

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2011-2011
Application: B.1.1 (Product chemistry - new source(site), same registrant)
Product: Bioprotec ECO
Registration Number: 27251
Active ingredients (a.i.): *Bacillus thuringiensis* subsp. *kurstaki* strain HD-1 (BTB)
PMRA Document Number English PDF: 2084544

Background

Bioprotec ECO (Registration Number 27251) is a domestic class end-use product containing *Bacillus thuringiensis* subsp. *kurstaki* strain HD-1 as its active ingredient. Bioprotec ECO is registered for the control of caterpillars on vegetables, fruits, shade trees, ornamentals, and evergreens.

Purpose of Application

The purpose of the application was to add a new formulation site for Bioprotec ECO.

Chemistry Assessment

The registrant has confirmed that the manufacturing methods, quality assurance program, and product specifications have not changed from those used at the current formulation site.

As a result of the *Bacillus thuringiensis* (Bt) re-evaluation, product guarantees for Bt-based products can no longer reference an international unit. The registrant has opted to express the guarantee as % dry weight of the spore-toxin complex. The guarantees for the five batches of Bioprotec ECO were determined and ranged from 8.01–8.40% dry weight of the spore-toxin complex. This is considered to be equivalent to the previous guarantee of 11400 international units (IU)/mg.

The methods for microbial contaminant analysis remain the same. The results of microbial contaminant analysis for five batches of Bioprotec ECO were submitted and found to be acceptable.

Health, Environmental and Value Assessments

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

Conclusion

The registrant has provided adequate information to support the addition of a new formulation site for Bioprotec ECO.

It should be noted, however, that the review of this application did not take into consideration the requirements of the Bt re-evaluation (e.g., label statements, company-specific strain designation, guarantee expression etc.). The registrant has submitted a separate application to address these requirements.

References

PMRA No.	Reference
2052014	2011, active ingredient, DACO: M2.10.1 CBI
2052015	2011, microbial contaminants, DACO: M2.10.2 CBI
2052016	2011, microbial contaminants, DACO: M2.10.2 CBI
2052017	2011, Manufacturing process and quality assurance, DACO: M2.8 CBI
2052018	2011, Manufacturing process and quality assurance, DACO: M2.8 CBI
2052019	2011, Potency estimation, DACO: M2.9.2 CBI
2052020	2011, Potency estimation, DACO: M2.9.2 CBI
2052021	2011, Potency estimation, DACO: M2.9.2 CBI
2052022	2011, Potency estimation, DACO: M2.9.2 CBI
2052023	2011, Unintentional ingredients, DACO: M2.9.3 CBI
2052024	2011, Unintentional ingredients, DACO: M2.10.3 CBI
2052025	2011, Manufacturing process and quality assurance, DACO: M2.8 CBI
2052026	2011, Manufacturing process and quality assurance, DACO: M2.8 CBI

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