

Evaluation Report for Category B, Subcategory 3.11 and 3.12 Application

Application Number: 2012-2180
Application: B.3.11 (Product label – new pest)
B.3.12 (Product label – new host)
Product: Bioprotec CAF Aqueous Biological Insecticide
Registration Numbers: 26854
Active ingredients (a.i.): *Bacillus thuringiensis* ssp. *kurstaki* strain EVB113-19
PMRA Document Number: 2224981

Background

Bioprotec CAF Aqueous Biological Insecticide [minimum of 8.12% dry weight *Bacillus thuringiensis* ssp. *kurstaki* strain EVB113-19 (formerly known as strain HD-1)] was first granted a full registration in 2001 for use as a commercial and restricted class end-use product. Bioprotec CAF Aqueous Biological Insecticide is intended to be used as a biological insecticide on a wide range of field, orchard, and greenhouse agricultural.

Purpose of Application

The purpose of this application was to add a number of pest/host combinations to the label of Bioprotec CAF Aqueous Biological Insecticide.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

The toxicological database for *B. thuringiensis* ssp. *kurstaki* strain EVB113-19 is complete and there are no outstanding toxicological concerns for this active ingredient. The application frequency, interval and methods are consistent with currently registered uses, but the proposed application rate for some of the new pest/crop combinations is slightly higher. Given the low toxicity and pathogenicity profile of the active ingredient in Bioprotec CAF Aqueous Biological Insecticide, additional risks to human health and safety are not expected as a result of the proposed label expansion.

The slightly higher application rates for some of the new pest/host combinations do not pose any additional occupational exposure concerns given the low toxicity and pathogenicity profile of the active ingredient as well as the required personal protective equipment.

The slightly higher application rates for some of the new pest/host combinations do not pose any additional dietary exposure concerns.

Environmental Assessment

The environmental database for *B. thuringiensis* ssp. *kurstaki* strain EVB113-19 is complete and there are no outstanding environmental concerns for this active ingredient. Although the application rates of some of the proposed new pest/host combinations are slightly higher than registered rates, no additional risks to the environment are expected.

Value Assessment

Bioprotec CAF Aqueous Biological Insecticide is expected to be effective for all of the newly registered uses based on extrapolation from similar uses already registered on the labels of Bioprotec CAF Aqueous Biological Insecticide and/or another of the registrant's products, Bioprotec 3P Dry Flowable Biological Insecticide.

Conclusion

The PMRA has completed an assessment of the available information and is able to support the addition of a number of pest/host combinations to the label of Bioprotec CAF Aqueous Biological Insecticide.

References

PMRA# 2281939 2013, Value summary, DACO: M10.1

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