

## Evaluation Report for Category B, Subcategory 1.1 Application

**Application Number:** 2011-2008  
**Application:** B.1.1 (Product chemistry - new source(site), same registrant)  
**Product:** Bioprotec HP  
**Registration Number:** 27099  
**Active ingredients (a.i.):** *Bacillus thuringiensis* subsp. *kurstaki* strain HD-1 (BTB)  
**PMRA Document Number English PDF:** 2084539

### Background

Bioprotec HP (Registration Number 27099) is a restricted class end-use product containing *Bacillus thuringiensis* subsp. *kurstaki* strain HD-1 as its active ingredient. Bioprotec HP is registered to control lepidopteran larvae in forests and woodlands.

### Purpose of Application

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

### 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 HP were determined and ranged from 21.49–23.05% dry weight of the spore-toxin complex. This is considered to be equivalent to the previous guarantee of 17500 international units (IU)/mg.

The methods for microbial contaminant analysis remain the same. The results of microbial contaminant analysis for five batches of Bioprotec HP 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 HP.

It should be noted, however, that the review of this submission 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

2051966	2011, active ingredient, DACO: M2.10.1 CBI
2051967	2011, microbial contaminants, DACO: M2.10.2 CBI
2051968	2011, microbial contaminants, DACO: M2.10.2 CBI
2051969	2011, Manufacturing process and quality assurance, DACO: M2.8 CBI
2051970	2011, Manufacturing process and quality assurance, DACO: M2.8 CBI
2051972	2011, Potency estimation, DACO: M2.9.2 CBI
2051975	2011, Potency estimation, DACO: M2.9.2 CBI
2051976	2011, Potency estimation, DACO: M2.9.2 CBI
2051978	2011, Potency estimation, DACO: M2.9.2 CBI
2051979	2011, Unintentional ingredients, DACO: M2.9.3 CBI
2051980	2011, Unintentional ingredients, DACO: M2.10.3 CBI
2051981	2011, Manufacturing process and quality assurance, DACO: M2.8 CBI
2051982	2011, Manufacturing process and quality assurance, DACO: M2.8 CBI

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