

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2018-1715
Application: B.1.1: New Source Same Registrant
Product: Bioprotec Technical Powder
Registration Number: 32424
Active ingredients (a.i.): *Bacillus thuringiensis* ssp. *kurstaki* strain EVB-113-19
PMRA Document Number : 2914099

Purpose of Application

The purpose of this application was to register a new source of the Technical Grade Active Ingredient (TGAI) Bioprotec Technical Powder. The product contains the active ingredient *Bacillus thuringiensis* ssp. *kurstaki* strain EVB-113-19.

Chemistry Assessment

The information submitted for the Product Characterization and Analysis fully satisfies the requirements in support of a new source of the TGAI, Bioprotec Technical Powder.

The MPCA is the same isolate as in Bioprotec Technical Powder (PCP Regn. No. 32424). The manufacturing processes, including the Quality Assurance program was described in adequate detail and confirmed to be the same procedures that are followed at the original manufacturing site.

The representative screening data from five batches of Bioprotec Technical Powder manufactured support the QA/QC program and demonstrates that the TGAI is free from contamination. The representative potency data also supports the guarantee of the TGAI.

Health, Environmental and Value Assessment

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

Conclusion

PMRA has reviewed the information provided to support the new source of Bioprotec Technical Powder. Based on the results of this review, the new source of Bioprotec Technical Powder is acceptable for registration.

References

1698736 Technical Chemistry BTB-AGA-1 Origin, Derivation and Identification of MPCA, DACO: M2.10.1 CBI

- 1698820 1998, Technical Chemistry BTB-AGA-1 Appendix Report on cry gene analyses using *Bacillus thuringiensis* colonies by polymerase chain reaction, DACO: M2.10.1 CBI
- 1698930 Technical Chemistry BTB-AGA-1 Analysis for Microbial Contaminants, DACO: M2.10.2 CBI
- 1698937 Technical Chemistry BTB-AGA-1 Method for Detection and Enumeration of Total Coliforms, DACO: M2.10.2 CBI
- 1698939 Technical Chemistry BTB-AGA-1 Method for Detection and Enumeration of Faecal Coliforms, DACO: M2.10.2 CBI
- 1698941 Technical Chemistry BTB-AGA-1 Method for Detection and Enumeration of Faecal Streptococci, DACO: M2.10.2 CBI
- 1698942 Technical Chemistry BTB-AGA-1 Method for Detection and Enumeration of *Pseudomonas aeruginosa*, DACO: M2.10.2 CBI
- 1698943 Technical Chemistry BTB-AGA-1 Method for Detection and Enumeration of *Staphylococcus aureus*, DACO: M2.10.2 CBI

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