

Evaluation Report for Category B, Subcategory B.4.1 Application

Application Number: 2007-7123
Application: B.4.1 (Conversion to full registration without consultation)
Product: Bioprotec HP
Registration Number: 27099
Active ingredients (a.i.): *Bacillus thuringiensis* subsp. *kurstaki*, strain HD-1 (BTB)
PMRA Document Number: 1573588

Purpose of Application

Bioprotec HP Aqueous Biological Insecticide, containing the active ingredient *Bacillus thuringiensis* subsp. *kurstaki* strain HD-1, was granted conditional registration in 2002. Additional information related to potency estimation and product guarantee, and storage stability data were required for conversion to full registration.

Chemistry Assessment

The registrant submitted potency data for five batches of Bioprotec HP Aqueous Biological Insecticide and has confirmed that the formulation ingredients are used to adjust the potency to meet the label guarantee of 17,500 IU/mg ($\pm 20\%$).

Storage stability data were also submitted. Three batches of Bioprotec HP Aqueous Biological Insecticide were stored at various temperatures (4–35°C) for various time periods (0–12 months). Bioprotec HP Aqueous Biological Insecticide maintained an acceptable level of potency after 12 months of storage at 4°C and at 15°C. Storage at 25°C for up to 6 months also maintained an acceptable level of potency.

Health Assessments

A health assessment was not required for this application.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

An efficacy evaluation was not required for this application.

Conclusion

The registrant has adequately addressed the requirements for conversion to full registration. Therefore, the PMRA can support this application provided that the Statement of Product Specifications Form (SPSF) is corrected to reflect the nominal guarantee.

References

PMRA Document Number	Reference
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1478218	2007, Potency estimation and product guarantee (required information), AMEN07HP-07, MRID: na, DACO: M2.9.2 CBI
1478219	2007, Storage stability testing (required information), AMEN07HP-08, MRID: na, DACO: M2.11 CBI

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