

Evaluation Report for Category B, Subcategory 2.1 and 4.6 Application

Application Number: 2010-1043
Application: Submission to fulfill a condition of registration on a product with full registration – Change in product chemistry guarantee
Product: Bioprotec HP
Registration Number: 27099
Active ingredients (a.i.): *Bacillus thuringiensis* subsp. *kurstaki* strain EVB113-19
PMRA Document Number : 2090626

Background

Bioprotec HP (Registration Number 27099) is a restricted class end-use product containing *Bacillus thuringiensis* (Bt) subsp. *kurstaki* strain EVB113-19 as its active ingredient. Bioprotec HP is registered for the control of lepidopteran larvae in forests and woodlands.

Purpose of Application

The purpose of this submission is to amend the Bioprotec HP 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 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 HP 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 17.88% dry weight. This is considered to be equivalent to the previous guarantee of 17500 international units (IU)/mg. The guarantees for five batches of Bioprotec HP 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 HP 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 HP has been reviewed and found to be adequate.

References

PMRA Document Number	Reference
2014320	2011, SOP, DACO: 2.13.1 CBI
2029871	2011, HP % Spores-Toxins, DACO: 2.13.3 CBI

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