

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5, 3.1, 3.14 Application

Application Number: 2010-3650
Application: B.2.1 (Product chemistry - guarantee)
B.2.3 (Product chemistry - identity of formulants)
B.2.4 (Product chemistry - proportion of formulants)
B.2.5 (Product chemistry - formulation type)
B.3.1 (Product labels - application rate increase)
B.3.14 (Product labels - classifications)
Product: Foray WG Biological Insecticide Water Dispersible Granule
Registration Number: 30026
Active ingredients (a.i.): *Bacillus thuringiensis* (berliner) subsp.*kurstaki* Strain HD-1 (BTB)
PMRA Document Number English PDF: 1990372

Purpose of Application

The purpose of this application was to register Foray WG Biological Insecticide Water Dispersible Granules, a new end-use product which contains the registered technical active ingredient, *Bacillus thuringiensis* subsp. *kurstaki*. Foray WG Biological Insecticide Water Dispersible Granules is to be used in ground and aerial applications for the control of lepidopteran larvae in forestry.

Chemistry Assessment

The applicant submitted the required information on the manufacturing process that included appropriate measures for quality assurance, and the limiting of microbial contaminants and unintentional ingredients. The data submitted supports the label claim for potency of at least 64,000 CLU/mg and for storage stability below 25°C for up to 24 months. The product characterization database for Foray WG Biological Insecticide Water Dispersible Granules is complete and acceptable.

Health Assessments

The applicant submitted new toxicity data that tested Foray WG Biological Insecticide Water Dispersible Granules in acute oral toxicity, acute dermal toxicity, acute inhalation, dermal irritation, dermal sensitization and eye irritation studies. This product is not of toxicological concern. The human health and safety database for Foray WG Biological Insecticide Water Dispersible Granules is complete and acceptable.

Environmental Assessment

The applicant submitted data that tested Foray WG Biological Insecticide Water Dispersible Granules in a honey bee study. The product does not pose a concern to terrestrial or aquatic environments. The environmental database for Foray WG Biological Insecticide Water Dispersible Granules is complete.

Value Assessment

Efficacy data on jackpine budworm were submitted to support label claims on Eastern and Western spruce budworm and Eastern blackheaded budworm. Based on the similarities in lifecycle and feeding damage of these pests, the submitted data can be used for extrapolation and the uses of Foray WG Biological Insecticide Water Dispersible Granules (*Bacillus thuringiensis*, subsp. *kurstaki*, strain ABTS-351) to control Eastern spruce budworm at a rate range of 15-30 BIU/ha, Western spruce budworm at a rate range of 30-40 BIU/ha, jackpine budworm at a rate range of 20-60 BIU/ha and Eastern blackheaded budworm at a rate range of 30-60 BIU/ha; all with up to two applications per year are supported.

Efficacy data on gypsy moth (*Lymantria dispar*) and nun moth (*Lymantria monacha* L.) were submitted to support label claims on gypsy moth. Based on similarities in lifecycle, host preference and feeding damage, the nun moth data can be extrapolated to support the use of Foray WG Biological Insecticide Water Dispersible Granules to control gypsy moth at a rate range of 30-50 BIU/ha with two or more applications applied at 7-10 day intervals if required.

Based on the efficacy data submitted on Eastern hemlock looper, the uses on the registered Foray 76B label (*Bacillus thuringiensis* subsp. *kurstaki* HD-1; Reg. No. 24976) and the similar feeding damage caused by both hemlock looper and Eastern and Western spruce budworm, the use of Foray WG Biological Insecticide Water Dispersible Granules to control Eastern hemlock looper at a rate range of 30-40 BIU/ha with repeat applications occurring at 3-14 day intervals are supported.

Based on the efficacy data submitted on tussock moth and the uses on the registered Foray 76B label, the use of Foray WG Biological Insecticide Water Dispersible Granules to control whitemarked tussock moth at a rate range of 30-50 BIU/ha with up to two applications per year applied with a reapplication interval of 5-7 days are supported.

Efficacy data on the pine processionary caterpillar has been submitted to support label claims on the forest tent caterpillar. Based on the similarities in lifecycle and feeding behaviour, the pine processionary caterpillar data can be extrapolated to support the use of Foray WG Biological Insecticide Water Dispersible Granules on forest tent caterpillar at a rate range of 12-20 BIU/ha with repeat applications if necessary every 7-10 days.

Conclusion

The PMRA has completed an assessment of the information provided and supports the full registration of Foray WG Biological Insecticide Water Dispersible Granules.

References

PMRA Doc.	Title
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1945247	2009, VBC-60074 Accelerated Storage Stability, DACO: M2.11,M2.12
1945248	2010, Toxicological Studies and Exposure Data and Information, DACO: M4.1
1945249	2006, Acute Oral Toxicity Up and Down Procedure in Rats, DACO: M4.2.2
1945250	2006, Acute Dermal Toxicity Study in Rats - Limit Test, DACO: M4.2.3,M4.4
1945251	2010, Acute Inhalation Toxicity Study of VBC-60074 in Rats (Limit Test), DACO: M4.4,M4.9
1945252	2006, Primary Eye Irritation in Rabbits, DACO: M4.5,M4.9
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1945255	2007, Assessment of Side Effects of VBC-60074 to the Honey Bee, <i>Apis mellifera</i> L. in the Laboratory, DACO: M9.5.1,M9.9
1945256	M10.2.2 Field Studies, DACO: M10.2.2
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- 1945264 2006, Efficacy Estimation Based Bioinsecticide – In the Protection of Forest Stands Against the Nun Moth *Lymantria monacha* L. (Lepidoptera: Lymantriidae, DACO: M10.2.2
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