

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 14 1995

468 / 5486633
 18 /
 469 / 5486634
 18 /

Novo Nordisk A/S
 c/o Ms. Joann Olster
 Novo Nordisk Bioindustrials, Inc.
 33 Turner Road
 Danbury, CT 06813-1907

Dear Ms. Olster:

Subject: Foray® 48B Master Label with Revised WPS
 Exclusionary Statements
 Your Submission Dated 4/7/95
 EPA Registration No. 58998-7

The master labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act is acceptable provided you make the following changes prior to shipment.

In the Directions for Use for Agricultural Applications, Special Instructions, Armyworm Control section on page 13 of your master label;

- a) Change "mature larvae" to read "late instar larvae."
- b) At the end of this section add "This product can be mixed and used with other pesticides only in accordance with the most restrictive of label limitations and precautions. This product cannot be mixed with any product containing a label prohibition against such mixing. No label dosage rates may be exceeded."

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product with revised labeling constitutes acceptance of these conditions.

CONCURRENCES

| | | | | | | | | |
|---------|---------|--|--|--|--|--|--|--|
| SYMBOL | 2501w | | | | | | | |
| SURNAME | March | | | | | | | |
| DATE | 4/13/95 | | | | | | | |

108 10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Foray 48B Label Amendment
Page 2

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

Sincerely,



Janet L. Andersen
Acting Director
Biopesticides and Pollution
Division (7501W)

)
Enclosure

)

CONCURRENCES

| SYMBOL | | | | | | | | |
|---------|--|--|--|--|--|--|--|--|
| SURNAME | | | | | | | | |
| DATE | | | | | | | | |



Foray® is the Registered Trademark of Novo Nordisk A/S

KEEP OUT OF REACH OF CHILDREN CAUTION

ACTIVE INGREDIENT *Bacillus thuringiensis* subspecies *kurstaki*, Lepidopteran Active Toxin.....2.1%
Inert Ingredients.....97.9%
TOTAL.....100%
POTENCY: 10,600 International Units (IU)/mg of product (equivalent to 48 billion IU/GAL.). Potency units should not be used to adjust use rates beyond those specified in the directions for use sections.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS: Causes moderate eye irritation. Avoid contact with skin, eyes, open wounds or clothing. Wash thoroughly with soap and water after handling.

USER SAFETY RECOMMENDATIONS:

Users should: Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

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.

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

For terrestrial agricultural 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.

STATEMENTS OF PRACTICAL TREATMENT: *If on Skin:* Wash with plenty of soap and water. Get medical attention. *If in Eyes:* Flush with plenty of water. Call a physician if eye irritation persists.

DIRECTIONS FOR USE FOR AGRICULTURAL APPLICATIONS:

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

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.

DIRECTIONS FOR USE Cont'd

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.

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 32 degrees C (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.

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.

ACCEPTED
with COMMENTS
in EPA Letter Dated

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
58998-7

EPA Registration No. 58998-7
EPA Est. No. 58998-DN-002

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

NET CONTENTS
U.S. Gallons: 3

weather conditions, spray equipment used and local experience.

Aerial Application: Use recommended amount of Foray 48B in aerial equipment undiluted or with quantities of water sufficient to provide thorough coverage of plant parts to be protected. In the western U.S. 5-10 gallons per acre is the normal minimum; in the eastern regions a minimum of 2-3 gallons is normally used. The minimum amount of water needed per acre will depend upon crop size, weather conditions, spray equipment used and local experience.

GENERAL AGRICULTURAL USE INSTRUCTIONS

Foray 48B is a biological insecticide for the control of lepidopterous larvae. It contains the spores and endotoxin crystals of *Bacillus thuringiensis kurstaki*. Foray 48B 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 Foray 48B cease feeding within a few hours and die within 2-5 days.

Foray 48B 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 Foray 48B 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.

| | Crop | Pests | Rate (pts./acre) | Special Instructions |
|-----|---|--|---------------------|-------------------------|
| | Citrus | Orangedog | 1.0-3.0 | |
| | | Fruittree Leafroller Citrus Cutworm | 1.5-5.5 | |
| | | Amorbia | 3.0-4.0 | ** See Below |
|)) | Small Fruit and Berries such as: Blackberries, Blueberries, Currants, Raspberries, Strawberries, Cranberries. | Gypsy Moth & Asian Gypsy Moth Blueberry Leafroller Loopers Fruittree Leafroller Grape Berry Moth Oblique Banded Leafroller Achema Sphinx Moth (Hornworm) | 1.5-3.0 | |
| | | Armyworms | 1.5-5.5 | * |
| | | Tobacco Budworm | 5.5 | **See Below |
| | Grapes | Cherry Fruitworm Green Fruitworm | 1.0-1.5 | |
| | | Grape Leaf folder Grapeleaf Skeletonizer Omnivorous Leafroller Orange Tortrix Saltmarsh Caterpillar | 1.5-4.0 | |

CROP GROUP

OTHER FRUITS

| | Crop | Pests | Rate (pts./acre) | Special Instructions |
|--|--------------------|--|---------------------|-------------------------|
| | Bananas | Banana Skipper | 1.5-3.0 | |
| | Tropical Fruits | Hornworms Leafrollers Loopers Omnivorous Looper | 1.5-5.5 | |
| | Kiwi | Omnivorous Leafroller | 1.5-5.5 | |

| | Crop | Pests | Rate (pts./acre) | Special Instructions |
|--|--|--|---------------------|-------------------------|
| | Bulb Vegetables such as: Garlic, Leeks, Onions, Shallot | Saltmarsh Caterpillar Omnivorous Leafroller Webworms | 1.5-3.0 | |
| | | ----- Hornworms | 0.5-3.0 | |
| | | ----- Imported Cabbageworm Green Cloverworm Loopers | 1.0-3.0 | |
| | | ----- Cutworms | 1.5-3.0 | |
| | | ----- Armyworms | 1.5-5.5 | * |
| | | ----- Diamondback Moth | 1.0-1.5 | |
| | | ----- European Corn Borer | 3.0-4.0 | |
| | | ----- <i>Heliothis</i> spp. | 3.0 | Suppression Only ** |
| | Leafy vegetables such as: Celery, Lettuce (Head and Leaf), Parsley, Endive, Spinach, Kale | Imported Cabbageworm Green Cloverworm | 1.0-3.0 | |
| | | ----- Hornworms | 0.5-3.0 | |
| | | ----- Cutworms Webworms | 1.5-3.0 | |
| | | ----- Loopers Diamondback Moth | 1.0-3.0 | |
| | | ----- Saltmarsh Caterpillar Omnivorous Leafroller | 1.5-3.0 | |
| | | ----- Armyworms | 1.5-5.5 | * |
| | | ----- European Corn Borer | 3.0-4.0 | |
| | | ----- | | |

| Crop | Pests | Rate (pts./acre) | Special Instructions |
|--|-----------------------|---------------------|-------------------------|
| Cucurbit vegetables such as: Cucumbers, Melons, Pumpkins, Squash, Watermelon. | Imported Cabbageworm | 1.0-3.0 | |
| | Green Cloverworm | | |
| | Diamondback Moth | | |
| | Loopers | | |
| | Saltmarsh Caterpillar | | |
| | Melonworm | | |
| | Pickleworm | | |
| | Rindworm complex | | |
| | ----- | | |
| | Armyworms | 1.5-5.5 | * |
| | ----- | | |
| | European Corn Borer | 3.0-4.0 | |
| | ----- | | |
| | Hornworms | 0.5-1.5 | |

OTHER VEGETABLES

| Crop | Pests | Rate (pts./acre) | Special Instructions |
|------------|-------------------------|---------------------|-------------------------|
| Artichokes | Artichoke Plume Moth | 1.5-4.0 | |
| | ----- | | |
| | Armyworms | 1.5-4.0 | * |
| | ----- | | |
| | Loopers | 1.0-4.0 | |
| Asparagus | Armyworms | 1.5-5.5 | * |
| | ----- | | |
| | Diamondback Moth | 1.0-1.5 | |
| | Green Cloverworm | | |
| | Imported Cabbageworm | | |
| | ----- | | |
| | Loopers | 1.0-3.0 | |
| Malanga | Armyworms | 1.5-5.5 | * |
| | ----- | | |
| | Saltmarsh Caterpillar | 1.5-3.0 | |
| Watercress | Loopers | 1.0-3.0 | |
| | Diamondback Moth | | |
| | ----- | | |
| | Armyworms | 1.5-5.5 | * |
| | ----- | | |
| | Green Cloverworm | 1.0-1.5 | |
| | Imported Cabbageworm | | |
| | ----- | | |
| | Saltmarsh Caterpillar | 1.5-3.0 | |
| | ----- | | |
| | European Corn Borer | 3.0-4.0 | |
| Sweet Corn | (see Other Crops, Corn) | | |

| Crop | Pests | Rate (pts./acre) | Special Instructions |
|----------------------------|------------------------------------|---------------------|-------------------------|
| Cotton (Except CA & AZ) | Loopers | 1.5-3.0 | |
| | Armyworms | 1.5-5.5 | * |
| | Cotton Bollworm Tobacco Budworm | 1.0-5.5 | See Below |

Special Instructions: For early season management of *Heliothis/Helicoverpa* species, initiate applications at pinhead square stage when eggs are present. For best results, application should be timed to coincide with egg hatch. Continue applications on 5 day intervals. Addition of an ovicide may be beneficial. Preservation of beneficial insects should be considered in selecting an ovicide. Applications of Foray 48B may continue throughout the season. As the larval population increases through the season, increase rates of Foray 48B, and tank-mix with other larvicides for increased control. When the crop canopy is dense and larvae are feeding in the lower canopy, aerial application of Foray 48B may not provide adequate deposit for acceptable control. When the crop canopy is dense and larvae are feeding in the lower canopy, aerial application of Foray 48B may not provide adequate deposit for acceptable control. This product can be mixed and used with other pesticides only in accordance with the most restrictive of label limitations and precautions. This product cannot be mixed with any product containing a label prohibition against such mixing. No label dosage rates may be exceeded.

| | | | |
|---------------------|--|---------|-----------|
| Cotton (CA & AZ) | Armyworms | 1.5-5.5 | * |
| | Cotton Leaf Perforator Cotton Leafworm Saltmarsh Caterpillar | 1.5-3.0 | |
| | Loopers | 1.5-3.0 | |
| | Cotton Bollworm Tobacco Budworm | 1.5-5.5 | See Below |

Special Instructions: Repeat as necessary throughout the season to maintain control. If egg laying frequency indicates future moderate to heavy larval populations, time application 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 Foray 48B may not provide adequate deposit to achieve acceptable control.

| | | | |
|---|---|---------|----------------|
| Canola/Rape Seed | Armyworms | 1.5-5.5 | * |
| | Diamondback Moth | 1.0-1.5 | |
| | Loopers | 1.5-3.0 | |
| | <i>Heliothis</i> spp. | 1.5-5.5 | |
| Corn Such as: Field, Sweet, Popcorn. | Armyworms | 1.5-5.5 | *** * |
| | European Corn Borer (Whorl Stage Only) | 1.5-4.0 | |
| | Southwestern Corn Borer | 3.0-4.0 | Air in Control |

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 | 1.5-5.5 | * |
| | | Azalea Moth Diamondback Moth Ello Moth (Hornworm) Io Moth Loopers Oleander Moth Omnivorous Leafroller Omnivorous Looper Tobacco Budworm | 1.0-1.5 | |

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. | 1.5-5.5 | * |
| | | Loopers | 1.5-3.0 | |

CROP GROUP
TURF

| | <u>Crop</u> | <u>Pests</u> | <u>Rate (pts./acre)</u> | <u>Special Instructions</u> |
|--|-------------|----------------------|-----------------------------|---------------------------------|
| | Turf | Sod Webworm | 3.0-5.5 | |
| | | Tropical Sod Webworm | 3.0 | |
| | | Armyworms | 3.0 | * |

PRODUCT CONTAINER LABEL

DIRECTIONS FOR USE FOR NON-AGRICULTURAL APPLICATIONS

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.

Not for use on plants being grown for sale or other commercial use, or for commercial seed production, or for research purposes. For use on plants intended for aesthetic purposes or climatic modification and being grown in interior plantscapes, ornamental gardens or parks, or on golf courses or lawns and grounds.

Not for use on trees being grown for sale or other commercial use, or for commercial seed production, or for the production of timber or wood products, or for research purposes except wide-area public pest control programs sponsored by government entities, such as mosquito abatement, gypsy moth control, and Mediterranean fruit fly eradication.

FORAY 48B contains the spores and endotoxin crystals of *Bacillus thuringiensis kurstaki*. FORAY 48B is a stomach poison and is effective against lepidopterous larvae. After ingestion, larvae stop feeding within hours and die 2-5 days later. Maximum activity is exhibited against early instar larvae. FORAY 48B may be used for both ground and aerial application. The product should be shaken or stirred before use. Add some water to the tank mix, pour the recommended amount of FORAY 48B into the tank and then add the remaining amount of water to obtain the proper mix ratio. Agitate as necessary to maintain the suspension. The diluted mix should be used within 72 hours.

Ground Application

Use an adequate amount of tank mix to obtain thorough coverage without excessive run off. Use the recommended per acre dosages of Foray 48B in up to the following amounts of water:

| | |
|--------------------------------|-------------|
| High volume hydraulic sprayers | 100 gallons |
| Mist blowers | 10 gallons |

Aerial Application

Foray 48B may be applied aurally, either alone or diluted with water at the dosages shown in the application rates table. Spray volumes of 32-128 ounces per acre are recommended. Best results are expected when Foray 48B is applied to dry foliage.

For smaller spray volumes mix the proper number of teaspoons of Foray 48B from the following chart to attain the desired rates:

| <u>If the rate is:</u> | <u>Add this amount per gallon of mix:</u> |
|------------------------|---|
| 0.5 pts./acre | 1/2 teaspoon |
| 1.0 pts./acre | 1 teaspoon |
| 1.5 pts./acre | 1 1/2 teaspoons |
| 2.0 pts./acre | 2 teaspoons |
| 3.0 pts./acre | 3 teaspoons |
| 4.0 pts./acre | 4 teaspoons |
| 5.5 pts./acre | 5 1/2 teaspoons |

HOME GARDEN USE DISPOSAL INSTRUCTIONS

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