

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2013-1819
Application: B.1.1 (Product chemistry - new source (site) same registrant)
Product: DiPel Technical Powder
Registration Number: 19316
Active ingredients (a.i.): *Bacillus thuringiensis* subsp. *kurstaki*, strain ABTS-351 (BTB)
PMRA Document Number: 2318268

Background

DiPel Technical Powder is currently registered in Canada for use in nine end-use products for controlling lepidopterans in forests and other wooded areas, tree nurseries, agricultural crops, horticultural crops, and ornamentals.

Purpose of Application

The purpose of this application was to add a new manufacturing site by the same registrant for the technical grade active ingredient DiPel Technical Powder.

Chemistry Assessment

The manufacturing process for Dipel Technical Powder at the new site has not changed from the currently registered site of manufacture. The product characterization and analysis database is largely complete. The applicant was requested to submit confirmatory microbial contamination analysis results on five batches of Dipel Technical Powder along with the test methods and protocols.

Health, Environmental and Value Assessments

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

Conclusion

The PMRA has completed an assessment of the available information and is able to support the addition of a new manufacturing site for the technical grade active ingredient DiPel Technical Powder.

References

PMRA No.	Reference
2286300	2005, Method of Production and Quality Control for DiPel/Foray Products (<i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i>), DACO: M2.8 CBI

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