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SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

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PRODUCT MANAGER NO. Hutton/Mendelsohn (PM-18)

PRODUCT NAME(S) Bacillus thuringiensis var. aizawai

ABG-6314

COMPANY NAME Abbott Laboratories

SUBMISSION PURPOSE EUP on minor cruciferous crops and leafy  
vegetables

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
<u>006403</u>	<u>B.t. var. aizawai</u>	<u>3 %</u>

EEB REVIEW

Pesticide Name: Bacillus thuringiensis var. aizawai  
Bioinsecticide, Company code ABG-6314

100.0.0 Submission Purpose and Label Information

100.1.0 Submission Purpose and Pesticide Use

Abbott laboratories has requested a 2 year EUP for a microbial pesticide containing Bacillus thuringiensis var. aizawai (ABG-6314). The product is a dispersible granule formulation which will be evaluated for the control of lepidopteran insects infesting cruciferous vegetable crops.

100.1.1 Proposed EUP Program

100.1.2 Objectives

The objectives of the EUP program are to evaluate the efficacy of ABG-6314, which contains spores and crystals of Bacillus thuringiensis variety aizawai, against lepidopteran insects infesting and damaging all cultivars of selected cruciferous vegetable crops. Both research and commercial development trials will be conducted on 4900 acres in ten States.

More specific objectives are to compare different application rates (0.5 to 2.0 lbs/a), evaluate efficacy to major individual species of lepidoptera, determine the most effective interval of application for light and heavy pest infestation and to determine consistency of performance with different types of application systems.

100.1.3 Date, Duration

The duration of the proposed EUP permit is for the 1991 and 1992 growing seasons.

100.1.4 Amount Shipped, Geographical Distribution

<u>State</u>	<u>Lbs. a.i.</u>	<u>BIU's</u>	<u>Acreage</u>
Florida	11250	76500	2500
Georgia	2250	15300	500
Louisiana	113	770	25
Michigan	113	770	25
Mississippi	113	770	25
New Jersey	563	3828	125
New York	563	3828	125
North Carolina	675	4590	150
Texas	5850	39780	1300
Wisconsin	563	3828	125
<u>TOTAL</u>	<u>22053</u>		<u>4900</u>

100.2.0 Formulation Information

WATER DISPERSIBLE GRANULE BIOLOGICAL INSECTICIDE

ACTIVE INGREDIENT:

Bacillus thuringiensis var. aizawai  
15,000 International Units of Potency per mg.  
(6.8 Billion International Units per pound).. 3.0 %

INERT INGREDIENTS ..... 97.0 %

100.3.0 Application Methods, Directions, Rates

Recommended Rates and Timing

ABG-6314 may be applied with conventional ground and aerial spray equipment with quantities of water sufficient to provide uniform coverage of infested plant parts. The volume of water per acre will depend on crop size, weather, spray equipment and local experience. Use at least 2 gallons of water per acre by air, except in the western U.S., where at least 5-10 gallons is the minimum.

There is no restriction on applying ABG-6314 up to the time of harvest.

Application rate:

<u>Crops</u>	<u>Pests</u>	<u>Pounds/Acre</u>
Cruciferous	:	1/4 to 1 -
vegetable crops	Lepidopteran insects	1/2 to 2

100.4.0 Target Organisms

Lepodoperteran insects including Diamondback Moth (Plutella xylostella), Cabbage Looper (Trichoplusia ni), Imported Cabbageworm (Pietis rapae) and Armyworms (Spodoptera spp.)

100.5.0 Precautionary Labeling

Pesticide and container storage and disposal directions are adequate.

101.0.0 Hazard Assessment

101.1.0 Discussion

Nontarget data waivers for the EUP were requested by the registrant at a pre-registration meeting and granted for the following considerations.

The EUP is given for a limited duration and acreage. The biochemical characteristics of Bacillus thuringiensis H-7 strain ABTS-1857 are very similar to those of Bacillus thuringiensis var. kurstaki HD-1, the active ingredient in Dipel. Of 19 characteristics tested, they differed only in two carbohydrate utilization tests (criteria of minor significance and frequent variability). No detectable (< 1 ppm) Beta-exotoxin is produced by the ABG-6305 Bacillus thuringiensis var. aizawai production strain (ABTS-1857, same as ATCC SD-1372). The strain produces a 135 kDa lepidopteran-active endotoxin. In addition, a strain of Bacillus thuringiensis var. aizawai is already registered with the EPA for indoor use on empty honeycombs.

#### 101.2.0 Likelihood of Adverse Effects on Nontarget Organisms

A Mouse Intraperitoneal Injection Test with ABG-6305 Technical Powder showed no deaths or signs of toxicity dosed at 1E6, 1E7 or 1E8/animal.

In addition, Abbott has submitted nontarget toxicity / pathogenicity data on three other registered species of Bacillus thuringiensis: kurstaki, israelensis, and tenebrionis. Among the species tested are the rat, bobwhite quail, mallard duck, rainbow trout, bluegill sunfish, sheepshead minnow, grass shrimp, daphnia, a benthic harpacticoid copepod, parasitic wasp, spider mite, predatory mite, green lacewing, lady beetle, stilt bug ant the honeybee. Although several of the above nontarget species showed some adverse effects at maximum hazard doses, none were significantly affected at the maximum field rate dosage.

As a result of the above considerations, no significant environmental impact is expected from the limited acreage EUP.

For unlimited Section 3 registration the ecological effects data requirements will have to be reevaluated according to the requirements of the Bacillus thuringiensis Reregistration Standard.

#### 101.3.0 Endangered Species Considerations

Based on the low exposure from the limited acreage and duration of the EUP, EEB feels that there will not be a "may affect" situation for endangered mammals, birds, invertebrates, plants and aquatic species.

#### 101.4.0 Adequacy of Toxicity Data

The registrant has addressed all of the data requirements outlined in the Pesticide Assessment Guidelines, Subdivision M by request of waivers or by citation of their data developed for similar products.

101.5.0 Adequacy of Labeling

The following Environmental hazards statement needs to be added to the label:

Do not contaminate water when disposing of equipment washwaters.

103.0.0 Conclusions

EEB has reviewed the proposed EUP registration of ABG-6314 bioinsecticide which contains spores and delta endotoxin crystals of Bacillus thuringiensis variety aizawai, for control of lepidopteran insects on 4900 acres of cruciferous vegetable crops in 10 States. Based upon the available data EEB concludes that the proposed limited uses provide a minimal risk to nontarget organisms or endangered species.

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