

Evaluation Report for Category B, Subcategory 4.6 Application

Application Number: 2016-5034

Application: Submission to fulfill conditions of registration on a product with full registration

Product: *Bacillus subtilis* GB03 Technical Fungicide

Registration Number: 30937

Active ingredients (a.i.): *Bacillus subtilis* strain GB03

PMRA Document Number: 2705086

Purpose of Application

The purpose of this application was to fulfill the conditions of full registration for *Bacillus subtilis* GB03 Technical Fungicide.

Chemistry Assessment

Additional quality control information and data were submitted to address outstanding conditions that were identified in a previous review. The described method for enumerating *Salmonella* spp. and the established limit on *Salmonella* spp. in the technical grade active ingredient, *Bacillus subtilis* GB03 Technical Fungicide, are adequate to ensure safety from this group of microorganisms and should also limit the potential for contamination in formulated end-use products. No additional information or data are required to complete the Product Characterization and Analysis database for *Bacillus subtilis* GB03 Technical Fungicide.

Health, Environmental and Value Assessments

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

Conclusion

The PMRA has conducted a review of the submitted information and has concluded that the conditions of full registration have been fulfilled.

References

- 2675107 2016, Analysis for microbial contaminants - Final report - Biological method and validation - *Bacillus subtilis* GB03 TC, DACO: M2.10.2 CBI
- 2675108 2016, Unintentional ingredients data for 3 batches of TGAI - Final report - Biological method and validation - *Bacillus subtilis* GB03 TC, DACO: M2.9.3 CBI

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