



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 22 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Christine A. Dively
ECOGEN INC.
2005 CABOT BLVD WEST
LANGHORNE, PA 19407

Subject: Label Amendment Submission of 01/07/94 in Response to PR Notice 93-7
EPA Reg. No. 55638-10
FOIL BFC OIL FLOWABLE BIOINSECTICIDE

Dear Registrant:

The labeling cited above and submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is accepted subject to the comments reflected on the enclosed sheet. A copy of your proposed labeling stamped "ACCEPTED WITH COMMENTS" is enclosed.

WHAT THIS ACCEPTANCE MEANS:

Based on your certification, the Agency has accepted the labeling changes that are necessary to comply with the Worker Protection Standard (WPS) labeling requirements of 40 CFR part 156, subpart K, described in PR Notices 93-7 and 93-11. Any other labeling changes submitted in connection with this amendment application but not directly related to compliance with the WPS have not been reviewed or accepted by the Agency. If you wish to make such changes, you must submit a separate amendment application proposing them. If your product is currently suspended, the acceptance of this labeling amendment does not affect the suspension in any way.

WHAT YOU NEED TO DO NEXT:

By the next label printing make all the specified changes to your labeling. Send to EPA one (1) copy of the final printed labeling:

- BEFORE selling or distributing any product bearing the final printed labeling
- AND
- WITHIN one year from date of this acceptance.



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

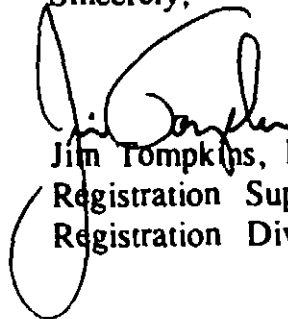
Submit the final printed labeling via the U.S. Postal Service to:

Document Processing Desk (FIN-LABEL)
Office of Pesticide Programs (7505C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460-0001

and for courier deliveries of final printed labeling may be made to:

Document Processing Desk (FIN-LABEL)
Office of Pesticide Programs
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Sincerely,



Jim Tompkins, Deputy Chief
Registration Support Branch
Registration Division (7505W)

Attachment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division

Christine A Dively
ECOGEN INC.
2005 CABOT BLVD WEST
LANGHORNE PA 19047

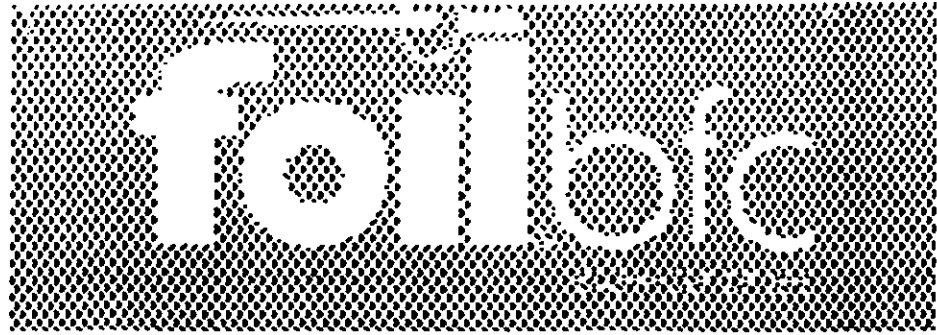
Comment for: EPA Reg Nr.55638-10
FOIL BFC OIL FLOWABLE BIOINSECTICIDE

The following specific comments pertain to your WPS labeling submission concerning the product cited above:

Add the following User Safety Recommendation to the label in the location shown in Section A on Part 1 of the Product Worksheet in Supplement Three-A to PR Notice 93-7: "Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

You have incorrect wording in the first paragraph in the Agricultural Use Requirements box on your proposed label. That paragraph must contain the exact wording of the paragraph shown as "2" in Section F on Part 2 of the Product Worksheet in Supplement Three-A to PR Notice 93-7.

Correct the typographical errors circled on your proposed label.



OIL FLOWABLE BIOINSECTICIDE

Active Ingredient:

Bacillus thuringiensis subspecies *kurstaki* strain EG2424

Lepidopteran active toxin.....	0.25%
Coleopteran active toxin.....	9.75%
Inert Ingredients.....	90.00%
TOTAL.....	100.00%

0.80 lbs. active ingredient per gallon

FOIL® BFC bioinsecticide is a biological insecticide for the control of the Colorado potato beetle.

KEEP OUT OF REACH OF CHILDREN

WARNING

AVISO

Si Usted no entiende la etiqueta, busque a alguien para que se la explique a Usted en detalle. (If you do not understand the label, find someone to explain it to you in detail).

STATEMENT OF PRACTICAL TREATMENT

If Swallowed: Drink promptly a large quantity of milk, egg whites, gelatin solution or, if these are not available, drink large quantities of water. Avoid alcohol. Get medical attention.

If On Skin: Wash with plenty of soap and water. Get medical attention.

If In Eyes: Flush with plenty of water. Call a physician.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Causes substantial but temporary eye injury. Causes skin irritation. Harmful if inhaled. Harmful if absorbed through skin. Do not get in eyes, on skin or clothing. Avoid breathing dust (vapor or spray mist).

ACCEPTED
with COMMENTS
in EPA Letter Dated

MAR 22 1991
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
55638-10

EPA Reg. No. 55638-10
EPA Est. No. 769-GA-1
Net Contents: 2.5 U.S. Gallons

Personal Protective Equipment

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear:

- Coveralls over short-sleeved shirt and short pants
- Chemical-resistant gloves such as Barrier Laminate, Nitrile Rubber (≥ 14 mils), Neoprene Rubber (≥ 14 mils) or Viton (≥ 14 mils).
- Chemical-resistant footwear plus socks
- Protective eyewear
- Chemical-resistant headgear for overhead exposure
- Chemical-resistant apron when cleaning equipment, mixing or loading

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations
User should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage

Store in a cool, dry place inaccessible to children.

Pesticide Disposal

Do not contaminate water when disposing of equipment washwaters. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.



Ecogen Inc.
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215/757-1590 · 800/220-2135

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DIRECTION FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific statements on this label about personal protective equipment (PPE) and restricted-entry intervals. The requirements in this section only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls over short-sleeved shirt and short pants
- Chemical-resistant gloves such as Barrier Laminate, Nitrile Rubber (≥ 14 mils), Neoprene Rubber (≥14 mils) or Viton (≥ 14 mils).
- Chemical-resistant footwear plus socks
- Protective eyewear
- Chemical-resistant headgear for overhead exposure

Preharvest Interval:

There are no restrictions for applying FOIL® BFC bioinsecticide up to and on the day of harvest.

Mode of Action:

After consuming a lethal dose of FOIL BFC larvae will cease to feed, but may remain alive on foliage for several days before dying. Immediately after ingestion of FOIL BFC larvae begin to move slowly, become discolored, shrivel and blacken prior to death.

MIXING INSTRUCTIONS

FOIL BFC may be applied with conventional ground, aerial or handheld equipment with quantities of water sufficient to provide thorough coverage of infested plants. To obtain a suitable mixture with water, fill the mix tank or plane hopper with the desired quantity of water. Mechanical or hydraulic agitation may be used to provide moderate circulation. For best results, shake container well, empty 1/2 of contents, reshake, do not add water to container until completely empty.

If a sticker is to be included, add after the addition of FOIL BFC. FOIL BFC should be mixed well and never added before introducing water into the tank. Maintain suspension while loading and spraying. Do not mix more FOIL BFC than can be used in a 24-hour period. Rinse and flush spray equipment thoroughly following each use. Dispose of rinsate as described in the Storage and Disposal section of this label.

APPLICATION INSTRUCTIONS

FOIL BFC is a highly selective insecticide for use against the coleopteran larvae listed in the **APPLICATION RATE TABLE**. Larvae must consume deposits of FOIL BFC to be affected. Always follow these directions:

- Careful scouting and early attention to infestations are essential to good control.
- Treat when larvae are young (early instars) and are actively feeding on foliage.
- Apply before extensive foliar damage has occurred.
- Thorough spray coverage is essential for good insect control.
- When insect infestations are heavy, use the higher label rates, shorten the spray interval and/or use larger total spray volume to improve spray coverage.
- Spray water/spray tank solutions should not exceed pH 8.0. If necessary, buffer water to near neutral (pH 7.0).
- For ground applications, use a spray volume of at least 20 gallons of water per acre. For aerial applications, use a spray volume of at least 5 gallons of water per acre.

HAND HELD EQUIPMENT

When using hand held equipment, mix 6 teaspoons per gallon of water or 3 quarts per 100 gallons of spray solution. Spray to wet, but not to runoff.

PRECAUTIONS

- Do not use FOIL® bioinsecticide BFC in combination with any chlorothalonil based fungicide (eg. Bravo®, Evade®, Terranil®, Echo®, etc.) .
- Use caution when mixing FOIL BFC with other oil based products or surfactants as such combinations could increase the risk of phytotoxicity. If unsure test on a small area first.
- If any phytotoxicity occurs, discontinue use immediately.

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IRRIGATOR

Apply this product only through center pivot, lateral move, end tow, side (wheel) roll, traveler, big gun, solid set or hand move sprinkler systems. **Do Not apply this product through any other type of irrigation system.** Crop injury or lack of effectiveness can result from nonuniform distribution of treated water.

If you have questions about calibration, contact your State Extension Service Specialist, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Chemigation Systems Connected to Public Water Systems:

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone (RPZ), backflow preventer or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump), effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

Sprinkler Chemigation:

The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.

The pesticide injection pipeline must contain a functional automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.

The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.

The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

The active ingredient in FOIL BFC will settle in the tank and injection lines; adequate agitation must be provided before and during the injection period. Use only in systems that apply uniformly and have appropriate check valves. When application is complete, thoroughly flush the injection system and sprinkler lines.

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Mixing Recommendations for Chemigation:

Follow general **MIXING INSTRUCTIONS** and keep the ratio at three parts water to one part FOIL® BFC bioinsecticide. Also, provide mild uniform agitation throughout the solution but do not agitate excessively.

For undiluted injection for chemigation: flush and clean nurse tank, lines, screen canister and pump with diesel fuel or a nonemulsifiable oil until they are water free before and after application. Use a 25-mesh screen. Continue agitation during injection.

Spray Volume:

For chemigation use irrigation levels of 0.15 to 0.5 inches of water per acre. Up to 1 inch of irrigation water may be used, but efficacy may be reduced.

WARRANTY AND CONDITIONS OF SALE

Ecogen warrants that this product conforms to the description on this label and is reasonably fit for the purposes stated on this label when used in accordance with the directions on this label under normal conditions of use.

ECOGEN MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

If this product is defective, Buyer's exclusive remedy shall be the replacement of the product, or if replacement is impracticable, refund of the purchase price. In no case will Ecogen be liable for incidental, consequential or special damages resulting from the handling, storage or use of this product.

APPLICATION RATE TABLE

Crop	Pest	Quarts/Acre ¹
Potatoes Tomatoes Eggplant	Colorado potato beetle ²	1 to 3

¹For ground applications, use a minimum spray volume of 20 gallons of water per acre. For aerial applications, use a minimum spray volume of 5 gallons of water per acre.

²Timing: Initial application should be made when 30% of observed egg masses have hatched. Repeat application at an interval sufficient to maintain control, usually 5-7 days depending upon plant growth, insect activity and weather conditions after spraying.

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