



58998-2

File 10/17

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

MAR 23 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Janet M. Overholt
NOVO NORDISK A/S
AGENT FOR: NOVO NORDISK A/S
33 Turner Road - Box 1907
Danbury, CT 06813

Subject: Label Amendment Submission of 07/26/93 in Response to PR Notice 93-7
EPA Reg. No. 58998-2
BIOBIT FLOWABLE CONCENTRATE

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

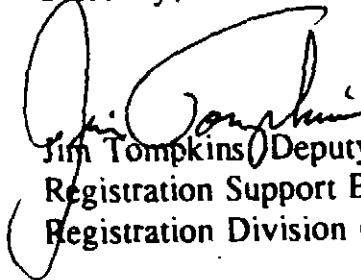
Submit the final printed labeling via the U.S. Postal Service to:

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

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

Comment for: EPA Reg Nr.58998-2
BIOBIT FLOWABLE CONCENTRATE

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

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.

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 handles may be in the area during application" from its current position within the AG Use Box and place it under the Direction for Use.

Biobit® is the Registered Trademark of Novo Nordisk

KEEP OUT OF REACH OF CHILDREN CAUTION

BEST AVAILABLE COPY

STATEMENT OF PRACTICAL TREATMENT

If in eyes, flush with plenty of water. Get medical attention irritation persists.

ACTIVE INGREDIENT *Bacillus thuringiensis* Berliner
subspecies *kurstaki*,
8,000 International units (IU)/mg of product (equivalent to
32 billion IU/GAL).....1.6%
Inert Ingredients.....98.4%

Directions For Use, Cont.

For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

May cause eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

PERSONAL PROTECTIVE EQUIPMENT

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

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.

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

Refer to the 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. Refer to supplemental labeling under "Agricultural Use Requirements" in the Directions For Use section for information about this standard.

STORAGE AND DISPOSAL:

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

Storage: Store in a cool, dry place. Keep containers tightly closed when not in use. Store in temperatures above freezing and below 90 degrees F.

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: Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

HOME GARDEN USE DISPOSAL INSTRUCTIONS

Securely wrap original container in several layers of newspaper and discard in trash.

NOTICE OF 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. registration for the active ingredient. Biobit is manufactured by Novo Nordisk.

RECEIVED
MAR 23 1994
In EPA Letter Dated

EPA Registration No. 58998-2
EPA Est. No. 58998-DN-002

MANUFACTURED FOR:
Novo Nordisk
33 Turner Road
Danbury, Connecticut 06813-1907

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

NET CONTENTS

U S Gallons

labeling.

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

For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

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, shoes plus socks.

APPLICATION

Biobit may be applied by ground or aerial equipment with quantities of water sufficient to provide thorough coverage of plant parts to be protected. The amount of water needed per acre will depend upon crop size, weather, spray equipment, and local experience.

MIXING

Fill spray or mixing tank half full of water. Begin agitation and pour Biobit into water while maintaining continuous agitation. Add other spray material (if any) and balance of water. Agitate as necessary to maintain suspension. Do not allow diluted mixture to remain in the tank for more than 48 hours.

The use of a spreader-sticker is recommended for hard to wet crops such as cole crops or to improve weather-fastness of the spray deposits. Combinations with commonly used spray tank adjuvants are generally not deleterious to Biobit, if the mix is used promptly. Before mixing in the spray tank, it is advisable to test physical compatibility by mixing all components in a small container in proportionate quantities.

For smaller spray volumes mix the proper number of teaspoons of Biobit from the following chart to attain the desired rates:

<u>If the rate is:</u>	<u>Add this amount per gallon of mix:</u>
1.0 pts./acre	1 teaspoon
2.0 pts./acre	2 teaspoons
3.0 pts./acre	3 teaspoons
3.5 pts./acre	3.5 teaspoons

SPRAY VOLUMES

Aerial Application: Use recommended amount of Biobit in a minimum of 5 gallons of water per acre. Apply early morning or evening when air is calm.

Ground Applications: Use recommended amount of Biobit in a minimum of 20 gallons of water per acre.

Ground applications to trees and vines: Apply specific dosage per acre of Biobit in a minimum of 100 gallons of water per acre for dilute applications. Wet foliage thoroughly with spray but not to the point of excessive runoff. For mist blowers, use recommended amount of Biobit (per acre rate) in a minimum of 20 gallons of water per acre.

GENERAL USE INSTRUCTIONS

Biobit is a highly selective biological insecticide specific for the control of lepidopterous larvae. Biobit must be ingested by the larvae to be effective. For consistent control, apply at first sign of newly hatched larvae (1st and 2nd instar larvae). Susceptible larvae that ingest Biobit cease feeding within a few hours and die within 2-5 days.

Biobit may be applied up to and on the day of harvest.

For maximum effectiveness the following is recommended:

Monitor fields to detect early infestations.

Apply Biobit when eggs start hatching and larvae are small (early instars) and before significant crop damage occurs. Larvae must be actively feeding to be affected.

Repeat applications every 3 to 14 days to maintain control and protect new plant growth. Factors affecting spray interval include rate of plant growth, weather conditions, and reinfestation. Monitor populations of pests and beneficials to determine proper timing of applications.

Under conditions of heavy pest pressures or when large worms are present use the higher rate, shorten the application interval, and/or improve spray coverage to enhance control. When these conditions are present, a contact insecticide should be used to enhance control.

Thorough coverage is essential for optimum performance. Ground applicators equipped with directed drop nozzles can improve coverage.

APPLICATION RATES:

CROP GROUP				
FORAGE, FODDER, HAY				
	Crop	Pests	Rate (pts./acre)	Special Instructions
	Alfalfa (Hay & Seed) and Other Non-grass Animal Feeds, Grasses Grown For Feed (pasture, ranges, hay or silage)	Alfalfa Caterpillar Loopers	1.0-3.5	
		Armyworms	2.0-7.0	*
		European Skipper (Essex Skipper)	2.0-3.5	

CROP GROUP				
FRUITS & NUTS				
	Crop	Pests	Rate (pts./acre)	Special Instructions
	Pome and Stone Fruit Trees such as: Apples, Pears, Quince, Apricots, Cherries, Nectarines, Peaches, Plums, Prunes. Nut Trees such as: Almonds, Filbert, Chestnuts, Walnuts, Pecans.	Redhumped Caterpillar Tent Caterpillars Omnivorous Leafroller Tortrix Moths Cankerworms Fruittree Leafroller Gypsy Moth Tufted Apple Budmoth Fall Webworm	2.0-7.0	
		Variegated Leafroller Redbanded Leafroller Walnut Caterpillar Codling Moth Cutworms Filbert Leafroller Oblique Banded Leafroller		
		Filbert Webworm	2.0-3.5	
		Citrus Cutworm	2.0-4.5	
		Roughskinned Cutworm	1.0-2.0	

<u>Crop</u>	<u>Pests</u>	<u>Rate (pts./acre)</u>	<u>Special Instructions</u>	
Citrus	Orangedog	1.0-3.5		
	Fruittree Leafroller Citrus Cutworm	2.0-7.0		
	Amorbia	3.5-5.5	** See Below	
Small Fruit and Berries such as: Blackberries, Blueberries, Currants, Raspberries, Strawberries, Cranberries.	Gypsy Moth Blueberry Leafroller Loopers Fruittree Leafroller Grape Berry Moth Oblique Banded Leafroller Achema Sphinx Moth (Hornworm)	2.0-3.5		
	Armyworms	2.0-7.0	*	
	Tobacco Budworm	7.0	**See Below	
	Grapes	Cherry Fruitworm Green Fruitworm	1.0-2.0	
		Grape Leaffolder Grapeleaf Skeletonizer Omnivorous Leafroller Orange Tortrix Saltmarsh Caterpillar	2.0-4.5	

CROP GROUP

OTHER FRUITS

<u>Crop</u>	<u>Pests</u>	<u>Rate (pts./acre)</u>	<u>Special Instructions</u>
Bananas	Banana Skipper	2.0-3.5	
Tropical Fruits	Hornworms Leafrollers Loopers Omnivorous Looper	2.0-7.0	
Kiwi	Omnivorous Leafroller	2.0-7.0	

	<u>Crop</u>	<u>Pests</u>	<u>Rate (pts./acre)</u>	<u>Special Instructions</u>
	Pineapple	<i>Gummosos-Batrachedra commosae</i> (Hodges) <i>Thecla-Thecla basilides</i> (Geyr)	1.0-2.0	
	Melons	(See Vegetable Crops, Cucurbits)		

CROP GROUPS

**VEGETABLES AND
COLE CROPS**

	<u>Crop</u>	<u>Pests</u>	<u>Rate (pts./acre)</u>	<u>Special Instructions</u>
	Root & Tuber Vegetables, and leaves of Root and Tuber vegetables such as: Beets, Carrot, Horseradish, Radish, Potato, Sweet Potato, Turnip and Turnip Greens, Sugarbeets.	Imported Cabbageworm Green Cloverworm	1.0-3.5	
		----- Hornworms	0.50-3.5	
		----- Cutworms Loopers Webworms Saltmarsh Caterpillar Omnivorous Leafroller	2.0-3.5	
		----- Armyworms	2.0-7.0	*
		----- Diamondback Moth	1.0-3.5	
		----- European Corn Borer	3.5-5.5	
		----- Alfalfa Caterpillar	0.50-1.0	

	Crop	Pests	Rate (pts./acre)	Special Instructions
	Bulb Vegetables such as: Garlic, Leeks, Onions, Shallot	Saltmarsh Caterpillar Omnivorous Leafroller Webworms	2.0-3.5	
		----- Hornworms	----- 0.50-3.5	
		----- Imported Cabbageworm Green Cloverworm Loopers	----- 1.0-3.5	
		----- Cutworms	----- 2.0-3.5	
		----- Armyworms	----- 2.0-7.0	----- *
		----- Diamondback Moth	----- 1.0-2.0	
		----- European Corn Borer	----- 3.5-5.5	
		----- <i>Heliothis</i> spp.	----- 3.5	----- Suppression Only **
	Leafy vegetables such as:	Imported Cabbageworm Green Cloverworm	1.0-3.5	
		----- Hornworms	----- 0.50-3.5	
	Celery, Lettuce (Head and Leaf), Parsley, Endive, Spinach, Kale	----- Cutworms Webworms	----- 2.0-3.5	
		----- Loopers Diamondback Moth	----- 1.0-3.5	
		----- Saltmarsh Caterpillar Omnivorous Leafroller	----- 2.0-3.5	
		----- Armyworms	----- 2.0-7.0	----- *
		----- European Corn Borer	----- 3.5-5.5	

<u>Crop</u>	<u>Pests</u>	<u>Rate (pts./acre)</u>	<u>Special Instructions</u>
Cucurbit vegetables such as: Cucumbers, Melons, Pumpkins, Squash, Watermelon.	Imported Cabbageworm Green Cloverworm Diamondback Moth Loopers	1.0-3.5	
	Saltmarsh Caterpillar Melonworm Pickleworm Rindworm complex		
	----- Armyworms	2.0-7.0	*
	----- European Corn Borer	3.5-5.5	
	----- Hornworms	0.50-2.0	

OTHER VEGETABLES

<u>Crop</u>	<u>Pests</u>	<u>Rate (pts./acre)</u>	<u>Special Instructions</u>
Artichokes	Artichoke Plume Moth	2.0-4.5	
	----- Armyworms	2.0-5.5	*
	----- Loopers	1.0-4.5	
Asparagus	Armyworms	2.0-7.0	*
	----- Diamondback Moth Green Cloverworm Imported Cabbageworm	1.0-2.0	
	----- Loopers	1.0-3.5	
	----- Armyworms	2.0-7.0	*
Malanga	Armyworms	2.0-7.0	*
	----- Saltmarsh Caterpillar	2.0-3.5	
Watercress	Loopers Diamondback Moth	1.0-3.5	
	----- Armyworms	2.0-7.0	*
	----- Green Cloverworm Imported Cabbageworm	1.0-2.0	
	----- Saltmarsh Caterpillar	2.0-3.5	
	----- European Corn Borer	3.5-4.5	
Sweet Corn	(see Other Crops, Corn)		

CROP GROUP				
HERBS, SPICES, MINTS				
	Crop	Pests	Rate (pts./acre)	Special Instructions
	Such as: Basil, Dill, Oregano, Thyme, Peppermint.	Loopers	1.0-3.5	
		-----	-----	
		Diamondback Moth Green Cloverworm Imported Cabbageworm	1.0-2.0	
		-----	-----	
		Armyworms	2.0-7.0	*
		-----	-----	
		European Corn Borer	3.5-5.5	

CROP GROUP				
OTHER CROPS				
	Crop	Pests	Rate (pts./acre)	Special Instructions
	Avocadoes	Loopers	3.5-4.5	
		-----	-----	
		Orange Tortrix Omnivorous Leafroller Omnivorous Looper Spanworm	2.0-7.0	
		-----	-----	
		Amorbia	2.0-7.0	Suppression Only **
	Rice	Armyworms	2.0-5.5	*
		-----	-----	
		Loopers Saltmarsh Caterpillar	2.0-3.5	
		-----	-----	
		Cutworms	2.0-5.5	
		-----	-----	
		Green Cloverworm Velvetbean Caterpillar	1.0-2.0	
		-----	-----	
		<i>Heliothis</i> spp.	3.5	Suppression Only **

Crop	Pests	Rate (pts./acre)	Special Instructions
Cotton (Except CA & AZ)	Loopers	2.0-3.5	
	Armyworms	2.0-7.0	*
	Cotton Bollworm Tobacco Budworm	1.0-7.0	See Below
<p><u>Special Instructions:</u> For early season management of <i>Heliothis</i> species. Initiate applications when 50% of plants are at pinhead square cotton stage independent of <i>Heliothis</i> egg and larval counts or at first egg lay, whichever occurs earlier. Continue applications on a five day spray interval up to the pyrethroid spray window.</p>			
Cotton (CA & AZ)	Armyworms	2.0-7.0	*
	Cotton Leaf Perforator Cotton Leafworm Saltmarsh Caterpillar	2.0-3.5	
	Loopers	2.0-3.5	
	Cotton Bollworm Tobacco Budworm	2.0-7.0	See Below
<p><u>Special Instructions:</u> Repeat as necessary throughout the season to maintain control. If egg laying frequency indicates future moderate to heavy larval populations, time application spray to coincide with the second instar larvae. During periods of high temperatures, larvae will progress through first to third instars very rapidly and early application timing is necessary for control. When plant cover is dense and larvae are feeding in the lower 2/3 portion of the plant, aerial application of Biobit may not provide adequate control.</p>			
Canola/Rape Seed	Armyworms	2.0-7.0	*
	Diamondback Moth	1.0-2.0	
	Loopers	2.0-3.5	
	<i>Heliothis</i> spp.	2.0-7.0	
Corn Such as: Field, Sweet, Popcorn.	Armyworms	2.0-7.0	*
	European Corn Borer (Whorl Stage Only)	2.0-5.5	
	Southwestern Corn Borer	3.5-5.5	Aids in Control

	Crop	Pests	Rate (pts./acre)	Special Instructions
	Hops	Armyworms ----- Loopers ----- Omnivorous Leaf-tier Spotted Cutworm Oblique Banded Leafroller	2.0-7.0 ----- 1.0-3.5 ----- 2.0-3.5	*
	Jojoba	Looper (<i>Anacamptodes</i> spp.)	2.0-3.5	
	Peanuts	Green Cloverworm Loopers Velvetbean Caterpillar Podworms ----- <i>Heliothis</i> spp.	2.0-3.5 ----- 3.5	Suppression Only **
	Persimmons, Pomegranate	Fall Webworm Filbert Webworm Omnivorous Leafroller Redhumped Caterpillar Tent Caterpillars ----- Citrus Cutworm	2.0-3.5 ----- 2.0-4.5	
	Safflower	Armyworms ----- Loopers Saltmarsh Caterpillar	2.0-7.0 ----- 2.0-3.5	*
	Sorghum	Headworm	2.0-3.5	
	Soybeans	(see Vegetable Crops, Legumes)		
	Sunflowers	Headmoth Loopers	2.0-3.5	
	Small Grains	Armyworms ----- Loopers	2.0-7.0 ----- 2.0-3.5	*
	Tobacco	Tobacco Hornworm ----- Loopers ----- Tobacco Budworm	0.50-2.0 ----- 1.0-3.5 ----- 3.5	Suppression Only **

CROP GROUP
FLOWERS BEDDING PLANTS,
AND ORNAMENTALS

	<u>Crop</u>	<u>Pests</u>	<u>Rate (pts./acre)</u>	<u>Special Instructions</u>
	Ornamentals Flowers, Bedding Plants	Armyworms	2.0-7.0	*
		Azalea Moth Diamondback Moth Ello Moth (Hornworm) Io Moth Loopers Oleander Moth Omnivorous Leafroller Omnivorous Looper Tobacco Budworm	1.0-2.0	

CROP GROUP
GREENHOUSE,
AND OUTDOOR NURSERY CROPS

	<u>Crop</u>	<u>Pests</u>	<u>Rate (pts./acre)</u>	<u>Special Instructions</u>
	Such as: Flowers, Brassica, Fruiting Groups, Herbs, and Leafy	Armyworms <i>Heliothis</i> spp.	2.0-7.0	*
		Loopers	2.0-3.5	

CROP GROUP
TURF

	<u>Crop</u>	<u>Pests</u>	<u>Rate (pts./acre)</u>	<u>Special Instructions</u>
	Turf	Sod Webworm	3.5-7.0	
		Tropical Sod Webworm	3.5	
		Armyworms	3.5	*

17.8.17

CROP GROUP				
	Crop	Pests	Rate (pts./acre)	Special Instructions
	Home Garden Use	Biobit may be used for any labeled pest and crop using the rates, mixing, and general use instructions specified rates on this label.		

CROP GROUP				
Forests, Shade Trees, Ornamentals, Shrubs, Sugar Maple Trees				
	Crop	Pests	Rate (pts./acre)	Special Instructions
	Forests, Shade Trees, Ornamentals, Shrubs, Sugar Maple Trees	Gypsy Moth Spruce Budworm Browntail Moth -----	2.0-4.5	
		Tussock Moths Pine Butterfly Bagworm Leafrollers Tortrix Moths Mimosa Webworm Tent Caterpillars Jackpine Budworm Blackheaded Budworm Elm Spanworm Saddled Prominent Saddleback Caterpillars -----	1.5-3.5	
		Redhumped Caterpillar Spring Cankerworm Fall Cankerworm California Oakworm Fall Webworm	1.0-2.0	

Special Instructions

- * Armyworm Control: Biobit may be used to control small armyworms (first and second instar) when populations are light and full coverage sprays are applied. Repeat treatment as necessary. If mature larvae or heavy populations are present, a contact insecticide should be added to enhance control.
- ** Suppression Only: Use to aid in control of light to moderate populations of first and second instars in Integrated Pest Management conditions. Repeat treatments at four to five day intervals. The use of additional ovicidal or larvicidal insecticide will aid in control.