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SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

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PRODUCT MANAGER NO. L. Dye/P. Hutton (PM-18)

PRODUCT NAME(S) Foil

COMPANY NAME Ecogen, Inc.

SUBMISSION PURPOSE Section 3 Registration

SHAUGHNESSEY NO. CHEMICAL, & FORMULATION

006401 Bacillus thuringiensis var. kurstaki 7.5%

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EEB REVIEW

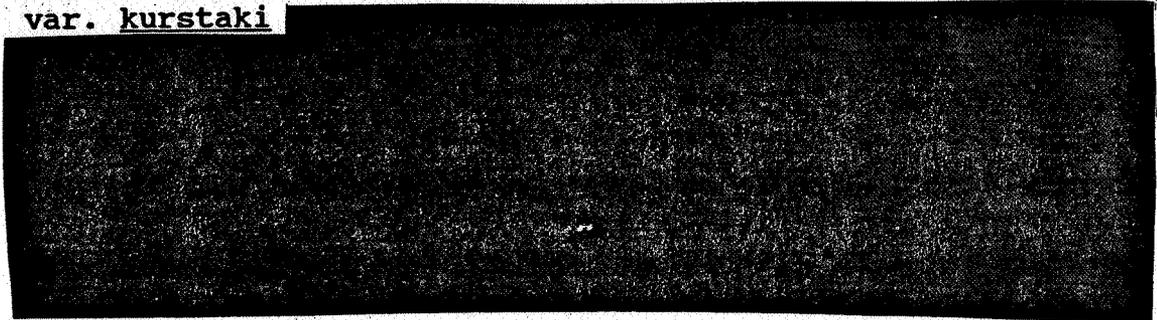
Pesticide Name Foil - Bacillus thuringiensis var. kurstaki
strain EG2424

100.0.0 Submission Purpose and Label Information

100.1.0 Submission Purpose and Pesticide Use

Ecogen, Inc. has requested a Section 3 Registration for Foil which has Bacillus thuringiensis var. kurstaki as the active ingredient. The product is active against insect pests of potato.

EG2424 is derived as follows: Bacillus thuringiensis var. kurstaki



100.2.0 Formulation Information **MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED**

Wetable Powder Bioinsecticide

ACTIVE INGREDIENT: <u>Bacillus thuringiensis</u>	
var. <u>kurstaki</u> strain EG2424	
protein toxin.....	7.5%
Inert Ingredients.....	92.5 %
TOTAL	100.0 %

0.64 lbs active ingredient per gallon

Foil is a biological insecticide for use against coleopteran and lepidopteran insects.

100.3.0 Application Methods, Directions, Rates

Foil bioinsecticide can be applied with conventional ground or aerial application equipment. The product must have maximum agitation to be effective. Sufficient quantities of water must be used to obtain a sprayable mixture of the product and to provide thorough coverage of infested plants. Foil is not to be used in irrigation systems. The following application rates are to be used:

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APPLICATION RATE

<u>Crop</u>	<u>Pest</u>	<u>Quarts/acre¹</u>
Potatoes	Colorado Potato Beetle ²	1 to 4
Potatoes	European Corn Borer ³	1 to 4
Potatoes	Armyworms ⁴ and Loopers ⁴	2 to 4

¹For ground applications, use up to 100 gallons of water. For aerial applications, use up to 10 gallons of water. FOIL Oil Flowable should always be mixed with at least an equal volume of water.

²Timing: Initial application should be made when 30% of observed egg masses have hatched. Repeat application at an interval sufficient to maintain control, usually 5-10 days depending upon plant growth, insect activity and weather conditions after spraying. Subsequent sprays should be applied as needed.

³Timing: Initial application should be made at peak moth activity. Subsequent sprays (1-3) should be applied weekly as needed.

⁴Timing: Treat when larvae are young (early instars) and are actively feeding on exposed plant parts. Apply before extensive foliar damage has occurred.

100.4.0 Target Organisms

Colorado Potato Beetle, European Corn Borer, Armyworms and Loopers

100.5.0 Precautionary Labeling

The label contains the following precautions:

KEEP OUT OF REACH OF CHILDREN

CAUTION

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): (adequate)

BENEFICIAL INSECTS: (adequate)

ENVIRONMENTAL HAZARD STATEMENT: Do not contaminate water by cleaning equipment or disposing of waste.

(Pesticide and container disposal directions are adequate)

101.0.0 Hazard Assessment

101.1.0 Discussion

The Bacillus thuringiensis var. kurstaki strain (EC2424) used as the a.i. in this product is a transconjugant of naturally occurring Bt strains derived by natural plasmid exchange processes and not by recombinant DNA technology. This recombinant Bt strain was field tested in 1987 and 1988. Subsequent to this testing, EPA decided to allow the registrant to use existing data from other Bt strains to fulfill nontarget testing requirements. However, the agency continued to require the registrant to submit nontarget beneficial predatory insect and honey bee toxicity data for each strain to be registered. The appropriateness of the data bridging and the requirement for nontarget insect and honey bee testing for all strains will be reviewed during the Bt reregistration process and a final decision on these matters will be made at that time.

Some of the nontarget studies used to support the registration of Foil were those submitted for the Bt product Condor (strain EG2348). EG2348 was derived as follows: Bacillus thuringiensis var. kurstaki

Also, studies on a second strain (EG2101) were used to fulfill some of the nontarget data requirements. This strain was derived as follows: Bacillus thuringiensis var. kurstaki

A review of the studies submitted with this application demonstrated that there is some intrinsic toxicity to aquatic invertebrates and to some nontarget insects at maximum hazard doses. However, no significant acute risk to nontarget wildlife is expected from exposure to Foil at the proposed use rates.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

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101.2 Likelihood at Adverse Effects to Nontarget Organisms

Avian Studies

When administered by oral gavage at 3.33 gm/kg of body weight, EG2404 had no apparent effect upon mallard ducks for 30 days. The acute pathogenicity LD₅₀ value to mallards by gavage was determined to be greater than 3.33 gm/kg of body weight. When administered by oral gavage at 3.33 gm/kg of body weight EG2424 had no apparent effect upon bobwhite quail for 30 days. The acute pathogenicity LD₅₀ value to bobwhite by gavage was determined to be greater than 3.33 gm/kg of body weight. In view of the lack of oral toxicity, no avian hazard is expected from the proposed uses of Foil insecticide.

Fish Studies

A 30 day static renewal toxicity and pathogenicity study of EG2424 was conducted with rainbow trout. Thirty fish were exposed to a maximum hazard dose of 1×10^6 spores/ml of water and 1×10^8 spores/mg in food. No toxic or pathogenic responses were noted. At necropsy (14 and 30 days) internal organs were found normal in appearance. Upon culture some organs were found to harbor the MPCA. No systemic blood involvement, however, was apparent. In view of the above results, no freshwater fish hazard is expected from exposure to Foil insecticide at the proposed label use rates.

Mammalian Wildlife

These studies are required only when toxicology data are inadequate for assessment of hazard to wild mammals. The anticipated low exposure of mammalian wildlife during application indicates that risk to wild mammals from the proposed use of Foil insecticide is minimal.

Aquatic Invertebrate Studies

A 21 day static renewal toxicity and pathogenicity study of EG2424 was conducted with Daphnia magna. Forty daphnids were tested for each of three concentration levels, including a maximum hazard dose of 1×10^6 spores/ml of water. Statistical analysis of survival for Daphnia magna in treated levels showed a difference in survival in the 1.1×10^6 concentration from that of the untreated controls. A 21 day EC₅₀ was calculated to be 9.5×10^5 spores/ml. The point estimate for the MATC value was 8.1×10^5 spores/ml. In view of the terrestrial uses of the insecticide, the exposure to aquatic organisms is expected to be several orders of

magnitude lower than the MATC. Thus no freshwater aquatic above results for Condor, no freshwater aquatic invertebrate hazard is expected from the proposed uses of Foil insecticide.

Estuarine and Marine Animal Studies

None submitted. These studies will need to be submitted prior to use of this product on or near estuarine or marine environments.

Nontarget Plant Studies

1. A 96 hour exposure to 1.476 mg/L of the typical end use product (TEP) (EG2101-LX186-05 Oil Based Flowable) showed no reduction in the growth rate of the green alga Selenostrum capricornutum.

2. Vegetative vigor test (Tier II)

All 10 plant species tested with 2348-05 had a statistical no-effect level of 4.0 qt/a (0.622 lb. ai/a), the highest concentration tested, in phytotoxicity ratings and plant height. All plant species had a no-effect level for plant dry weight of 4.0 qt/a except lettuce which had a no-effect level of 2.0 qt/a. Lettuce dry weight was the only crop/parameter to exhibit a dose response. Probit analysis showed EC₂₅ and EC₅₀ values of 51.4 and 61211 qt/a respectively.

3. Seed germination/emergence

Seed germination and seedling emergence studies were performed on 10 plant species using the maximum label rate of 2.0 qt/a (0.311 lb ai/a) of 2348-OF. The seed germination study showed no statistically significant ($p \leq 0.05$) effect on radicle length or the percentage of seeds germinating, regardless of plant species. The seedling emergence study showed that 2348-OF did not result in a greater than 25% detrimental effect on seedling height, percentage of seedlings emerged or plant dry weight.

In view of the above results, no nontarget plant hazard is expected from the proposed used of Foil insecticide.

Honey Bee Studies

A 4 day bell-jar dusting chamber study with honey bees exposed to 25 ug/bee of 100% a.i. EG2424 (equiv. to 25 lb/A application rate) showed no apparent detrimental

effects. A dietary study using EG2424 demonstrated an $LC_{50} > 10^8$ after 4 days. In view of the above results, no significant acute contact or dietary toxicity to honey bees is expected from exposure to Foil insecticide at the proposed label use rates.

Nontarget Beneficial Insect Studies

1. Ladybird beetles: the 48-hr acute contact toxicity LD_{50} with 100% a.i. (EG2424) was > 0.56 mg/beetle.
2. Parasitic hymenoptera: (*Brachymeria intermedia*): The 48-hr acute contact toxicity LD_{50} with 100% a.i. (EG2424) was > 0.56 mg/insect. The mortality was 28% at 0.56 mg, the highest dose tested and may have been treatment related. A 30 day dietary toxicity/pathogenicity LC_{50} was determined to be greater than 250 ug/ml feed. The mortality at 30 days in the 250 ug/ml treatment group was 22% showing possible chronic toxicity at maximum hazard dose levels.
3. Green Lacewing larvae: A 96 hr. bell-jar dusting chamber study with 100% a.i. EG2371 of 10 times the field application rate (2 lbs/A) showed no adverse effects. A dietary study demonstrated an $LC_{50} > 10^8$ cfu/g feed after 6 days.

No toxicity to predatory beneficial insects is expected from the proposed uses of Foil insecticide.

101.3.0 Endangered Species Considerations

This product may be expected to be used throughout the United States with possible exposure to all endangered/threatened species that are susceptible to the Bacillus thuringiensis var. kurstaki delta endotoxin. Based on the toxicity and exposure data, EEB feels that there will not be a "may effect" situation for endangered mammals, birds, non-lepidopteran and non-coleopteran invertebrates, plants and aquatic species.

The use of Foil insecticide in Washington, Oregon, California and Florida, however, may affect endangered lepidopteran insect species. Based on information available to EEB, the following are counties in which the use of anti-lepidopteran Bacillus thuringiensis delta endotoxin may result in hazard to endangered/threatened species of lepidopterans:

County, State

Species of Concern

Los Angeles, CA	El Segundo blue butterfly
	Palos Verdes blue butterfly
Contra Costa, CA	Lange's metalmark butterfly
Mendocino, CA	Lotis blue butterfly
San Francisco, CA	Mission blue butterfly
San Mateo, CA	Mission blue butterfly
	San Bruno elfin butterfly
Monterey, CA	Smith's blue butterfly
Kern, CA	Kern primrose sphinx moth
Dade, FL	Schaus swallowtail butterfly
Monore, FL	Schaus swallowtail butterfly
Lane, OR	Oregon silverspot butterfly
Pacific, WA	Oregon silverspot butterfly
Tillamook, WA	Oregon silverspot butterfly

Reasonable and prudent alternatives

The 1978 Amendments to the Endangered Species Act include a mandate that "reasonable and prudent alternatives" be provided when a US Fish and Wildlife Service Biological Opinion indicates a jeopardy to a listed species. The US Fish and Wildlife Service Biological Opinion, dated January 12, 1987, provides the following reasonable and prudent alternative for the use of Bacillus thuringiensis var. kurstaki (anti-lepidopteran delta endotoxin):

Anti-lepidopteran delta endotoxin, or any formulations thereof, should not be aerially applied within 1/4 mile of any habitats of endangered or threatened lepidoptera. No manual application should be made within 300 feet of any threatened or endangered Lepidoptera.

1. In California these measures are to be applied to the following species and the area of concern:

Lotis blue butterfly - Mendocino County - 3 miles south of Mendocino City to Fort Bragg along a 2 mile corridor along Highway 1.

Lange's metalmark butterfly - Contra Costa County - Antioch Sand Dunes Wildlife Refuge.

Mission blue butterfly and San Bruno elfin butterfly - San Mateo County - San Bruno Mountain, Milgara Ridge, Skyline College (Guadalupe Canyon Parkway), Sweeney Ridge, and Montana Mountain.

Smith's blue butterfly - Monterey County - Seaside Marina coastal dune complex from the City of

Monterey to Point Gorda, Fort Ord Military Reservation, Seaside Dunes, California Department of Fish and Game preserve near the mouth of the Salinas River, Monterey Sand Hills, Lobos State Preserve, Partington Canyon between Highway 1 and Partington Cove, Burns Creek, several west-facing canyons to Highway 1 between Malpaso and Garrapatacreeks, north-facing slopes adjacent to Carmel River between Boronda and Paso Hondo roads near Carmel Valley, Vasquez Knob, and Paraiso springs.

El Segundo blue butterfly - Los Angeles County - International Airport and Chevron Refinery.

Kern primrose sphinx moth - Kern County - Walker Basin.

2. In Florida, the Anti-lepidopteran delta endotoxin, or any formulations thereof, should not be used in the Dade County Keys in Key Biscayne national Park, thence southward to Lower Metacumbe Key in Monroe County
3. Anti-lepidoptera delta endotoxin, or any formulations thereof, should not be used within one mile of the Pacific Ocean in Tillamook County, Oregon and Pacific County, Washington, where the Oregon silverspot butterfly is known to occur.

The following is a list of coleopteran insects that are endangered/threatened and the county/state where they are located. The use of Foil in close proximity to these insects could present a hazard to these endangered species.

<u>County/State</u>	<u>Species of Concern</u>
Butte, CA	Valley Elderberry Longhorn Beetle
Colusa, CA	Valley Elderberry Longhorn Beetle
Glenn, CA	Valley Elderberry Longhorn Beetle
Merced, CA	Valley Elderberry Longhorn Beetle
Sacramento, CA	Valley Elderberry Longhorn Beetle
Solano, CA	Delta Green Ground Beetle
	Valley Elderberry Longhorn Beetle
Sutter, CA	Valley Elderberry Longhorn Beetle
Tehama, CA	Valley Elderberry Longhorn Beetle
Yolo, CA	Valley Elderberry Longhorn Beetle
Middlesex, CT	Puritan Tiger Beetle
Dukes, MA	Northeastern Beach Tiger Beetle
Hampshire, MA	Puritan Tiger Beetle
Calvert, MD	Northeastern Beach Tiger Beetle
	Puritan Tiger Beetle
Cecil, MD	Puritan Tiger Beetle

Kent, MD	Puritan Tiger Beetle
Washington, RI	American Burying Beetle
Travis, TX	Kretschmarr Cave Mold Beetle
	Tooth Cave Ground Beetle
Williamson, TX	Kretschmarr Cave Mold Beetle
	Tooth Cave Ground Beetle
Accomack, VA	Northeastern Beach Tiger Beetle
Gloucester, VA	Northeastern Beach Tiger Beetle
Lancaster, VA	Northeastern Beach Tiger Beetle
Mathews, VA	Northeastern Beach Tiger Beetle
Northhampton, VA	Northeastern Beach Tiger Beetle
Northumberland, VA	Northeastern Beach Tiger Beetle

101.4.0 Adequacy of Toxicity Data

The registrant has addressed the data requirements outlined in the Pesticide Assessment Guidelines, Subdivision M.

101.5.0 Adequacy of Labeling

The precautionary labeling (see sec. 100.5.0) is adequate and no additions/modifications need to be made.

Endangered Species Labeling: Endangered species labeling is deferred until the Technical Bulletin information is made available by OPP.

102.0.0 Classification: N/A

103.0.0 Conclusions

EEB has reviewed the proposed Section 3 Registration of Foil by Ecogen, Inc. for control of Colorado potato beetle, European corn borer, armyworm and loopers on potatoes. EEB concludes that acute toxicity risk to nontarget wildlife from the proposed uses of Foil will be minimal to nonexistent at the proposed label use rates.

Endangered species considerations

The use of Foil insecticide in Washington, Oregon, California and Florida may affect endangered Lepidopteran insect species and in California, Connecticut, Massachusetts, Maryland, Rhode Island, Texas, and Virginia may affect endangered Coleopteran insect species. The location of the endangered species and restrictions for use of Bacillus thuringiensis delta endotoxin in these areas are listed in section 101.3.0.

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