

PU 18 58998-17 p. 134 File



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

APR 6 1994

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Janet Overholt  
NAVO NORDISK BIOINDUSTRIALS, INC.  
Agent for: NOVO NORDISK A/S  
33 Turner Road - Box 1907  
Danbury, CT 06813

Subject: Label Amendment Submission of 09/20/93 in Response to PR Notice 93-7  
EPA Reg. No. 58998-17  
FORAY 76 B

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.

**BEST AVAILABLE COPY**



Recycled/Recyclable  
Printed with Soy/Candor ink on paper that  
contains at least 50% recycled fiber

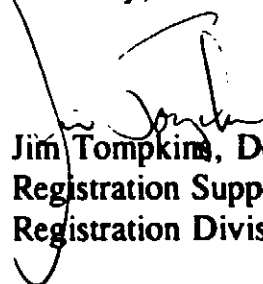
Submit the final printed labeling via the U.S. Postal Service to:

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

**BEST AVAILABLE COPY**

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division

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

Comment for: EPA Reg Nr.58998-17  
FORAY 76 B

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."

Add the following User Safety Recommendation to the label in the location shown in Section A on Part 1 of the Product Worksheet in Supplement Three-A to PR Notice 93-7: "Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

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.

Delete the crossed-out statements on your proposed label. They are redundant statements or phrases.

**BEST AVAILABLE COPY**

# KEEP OUT OF REACH OF CHILDREN CAUTION

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

**ACTIVE INGREDIENT:**

*Bacillus thuringiensis* subsp. *kurstaki*.....3.3%  
Lepidopteran Active Toxin.....3.3%  
INERT INGREDIENTS.....96.7%  
TOTAL.....100%

POTENCY: 16,700 International Units (IU)/mg of product (equivalent to 76 billion IU/GAL.). 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:** 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.

**PERSONAL PROTECTIVE EQUIPMENT:** Applicators and other handlers should 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.

**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.

**DIRECTIONS FOR USE:**

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.

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 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.

**PREHARVEST INTERVAL:**

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 of waste.

**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, 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, tortix, 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

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.  
58998-17

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

**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.

