



## Evaluation Report for Category B, Subcategory 1.1 Application

**Application Number:** 2017-7849  
**Application:** New / Changes TGAI Product Chemistry - New Source (Site) / Same Registrant  
**Product:** Bioprotec Technical Powder  
**Registration Number:** 32424  
**Active ingredient (a.i.):** *Bacillus thuringiensis* ssp. *kurstaki* strain EVB-113-19  
**PMRA Document Number:** 2860669

### Purpose of Application

The purpose of this application was to add a new, alternate manufacturing site (source) for the technical grade active ingredient (TGAI) Bioprotec Technical Powder.

### Product Characterization and Analysis

Information and data were provided on the manufacturing and quality control of Bioprotec Technical Powder (TGAI) at the new manufacturing site. The described manufacturing and quality control processes, and representative batch data were adequate to demonstrate that the TGAI manufactured at the new location is equivalent to the previously registered source. No additional information or data are required to complete the product characterization and analysis database for Bioprotec Technical Powder.

### Health, Value and Environmental Assessments

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

### Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of a new manufacturing site for the TGAI Bioprotec Technical Powder.

## References

<b>PMRA Document Number</b>	<b>Title</b>
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 <i>Bacillus thuringiensis</i> 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 <i>Pseudomonas aeruginosa</i> , DACO: M2.10.2 CBI
1698943	Technical Chemistry BTB-AGA-1 Method for Detection and Enumeration of <i>Staphylococcus aureus</i> , DACO: M2.10.2 CBI
1698945	Technical Chemistry BTB-AGA-1 Method for Detection and Enumeration of Yeasts and Fungi, DACO: M2.10.2 CBI
1698946	Technical Chemistry BTB-AGA-1 Method for Detection of Salmonella, DACO: M2.10.2 CBI
2583119	2015, Manufacturing process M8.1-3, DACO: M2.8 CBI
2583122	2015, Unintentional ingredients, DACO: M2.9.3 CBI
2624712	2016, Unintentional Ingredient, DACO: M2.9.3 CBI
2624713	2016, Unintentional Ingredient, DACO: M2.9.3 CBI
2833696	2017, Manufacturing process and quality control, DACO: M2.8 CBI
2833697	2017, Results of the mouse toxicity test, DACO: M2.8 CBI
2833698	2017, Results of microbial contaminants analysis, DACO: M2.8 CBI
2833699	2017, Product specifications, DACO: M2.9.1 CBI
2833700	2017, Potency estimation and product guarantee, DACO: M2.9.2 CBI
2833701	2017, Unintentional ingredients, DACO: M2.9.3 CBI
2833705	2017, Analytical methodology MPCA, DACO: M2.10.1 CBI
2833710	2017, Analysis for microbial contaminants, DACO: M2.10.2 CBI
2833713	2017, Unintentional ingredients, DACO: M2.10.3 CBI

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