Health Canada Santé Canada

Evaluation Report for Category C, Subcategory 6.3 (URMULE) Application

Application Number: 2024-0568
Application: **Category C, subcategory 6.3 (URMULE)**
Product: Bioprotec PLUS
Registration Number: 32425
Active ingredients (a.i.): *Bacillus thuringiensis* subspecies *kurstaki*, strain EVB113-19
PMRA Document Number: 3624749

Background

Bioprotec PLUS has been registered since November 1, 2016. Bioprotec PLUS is registered for the control of listed insect pests on field, orchard and greenhouse crops. For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

Purpose of Application

The purpose of this application was to amend the registration of Bioprotec PLUS to include the claim of control of corn borer, beet webworm and fall armyworm on quinoa and to include the claim of control of forest tent caterpillar, eastern hemlock looper and whitemarked tussock moth on Crop Group 13-07B Bushberries and Crop Group 13-07C: Large Shrub/Tree Berries. The product is intended for application at a rate of 2.5-2.5 L/ha with a maximum of 6 applications per year at a 5-10 day interval between applications for quinoa. And for application at a rate of 1.0-1.6 L/ha with a 3-10 day interval for forest tent caterpillar, 2.4-3.2 L/ha with a 3-10 day interval for eastern hemlock looper and 4 L/ha with a 2-5 day interval for whitemarked tussock moth on Crop Group 13-07B: Bushberries and Crop Group 13-07C: Large Shrub/Tree Berries.

Health Assessment

Since no changes in the formulation of Bioprotec PLUS were proposed and the human health and safety database for this end-use product is considered complete, no additional toxicological information is required for the end-use product and the technical grade of the active ingredient, Bioprotec Technical.

The minor use for control of forest tent caterpillar, eastern hemlock looper, and white marked tussock moth on crop groups 13-07B (bushberries) and 13-07C (large shrub/tree berries), and control of corn borer, beet webworm, and fall armyworm on quinoa is consistent with with application rates and methods currently registered on the Bioprotec PLUS label.

Canada

The potential for dietary and occupational exposure from the new use of Bioprotec PLUS is not expected to increase, and therefore, no additional exposure information is required. The available information is sufficient to support the new minor use of Bioprotec PLUS.

Maximum Residue Limit (MRL)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally specified as a maximum residue limit (MRL) under the *Pest Control Products Act* (PCPA) for the purposes of adulteration provision of the *Food and Drugs Act* (FDA). Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

The specification of a maximum residue limit is not required for *Bacillus thuringiensis* subsp. *kurstaki* strain EVB113-19.

Environmental Assessment

Since no changes to the formulation of Bioprotec PLUS were proposed and the environmental toxicological database for this end-use product is considered complete, no additional environmental toxicological information is required for the end-use product or the technical grade of the active ingredient, Bioprotec Technical.

The minor use is consistent with with application rates and methods currently registered on the Bioprotec PLUS label. The addition of control of forest tent caterpillar, eastern hemlock looper, and white marked tussock moth on crop groups 13-07B (bushberries) and 13-07C (large shrub/tree berries), and control of corn borer, beet webworm, and fall armyworm on quinoa is not expected to pose an additional risk to the environment.

Value Assessment

Label claims for use of Bioprotec PLUS for control of forest tent caterpillar, eastern hemlock looper, and whitemarked tussock moth in Crop Group 13-07B (Bushberries) and Crop Group 13-07C (Large Shrub/Tree Berries) were supported based on extrapolation from registered control claims on similar product labels for these pests on other crops with a similar plant structure.

Label claims for control of corn borer, beet webworm, and fall armyworm in quinoa were based on extrapolation from registered claims for these pests on quinoa on the label of the similar product, Bioprotec CAF.

Conclusions

Health Canada has completed an evaluation of the subject application and has found the information sufficient to amend the registration of Bioprotec PLUS to include the claim of control of corn borer, beet webworm and fall armyworm on quinoa and to include the claim of control of forest tent caterpillar, eastern hemlock looper and whitemarked tussock moth on Crop Group 13-07B: Bushberries and Crop Group 13-07C: Large Shrub/Tree Berries.