

## Evaluation Report for Category B, Subcategory 2.1 and 4.6 Application

**Application Number:** 2010-1042  
**Application:** Submission to fulfill a condition of registration on a product with full registration – Change in product chemistry guarantee  
**Product:** Bioprotec 3P Dry Flowable Biological Insecticide  
**Registration Number:** 27750  
**Active ingredients (a.i.):** *Bacillus thuringiensis* subsp. *kurstaki* strain EVB113-19  
**PMRA Document Number :** 2090577

### Background

Bioprotec 3P Dry Flowable Biological Insecticide (Registration Number 27750) is a commercial class end-use product containing *Bacillus thuringiensis* (Bt) subsp. *kurstaki* strain EVB113-19 as its active ingredient. Bioprotec 3P Dry Flowable Biological Insecticide is registered for the control of lepidopteran larvae on a variety of food crops and ornamentals in both outdoor fields and greenhouses.

### Purpose of Application

The purpose of this application was to amend the Bioprotec 3P Dry Flowable Biological Insecticide label as per the requirements outlined in PACR2006-09: *Re-evaluation of Bacillus thuringiensis*, RVD2008-18: *Bacillus thuringiensis* and REV2010-06: *Update of Re-evaluation of Bacillus thuringiensis*.

Re-evaluation Note REV2010-06 states that until a recognized global potency standard for *Bacillus thuringiensis* subspecies *kurstaki* insecticides is established, the guarantee sections of the product labels must not imply a standardized or international potency unit (e.g. billion international units). Instead, the guarantee sections of the product labels must specify a company-specific strain (or other appropriate) designation of *B. thuringiensis* for the active ingredient. Under the current submission the applicant has changed the expression of the guarantee on the label from a potency unit (IU, BIU) to a percent dry weight.

### Chemistry Assessment

As a result of the Bt re-evaluation, registrants were required to provide a company-specific strain designation of Bt for the active ingredient. The active ingredient in Bioprotec 3P Dry Flowable Biological Insecticide has been re-designated as *B. thuringiensis* subsp. *kurstaki* strain EVG113-19.

Furthermore, product guarantees for Bt-based products can no longer reference an international unit. The registrant has opted to express the guarantee as a minimum of 21.70% dry weight. This is considered to be equivalent to the previous guarantee of 25000 international units (IU)/mg. The guarantees for five batches of Bioprotec 3P Dry Flowable Biological Insecticide were submitted and found to be acceptable.

### **Health and Environmental Assessments**

Health and environmental assessments were not required for this application.

### **Value Assessment**

The change in the expression of guarantee to a % w/w for Bioprotec 3P Dry Flowable Biological Insecticide is supported from a value and sustainability perspective since no changes were made to the product potency, formulation or directions for use.

### **Conclusion**

The information and data submitted in support of this submission to fulfill the requirements identified by the Bt re-evaluation for Bioprotec 3P Dry Flowable Biological Insecticide has been reviewed and found to be adequate.

### **References**

PMRA Document Number	Reference
2014238	2011, SOP, DACO: 2.13.1 CBI
2025505	2011, 3P Batch Data, DACO: 2.13.3 CBI

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