

PM18

63947-3

File 1/8/12



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

MAY 11 1994

Thomas A. Plato
BACTEC CORP
2001 Holcombe Blvd, Suite 203
Houston, TX 77030

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: Label Amendment Submission of 04/15/94 in Response to PR Notice 93-7
EPA Reg. No. 63947-3
BACTEC BERNAN III BIOLOGICAL LARVICIDE DRY FLOWABLE

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

Hand or 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

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division

Thomas A. Plato
BACTEC CORP
2001 HOLCOMBE BLVD SUITE 203
HOUSTON TX 77030

Comment for: EPA Reg Nr.63947-3
BACTEC BERNAN III_BIOLOGICAL LARVICIDE DRY FLOWABL

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

Place the heading "Personal Protective Equipment" on your labeling in the location shown in Section A on Part I of the Product Worksheet in Supplement Three-A to PR Notice 93-7.

Add the following User Safety Recommendation to the label in the location shown in Section A on Part I of the Product Worksheet in Supplement Three-A to PR Notice 93-7: "Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Delete the crossed-out statements on your proposed label. They are redundant statements or phrases.

Correct the typographical errors circled on your proposed label.

(bag label)

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BACTEC BERNAN III BIOLOGICAL LARVICIDE

DRY FLOWABLE

ACTIVE INGREDIENT:	<i>Bacillus thuringiensis, var. kurstaki</i> , 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%

* Potency units should not be used to adjust use rates beyond those specified in the Directions for Use section.

KEEP OUT OF REACH OF CHILDREN

WARNING / AVISO

PRECAUTIONARY STATEMENTS - 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. Wash thoroughly with soap and water after handling.

Applicators and other handlers must wear: long-sleeved shirt and long pants, waterproof gloves, shoes plus socks and protective eyewear. Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

PRECAUCION AL USUARIO: 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 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, preferable mouth-to-mouth. Get medical attention.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment wash waters.

EPA Registration No. 63947-3

EPA Establishment No. 62171-MS-001

US Patent No. 4,950,471

ACCEPTED
with COMMENTS
In EPA Letter Dated

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

63947-3

NET WEIGHT:

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. NOT FOR HOUSEHOLD USE.

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.

Do not apply this product through any type of irrigation system.

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 instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE). The requirements in this box 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, waterproof gloves, shoes plus socks and protective eyewear.

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. BACTEC BERNAN may be applied up to and including the day of harvest.

MIXING:

Use standard dry-product mixing procedures for knapsack, tractor and aerial spray applications. Apply where there is at least one (1) hour of drying time free of rain and/or heavy dews. When possible, apply 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 and store in a dry, well-ventilated, cool place. **PRODUCT/CONTAINER DISPOSAL:** Wastes resulting from the use of the product may be disposed of on site or at an approved waste disposal facility. Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill, by incineration, or if allowed by state and local authorities, by burning (if burned, stay out of smoke).

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(insert label)

BACTEC BERNAN III BIOLOGICAL LARVICIDE

DRY FLOWABLE

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ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment wash waters.

EPA Registration No. 63947-3

EPA Establishment No. 62171-MS-001

US Patent No. 4,950,471

NET WEIGHT:

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DIRECTIONS FOR USE:

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DAYS TO HARVEST:

BACTEC BERNAN may be applied up to and including the day of 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 evaluated 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 ground machine 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. Use a buffering agent 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.

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.

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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.

SUGGESTED SPRAY VOLUMES			
VOLUME	GALLON/AC	LITER/HA	DILUTION RATE
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

STORAGE AND 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. **PRODUCT-CONTAINER DISPOSAL:** Wastes resulting from the use of the product may be disposed of on site or at an approved waste disposal facility. Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill, by incineration, or if allowed by state and local authorities, by burning (if burned, stay out of smoke).

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APPLICATION RATES

CROP	PEST (Common Name)	LBS/ACRE	GMS/HECTARE*
ALFALFA/HAY	Alfalfa Caterpillar	1/2 - 1	600 - 900 - 1200
	Loopers	1/2 - 1	600 - 900 - 1200
	Armyworms	1/2 - 1	600 - 900 - 1200
ALMONDS and WALNUTS	Redhumped Caterpillar	1/2 - 1	600 - 900 - 1200
	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, CANOLA/RAPE, CAULIFLOWER, COLLARD, MUSTARD GREENS, and TURNIP GREENS	Cabbage Looper	1/2 - 1	600 - 900 - 1200
	Imp. Cabbageworm	1/2 - 1	600 - 900 - 1200
	Diamondback Moth	1/2 - 1	600 - 900 - 1200
	Green Cloverworm	1/2 - 1	600 - 900 - 1200
	Loopers	1/2 - 1	600 - 900 - 1200
	Omnivorus Leafroller	1/2 - 1	600 - 900 - 1200
CELERY, LETTUCE, CHINESE CABBAGE, (Choysum) and POTATOES	Cabbage Looper	1/2 - 1	600 - 900 - 1200
	Hornworms	1/2 - 1	600 - 900 - 1200
	Webworm	1/2 - 1	600 - 900 - 1200
	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	
BEANS, SOYBEANS, PEAS, and PEANUTS	Velvetbean Caterpillar	1/2 - 1	600 - 900 - 1200
	Soybean Looper	1/2 - 1	600 - 900 - 1200
	Loopers	1/2 - 1	600 - 900 - 1200
	Head Moth	1/2 - 1	600 - 900 - 1200
	Green Cloverworm	1/2 - 1	600 - 900 - 1200
	Saltmarsh Caterpillar	1/2 - 1	600 - 900 - 1200
CUCUMBERS, WATERMELONS, and SQUASH	Armyworms	1/2 - 1	600 - 900 - 1200
	Rindworm Complex	1/2 - 1	600 - 900 - 1200
	Melonworms	1/2 - 1	600 - 900 - 1200
	Cabbage Looper	1/2 - 1	600 - 900 - 1200
CITRUS	Armyworms	1/2 - 1	600 - 900 - 1200
	Fruittree Leafroller	1/2 - 1	600 - 900 - 1200
	Orangedog	1/4 - 1	300 - 750 - 1200
	Citrus Cutworm	1/2 - 1	600 - 900 - 1200

* Easy - Moderate - Hard to control larvae

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APPLICATION RATES, CONT.

CROP	PEST (Common Name)	LBS/ACRE	GMS/HECTARE*
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, TOMATOES, and PEPPERS	Tomato Fruitworm	1/2 - 1	600 - 900 - 1200
	Tomato Hornworm	1/2 - 1	600 - 900 - 1200
	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, SWEET CORN, and SORGHUM	Corn Earworm	1/2 - 1	600 - 900 - 1200
	Headworms	1/2 - 1	600 - 900 - 1200
	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

11-8-12

STORED AGRICULTURAL COMMODITIES

APPLICATION RATES

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

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.

CROP	PEST (Common Name)	LBS/TON	GMS/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.

CROP	PEST (Common Name)	SUGGESTED RATE/COMMODITY
FLUE-CURED TOBACCO	Tobacco Moth	0.2 ounces per 100 lbs

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.

DISCLAIMER: The labeled directions for the use of this product reflect the opinion of experts, based on field use and tests. The directions are believed to be reliable and should be followed carefully; however, it is impossible to eliminate all risks inherently associated with use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presences of other materials, or the use or application of the product contrary to the label directions, all of which are beyond the control of BACTEC CORPORATION. All such risks shall be assumed by the user.

BACTEC CORPORATION warrants only that the material contained herein conforms to the chemical description on the label and is reasonably fit for the purpose stated on this label when used in accordance with the directions under normal conditions of use, subject to the risks referred to above. Any damages arising from a breach of this warranty shall be limited to product replacement and shall not include consequential commercial damages such as loss of profits or values or any other special direct or indirect damages.

BACTEC CORPORATION makes no other express or implied warranty, including any other express or implied warranty of FITNESS or MERCHANTABILITY. The sale of this product does not include a license under any patent controlled by BACTEC CORPORATION.