

US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (TS-767)
WASHINGTON, DC 20460

EPA REGISTRATION NO.

58998-17

DATE OF ISSUANCE
MAY 20 1992

TERM OF ISSUANCE

NAME OF PESTICIDE PRODUCT

Foray 76B

NOTICE OF PESTICIDE: REGISTRATION
 REREGISTRATION
(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, or amended)

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

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

166 / 420,124
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166 / 420,128 / 420,125
38 / 420,125

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is retained herewith.

Registration in no way to be construed as an indorsement or approval of this product by the Agency. In order to protect health and the environment, the Administrator, on his or her own motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under the Act shall not be construed as giving the registrant a right to exclusive use of the name, or its use if it has been covered by another.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) or FIFRA section 4 when the Agency requires all registrants of similar products to submit such data.
2. Add the phrase, "EPA Registration No. 58998-17" to your label before you release the product for shipment.
3. Submit a primary dermal irritation study and an acute dermal toxicity study, per Subdivision F of the Pesticide Assessment Guidelines, within 8 months of receiving this registration. The dose level used in the dermal toxicity study submitted and the surface area to which the test material was applied were both insufficient to resolve dermal toxicity categories. For future studies, please ensure that animal treatment levels are based on dose levels per animal body weight and the surface area to which the test material is applied is sufficiently small so that toxicity categories can be resolved. For questions regarding these studies or guidance in study design, please contact Thomas Ellwanger of our Precautionary Review Section

(See (7)(B) (1)(i)(4)(7)(B))

Signed: _____

DATE: 5/20/92

4. Clarify via data submission whether turbidity measured by light diffusion or viscosity measured by resistance to a propeller is used to determine the active ingredient percentage in your photometric immunoassay analytical method submitted in support of your Foray 48B amendment. Upon submission of this data, you must also submit a revised label based on the % lepidopteran toxin. Potency must remain on the label unless sufficient correlation between field activity and the analytical method is shown. Please see page 22 of the Bacillus thuringiensis Registration Standard and EPA's 5/22/90 letter amending the Registration Standard's Regulatory Position and Rationale No. 8.

5. Add the statement "Potency units should not be used to adjust use rates beyond those specified in the directions for use section." to the ingredients statement.

6. Modify the Hazards to Humans and Domestic Animals statements on the label to read as follows. "Harmful if inhaled. Causes moderate eye irritation. Harmful if absorbed through the skin. Do not get in eyes, on skin, or on clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash contaminated clothing before reuse."

7. Modify the Statements of Practical Treatment block under the signal word Caution as follows.

STATEMENTS OF PRACTICAL TREATMENT

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

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

If Inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

8. Your waiver request on the six month beta-exotoxin storage stability study has been denied. Submit within 15 months a storage stability study on the active ingredient at time 0 and up to 12 months of storage and a study for beta-exotoxin presence at time 0 and up to 6 months of storage.

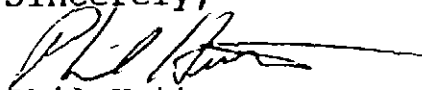
9. Submit five (5) copies of your final printed labeling modified as directed above before you release the product for shipment.

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

A stamped copy of the label is enclosed for your records.

Sincerely,



Phil Hutton
Product Manager 18
Insecticide-Rodenticide Branch
Registration Division (H7505C)

FORAY™ 76 B

FLOWABLE CONCENTRATE

FOREST, TREES AND SHRUBS

KEEP OUT OF REACH OF CHILDREN

CAUTION

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

ACTIVE INGREDIENT:

<u>Bacillus thuringiensis var. kurstaki</u>	16,700
International Units (IU)/mg	
of product (equivalent to 76 billion	
IU/gal).....	3.3%
Inert Ingredients.....	96.7%
Total.....	100%

PRECAUTIONARY STATEMENTS:

Hazards to Humans and Domestic Animals: May cause eye irritation. Avoid contact with skin, eyes, open wounds or clothing. Wash thoroughly with soap and water after handling.

Environmental Hazards: Do not contaminate water when disposing of equipment washwaters.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

5/19/82

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

58998-17

DIRECTIONS FOR USE:

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

FORAY contains the spores and endotoxin crystals of Bacillus thuringiensis kurstaki. FORAY is a stomach poison and has high specific activity 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 76B Flowable Concentrate 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 76B 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 76B in up to the following amounts of water:

High volume hydraulic sprayers	100 gallons
Mist blowers	10 gallons

Aerial Application: FORAY 76B may be applied aerially, 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 76B is applied to dry foliage.

RE-ENTRY: FORAY may be applied up to and including the day of harvest.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal.

Storage: Store in a cool, dry place. Keep containers tightly closed when not in use. Store in temperatures above freezing and below 25 degrees C (77 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. Reuse of thoroughly cleaned container is allowed.

APPLICATION RATES:

Crop	Pests	Rate* (oz./acre)	Dosage* (BIU/Acre)
Forests, Shade Trees, Ornamentals, Shrubs, Sugar Maple Trees, Seed Orchards, Ornamental Fruit, Nut and Citrus Trees	Gypsy moth	13.5-67.5	8-40
	Spruce budworm, browntail moth, Douglas fir tussock moth, coneworm	13.5-50.5	8-30
	Tussock moths, pine butterfly, bagworm, leafrollers, tortrix, mimosa webworm, tent caterpillar, jackpine budworm, black headed budworm, elm spanworm, saddled prominent, saddleback caterpillar and hemlock looper	10.0-27.0	6-16
	Redhumped caterpillars, spring and fall cankerworm, California oakworm, fall webworm	7.0-13.5	4-8

* Use the higher recommended rates on advanced larval stages or under high density larval populations.

EPA Reg. #58998-
EPA Est. #58998-DN-001

WARRANTY NOTICE: 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, special, or indirect damages resulting from the use or handling of this product. All such risks shall be assumed by the buyer.

MANUFACTURED FOR:

NOVO NORDISK
33 Turner Road
Danbury, CT 06813-1907

Batch No.:

NET CONTENT _____ (U.S. GALLONS)

5/91