Bacillus amyloliquefaciens*, Strain MBI 600 Technical, DACO: M2.2 CBI
3338788	2022, Analysis for Microbial Contaminants *Bacillus amyloliquefaciens*, Strain MBI 600 Technical, DACO: M2.10.2 CBI

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