

Evaluation Report for Category B, Subcategory 3.9, 3.12 Application

Application Number: 2019-6004
Application: Changes to Product Labels-New Site / Host and Level of Control
Product: Helicovex
Registration Number: 33169
Active ingredients (a.i.): *Helicoverpa armigera* Nucleopolyhedrovirus strain BV-0003
PMRA Document Number: 3078121

Purpose of Application

The purpose of this application was to amend the label of Helicovex to add use on field corn, seed corn, popcorn, and hemp and cannabis grown outdoors for suppression of corn earworm (*Helicoverpa zea*).

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

There are no changes in the formulation of Helicovex; therefore, no additional toxicological information was required for Helicovex or for the active ingredient, *Helicoverpa armigera* Nucleopolyhedrovirus strain BV-0003.

There are no toxicological concerns for the formulants or impurities.

The new use is consistent with the previously registered use on the label for sweet corn. The potential for dietary and occupational exposure from the new uses of Helicovex is not expected to increase, and therefore, no additional exposure information was required.

The available information is sufficient to support the use of Helicovex on field corn, seed corn, popcorn and hemp and cannabis grown outdoors from a health perspective.

Environmental Assessment

There are no changes in the formulation of Helicovex; therefore, no additional environmental toxicological information was required for Helicovex or for the active ingredient, *Helicoverpa armigera* Nucleopolyhedrovirus strain BV-0003. Previously provided information indicates that the outdoor use of Helicovex does not pose an environmental risk of concern to non-target organisms if the directions on the label are followed.

The new use on field corn, seed corn, popcorn and hemp and cannabis grown outdoors is consistent with those currently on the label for sweet corn. The application to these field crops is not expected to pose an additional risk to the environment.

Value Assessment

A scientific rationale and use history information submitted by the registrant supported the new uses of Helicovex on field corn, seed corn, popcorn, and hemp and cannabis grown outdoors. Helicovex provides a new mode of action for use on field corn, seed corn, and popcorn and is the first product registered for corn earworm on hemp or cannabis grown outdoors.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to add suppression of corn earworm (*Helicoverpa zea*) in field corn, seed corn, popcorn and hemp and cannabis grown outdoors to the label of Helicovex.

References

PMRA

Document

Number	Reference
3047311	2019, M10.2 Performance Assessment Scientific Rationale, DACO: M10.2
3047313	Britt, K., Taylor, S., and Kuhar, T., 2019, Corn earworm, <i>Helicoverpa zea</i> , a pest of hemp, <i>Cannabis sativa</i> , in Virginia, ENTO-328NP, Virginia Cooperative Extension (www.ext.vt.edu), DACO: M10.2
3047314	Cranshaw, W., Schreiner, M., Britt, K., Kuhar, T.P., McPortland, J., and Grant, J., 2019, Developing insect pest management systems for hemp in the United States: A work in progress, Journal of Integrated Pest Management 10(1): 26 (doi: 10.1093/jipm/pmz023), DACO: M10.2
3047335	2019, M10.4.3 Current Crop Protection Tools and Practices, DACO: M10.4.3

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