

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2011-2006
Application: B.1.1 (Product chemistry - new source(site), same registrant)
Product: Bioprotec CAF Aqueous Biological Insecticide
Registration Number: 26854
Active ingredients (a.i.): *Bacillus thuringiensis* subsp. *kurstaki* strain HD-1 (BTB)
PMRA Document Number English PDF: 2085412

Background

Bioprotec CAF Aqueous Biological Insecticide (Registration Number 26854) is a commercial class end-use product containing *Bacillus thuringiensis* subsp. *kurstaki* strain HD-1 as its active ingredient. Bioprotec CAF Aqueous Biological Insecticide is registered for use on agricultural and greenhouse crops, forests, woodlands, ornamentals, residential and other treed areas.

Purpose of Application

The purpose of the application was to add a new formulation site for Bioprotec CAF Aqueous Biological Insecticide.

Characterization

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 CAF Aqueous Biological Insecticide 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 CAF Aqueous Biological Insecticide 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 CAF Aqueous Biological Insecticide.

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

Document

Number	Reference
2051916	2011, active ingredient, DACO: M2.10.1 CBI
2051918	2011, microbial contaminants, DACO: M2.10.2 CBI
2051919	2011, microbial contaminants, DACO: M2.10.2 CBI
2051920	2011, Manufacturing process and quality assurance, DACO: M2.8 CBI
2051922	2011, Manufacturing process and quality assurance, DACO: M2.8 CBI
2051923	2011, Potency estimation, DACO: M2.9.2 CBI
2051924	2011, Potency estimation, DACO: M2.9.2 CBI
2051925	2011, Potency estimation, DACO: M2.9.2 CBI
2051926	2011, Potency estimation, DACO: M2.9.2 CBI
2051927	2011, Unintentional ingredients, DACO: M2.9.3 CBI
2051929	2011, Unintentional ingredients, DACO: M2.10.3 CBI
2051930	2011, Manufacturing process and quality assurance, DACO: M2.8 CBI
2051931	2011, Manufacturing process and quality assurance, DACO: M2.8 CBI

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