

Reg # 58998-29

PM-18

136



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

MAY 06 1994

Janet Overholt
NOVO NORDISK BIOINDUSTRIALS, INC.
AGENT FOR: NOVO NORDISK A/S
33 TURNER ROAD - BOX 1907
DANBURY, CT 06813

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: Label Amendment Submission of 04/04/94 in Response to PR Notice 93-7
EPA Reg. No. 58998-29
BACTOSPEINE-HG WETTABLE POWDER

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/Candle Ink on paper that
contains at least 50% recycled fiber

Page 2

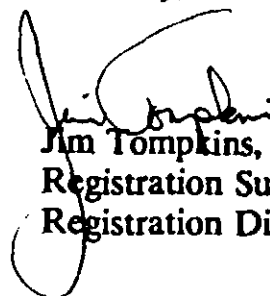
Submit the final printed labeling via the U.S. Postal Service to:

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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NOVO NORDISK BIOINDUSTRIALS, INC.
58998-29 04/04/94
BACTOSPEINE-HG WETTABLE POWDER
Original Submission

User Safety Recommendations must either be placed in a box or printed on the label in a contrasting color from surrounding text.

The Agricultural Use Requirements section must be located in a clearly separate box on the product labeling - - with lines or other graphic indicators (such as contrasting color) to separate the section from the surrounding text.

Remove the statement "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." from its current position within the Agricultural Use Box and place it above the Agricultural Use Box.

Correct the typographical errors circled on your proposed label.

Bactospeine® is a registered trademark of Novo Nordisk A/S

KEEP OUT OF REACH OF CHILDREN CAUTION

ACTIVE INGREDIENT:

Bacillus thuringiensis Berliner var. *kurstaki*, primary powder fermentation product.....20%

INERT INGREDIENTS.....80%
.....100%

* Bactospeine Wettable Powder contains 16,000 International Units per milligram of product, equivalent to 7.3 billion International Units per pound.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS: Avoid inhalation or contact with eyes or open wounds.

PERSONAL PROTECTIVE EQUIPMENT:

Applicators and other handlers must wear: Long-sleeved shirt and long pants, waterproof gloves, and shoes plus socks. 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 STATEMENTS:

Users 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.

For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.

DIRECTIONS FOR USE:

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

Refer to Directions for Use Booklet attached to this container for further directions.

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), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

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.

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, and shoes plus socks.

Bactospeine (*Bacillus thuringiensis*) Wettable Powder provides best control when caterpillars are newly hatched (1st or 2nd instar) and most susceptible to the product which must be eaten. Good leaf coverage is essential to achieve effective insect control. Higher rates are generally necessary when infestations are heavy and foliage is dense.

To obtain a suitable mixture with water, pour the recommended amount into a 1/2 filled tank and agitate. Fill tank and maintain agitation until the mixing process is complete. Bactospeine is compatible with various insecticides, fungicides, spreaders, and stickers except those that are highly alkaline in nature. Reagitate if dilute spray is allowed to stand for more than 6 hours. For most trees, the recommended amount of product may be applied by high pressure hydraulic sprayers in 100 gallons of water per acre. Cover foliage thoroughly, but avoid run-off. Mist blower applications may use 10-20 gallons of water per acre.

Spreaders and stickers improve coverage and are recommended.

For vine, pome, citrus and tropical fruits, use recommended amount per 100 gallons water and apply 100 to 500 gallons of spray dilution per acre.

Aerial application should use recommended rates in 1/4 to 10 gallons of water per acre during early morning or evening hours when winds are low. Spray systems which produce a 50-300 micron droplet size are preferable.

For small quantities, use 2 teaspoonfuls per gallon of water to provide an application rate of 1 lb/acre in 100 gallons of water.

Note: Because the active ingredient, *Bacillus thuringiensis*, is exempt from tolerance requirements, this product may be applied up to the day of harvest and in storage.

STORAGE AND DISPOSAL:

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

Storage: Tightly reclose containers of unused Bactospeine. Store in a cool, dry place.

Pesticide Disposal: Pesticide waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility in accordance with federal and local regulations.

Container Disposal: Completely empty bag into application equipment. Then dispose of empty bag and box in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY: NOVO NORDISK MAKES NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PURPOSE, OR OTHERWISE, EXPRESS OR IMPLIED, concerning this product or its uses which extend beyond the use of the product under normal conditions in accord with the statements made on this label. In no case shall the seller be liable for consequential, or indirect damages resulting from the use or handling of this product. All such risks shall be assumed by the buyer. Novo Nordisk holds U.S. registrations for the active ingredient. BACTOSPEINE is manufactured by Novo Nordisk.

APPLICATION RATES FOR BACTOSPEINE WETTABLE POWDER

Crop	Pest	Lb/Acre
Field and Greenhouse vegetables, including:		
Broccoli, Spinach, Collards,	Armyworms	1 - 2
Cauliflower, Kale, Lettuce, Rappini, Artichokes,	Tomato fruitworm/Corn earworm/Bollworm	1 (every 5-7 days)
Turnips, Turnip greens, Beets,	Variegated cutworm	1
Celery, Mustard greens, Beans,	Saltmarsh caterpillar	1/4 - 1
Cabbage, Brussels Sprouts, Peas,	Mimosa webworm	1/4 - 1
Chinese Cabbage, Sweet Potato,	Tobacco budworm	1/4 - 1
Kohlrabi, Endive, Sweet Corn,	Loopers, Melonworm, Pickleworm	1/4 - 1
Tomatoes, Peppers, Eggplant,	Diamondback moth	1/4 - 3/4
Escarole, Lentils, Potato,	Imported cabbageworm	1/4 - 3/4
Carrots, Cucumbers,	Green cloverworm	1/4 - 3/4
Melons, Squash, Watercress	Hornworm, Artichoke plume moth	1/4 - 3/4
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Tobacco	Tobacco budworm	1/2 - 1
	Loopers	1/2 - 1
	Hornworms	1/4 - 3/4
<p>To control tobacco moth during storage use 1.6 oz or 9 level tablespoons of Bactospeine in one gallon water per 400 lbs tobacco uniformly applied as a spray mist to leaf surfaces before bundling or to opened bundles and to walls and floors of storage area.</p>		
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Safflower, Sugar beets,	Tobacco budworm/bollworm	1/4 - 1
Mints, Peanuts, Alfalfa,	Loopers, Sunflower moth	1/4 - 1
Soybeans, Sunflower, Hay,	Saltmarsh caterpillar	1/4 - 1
Pastures, Small grains,	Green cloverworm, Sorghum headworm	1/4 - 1
Forage crops, Grain sorghum	Skippers	1/4 - 1/2
	Alfalfa caterpillar	- 1/4
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Turf,	Sod webworm	2 - 4
Rangeland	Rangeland caterpillar	1/8 - 1/4
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Grapes, Blueberries, Blackberries, Currants,	Grapeleaf skeletonizer	1/2 - 1
Raspberries, Hops,	Loopers, Saltmarsh caterpillar	1/4 - 1
Strawberries,	Grape leafroller/leafrollers	1/2 - 1
Dewberries	Hornworms	1/4 - 3/4
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Cotton	Loopers	1/2 - 1
	Tobacco budworm	1/4 - 1
	Bollworm	1/4 - 1

Apply at first sign of 1st and 2nd instar budworm or bollworm larvae. Use at least 7 gallons total spray with ground equipment or 2-5 gallons/acre with aerial equipment. To continue worm suppression reapply Bactospeine at 3-5 day intervals or use scouting report recommendations. Bactospeine at .25 to 1.0 lb/acre may be tank mixed with methomyl at .225 to .675 lbs active ingredient (AI)/acre to suppress infestations of early instar larvae.

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Crop	Pest	LB/100 Gallons (Ground Application)	LB/Acre (Air Application)
Peaches, Plums,	Gypsy moth	1/2 - 2	1 - 2
Cherries, Walnuts,	Walnut caterpillar	1/2 - 1	1/2 - 1
Almonds, Pecans,	Leafrollers	1/2 - 1	1/2 - 1
Filberts,	Cankerworms	1/4 - 1	1/2 - 1
Apples, Pears,	Tent caterpillars	1/4 - 1	1/2 - 1
Avocados, Kiwis,	Redhumped caterpillar	1/4 - 1	1/2 - 1
	Fall Webworm	1/2	1/2

Forests, Shade trees,	Armyworms	1 - 2	
Ornamental plants,	Pine butterfly	1	1
Flowers, Shrubs	Spruce budworm	1 - 2	1 - 2
	Western spruce budworm	1	1
	Douglas fir tussock moth	1	1
	Diamondback moth	1/4 - 3/4	1
	Gypsy moth	1/2 - 2	1 - 2
	Elm spanworm	1/2 - 1	1/2 - 5
	Bagworm, Saddled prominent	1/4 - 1	1/4
	Saddleback caterpillar, Leafrollers	1/2 - 1	1/2 - 1
	Loopers, Western tussock moth	1/2 - 1	1/2 - 1
	Tobacco budworm/Bollworm/Corn earworm	1/2 - 1	1/2 - 1
	Io moth, Mimosa webworm	1/2 - 1	1/2 - 1
	Jackpine budworm	1/2 - 1	1/2 - 1
	Oleander moth	1/2 - 1	1/2 - 1
	Fall webworm	1/2	1/2
	Tent caterpillars	1/4 - 1	1/4 - 1
	Redhumped caterpillars	1/4 - 1	1/4 - 1
	Cankerworms, Oakworms, Hornworms	1/4 - 1	1/4 - 1

For best control of Gypsy moth, apply when young larvae are present and when leaf expansion is 40-50%. Repeat in 1 to 3 weeks.

For best control of spruce budworm, apply on population below 35 larvae per 18-inch branch tip and when 50% of the larvae are in the 3rd and 4th instar.

Citrus	Leafrollers, Hornworms, Loopers	1/2 - 1	1/2 - 1
Tropical fruits	Orangedog	1/4 - 1/2	1/4 - 3/4

Stored Products:	Indian meat moth	10 lb/100 Gallons
grain, legumes,	Almond moth	(1.6 oz./Gallon)
peanuts, oilseeds,	Mediterranean flour moth	
and other seeds and grains		

BEST AVAILABLE COPY

Continuously agitate spray solution and spray at the rate of six pints per ten bushels to grain going into storage bins or bags on a conveyer or auger to obtain thorough mixing. Alternately, the top 4 - 6 inches of grain in a bin may be treated during the bin filling process or after filling with one pound bactospeine in ten gallons water per 500 square feet surface area and raked in.

NOTICE: Local conditions may affect the use of Bactospeine. Consult State Agricultural Extension or Experiment Station Specialists for specific recommendations related to local crop problems.