Washington, D. Application 1. NOTIFICATION RE: 1'R NOT	oc 20460 : Amendment : 125 Amendment
والتنابانة فحال كمنتب والمراجي المراجي المراجي المراجي المراجع المراجع المراجع المراجع المراجع المراجع المراجع	ction figure and the property of the page a mode of the first
1. Company/Product Number 58998-18	2. EPA Product Manager, 3. Proposed Classification P Hut ton
4. Company/Product (Name)	PM# (18 of higher 218 to the heart of the control o
5. Name and Address of Applicant (Include ZIP Code) Novo NOrdisk A/S Novo Alle 2880 Bagsvaerd Denmark Check if this is a new address	6. Expedited Review, in accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: Continue of the co
Sec	tion I I
Amendment - Explain below Resubmission in response to Agency letter dated X Notification - Explain below.	Final printed labels in response to Agency letter dated "Me Too" Application. Other - explain below.
Explanation: Use additional page(s) if recessary. (For sec io Notification to comply with PR Notice	e 93-3 NOTIFICATION LABEL NOT REVIEWED PER PR NOTICE 80-6 DATE. 7/12/93
Secti	on III
1. Material This Product With Be Packaged In: Child-Resistant Packaging Yes* No If "Yes," Unit Package wgt. No. px r Unit Package wgt.	Water Soluble Packaging 2. Type of Container Metal Plastic Glass Paper Package wgt. No. per Container Other (Specify)
Label Container	Retail Container 5. Location of Label Directions On Label On Labeling accompanying product
Paper Stend	or glued Cition IV In of individual to be contacted, if necessary, to process this application.)
Name Janet M. Overholt	Title Telephone No. (Include Area Code) Registration Agent 77, 77, 77, 77, 77, 77, 77, 77, 77, 77
Cert fication I certify that the statements I have med on unit form and all a lacknowledge that any knowingly false or misler ding statements both under applicable law.	attachments thereto are true, accurate and complete.
Junet M. Onelrott	3. Title Registration Agent
4. Typed Name Janet M. Overholt	BEST AVAILABLE COPY 4/30/93



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KEEP OUT OF REACH OF CHILDREN CAUTION

NOTIFICATION LABEL NOT REVIEWED PER PRINOTICE 86-6

DATE 7/12/93

STATEMENTS OF PRACTICAL TREATMENT

If in Eyes: Flush with plenty of water. Call a physician if eye irritation persists.

If on Skin: Flush skin with plenty of soap and water. Get medical attention if irritation persists.

ACTIVE INGREDIENT

Bacillus thuringiensis Berliner subspecies kurstaki

By Weight

POTENCY:

32,000 International Units (IU) per mg of product equivalent to 14.5 Billion IU per pound of product. Potency units should not be used to adjust use rates beyond those specified in the Directions For Use Section.

PRECAUTIONARY STATEMENTS

HAZARDS TO 'HUMANS AND DOMESTIC ANIMALS

May cause eye injury 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.

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.

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

HOME CARDEN USE DISPOSAL INSTRUCTIONS

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

Container Disposal: Do not reuse bag. Discard bag 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 indiffect 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 HPWP is manufactured by Novo Nordisk,

EPA Registration No. 58998-18 EPA Est. No. 58998-DN-002 MANUFACTURED FOR:
Novo Nordisk
33 Turner Road
Danbury, Connecticut 06813-1907

NET CONTENTS,

Pounds

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

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

Re-entry

Do not enter treated area without protective clothing until sprays have dried.

Because certain states may require more restrictive reentry intervals for various crops treated with this product, consult your State Department of Agriculture for further information.

Do not apply this product in such a manner as to directly or through drift expose workers or other persons. The area being treated must be vacated by unprotected persons.

Written or oral warnings must be given to workers who are expected to be in a treated area or in an area about to be treated with this product. Oral warnings must include the following information:

Inform workers of area of fields that must not be entered without appropriate protective clothing until sprays have dried. In case of accidental exposure, wash thoroughly with soap and water. If in eyes, flush with plenty of water. Get medical attention if eye irritation persists.

When oral warnings are given, warnings shall be given in a language customarily understood by workers. Written warnings must include the following information:

CAUTION: Area treated with Biobit HPWP on (date of application). Do not enter without appropriate protective clothing until sprays have dried. In case of accidental exposure, wash thoroughly with soap and water. If in eyes, flush with plenty of water. Get medical attention if eye irritation persists.

APPLICATION

Biobit HPWP 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 HPWP 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 HPWP 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 HPWP from the following chart to attain the desired rates:

If the rate is: Add this amount per gallon of mix:

0.5 lb/a :re	1 teaspoons
1.0 lb/acre	2 teaspoons
2.0 lb/acre	4 teaspoons

The above rate calculations assume that the final mix will be applied to runoff on the target crop and that thorough coverage will be obtained.

SPRAY VOLUMES

Aerial Application: Use recommended amount of Biobit HPWP 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 HPWP in a minimum of 20 gallons of water per acre.

Ground applications to trees and vines: Apply specific dosage per acre of Biobit HPWP 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 HPWP (per acre rate) in a minimum of 20 gallons of water per acre.

GENERAL USE INSTRUCTIONS

Biobit HPWP is a highly selective biological insecticide specific for the control of lepidopterous larvae. Biobit HPWP 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 HPWP cease feeding within a few hours and die within 2-5 days.

For maximum effectiveness the following is recommended:

Monitor fields to detect early infestations.

Apply Biobit HPWP when eggs start hatching and larvae are small (early instars) and before significant grop 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 that 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.

PREHARVEST INTERVAL

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

0.5-2.0

0.5-1.0

APPLICATION RATES:

CROP GROUP				
FORAGE,	FODDER, HAY			
	Crop Crop	Pests	Rate (1bs./acre)	Special Instructions
	Alfalfa (Hay & Seed) and Other	Alfalfa Caterpillar Loopers	0.25-1.0	

European Skipper (Essex Skipper)

Armyworm

CROP GROUP

Non-grass

For Feed

Animal Feeds,

Grasses Grown

(pasture, ranges, hay or silage)

FRUITS & NUTS			
Crop	Pests	Rate (lbs./acre)	Special Instructions
Pome and Jtone Fruit Trees such as: Apples, Pears, Quince, Apricots, Cherries, Nectarines, Peaches, Plums, Prunes. Nut Trees such as: Almonds, Filbert, Chestnuts, Walnuts, Pecans.	Tortrix Moths Cankerworms Peach Twig Borer	0.5-2.0	

		1)
CROP GRO	UP.			
FRUITS &	NUTS Cont'd			1 1
	Citrus	Orangedog	0.25-1.0	
		Fruittree Leafroller Citrus Cutworm	0.5-2.0	
		Amorbia	1.0-1.5	Suppression Only **
	Small Fruit and Berries such as: Blackberries, Blueberries, Currants Raspberries, Strawberries	Gypsy Moth Blueberry Leafroller Loopers Fruittree Leafroller Grape Berry Moth Oblique Banded Leafroller Achema Sphinx Moth (Hornworm)	0.5-1.0	
1	Cranberries,	Armyworm	0.5-2.0	*
		Tobacco Budworm	2.0	
	Grapes	Cherry Fruitworm Green Fruitworm	0.25-0.5	
		Grape Leaffolder Grapeleaf Skeletonizers Omnivorous Leafroller Orange Tortrix Saltmarsh Caterpillar	0.5-1.25	

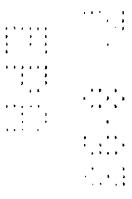
Bananas Banana Skipper 0.5-1.0 Tropical Fruits Hornworms Leafrollers Loopers Omnivorous Leafroller Kiwi Omnivorous Leafroller 0.3-2.0 Pineapple Gummosos-Batrachedra commosae (Hodg@s) Thecla-Thecla basilides (Geyr) Melons (see Vegetable Crops, Curcubits)	CROP GROUP			
Tropical Fruits Hornworms Leafrollers Loopers Omnivorous Leafroller Kiwi Omnivorous Leafroller Pineapple Gummosos-Batrachedra commosae (Hodges) Thecla-Thecla basilides (Geyr) O.5-2.0 0.5-2.0 0.5-2.0 0.5-2.0	OTHER FRUITS			
Leafrollers Loopers Omnivorous Leafroller Kiwi Omnivorous Leafroller Pineapple Gummosos-Batrachedra commosae (Hodges) Thecla-Thecla basilides (Geyr)	Bananas	Banana Skipper	0.5-1.0	
Kiwi Omnivorous Leafroller 0.3-3.0 Pineapple Gummosos-Batrachedra commosae (Hodges) Thecla-Thecla basilides (Geyr) 0.25-0.5	Tropical Fruits	Leafrollers Loopers	0.5-2.0	
commosae (Hodg@s) Thecla-Thecla basilides (Geyr) (Geyr)	Kiwi	Omnivorous Leafroller	0.5-2.0	,
Melons (see Vegetable Crops, Curcubits)	Pineapple	commosae (Hodg@s) Thecla-Thecla basilides	,,,,,	****
	Melons	(see Vegetable Crops, Curcubits)		

CROP GROUPS

VEGETABLES AND COLE CROPS

Crop	Pests	Rate (1bs./acre)	Special Instructions
Root & Tuber Vegetables, and leaves of Root and Tuber vegetables such as	Imported Cabbageworm Green Cloverworm	0.25-1.0	
Beet, Carrot,	Hornworms	0.125-1.0	
Horseradish, Radish, Potato Sweet Potato, Turnip and Turnip Greens, Sugarbeets,	Loopers Webworms	0.5-1.0	
	Armyworm	0.5-2.0	*
	Diamondback Moth	0.25-2.0	
	European Corn Borer	1.0-1.5	
	Alfalfa Caterpillar	0.125- 0.25	
Bulb Vegetables such as:	Saltmarsh Caterpillar Omnivorous Leafroller Webworms Cutworms	0.5-1.0	
Garlic, Leeks, Onions, Shallot	Hornworms	0.125-1.0	
	Imported Cabbageworm Green Cloverworm Loopers	0.25-1.0	
	Armyworm	0.5-2.0	*
	Diamondback Moth	0.25-2.0	
	European Corn Borer	1.0-1.5	,,,
	Helicoverpa (Heliothis) sp	1.0 ';';	Suppression Only, **
		, ,	

Crop	Pests	Rate (lbs./acre)	Special Instructions
Leafy vegetables, such as:	Imported Cabbageworm Green Cloverworm Loopers	0.25-1.0	
Celery,	Hornworms	0.125-1.0	
Lettuce(Head and Leaf), Parsley, Endive,	Cutworm, Webworms	0.5-1.0	
Spinach, Kale	Diamondback Moth	0.25-2.0	
	Saltmarsh Caterpillar Omnivorous Leafroller	0.5-1.0	
	Armyworm	0.5-2.0	*
	European Corn Borer	1.0-1.5	
Legume and foliage of Legume	Loopers	0.25-1.0	
vegetables,	Hornworms	0.125-0.5	
such as Beans, Lentils, Peas, Soybeans	Podworms Imported Cabbageworm Green Cloverworm Saltmarsh Caterpillar Soybean Loopers	0.5-1.0	
	Armyworm	0.5-2.0	*
	Diamondback Moth Velvetbean Caterpillar	0.25-2.0	
	European Corn Borer	1.0-1.5	
	Cutworm	0.5-1.5	



	Crop	Pests	Rate (lbs./acre)	Special Instructions
	Fruiting Vegetables	Imported Cabbageworm Green Cloverworm	0.25-0.5	
	such as: Eggplant,	Diamondback Moth	0.25-2.0	
	Peppers, Tomatoes	Hornworms	0.125-1.0	
	Tomacoes	Tomato Fruitworm(Heliothis) Variegated Cutworm Saltmarsh Caterpillar Loopers	0.5-1.0	
		Armyworm	0.5-2.0	*
		European Corn Borer	1.0-1.5	
	Brassica(cole)	Diamondback Moth	0.25-2.0	
]	vegetables such as: Broccoli,	Hornworms	0.125-1.0	
	Brussels sprouts, Cabbage, Cauliflower, Collards, Kohlrabi,	Webworms Loopers Cutworms Saltmarsh Caterpillar Omnivorous leafroller	0.5-1.0	
	ROIIII ADI,	Imported Cabbageworm Green Cloverworm	0.25-1.0	
		Armyworms	0.5-2.0	*
!		European Corn Borer	1.0-1.5	,
	Cucurbit vegetables such as:	Imported Cabbageworm Green Cloverworm Loopers	0.25-1.0	
	Cucumbers,	Diamondback Moth	0.25-2.0	
	Melons, Pumpkins, Squash, Watermelon	Saltmarsh Caterpillar Melonworm Pickleworm Rindworm complex	0.25-1.0	,,,,,
		Armyworm	0.5 2.0	*
		European Corn Borer	1.0-1:5	
		Hornworms	0.125 - 0; -5,	1 1 1

CROP GROUP	
OTHER VEGETABLES	

7 7

OTHER VEGETABLES		_	
Crop	Pests	Rate (lbs./acre)	Special Instructions
Artichokes	Artichoke Plume Moth	0.5-1.25	
	Armyworm	0.5-1.5	*
	Loopers	0.25-1.25	
Asparagus	Armyworms	0.5-2.0	*
	Diamondback Moth	0.25-2.0	
	Green Cloverworm Imported Cabbageworm	0.25-0.5	
	Loopers	0.25-1.0	
Malanga	Armyworms	0.5-2.0	*
	Saltmarsh Caterpillar	0.5-1.0	
Watercress	Loopers Diamondback Moth	0.25-2.0	
	Armyworms	0.5-2.0	*
	Green Cloverworm Imported Cabbageworm	0.25-0.5	
	Saltmarsh Caterpillar	0.5-1.0	
	European Corn Borer	1.0-1.25	
Sweet Corn	(see Other Crops, Corn)		

CROP GROUP			
HERBS, SPICES, MINTS			
such as Basil,	Loopers	0.25-1.0	
Dill, Oregano, Peppermint,	Diamondback Moth	0.5-2.0	
Tyme	Green Cloverworm Imported Cabbageworm	0.25-0.5	,
	Armyworm	0.5.2.0	· · · · · · · · ·
	European Corn Borer	1.0-1.5	* * * * * * * * * * * * * * * * * * *

CROP	GROUP
OTHER	CROPS

Crop	Pests	Rate (lbs./acre)	Special Instructions
Avocadoes	Loopers	1.0-1.25	
	Orange Tortrix Omnivorous Leafroller Omnivorous Looper Spanworm	0.5-2.0	
	Amorbia	0.5-2.0	Suppression Only **
Rice	Armyworms	0.5-1.5	*
	Loopers Saltmarsh Caterpillar,	0.5-1.0	
	Cutworm	0.5-1.5	
	Green Cloverworm, VelvetBean Caterpillar	0.25-0.5	
	Helicoverpa (Heliothis) spp	1.0	Suppression Only **



			
Crop	Pests	Rate (lbs./acre)	Special Instructions
. Cotton (Except	Loopers	0.5-1.0	
CA & AZ)	Armyworm	0.5-2.0	*
	Cotton bollworm Tobacco budworm	0.25-2.0	see below
	Special Instructions: For a Helicoverpa species. Init of plants are at pinhead so independent of Heliothis egor at first egg lay, which Continue applications on a up to the pyrethroid spray	iate applicat: quare cotton a gg and larval ever occurs ea five day spra	ions when 50% stage counts arlier.
Cotton (CA &	Armyworm	0.5-2.0	*
AZ)	Cotton Leaf Perforator Cotton Leafworm Saltmarsh Caterpillar	0.5-1.0	
	Loopers	0.5-1.0	
	Cotton Bollworm Tobacco Budworm	0.5-2.0	See Below
Special Instructions: Repeat as necessar the season to maintain control. If egg ency indicates future moderate to heavy ulations, time application spray to coin second instar larvae. During periods of atures larvae will progress through first instars very rapidly and early application necessary for control. When plant cover larvae are feeding in the lower 2/3 portiplant, aerial application of Biobit HPWI provide adequate control.			laying freq- larval pop- cide with the high temper- to third on timimg is is dense and ion of the
Canola/Rape	Armyworm	0.5-2.0	*
Seed	Diamondback Moth	0.25-2.0	
	Looper	0.5-1.0	
	Helicoverpa (Heliothis)	0.5-2.0	.,,
Corn	Armyworms	0.5-2.0	*
Field, Sweet, Popcorn	European Corn Borer (whorl Stage Only)	0.5-2:0	
	Southwestern Corn Borer	1.0-1.5	Aids in Control

	· · · · · · · · · · · · · · · · · · ·		
Crop	Pests	Rate (lbs./acre)	Special <u>Instructions</u>
Hops	Armyworm	0.5-2.0	*
	Loopers	0.25-1.0	
	Omnivorous Leaftier Spotted Cutworm Oblique Banded Leafroller	0.5-1.0	
Jojoba	Looper (Anacamptodes spp.)	0.5-1.0	
Peanuts	Green Cloverworm Loopers Velvetbean Caterpillar Podworms	0.5-1.0	
	Helicoverpa (Heliothis) spp	1.0	Suppression Only **
Persimmons, Pomegranate	Fall Webworm Filbert Webworm Omnivorous Leafroller Redhumped Caterpillar Tent Caterpillar	0.5-1.0	
	Citrus Cutworm	0.5-1.25	
Safflower	Armyworm	0.5-2.0	*
	Loopers Saltmarsh Caterpillar	0.5-1.0	
Sorghum	Headworm	0.5-1.0	
Soybeans	(see Vegetable Crops, Legumes)		
Sunflowers	Headmoth Loopers	0.5-1.0	
Small Grains	Armyworms	0.5-2.0	*
	Loopers	0.5-1.0	7.7.5
Tobacco	Tobacco Hornworm	0.125-0.5	,
	Looper	0.25-1:.'0;	
	Tobacco Budworm	2.0	Suppression Only **

CROP GRO	ΠĐ .	
FLOWERS,	BEDDING	PLANTS,

Crop	Pests	Rate lbs./acre	Special Instructions
Ornamentals, Flowers, Bedding plants	Diamondback Moth Armyworm	0.5-2.0	*
	Azalea Moth Ello Moth (Hornworm) Io Moth Loopers Oleander Moth Omnivorous Leafroller Omnivorous Looper Tobacco Budworm	0.25-0.5	
CROP GROUP			
GREENHOUSE, SHADE TREES AND OUTDOOR NURSERY CRO			
Crop	Pests	Rate (lbs./acre)	Special Instructions
Such as	Armyworms	0.5-2.0	*
Brassica, Fruiting Groups, Herbs, and Leafy	Loopers	0.5-1.0	
CROP GROUP			J
TURF			
Crop	Pests	Rate (lbs./acre)	Special Instructions
Turf	Sod Webworm	1.0-2.0	
	Tropical Sod Webworm	1.0	
	Armyworm	1.0	*
CROP GROUP			
Crop	Pests	Rate (lbs./acre)	Special Instructions
Home Garden Use			

instructions specified on this label. Thorough applications to spray runoff should be made.

CROP GROUP

Forests, Shade Trees, Ornamentals, Shrubs, Sugar Maple Trees

Crop	Pests	Rate (lbs./acre)	Special Justructions
Forests, Shade Trees, Ornamentals,	Gypsy Moth Spruce Budworm Prowntail Moth	0.5-1.25	
Shrubs, Sugar Maple Trees	Tussock Moths Pine Butterfly Bagworm Leafrollers Tortrix Moths Mimosa Webworm Tent Caterpillars Jackpine Budworm Blackheaded Budworm Elm Spanworm Saddled Prominent Saddleback Caterpillars	0.5-1.0	
	Redhumped Caterpillar Spring Cankerworm Fall Cankerworm California Oakworm Fall Webworm	0.25-0.5	

Special Instructions

- * Biobit HPWP 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.
- ** Supression 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.

July 1, 1993

Mr. Phil Hutton Product Manager (18) Insecticide Rodenticide Branch Registration Division (H7505C) Office of Pesticide Programs U.S. Environmental Protection Agency 401 M Street S.W. Washington, D.C. 20460

Novo Nordisk Bioindustrials, Inc.

33 Turner Road P.O. Box 1907 Danbury, CT 06813-1907

Tel. 203-790-2600 FAX 203-790-2748

RE: Response to PR Notice 93-3

Notification, Biobit® HPWP, EPA Registration No. 58998-18

Dear Mr. Hutton:

This Notification is submitted to comply with PR Notice 93-3.

This label also incorporates the removal of the words "High Potency" from the banner block containing the product name. separate EPA Form 8570-1 and label is submitted within this parcel in compliance with PR Notice 93-6. The label submitted in compliance with PR Notice 93-6 only reflects the removal of the words "High Potency".

Sincerely,

fant M. Overhold/IAMI)

Janet M. Overholt Regional Manager Regulatory Affairs

Plant Protection Division

Enc: EPA Form 8570-1

1 !abel

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 11-30-93 United States Environmental Protection Agency **OPP Identifier Number** Registration Office of Pesticide Programs (H7505C) **Amendment** Washington, DC 20460 RE: PR NOTICE 93-6 for Pesticide: Other Section I. 2. EPA Product Manager 3. Proposed Classification 1. Company/Product Number grand and the property of the P. Hutton 58998-18 Restricted : None -PM# Company/Product (Name) ** Biobit HPWP 18.. 6. Expedited Review. In assordance with FJFRA Section 3(c)(3) 5. Name and Address of Applicant (Include ZIP Code) Novo Nordisk A/S (b)(i), my product is similar or identical in composition and labeling Novo Alle to: 2880 Bagsvaerd EPA Reg. No. Denmark Check if this is a new address **Product Name** Section 11 Final printed labels in response to Amendment - Explain below Agency letter dated Resubmission in response to Agency letter dated "Me Too" Application. Notification - Explain below. Other - explain below. Explanation: Use additional page(s) if necessary. (For section I and Section II.) The words "High Potency" are removed Notification to comply with PR Notice 93-6. rom the banner block containing product name. Section III 1. Material This Product Will Be Packaged In: 2. Type of Container Child-Resistant Packaging **Unit Packaging** Water Soluble Packaging Yes* Yes Metal Yes **Plastic** Nο Glass No No Paper If "Yes." If "Yes," No. per Other (Specify) Unit Package wgt. container. Package wgt. - container Certification must be 1. 2. 40 . 3 submitted. 4. Size(s) of Retail Container 5. Location of Label Directions 3. Location of Net Contents Information On Label Label Container On Labeling accompanying product 6. Manner In Which Label Is Affixed To Product Lithograph Other (Paper glued Stendiled Section IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Name Telephone No. (Include Area Code) Janet M. Overholt Registration Agent 6. Date Application 57. Certification Received I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. (Stamped) I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment o. both under applicable law. 2. Signature Registration Agent Typed Name 5. Date

Janet M. Overholt



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KEEP OUT OF REACH OF CHILDREN CAUTION

STATEMENTS OF PRACTICAL TREATMENT

If in Eyes: Flush with plenty of water. Call a physician if eye irritation persists.

If on Skin: Flush skin with plenty of soap and water. Get medical attention if irritation persists.

ACTIVE INGREDIENT

Bacillus thuringiensis Berliner subspecies kurstaki

By Weight

Lepidopteran Active Toxin......6.4%
Inert Ingredients......93.6%
TOTAL......100.0%

POTENCY:

32,000 International Units (iU) per mg of product equivalent to 14.5 Billion IU per pound of product. Potency units should not be used to adjust use rates beyond those specified in the Directions For Use Section.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS
May cause eye injury 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, 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: Completely empty bag into application equipment then dispose of empty bag 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

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

Container Disposal: Do not reuse bag. Discard bag 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 the 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 HPWP is manufactured by Novo Nordisk

EPA Registration No. 58998-18 EPA Est. No. 58998-DN-002 MANUFACTURED FOR:
Novo Nordisk
33 Turner Road
Danbury, Connecticut 06813-1907

NET CONTENTS

Pounds

labeling.

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

Re-entry

Do not enter treated area without protective clothing until sprays have dried.

Because certain states may require more restrictive reentry intervals for various crops treated with this product, consult your State Department of Agriculture for further information.

Do not apply this product in such a manner as to directly or through drift expose workers or other persons. The area being treated must be vacated by unprotected persons.

Written or oral warnings must be given to workers who are expected to be in a treated area or in an area about to be treated with this product. Oral warnings must include the following information:

Inform workers of area of fields that must not be entered without appropriate protective clothing until sprays have dried. In case of accidental exposure, wash thoroughly with soap and water. If in eyes, flush with plenty of water. Get medical attention if eye irritation persists.

When oral warnings are given, warnings shall be given in a language customarily understood by workers. Written warnings must include the following information:

CAUTION: Area treated with Biobit HPWP on (date of application). Do not enter without appropriate protective clothing until sprays have dried. In case of accidental exposure, wash thoroughly with soap and water. If in eyes, flush with plenty of water. Get medical attention if eye irritation persists.

APPLICATION

Biobit HPWP 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 sile, weather, spray equipment, and local experience.

MIXING

Fill spray or mixing tank half full of water. Begin agitation and pour Biobit HPWP 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 HPWP 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 preportionate quantities.

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For smallar spray volumes mix the proper number of teaspoons of Biobit HPWP from the folio ving chart to attain the desired rates:

If the rate is:	Add this	amount per	gallon of mix	Κ:

0.5 lb/acre	1 teaspoors
1.0 lb/acre	2 teaspoons
2.0 lb/acre	4 teaspoons

The above rate calculations assume that the final mix will be applied to runoff on the target crop and that thorough coverage will be obtained.

SPRAY VOLUMES

Aerial Application: Use recommended amount of Biobit HPWP 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 HPWP in a minimum of 20 gallons of water per acre.

Ground applications to trees and vines: Apply specific dosage per acre of Biobit HPWP 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 HPWP (per acre rate) in a minimum of 20 gallons of water per acre.

GENERAL USE INSTRUCTIONS

Biobit HPWP is a highly selective biological insecticide specific for the control of lepidopterous larvae. Biobit HPWP 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 HPWP cease feeding within a few hours and die within 2-5 days.

For maximum effectiveness the following is recommended:

Monitor fields to detect early infestations.

Apply Biobit HPWP 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.

PREHARVEST INTERVAL

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



APPLICATION RATES:

	FORAGE, FODDER, HAY				
		Crop	_	Pests	

Crop	Pests	Rate (lbs./acre)	Special Instructions
Alfalfa (Hay & Seed) and Other	Alfalfa Caterpillar Loopers	0.25-1.0	
Non-grass Animal Feeds,	Armyworm	0.5-2.0	*
Grasses Grown For Feed (pasture, ranges, hay or silage)	European Skipper (Essex Skipper)	0.5-1.0	

CROP GROUP	
FRUITS & M	UTS

Crop	Pests	Rate (lbs./acre)	Special <u>Instructions</u>
Pome and Stone Fruit Trees such as: Apples, Pears, Quince, Apricots, Cherries, Nectarines, Peaches, Flums, Prunes. Nut Trees such as: Almonds, Filbert, Chestnuts, Walnuts, Pecans.	Redhumped Caterpillars Tent Caterpillars Omnivorous Leafroller Tortrix Moths Cankerworms Peach Twig Borer Fruittree Leafroller Gypsy Moth Tufted Apple Budmoth Fall Webworm Variegated Leafroller Redbanded Leafroller Filbert Webworm Codling Moth Cutworms Filbert Leafroller Oblique Banded Leafroller	0.5-2.0	• • • • • • • • • • • • • • • • • • • •
	Walnut Caterpillar Citrus Cutworm Roughskinned Cutworm	0.25-0.5	· · · · · · · · · · · · · · · · · · ·

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CROP GROUP			
FRUITS & NUTS Cont'd		1	1
Citrus	Orangedog	0.25-1.0	
	Fruittree Leafroller Citrus Cutworm	0.5-2.0	
	Amorbia	1.0-1.5	Suppression Only **
Small Fruit and Berries such as: Blackberries, Blueberries, Currants Raspberries,	Gypsy Moth Blueberry Leafroller Loopers Fruittree Leafroller Grape Berry Moth Oblique Banded Leafroller Achema Sphinx Moth (Hornworm)	0.5-1.0	
Strawberries Cranberries,	Armyworm	0.5-2.0	*
	Tobacco Budworm	2.0	
Grapes	Cherry Fruitworm Green Fruitworm	0.25-0.5	
	Grape Leaffolder Grapeleaf Skeletonizers Omniverous Leafroller Orange Tortrix Saltmarsh Caterpillar	0.5-1.25	

CROP GROUP			
OTHER FRUITS			
Bananas	Banana Skipper	0.5-1.0	
Tropical Fruits	Hornworms Leafrollers Loopers Omnivorous Leafroller	0.5-2.0	•••
Kiwi	Omnivorous Leafroller	0.5-2.1)	•
Pineapple	Gummosos-Batrachedra commosae (Hodges) Thecla-Thecla basilides (Geyr)	0.25-0.5	
Melons	(see Vegetable Crops, Curcubits)		

CROP GROUPS

VEGETABLES AND COLE CROPS

	Crop	Pests	Rate (lbs./acre)	Special Instructions
	Root & Tuber Vegetables, and leaves of Root and Tuber vegetables such as	Imported Cabbageworm Green Cloverworm	0.25-1.0	
	Beet, Carrot,	Hornworms	0.125-1.0	
	Horseradish, Radish, Potato Sweet Potato, Turnip and Turnip Greens, Sugarbeets,	Cutworms Loopers Webworms Saltmarsh Caterpillar Omnivorous Leafroller	0.5-1.0	
		Armyworm	0.5-2.0	*
		Diamondback Moth	0.25-2.0	
		European Corn Borer	1.0-1.5	
		Alfalfa Caterpillar	0.125- 0.25	
	Bulb Vegetables such as:	Saltmarsh Caterpillar Omnivorous Leafroller Webworms Cutworms	0.5-1.0	
	Garlic, Leeks, Onions, Shallot	Hornworms	0.125-1.0	
		Imported Cabbageworm Green Cloverworm Loopers	0.25-1.0	
		Armyworm	0.5-2.0	*
;		Diamondback Moth	0.25-2.0	
		European Corn Borer	1.0-1.5	
		Helicoverpa (Heliothis) sp	1.0	Suppression Only **

Crop	Pests	Rate (lbs./acre)	Special Instructions
Leafy vegetables, such as:	Imported Cabbageworm Green Cloverworm Loopers	0.25-1.0	
Celery,	Hornworms	0.125-1.0	
Lettuce(Head and Leaf), Parsley, Endive,	Cutworm, Webworms	0.5-1.0	
Spinach, Kale	Diamondback Moth	0.25-2.0	
	Saltmarsh Caterpillar Omnivorous Leafroller	0.5-1.0	
	Armyworm	0.5-2.0	*
	European Corn Borer	1.0-1.5	
Legume and foliage of Legume	Loopers	0.25-1.0	
vegetables,	Hornworms	0.125-0.5	
such as Beans, Lentils, Peas, Soybeans	Podworms Imported Cabbageworm Green Cloverworm Saltmarsh Caterpillar Soybean Loopers	0.5-1.0	
	Armyworm	0.5-2.0	*
	Diamondback Moth Velvetbean Caterpillar	0.25-2.0	
	European Corn Borer	1.0-1.5	
	Cutworm	0.5-1.5	

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	Crop	Pests	Rate (lbs./acre)	Special Instructions
	Fruiting Vegetables	Imported Cabbageworm Green Cloverworm	0.25-0.5	
	such as:	Diamondback Moth	0.25-2.0	
	Eggplant, Peppers, Tomatoes	Hornworms	0.125-1.0	
	Tomatoes	Tomato Fruitworm(Heliothis) Variegated Cutworm Saltmarsh Caterpillar Loopers	0.5-1.0	
		Armyworm	0.5-2.0	*
		European Corn Borer	1.0-1.5	
	Brassica(cole)	Diamondback Moth	0.25-2.0	
	vegetables such as:	Hornworms	0.125-1.0	
	Broccoli, Brussels sprouts, Cabbage, Cauliflower, Collards,	Webworms Loopers Cutworms Saltmarsh Caterpillar Omnivorous leafroller	0.5-1.0	
	Kohlrabi,	Imported Cabbageworm Green Cloverworm	0.25-1.0	
		Armyworms	0.5-2.0	*
		European Corn Borer	1.0-1.5	
	Cucurbit vegetables such as:	Imported Cabbageworm Green Cloverworm Loopers	0.25-1.0	
	Cucumbers,	Diamondback Moth	0.25-2.0	,
	Melons, Pumpkins, Squash, Watermelon	Saltmarsh Caterpillar Melonworm Pickleworm Rindworm complex	0.25-1.0	
		Armyworm	0.5-2.0	*,;*
		European Corn Borer	1.0-1.5	
		Hernworms	0.125-0.5	

OTHER VEGETABLES

Cro	<u> </u>	Pests	Rate (lbs./acre)	Special Instructions
Arti	ichokes	Artichoke Plume Moth	0.5-1.25	
		Armyworm	0.5-1.5	*
		Loopers	0.25-1.25	
Aspa	aragus	Armyworms	0.5-2.0	*
		Diamondback Moth	0.25-2.0	
		Green Cloverworm Imported Cabbageworm	0.25-0.5	
		Loopers	0.25-1.0	
Mala	anga	Armyworms	0.5-2.0	*
		Saltmarsh Caterpillar	0.5-1.0	
Wate	ercress	Loopers Diamondback Moth	0.25-2.0	
		Armyworms	0.5-2.0	*
		Green Cloverworm Imported Cabbageworm	0.25-0.5	
		Saltmarsh Caterpillar	0.5-1.0	
		European Corn Borer	1.0-1.25	
Swe	eet Corn	(see Other Crops, Corn)		

CROP GROUP			
HERBS, SPICES, MINTS			
such as Basil,	Loopers	0.25-1.0	
Dill, Oregano, Peppermint, Tyme	Diamondback Moth	0.5-2.0	•••
	Green Cloverworm Imported Cabbageworm	0.25-0.15	•••
	Armyworm	0.5-2.0	*
	European Corn Borer	1.0-1.5	•

CROP GROU	P
OTHER CRO	PS

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Crop		Pests		Rate (lbs./acre)	Special Instructions
Avoca	adoes I	Loopers	•	1.0-1.25	
		Orange Tortrix Omnivorous Leafroller Omnivorous Looper Spanworm		0.5-2.0	
		Amorbia		0.5-2.0	Suppression Only **
Rice	1	Armyworms		0.5-1.5	*
		Loopers Saltmarsh Caterpillar,		0.5-1.0	
		Cutworm		0.5-1.5	
		Green Cloverworm, VelvetBean Caterpillar		0.25-0.5	
		Helicoverpa (Heliothis)	spp	1.0	Suppression Only **

,	Crop	Pests	Rate (lbs./acre)	Special Instructions	
	Cotton (Except	Loopers	0.5-1.0		
	CA & AZ)	Armyworm	0.5-2.0	*	
		Cotton bollworm Tobacco budworm	0.25-2.0	see below	
		Special Instructions: For endelicoverpa species. Inition of plants are at pinhead so independent of Heliothis egor at first egg lay, which continue applications on a up to the pyrethroid spray	iate applicat: quare cotton s gg and larval ever occurs es five day spra	ions when 50% stage counts arlier.	
	Cotton (CA & AZ)	Armyworm	0.5-2.0	*	
	A2)	Cotton Leaf Perforator Cotton Leafworm Saltmarsh Caterpillar	0.5-1.0		
		Loopers	0.5-1.0		
		Cotton Bollworm Tobacco Budworm	0.5-2.0	See Below	
		Special Instructions: Repeat as necessary throughout the season to maintain control. If egg laying freqency indicates future moderate to heavy larval populations, time application spray to coincide with the second instar larvae. During periods of high temperatures larvae wil 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 HPWP may not provide adequate control.			
	Canola/Rape	Armyworm	0.5-2.0	*	
	Seed	Diamondback Moth	0.25-2.0		
		Looper	0.5-1.0		
		Helicoverpa (Heliothis)	0.5-2.0		
	Corn	Armyworms	0.5-2.0	****	
	Field, Sweet, Popcorn	European Corn Borer (whorl Stage Only)	0.5-2.0		
		Southwestern Corn Borer	1.0.1.5	Aids in Control	

. 9	Prop	Pests	Rate (lbs./acre)	Special <u>Instructions</u>
	Hops	Armyworm	0.5-2.0	*
		Loopers	0.25-1.0	
		Omnivorous Leaftier Spotted Cutworm Oblique Banded Leafroller	0.5-1.0	
	Jojoba	Looper (Anacamptodes spp.)	0.5-1.0	
	Peanuts	Green Cloverworm Loopers Velvetbean Caterpillar Podworms	0.5-1.0	
		Helicoverpa (Heliothis) spp	1.0	Suppression Only **
	Persimmons, Pomegranate	Fall Webworm Filbert Webworm Omnivorous Leafroller Redhumped Caterpillar Tent Caterpillar	0.5-1.0	
		Citrus Cutworm	0.5-1.25	
	Safflower	Armyworm	0.5-2.0	*
		Loopers Saltmarsh Caterpillar	0.5-1.0	
	Sorghum	Headworm	0.5-1.0	
	Soybeans	(see Vegetable Crops, Legumes)		
	Sunflowers	Headmoth Loopers	0 5-1.0	
	Small Grains	Armyworms	0.5-2.0	*
		Loopers	0.5-1.0	
7	Tobacco	Tobacco Hornworm	0.125-0.5	***
		Looper	0.25.1.0	,
		Tobacco Budworm	2.0	Suppression Only **

,GROP	GROUP	·
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FLOWERS, BEDDING PLANTS, AND ORNAMENTALS

Crop	Pests	Rate lbs./acre	Special Instructions
Ornament Flowers, Bedding	Diamondback Moth	0.5-2.0	*
	Azalea Moth Ello Moth (Hornworm) Io Moth Loopers Oleander Moth Omnivorous Leafroller Omnivorous Looper Tobacco Budworm	0.25-0.5	

CROP GROUP

GREENHOUSE, SHADE TREES, AND OUTDOOR NURSERY CROPS

	Crop	Pests_	Rate (lbs./acre)	Special Instructions
-	Such as Brassica,	Armyworms	0.5-2.0	*
	Fruiting Groups, Herbs, and Leafy	Loopers	0.5-1.0	

CROP GROUP

TURF

Crop	Pests	Rate (lbs./acre)	Special <u>Instructions</u>
Turf	Sod Webworm	1.0-2.0	
	Tropical Sod Webworm	1.0	
	Armyworm	1.0	*

CROP G	ROUP			••••
	Crop	Pests	Rate (lbs./acre)	Special Instructions
Home Garden Use		Biobit HPWP may be used for any labeled pest and crop using the rates, mixing, and general use instructions specified on this label. Thorough applications to spray runoff should be made:		

CROP	GROUP

Forests, Shade Trees, Ornamentals, Shrubs, Sugar Maple Trees

Crop	Pests	Rate (lbs./acre)	Special Instructions
Forests, Shade Trees, Ornamentals, Shrubs,	Gypsy Moth Spruce Budworm Browntail Moth	0.5-1.25	
Sugar Maple Trees	Tussock Moths Pine Butterfly Bagworm Leafrollers Tortrix Moths Mimosa Webworm Tent Caterpillars Jackpine Budworm Blackheaded Budworm Elm Spanworm Saddled Prominent Saddleback Caterpillars	0.5-1.0	
	Redhumped Caterpillar Spring Cankerworm Fall Cankerworm California Oakworm Fall Webworm	0.25-0.5	

Special Instructions

- * Biobit HPWP 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.
- ** Supression 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.