

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 29 1992

BACTEC TECHNICAL POWDER I

BACTEC CORPORATION
9601 Katy Freeway, Suite 350
Houston, Texas 77024

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This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) for a period not to exceed December 15, 1993. During the period in which this registration is in effect, you must do the following.

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) or FIFRA section 4 when the Agency requires all registrants of similar products to submit such data.
2. Submit a revised Analysis of Samples, guideline reference number 151A-13, which utilizes the analytical method for determining percent lepidopteran toxin that you have cited.
3. Submit a primary dermal irritation, a primary eye irritation study, and an acute dermal toxicity study per Subdivision F of the Pesticide Assessment Guidelines within 8 months of receiving this registration. The dose level used in the dermal toxicity study submitted and the surface area to which the test material was applied were both insufficient to resolve dermal toxicity categories. For future studies, please ensure that animal treatment levels are based on dose levels per animal body weight and the surface area to which the test material is applied is sufficiently small so that toxicity categories can be resolved. For questions regarding these studies or guidance in study design, please contact Thomas Ellwanger of our Precautionary Review Section at (703) 305-7783.

CONCURRENCES

SYMBOL	H7505C						
SURNAME	Mondt						
DATE	6/29/92						

4. Per the enclosed 5/21/92 Health Effects Division review, repeat and submit anaerobic growth testing for the Bernan I strain.

5. Submit a revised Confidential Statement of Formula in which the upper limit for technical material does not exceed 100%.

6. Make the following label changes before you release your product for shipment.

a. Add the phrase, "EPA Registration No. 63947-2."

b. Change the signal word to "WARNING" and add a Statement of Practical Treatment and modify the Hazards to Humans and Domestic Animals as listed below.

STATEMENT OF PRACTICAL TREATMENT

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 SWALLOWED: Drink promptly a large quantity of milk, egg white, gelatin solution, or if these are not available, large quantities of water. Avoid alcohol.

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

Hazards to Humans and Domestic Animals

Causes substantial but temporary eye injury. Causes skin irritation. Harmful if absorbed through skin. Harmful if inhaled. Avoid breathing dust or spray mist. Do not get on skin, eyes, or clothing. Wear goggles or face shield. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

c. Modify the ingredients statement as follows.

ACTIVE INGREDIENT: Bacillus thuringiensis subspecies kurstaki, BACTEC BERNAN I, fermentation solids and solubles, 68,000 International Units of potency per milligram - equivalent to 0.31 Billion International Units per pound

CONCURRENCES							12.92%
SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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INERT INGREDIENTS: 87.08%
 TOTAL.....100.00%

d. In the Environmental Hazards statement, modify "addressin" to read "addressed in."

7. Any hypersensitivity incidents related to this product must be promptly reported to the Agency.

8. Submit five (5) copies of your final printed labeling modified as directed above before you release the product for shipment.

You should note that if you fail to satisfy any of the conditions imposed on this registration EPA may issue a Notice to Cancel this product under FIFRA section 6(e).

You should note that, regardless of whether you satisfy all applicable conditions, this conditional registration will expire automatically on December 15, 1993. Sale and distribution of the subject product after December 15, 1993 will be illegal.

Once the required data have been submitted and evaluated, EPA will entertain an application to again register the subject product.

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

Sincerely,



Phil Hutton
 Product Manager 18
 Insecticide-Rodenticide Branch
 Registration Division (H7505C)

CONCURRENCES

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SURNAME								
DATE								

BACTEC TECHNICAL POWDER I

AN INSECTICIDE FOR FORMULATING USE ONLY
INTO REGISTERED END-USE INSECTICIDES

ACTIVE INGREDIENT: <u>Bacillus thuringiensis, var. kurstaki</u> , BACTEC	
BERNAN I, fermentation solids and solubles, _____ International	
Units of potency per milligram - _____ Billion International	
Units per pound	97.9%
INERT INGREDIENTS:	2.1%
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMAN AND DOMESTIC ANIMALS

Do not get in eyes or on clothing. Wear goggles or face shield.
Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

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

NET WT: 44 Pounds

EPA Reg. No. 63947-

EPA Est. 59441-NY-001

Patent No. (Applied for worldwide)

ACCEPTED
with COMMENTS
in EPA Letter Dat

JUN 29 1992

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
63947-2

DIRECTIONS FOR USE

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

Formulators using this product are responsible for obtaining EPA registration for their formulated products.

This pesticide may be used only for the formulation of end-use insecticide for use:

on the following terrestrial food and/or feed crops:

alfalfa, almonds, walnuts, avocados, broccoli, cabbage, canola/rape, cauliflower, collards, mustard greens, turnip greens, celery, lettuce, chinese cabbage (choysum), potatoes, beans, soybeans, peas, peanuts, cucumbers, watermelons, squash, citrus, grapes, eggplant, tomatoes, peppers, field corn, sweet corn, sorghum, and cotton.

on the following terrestrial non-food sites:

tobacco and turf

on the following stored agricultural commodities:

grains, soybeans, crop seed, peanuts, and flue-cured tobacco

STORAGE AND DISPOSAL

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

STORAGE: Store tightly closed containers in a cool, dry place.

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: Do not reuse empty container. Completely empty by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into manufacturing equipment. Then dispose of container in a sanitary landfill or by incineration if allowed by state and local authorities.

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LIMITED WARRANTY AND LIABILITY - NOTICE: Read the Limited Warranty and Liability before buying or using this product. If terms are not acceptable, return it at once, unopened.

BACTEC CORPORATION
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FAX: (713) 464-1421

July 11, 1990