PM 92 55638-41 Best Available Image 9/30/98 Pg 1/5

~~UNITED STATES ENVIRONMENTAL PROTECTION AGENCY~~

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
(7511C) 401 M St., S.W.
Washington, D.C. 2046[illegible]

NOTICE OF PESTICIDE:
__x__ Registration
_____ Reregistration

(under FIFRA, as amended)

EPA Reg. Number: 55638-41

Date of Issuance: SEP 30 1998

Term of Issuance: Conditional

Name of Pesticide Product: BTI Technical Powder Bioinsecticide

Name and Address of Registrant (include ZIP Code):

Ecogen, Inc.
2005 Cabot Blvd. West
Langhorne, PA 19047

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant the above named pesticide is hereby registered/reregistered under the Federal Insecticide Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(C), since you have agreed to the conditions in our letter of August 10, 1998. The conditions are as follows:

(1) A *Daphnia* study with a 10 day exposure period must be completed using a maximum hazard dose. This test (as described in the *Bacillus thuringiensis* Reregistration Eligibility Decision, EPA Pub. No. EPA-738-R-004) is required to ensure that the manufacturing process has been optimized to sufficiently prevent production of significant amounts of heat labile exotoxins. Test materials should include the actual test substance at 100 times the expected environmental concentration, an autoclaved attenuated control, and filter sterilized fermentation broth or supernatant that is not

see page 2

Signature of Approving Official:

Date: SEP 30 [illegible]

EPA Form 8570-6

CONCURRENCES

SYMBOL	[illegible]	7511C						
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DATE		9/30/98						

autoclaved and one that is autoclaved. Positive and negative controls are also recommended. Should this test show significant mortality, a dose response *Daphnia* test must be preformed to derive an LC_{50}. Pending the results of the dose response assay, further non-target species testing may be required by the Agency. The *Daphnia* assay is now being required for all registrant of products containing *Bacillus thuringiensis*. This requirement must be completed within 6 months of the date of the conditional registration.

(2) An Intraperitoneal injection study must be completed. This test is part of the product identity data requirements (151A-12C) to demonstrate lack of mammalian toxicity in the Technical Grade of the Active Ingredient (TGAI). The assay should be conducted using mice with three doses (10^6, 10^7, 10^8 CFU per animal) and mortality should be recorded. If the results from this test show significant mortality at the lower doses, additional data may be required by the Agency. This requirement must be completed within 6 months of the date of the conditional registration.

(3) The results from a mosquito bioassay to verify the potency of the toxin must be submitted. This test, part of the product characterization, is needed specifically for *Bacillus thuringiensis israelensis* strain EG2215 and was lacking from the original data submission. This requirement must be completed within 6 months of the date of the conditional registration.

(4) An eye irritation study (81-4) and a dermal irritation study (81-5) must be completed. These studies are required due to the fact that manufacturing process for the Ecogen BTI differs from the cited manufacturing process in terms of the ingredients used. Therefore, these tests are needed to confirm the lack of irritation in the final technical product. Until these tests are completed, Ecogen BTI must be labeled with Toxicity Category II statements for eye irritation. These requirements must be completed within 6 months of the date of the conditional registration.

(5) Make the labeling changes below before you release the product for shipment:

a. Add the phrase "EPA Registration Number 55638-41"

(6) Submit five (5) copies of your final printed labeling before release of the product for shipment.

If these conditions are not complied with, the registration will be cancelled in accordance with FIFRA section 6(e).

A stamped copy of the label is enclosed for your records.

Sincerely,

Janet L. Andersen

Janet L. Andersen, Director
Biopesticides and Pollution
Prevention Division (7511C)

Enclosure

BTI Technical Powder Bioinsecticide

Active Ingredient:	
Bacillus thuringiensis subspecies *israelensis* strain EG2215	20.0%
Inert Ingredients	80.0%
TOTAL	100.0%

Potency: 16,000 International Toxic Units (ITU) per milligram of product.

KEEP OUT OF REACH OF CHILDREN

WARNING

STATEMENT OF PRACTICAL TREATMENT

If Swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If Inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

If in Eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

If on Skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

NOT REVIEWED
In Accordance with PR Notice 82-2
Based On Draft Labeling Dated
9/30/98

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if inhaled. Avoid breathing dust. Harmful if swallowed. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Remove contaminated clothing and wash before reuse. Avoid contact with skin. Wash thoroughly with soap and water after handling.

As a general precaution when exposed to potentially high concentrations of living microbial products such as this, all mixer/loaders and applicators not in enclosed cabs or aircraft must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board of Regional Office of the EPA.

STORAGE AND DISPOSAL

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

Storage: Store in cool, dry place inaccessible to children.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If drum cannot be reused, dispose of in the same manner.

EPA REG. No. 55638-41
EPA EST. No. 67250-IL-2 09
(Subscript refers to last 2 digits of lot number on container.)
Net Contents: 125 U.S. Pounds

ECOGEN.

Ecogen Inc.
2005 Cabot Blvd. West, P.O. Box 3023
Langhorne, PA 19047-3023
215/757-1590 or 800/220-2135

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For manufacture of bioinsecticide end-use products for application to Mosquitoes Habitat such as: irrigation ditches, roadside ditches, flood water, standing ponds, woodland pools, snow melt pools, pastures, catch basins, storm water retention areas, tidal water, salt marshes, and rice fields.

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.