

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 29 1992

BACTEC BERNAN III

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

166/420,899
18

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. Additional product uniformity and test sample identification data is necessary in order to upgrade the oral, eye irritation, and inhalation studies performed on this end-use product. Further, although item 6 of this letter addresses the need for additional dermal toxicity and irritation testing, adequate sample identification and product uniformity data would be necessary prior to these new studies being found acceptable by the Agency.

In order to verify that the substance tested is essentially the same as the product sold in commerce, you should submit adequate sampling and bioassay data to show basic product

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equivalency. Sufficient statistical sampling is essential. We recommend that you prepare and submit a study protocol for EPA review and that you incorporate EPA comments into your study design to make sure that the study could show product equivalency.

4. Submit a primary dermal 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.

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

a. Add the phrase, "EPA Registration No. 63947-3."

b. Per the 6/10/92 Precautionary Review Section review, this product is tentatively classified as toxicity category II for both skin and eye irritation. You must therefore 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. Further, you must add the statement "Not for household use." to the Directions for Use section.

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.

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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. Delete "Do not apply directly to water or wetlands." from the environmental hazards statement.

d. Delete the "BENEFICIAL INSECTS" heading and accompanying text.

e. Bring the label into compliance with item II.(4) of PR Notice 82-1 regarding tank mixing.

f. Bring the label into compliance with PR Notice 83-2.

g. Delete the phrase "Bacillus thuringiensis (BT) is exempt from the requirement of a tolerance on all raw agricultural commodities, thus." as this is an implied safety claim.

h. Add the statement "Potency units should not be used to adjust use rates beyond those specified in the Directions for Use section." below the ingredients statement as required on page 22 of the Bacillus thuringiensis Registration Standard.

i. Delete references to specific buffer "Buffer Extra Strength." You may include references to generic buffers on the label or if you can provide evidence of a tolerance exemption under section 409 of the Federal Food Drug and Cosmetic Act you may list a specific buffer.

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

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

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

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

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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)

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(bottle label)

BACTEC BERNAN III
BIOLOGICAL LARVICIDE
DRY FLOWABLE

ACTIVE INGREDIENT: <u>Bacillus thuringiensis, var. kurstaki</u> , BACTEC BERNAN III, 32,000 International Units of potency per milligram - 14.52 Billion International Units per pound	6.4%
INERT INGREDIENTS:	93.6%
TOTAL:	100.0%

EPA Reg. No. _____
EPA EST. 59441-NY-001
PATENT No. (Applied for worldwide)

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS 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 contaminate water when disposing of equipment wash waters. Do not apply directly to water or wetlands.

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NET WT: 1200 GMS. - 2.64 LBS.

ACCEPTED
with COMMENTS
to EPA Label 6347-3

JUN 29 1992

Product of Bactec Corporation, Inc.,
EPA Registration No. 59441-NY-001
as a biological larvicide
registered under EPA Reg. No.

6347-3

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. REFER TO ATTACHED DETAILED INSTRUCTIONS FOR SPECIFIC CROP USE AND APPLICATION RATES.

BENEFICIAL INSECTS: Honeybees foraging treated areas are not harmed by BACTEC BERNAN nor does it interrupt the activities of other beneficial or predacious arthropods in Integrated Pest Management Programs.

GENERAL: Apply BACTEC BERNAN at first sign of infestation when larvae are small and repeat at 3 to 7 day intervals as needed to maintain control below damage levels. BACTEC BERNAN destroys the larval gut and as such must be ingested by the insect to provide mortality. Thorough foliage/fruit coverage is needed to achieve maximum results. Shortly after eating a lethal dose of BACTEC BERNAN, the larvae become paralyzed, stop eating and die within 1-3 days. The active ingredient, Bacillus thuringiensis (BT), is exempt from the requirements of a tolerance on all raw agricultural commodities, thus BACTEC BERNAN may be applied up to and including the day of harvest or after harvest.

MIXING: Use standard dry-product mixing procedures for knapsack, tractor and aerial spray applications. Add the Buffer Extra Strength to assist in maximum control. Apply where there is at least one (1) hour of drying time free of rain and/or heavy dews. When possible, apply in early morning or evening in calm air conditions.

CROP APPLICATION: Specific instructions are attached for each crop and insect.

STORAGE & DISPOSAL: Do not contaminate feed, food, or water by storage or disposal. **STORAGE:** Tightly reclose containers of unused BACTEC BERNAN Bio-Larvicide and store in a dry, well-ventilated, cool place at temperatures less than 122°F/50°C. **PRODUCT/CONTAINER DISPOSAL:** Wastes resulting from the use of the product may be disposed of on site or at an approved waste disposal facility. Triple rinse (or equivalent) then puncture and dispose of empty container in a sanitary landfill, by incineration, or if allowed by state and local authorities, by burning (if burned, stay out of smoke).

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
9601 KATY FREEWAY, SUITE 350
HOUSTON, TX 77024

PHONE: (713) 464-5444
FAX: (713) 464-1421

July 11, 1990

(insert labeling)

BACTEC BERNAN III
BIOLOGICAL LARVICIDE
DRY FLOWABLE

ACTIVE INGREDIENT: <u>Bacillus thuringiensis, var. kurstaki</u> , BACTEC BERNAN III, 32,000 International Units of potency per milligram -	
14.52 Billion International Units per pound	6.4%
INERT INGREDIENTS:	93.6%
TOTAL:	100.0%

EPA Reg. No. _____
EPA EST. 59441-NY-001
PATENT No. (Applied for worldwide)

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS 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 contaminate water when disposing of equipment wash waters. Do not apply directly to water or wetlands.

DIRECTIONS 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 through any type of irrigation system.

DAYS TO HARVEST: Bacillus thuringiensis (BT) is exempt from the requirement of a tolerance on all raw agricultural commodities, thus BACTEC BERNAN may be applied up to and including the day of harvest or after harvest.

SITES: BACTEC BERNAN may be applied for control of any labeled pest in both field and greenhouse uses. BACTEC BERNAN is a highly specific larvicide to be used against listed caterpillars (larvae) of lepidopterous insects. Close observation and attention to insect infestations is strongly recommended. Larvae must eat spray deposits of BACTEC BERNAN to be affected and induce mortality. ALWAYS FOLLOW THESE GUIDELINES:

- * Treat when larvae are young (early instars) before the crop is extensively damaged.
- * Larvae must be actively feeding on treated, exposed plant parts.
- * Thorough spray coverage is needed to provide a uniform deposit of BACTEC BERNAN on the sites of larval feeding. For certain crops, directed spray nozzles by tractor are required.
- * Under heavy pest population pressure, use the higher label rates, shorten the spray intervals, and/or raise the gallonage to improve spray coverage.
- * Repeat applications at intervals sufficient to maintain control, usually 3 to 14 days depending on plant growth rate, moth activity, rainfall after treating, and other factors. If attempting to control a pest with a single spray, make the treatment when egg hatch is essentially complete, but before extensive crop damage occurs.
- * The pH of the spray solution should be held within a range of 6.6 to 6.9. Buffer Xtra Strength (buffering agent) is provided for use with BACTEC BERNAN products when spray water has a pH exceeding 8.0.
- * A spreader-sticker which has been approved for use on growing and harvested crops may be added for hard-to-wet crops, such as cole crops, or to improve weather-fastness of the spray deposits.
- * BACTEC BERNAN may be tank mixed with other labeled insecticides to enhance pest infestation control; however, before tank mixing with other labeled products, check for tank-mix compatibility.

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After eating a lethal dose of BACTEC BERNAN, larvae usually stop feeding, develop paralysis, and die within 1 to 3 days. Dying larvae move slowly, discolor, and eventually shrivel, and die.

MIXING & APPLICATION: BACTEC BERNAN may be applied in conventional knapsack, tractor or aerial spray equipment with quantities of water sufficient to provide thorough coverage of infested plant parts. The amount of water needed per acre (hectare) will depend on crop size, weather, spray equipment, and local experience. Unless otherwise indicated by local instructions, use the following chart for spray volumes. When possible, apply early morning or evening in calm air conditions. Add water to the spray or mixing tank at the level that provides maximum agitation. With the agitator running, sprinkle BACTEC BERNAN into the tank and continue agitation. Then, add other spray materials, if any (a sticker, adhesive or deposit builder may be added when a heavy dew or rain is encountered). Add the balance of the water and agitate until mixed. Be sure to maintain the suspension while loading and spraying. For applications to trees, use the recommended amount of BACTEC BERNAN in 100 gallons/acre (1000 liters/hectare) of water in high-pressure, high-gallonage hydraulic sprayers, wetting the foliage thoroughly but avoiding excessive run-off. For mist blowers, use recommended amount in 10 gallons/acre (100 liters/hectare) of water. Do not mix more BACTEC BERNAN than can be used in a 12-hour period.

SPRAY VOLUMES

<u>VOLUME</u>	<u>GALLON/ACRE</u>	<u>LITER/HECTARE</u>	<u>DILUTION RATE</u>
AERIAL	3 to 5	30 to 50	1:100
GROUND	5 to 10	50 to 100	1:200
KNAPSACK	40	400	1:1000
ORCHARD	100	1000	1:3000

BENEFICIAL INSECTS: Honeybees foraging in treated areas are not harmed or affected by BACTEC BERNAN use. BACTEC BERNAN does not interrupt the activities of beneficial and predacious arthropods in Integrated Pest Management Programs.

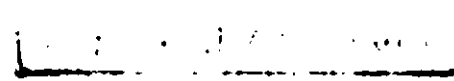
STORAGE & DISPOSAL: Do not contaminate feed, food, or water by storage or disposal of this product or its container. STORAGE: Tightly reclose containers of unused BACTEC BERNAN and store in a dry, well-ventilated, cool place at temperatures less than 122°F/50°C. PRODUCT/CONTAINER DISPOSAL: Wastes resulting from the use of the product may be disposed of on site or at an approved waste disposal facility. Triple rinse (or equivalent) then puncture and dispose of empty container in a sanitary landfill, by incineration, or if allowed by state and local authorities, by burning (if burned, stay out of smoke).

BEST AVAILABLE COPY

APPLICATION RATES

<u>CROP</u>	<u>PEST NAME (Common Name)</u>	<u>POUNDS/ACRE</u>	<u>GRAMS/HECTARE</u>	
ALFALFA/HAY	Alfalfa Caterpillar	1/2-1	600-900-1200	
	Loopers	1/2-1	600-900-1200	
	Armyworms	1/2-1	500-900-1200	
ALMONDS	Redhumped Caterpillar	1/2-1	600-900-1200	
WALNUTS	Tent Caterpillar	1/2-1	600-900-1200	
	Walnut Caterpillar	1/2-1	600-900-1200	
	Filbert Leafroller	1/2-1	600-900-1200	
	Fall Webworm	1/2-1	600-900-1200	
	Leafrollers	1/2-1	600-900-1200	
	Cankerworms	1/2-1	600-900-1200	
	AVOCADOS	Amorbia Moth	1/2-1	600-900-1200
	Omnivorous Leafroller	1/2-1	600-900-1200	
	Omnivorous Looper	1/2-1	600-900-1200	
	Orange Tortix	1/2-1	600-900-1200	
	Spanworm	1/2-1	600-900-1200	
BROCCOLI/CABBAGE	Cabbage Looper	1/2-1	600-900-1200	
CANOLA/RAPE	Imp. Cabbageworm	1/2-1	600-900-1200	
CAULIFLOWER	Diamondback Moth	1/2-1	600-900-1200	
COLLARDS	Green Cloverworm	1/2-1	600-900-1200	
MUSTARD GREENS	Loopers	1/2-1	600-900-1200	
TURNIP GREENS	Omnivorous Leafroller	1/2-1	600-900-1200	
CELERY	Cabbage Looper	1/2-1	600-900-1200	
LETTUCE	Hornworms	1/2-1	600-900-1200	
CHINESE CABBAGE (Choysum)	Webworm	1/2-1	600-900-1200	
POTATOES	Potato Beetle	1/2-1	600-900-1200	
	Armyworms	1/2-1	600-900-1200	
	Diamondback Moth	1/2-1	600-900-1200	
	Green Cloverworm	1/2-1	600-900-1200	
	Saltmarsh Caterpillar	1/2-1	600-900-1200	
	Cutworms	1/2-1	600-900-1200	
	Loopers	1/2-1	600-900-1200	
	Omnivorous Leafroller	1/2-1	600-900-1200	
	Heliothis spp.	1/2-1	600-900-1200	
	Navel Orangeworm	1/2-1	600-900-1200	
	Leaf Miner	1/2-1	600-900-1200	
	BEA. 3	Velvetbean Caterpillar	1/2-1	600-900-1200
	SOYBEANS	Soybean Looper	1/2-1	600-900-1200
PEAS	Loopers	1/2-1	600-900-1200	
PEANUTS	Head Moth	1/2-1	600-900-1200	
	Green Cloverworm	1/2-1	600-900-1200	
	Saltmarsh Caterpillar	1/2-1	600-900-1200	
	Armyworms	1/2-1	600-900-1200	

EASY-MODERATE-HARD TO CONTROL LARVAE



APPLICATION RATES

<u>CROP</u>	<u>PEST NAME (Common Name)</u>	<u>POUNDS/ACRE</u>	<u>GRAMS/HECTARE*</u>
CUCUMBERS	Rindworm Complex	1/2-1	600-900-1200
WATERMELONS	Melonworms	1/2-1	600-900-1200
SQUASH	Cabbage Looper	1/2-1	600-900-1200
	Armyworms	1/2-1	600-900-1200
CITRUS	Fruittree Leafroller	1/2-1	600-900-1200
	Orangedog	1/4-1	300-750-1200
	Citrus Cutworm	1/2-1	600-900-1200
GRAPES	Omnivorous Leafroller	1/2-1	600-900-1200
	Grapeleaf Skeletonizer	1/2-1	600-900-1200
	Roughskinned Cutworm	1/2-1	600-900-1200
	Grapeleaf Folder	1/2-1	600-900-1200
	Grape Leafroller	1/2-1	600-900-1200
	Saltmarsh Caterpillar	1/2-1	600-900-1200
	Achema Sphinx Moth (Hornworm)	1/2-1	600-900-1200
	Orange Tortix	1/2-1	600-900-1200
	Obliquebanded Leafroller	1/2-1	600-900-1200
	Tobacco Budworm	1/2-1	600-900-1200
	Loopers	1/2-1	600-900-1200
	Armyworms	1/2-1	600-900-1200
EGGPLANT	Tomato Fruitworm	1/2-1	600-900-1200
TOMATOES	Tomato Hornworm	1/2-1	600-900-1200
PEPPERS	Variegated Cutworm	1/2-1	600-900-1200
	Saltmarsh Caterpillar	1/2-1	600-900-1200
	Loopers	1/2-1	600-900-1200
	Tomato Pinworm	1/2-1	600-900-1200
	Armyworms	1/2-1	600-900-1200
FIELD CORN	Corn Earworm	1/2-1	600-900-1200
SWEET CORN	Headworms	1/2-1	600-900-1200
SORGHUM	Armyworms	1/2-1	600-900-1200
	Corn Borer	1/2-1	600-900-1200
COTTON	Tobacco Budworm	1/2-1	600-900-1200
	Cotton Bollworm	1/2-1	600-900-1200
	Saltmarsh Caterpillar	1/2-1	600-900-1200
	Loopers	1/2-1	600-900-1200
	Armyworms	1/2-1	600-900-1200
TOBACCO	Tobacco Budworm	1/2-1	600-900-1200
	Tobacco Hornworm	1/4-1/2	300-450-600
	Loopers	1/2-1	600-900-1200
TURF	Sod Webworm	1/2-1	600-900-1200

* EASY-MODERATE-HARD TO CONTROL LARVAE

STORED AGRICULTURAL COMMODITIES

APPLICATION RATES

CROP	PEST NAME (Common Name)	POUNDS	GRAMS
		per 100 bushels (diluted and undiluted)	
GRAINS	Indian Meal Moth	3/8-1/2	175-250
SOYBEANS	Almond Moth	3/8-1/2	175-250
CROP SEED			

To control and prevent these pests, apply BACTEC BERNAN in a constantly agitated water suspension to the top four-inch surface layer of grain in the bin. Use a sprinkler can or sprayer to apply the dosage into the grain stream as the last (top) four-inch layer is augered into the bin, applying 0.6 pint of mixture per bushel. The dosage can also be sprinkled onto the surface of the grain in the bin and mixed thoroughly with a scoop or rake to a depth of four inches. More thorough coverage may be achieved by dividing the suggested dosage into three applications and mixing the grain between applications. As a surface treatment, apply 1/2 pound or 250 grams in 5 to 10 gallons of water per 500 square feet of grain surface area; mix into top four inches. For commodities coarser than shelled corn, increase depth of treatment according to the habit of the pest.

APPLICATION RATES

CROP	PEST NAME (Common Name)	POUNDS/TON	GRAMS/TON
PEANUTS	Indian Meal Moth	1/4	125
	Almond Moth	1/4	125

Apply this rate to the top four to eight feet of nuts when filling the warehouse.

To prevent and control these pests, spray an even coating of BACTEC BERNAN on the farmer stock peanuts while filling the warehouse. To make the spray solution, mix 3.75 pounds or 1700 grams per 5 gallons of water; this amount should treat 15 tons of commodity. Keep the spray suspension agitated during application and use pressures and nozzles sufficient to handle this suspension. For bagged peanuts, treat the whole mass of commodity at the suggested rate before bagging. Before a warehouse is filled, the cleaned interior can be sprayed using 1/2 pound or 250 grams per 100 gallons of water; apply to interior and spray into cracks.

APPLICATION RATES

CROP	PEST NAME (Common Name)	SUGGESTED RATE/COMMODITY
FLUE-CURED TOBACCO	Tobacco Moth	0.2 ounce per 100 pounds
NOTE: 0.2 ounce is equivalent to approximately 2.5 teaspoons; mix this amount in one quart of water per 100 pounds of tobacco.		

TOBACCO TO BE STORED UP TO 12 MONTHS: Spray loose leaves as the tobacco is being bundled from the curing barn. For tobacco sticks, treat both sides of the leaves.

STORED TOBACCO: For tobacco which is to be carried over, rebundle or restack sticks, fluff up tobacco and spray loose leaves. For tobacco that has been stored over three weeks, apply at first signs of infestations; promptly open bundles, spray loose leaves and then rebundle.

TREATMENT OF STORAGE BARNs: If tobacco has been treated, or is going to be treated, treatment of the floors and walls may be made to aid in control. Sweep out the area, especially cracks and corners, and remove all of the loose tobacco pieces where the moth might breed. Make a spray mixture containing 1/2 ounce per 2.5 gallons of water and apply at a rate of 1/2 gallon per 1000 square feet of surface area. Be sure to spray into cracks and floorboards.

BACTEC CORPORATION
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 HOUSTON, TX 77024

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 FAX: (713) 464-1421

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