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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Novo Nordisk A/S
c/o Ms. Janet M. Overholt
Novo Nordisk Bioindustrials, Inc.
33 Turner Road
Danbury, Ct. 06813

300 / 343,270
17

Dear Ms. Overholt:

Subject: Biobit Flowable Concentrate Final Printed Labeling
EPA Registration No. 58998-2

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act is acceptable subject to the following comments.

1. Since your revised formulation contains an inert ingredient that is only exempt from tolerance requirements under 40 CFR 180.1001(d), delete the stored products crop group from the label. If and when this inert becomes exempt from tolerance requirements under 40 CFR 180.1001(c), you may then submit a revised label with the stored products group for approval.

2. Delete the following statements. **Biobit is harmless to honeybees when used as directed and is appropriate for many integrated pest management programs.** Although you may have submitted nontarget organism data, this data must be reviewed and shown to support the above statements. If you have submitted honeybee toxicity studies and if you wish to add the above statement, please cite the MRID number(s) of the studies and apply for a label amendment.

3. Delete the statement **Populations of lepidopterous larvae that are resistant to chemical insecticides can be controlled by Biobit.** This statement is too general. Furthermore, no field efficacy data have been submitted.

A stamped copy of the label is enclosed for your records.
Submit five (5) copies of final printed labeling.

Sincerely,



Phil Hutton
Product Manager 17
Insecticide-Rodenticide Branch
Registration Division (H7505C)

ACTIVE INGREDIENT

Bacillus thuringiensis Berliner subspecies *kurstaki*,
8,000 International Units (IU)/mg of product
(equivalent to 32 billion IU/GAL.)

INERT INGREDIENTS 1.6 %
..... 98.4 %

KEEP OUT OF REACH OF CHILDREN
CAUTION
STATEMENT OF PRACTICAL TREATMENT
If in eyes, flush with plenty of water. Get medical attention if irritation persists.

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.
ENVIRONMENTAL HAZARDS
Do not contaminate water when disposing of equipment washwaters.

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.

STORAGE AND DISPOSAL
Do not contaminate water, food or feed by storage or disposal of waste.
Storage: Store in a cool 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, EXPRESSED OR IMPLIED, concerning this product or its label 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 Biobit is manufactured by Novo Nordisk

EPA Reg. No.: 58998-2

EPA Est. No.: 58998-DN-001

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Mar 26 1991

Biobit is the Registered Trademark of Novo Nordisk

Manufactured For
Novo Nordisk
33 Turner Road
Danbury, CT 06813-1907

NET CONTENTS _____ U.S. Gallons

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 Application: 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 is harmless to honeybees when used as directed and is appropriate for many integrated pest management programs. Populations of lepidopterous larvae that are resistant to chemical insecticides can be controlled by Biobit.

For maximum effectiveness the following is recommended:

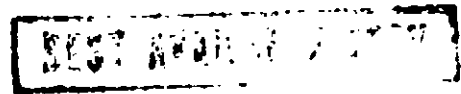
Monitor fields to detect early infestations.

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.



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.

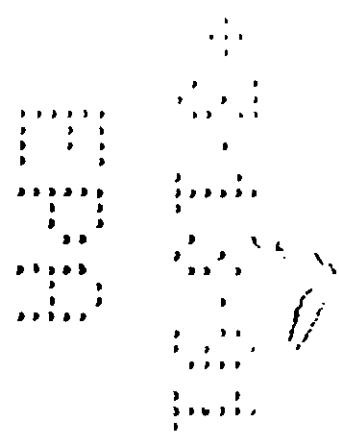
For smaller spray volumes, mix the proper number of teaspoons of Biobit from the following chart to attain the desired rates:

If the rate is:

- 1.0 pts./acre
- 2.0 pts./acre
- 3.0 pts./acre
- 3.5 pts./acre

Add this amount per gallon of mix:

- 1 teaspoon
- 2 teaspoons
- 3 teaspoons
- 3.5 teaspoons



ROP GROUP

FRUITS & NUTS

	<u>Crop</u>	<u>Pests</u>	<u>Rate (pts./acre)</u>	<u>Special Instructions</u>
	<p>Pome and Stone Fruit Trees such as: Apples, Pears, Quince, Apricots, Cherries, Nectarines, Peaches, Plums, Prunes.</p> <p>Nut Trees such as: Almonds, Filbert, Chestnuts, Walnuts, Pecans.</p>	<p>Redhumped Caterpillar Teat Caterpillars Omnivorous Leafroller Tortrix Moths Cankerworms Fruitree Leafroller Gypsy Moth Tufted Appl. Budmoth Fall Webworm Variegated Leafroller Redbanded Leafroller Walnut Caterpillar Codling Moth Cutworms Filbert Leafroller Oblique Banded Leafroller</p> <hr/> <p>Filbert Webworm</p> <hr/> <p>Citrus Cutworm</p> <hr/> <p>Roughskinned Cutworm</p>	<p>2.0-7.0</p> <hr/> <p>2.0-3.5</p> <hr/> <p>2.0-4.5</p> <hr/> <p>1.0-2.0</p>	
	Citrus	<p>Orangedog</p> <hr/> <p>Fruitree Leafroller Citrus Cutworm</p> <hr/> <p>Amorbia</p>	<p>1.0-3.5</p> <hr/> <p>2.0-7.0</p> <hr/> <p>3.5-5.5</p>	<p>**See Below</p>
	<p>Small Fruit and Berries such as: Blackberries, Blueberries, Currants, Raspberries, Strawberries, Cranberries.</p> <p>Grapes</p>	<p>Gypsy Moth Blueberry Leafroller Loopers Fruitree Leafroller Grape Berry Moth Oblique Banded Leafroller Achema Sphinx Moth (Hornworm)</p> <hr/> <p>Armyworms</p> <hr/> <p>Tobacco Budworm</p> <hr/> <p>Cherry Fruitworm Green Fruitworm</p> <hr/> <p>Grape Leaf folder Grapeleaf Skeletonizer Omnivorous Leafroller Orange Tortrix Salmarsh Caterpillar</p>	<p>2.0-3.5</p> <hr/> <p>2.0-7.0</p> <hr/> <p>7.0</p> <hr/> <p>1.0-2.0</p> <hr/> <p>2.0-4.5</p>	<p>*</p> <p>**See Below</p>

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APPLICATION RATES:

ROP GROUP				
FORAGE, FODDER, HAY				
	<u>Crop</u>	<u>Pests</u>	<u>Rate (pts./acre)</u>	<u>Special Instructions</u>
	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	

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Crop	Pests	Rate (pts./acre)	Special Instructions
Leafy vegetables such as: Celery, Lettuce (Head and Leaf), Parsley, Endive, Spinach, Kale	Imported Cabbageworm Green Cloverworm	1.0-3.5	
	Hornworms	0.50-3.5	
	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	
Legume and foliage of Legume vegetables, such as: Lentils, Peas, Beans, Soybeans	Loopers	1.0-3.5	
	Hornworms	0.50-2.0	
	Podworms Imported Cabbageworm Green Cloverworm Saltmarsh Caterpillar Soybean Loopers Velvetbean Caterpillar	2.0-3.5	
	Armyworms	2.0-7.0	*
	Diamondback Moth	1.0-3.5	
	European Corn Borer	3.5-5.5	
	Cutworms	2.0-5.5	

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Crop	Pests	Rate (pts./acre)	Special Instructions
Fruiting Vegetables such as: Eggplant, Peppers, Tomatoes.	Imported Cabbageworm Diamondback Moth Green Cloverworm	1.0-2.0	
	Hornworms	0.50-3.5	
	Tomato Fruitworm (<u>Heliothis</u>) Variegated Cutworm Saltmarsh Caterpillar Loopers	2.0-3.5	
	Armyworms	2.0-7.0	*
	European Corn Borer	3.5-5.5	
Brassica (cole) vegetables such as: Broccoli, Brussels Sprouts, Cabbage, Cauliflower, Collards, Kohlrabi.	Hornworms	0.50-3.5	
	Webworms Loopers Cutworms Saltmarsh Caterpillar Omnivorous Leafroller	2.0-3.5	
	Diamondback Moth Imported Cabbageworm Green Cloverworm	1.0-3.5	
	Armyworms	2.0-7.0	*
	European Corn Borer	3.5-5.5	
Cucurbit vegetables such as: Cucumbers, Melons, Pumpkins, Squash, Watermelon.	Imported Cabbageworm Green Cloverworm Diamondback Moth Loopers Saltmarsh Caterpillar Melonworm Pickleworm Rindworm Complex	1.0-3.5	
	Armyworms	2.0-7.0	*
	European Corn Borer	3.5-5.5	
	Hornworms	0.50-2.0	

CROP GROUP

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	
	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)		

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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
	Avocados	Loopers	3.5-4.5	
		Orange Tortrix Omnivorous Leafroller Omnivorous Looper Spanworm	2.0-7.0	
		Amorbia	2.0-7.0	
	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	
		Heliothis spp.	3.5	Suppression Only **

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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>Special Instructions: 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>Special Instructions: 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>			

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Crop	Pests	Rate (pts./acre)	Special Instructions
Canola/Rape Seed	Armyworms	2.0-7.0	*
	Diamondback Moth	1.0-2.0	
	Loopers	2.0-3.5	
	Heliopsis 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
Hops	Armyworms	2.0-7.0	*
	Loopers	1.0-3.5	
	Omnivorous Leaf-tier Spotted Cutworm Oblique Banded Leafroller	2.0-3.5	
Jojoba	Looper (Anacamptodes spp.)	2.0-3.5	
Peanuts	Green Cloverworm Loopers Velvetbean Caterpillar Podworms	2.0-3.5	
	Heliopsis spp.	3.5	Suppression Only **
Persimmons, Pomegranate	Fall Webworm Filbert Webworm Omnivorous Leafroller Redhumped Caterpillar Tent Caterpillars	2.0-3.5	
	Citrus Cutworm	2.0-4.5	

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Crop	Pests	Rate (pts./acre)	Special Instructions
Safflower	Armyworms	2.0-7.0	*
	Loopers Saltmarsh Caterpillar	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	2.0-7.0	*
	Loopers	2.0-3.5	
Tobacco	Tobacco Hornworm	0.50-2.0	
	Loopers	1.0-3.5	
	Tobacco Budworm	3.5	Suppression Only **

TOP GROUP				
STORED PRODUCTS				
<u>Crop</u>	<u>Pests</u>	<u>Rate</u>	<u>Special Instructions</u>	
Stored Products, such as: Soybeans, Grains	Tobacco Moth Almond Moth Indian Meal Moth Flour Moth	See Below	See Below	

Rate and Special Instructions: To control and prevent Indian Meal Moth, Flour Moth, Tobacco Moth, and Almond Moth infestations of stored grains and soybeans, prepare a spray mixture which includes 1 gallon of water for every 1/3 pint (162 ml) by volume of Biobit. The spray mixture may be applied either by treating the top 4 inches of the grain as it is being augered into storage (applying 0.6 pint of mixture per bushel in the grain stream), or by treating the surface of grain after it is in the bin. The table below can be used as a guide in determining the total amount of Biobit needed according to the bin diameter or the number of bushels to be treated.

Bin Diameter (ft.)	Surface Area (sq. ft.)	Bushels (to 4 in. depth)	Biobit Rate (by Volume)	
			ml	oz.
8	50	13	89	3.0
12	113	30	192	6.5
16	201	53	326	11.0
20	314	84	473	16.0
24	452	120	710	24.0
28	615	163	976	33.0
32	804	214	1,242	42.0

To insure thorough coverage when making applications to the grain surface after it is in the bin, apply spray mixture in 3 applications. Mix the grain to a dept of 4 inches after each application.

Stored grain may be treated anytime, but for best results, treat grain at the time it is placed into storage or shortly thereafter, or in the early spring prior to egg laying. Full season control is usually experienced. Re-treat only if reinfestation occurs.

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CROP GROUP
FLOWERS, BEDDING PLANTS, AND ORNAMENTALS

	<u>Crop</u>	<u>Pests</u>	<u>Rate (pts./acre)</u>	<u>Special Instructions</u>
	Ornamamentals, 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 Heliiothis 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	

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

CROP GROUP			Rate (pts./acre)	Special Instructions
Crop	Pests			
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	

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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 used 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.

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