



United States
Environmental Protection Agency
 Washington, DC 20460
NOTIFICATION

Registration
 Amendment
 Other

OPP Identifier Number

239635

Application for Pesticide - Section I

1. Company/Product Number 58998-7	2. EPA Product Manager J. Anderson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Foray 48B Flowable Concentrate	PM# 18	
5. Name and Address of Applicant (Include ZIP Code) Novo Nordisk A/S Novo Alle 2800 Bagsvaerd <input type="checkbox"/> 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: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
 Notification to revise REI to 4hrs as allowed by Policy Statement on Worker Protection Standard; Reduced Restricted Entry Intervals for Certain Pesticides, Effective May 3, 1995.
 Notification under PR Notice 95-3

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	If "Yes" Unit Packaging wgt. No. per container		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Package wgt.	No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompany product	
6. Manner in Which Label Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Carmen M. Sanchez Lopez, Ph.D.	Title Regional Manager Regulatory Affairs	Telephone No. (include Area Code) 916-757-4738
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature	3. Title Regional Manager Regulatory Affairs	
4. Typed Name Carmen M. Sanchez Lopez, Ph.D.	5. Date	

KEEP OUT OF REACH OF CHILDREN CAUTION

ACTIVE INGREDIENT:

Bacillus thuringiensis subsp. *kurstaki*, 10,600 International Units (IU)/mg of product (equivalent to 48 billion IU/GAL.)..... 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. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. Do not apply this product through any type of irrigation system.

AGRICULTURAL USE REQUIREMENTS: Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: Coveralls, waterproof gloves, shoes plus socks.

instar larvae. FORAY 48B 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 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 the following amounts of water:

High volume hydraulic sprayers	100 gallons
Mist blowers	10 gallons

Aerial Application: FORAY 48B 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 48B is applied to dry foliage.

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.

APPLICATION RATES:

Crop	Pests	Rate ¹ (pts/acre)	Dosage ¹ (BIU/Acre)
Forests,	Gypsy moth & Asian Gypsy moth,		
Shade Trees,	Elm Spanworm	1.3-6.7	8-40
Ornamentals,	Spruce Budworm, Browntail		
Shrubs,	moth, Douglas fir tussock		
Sugar Maple	moth, Coneworm	1.3-5	8-30
Trees,	Tussock moths, Pine Butterfly,		
Seed Orchards,	Bagworm, Leafrollers, Tortix,		
Ornamental	Mimosa Webworm, Tent Caterpillar,		
Fruit, Nut	Jackpine Budworm, Blackheaded		
and Citrus	Budworm, Saddled Prominent, Saddle-		
Trees ²	back Caterpillar, Eastern and		
	Western Hemlock Looper, Orange		
	striped Oakworm, Satin moth	1.2-7	6-16
	Redhumped Caterpillars,		
	Spring and Fall Cankerworm,		
	California Oakworm,		
	Fall Webworm	0.7-1.3	4-8

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

2) In treating gypsy moth infested trees and shrubs in urban, rural, and semi-rural areas, exposure of non target vegetation including, but not limited to, native and ornamental species and food or feed crops is not permitted.

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



DATA EVALUATION REPORT

STUDY TYPE: Guideline 81-3; Acute inhalation toxicity

EPA IDENTIFICATION NUMBERS

Tox Chem. No.:

MRID No.: 423931-01

PC Number:

TEST MATERIAL: FORAY® 48B, FC

SPONSOR: Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd, Denmark

LABORATORY PROJECT ID NUMBER/REPORT NUMBER: 651213/7701

TESTING FACILITY: Inveresk Research International Limited, Tranent EH33 2NE, Scotland

TITLE OF REPORT: FORAY 48B, FC Acute Inhalation Toxicity Study in Rats (Limit Test)

AUTHORS: P. McDonald and D.G. Scott

STUDY COMPLETED: August 10, 1991

CONCLUSIONS: 4-Hour acute inhalation LC₅₀ in males and females: >6.81 mg/L

CORE CLASSIFICATION: Core Minimum. This study is classified as Core Minimum because the study author did not report if appropriate additional time for equilibrium was allowed.

TOXICITY CATEGORY: IV (Caution)