



United States
Environmental Protection Agency
Washington, DC 20460
NOTIFICATION

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

239633

Application for Pesticide - Section I

1. Company/Product Number 58998-16	2. EPA Product Manager J. Anderson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Novodor 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:			
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	2. Type of 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" Unit Packaging wgt. No. per container	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 accompanying product	
6. Manner in Which Label is 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 Sept. 10, 1995		

Shade Trees and Ornamentals.

Novodor® is a registered trademark of Novo Nordisk A/S

KEEP OUT OF REACH OF CHILDREN CAUTION

New

ACTIVE INGREDIENT: *Bacillus thuringiensis* subspecies *tenebrionis*

Coleopteran Active Toxin.....3%

INERT INGREDIENTS.....97%

TOTAL.....100%

POTENCY: 15,000 Leptinotarsa Units (LTU) per gram of product equivalent to 16.3 Million LTU's per quart 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: Causes moderate eye injury (irritation). Harmful if absorbed through the skin. Avoid contact with skin, eyes or clothing.

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

PERSONAL PROTECTIVE EQUIPMENT:

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category chart. Applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical-resistant gloves such as barrier laminate or butyl rubber or nitrile rubber or neoprene rubber or polyvinyl chloride or viton, 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 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 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.

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

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. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

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 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, chemical-resistant gloves such as barrier laminate or butyl rubber or nitrile rubber or neoprene rubber or polyvinyl chloride or viton, shoes plus socks.

GENERAL USE INSTRUCTIONS:

NOVODOR FC is a highly effective biological insecticide containing the active protein crystal produced by *Bacillus thuringiensis* subspecies *tenebrionis*. NOVODOR FC is recommended for use against the larval stage of the Colorado Potato Beetle, *Leptinotarsa decemlineata*, and the Elm Leaf Beetle, *Pyrrhota luteola*. NOVODOR FC is most effective against

first and second instar larvae. Therefore, applications should be timed to coincide with the first egg hatch of the target pest. Applications should be followed by close scouting for signs of reinfestations. Reapply as necessary to maintain control.

Due to its unique mode of action, NOVODOR FC must be ingested by the target insect larvae to be effective. Therefore, thorough coverage of the crop to be protected is essential for best results. Upon ingestion, the protein is activated under the specific gut conditions of the target insect causing general gut paralysis and cessation of feeding within hours. Death occurs in 2-5 days.

When larvae and adult beetles are present an effective adulticide with rapid knockdown activity should be used.

MIXING: Shake or stir NOVODOR FC thoroughly before use. Fill spray or mixing tank half full of water and begin agitation. Add the recommended amount of NOVODOR FC into water while maintaining agitation. Add other spray materials, if any, and balance of water. Do not allow diluted spray to remain in the tank for more than 72 hours.

While NOVODOR FC is formulated to provide desirable coverage and adherence to crop surfaces, additional adjuvants, spreaders, or stickers may be added to improve product performance, especially under rainy conditions or heavy dew. Avoid application if rainfall is imminent. Combinations with commonly used insecticides, fungicides, or other spray tank adjuvants are generally not deleterious to NOVODOR FC if the tank 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. Use of tank mixes should be in accordance with the most restrictive of label limitations and precautions. No label dosage rates should be exceeded. This product cannot be mixed with any product containing a label prohibition against such mixing.

APPLICATION VOLUME:

NOVODOR FC may be applied by ground or aerial equipment with sufficient quantities of water 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.

Ground Application: Use the recommended amount of NOVODOR FC in a minimum of 20 gallons of water per acre.

Aerial Application: Use recommended amount of NOVODOR FC in a minimum of 3 gallons of water per acre.

APPLICATION RATE: The NOVODOR FC application rate depends on the population pressure and the stage of the larval development. For light to moderate populations of early instar larvae (newly hatched to 1/4 inch in length) apply 1 to 3 quarts of NOVODOR FC per acre. Against heavy infestations of early instar larvae apply 2 to 3 quarts per acre. When mixed populations of younger and older larvae are present, apply NOVODOR FC at 3 to 4 quarts per acre.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal of waste.

Storage: Store in a cool place. Storage at temperatures between 40 and 50 degrees F. is recommended for maximum product stability. Storage at temperatures above 90 degrees F. for an extended period of time should be avoided.

Keep containers tightly closed when not in use.

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, 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 A LIMITED WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PURPOSE, OR OTHERWISE. EXPRESS OR IMPLIED, concerning this product or its use, which shall extend beyond the use of this product under normal and fair conditions with the statements made on this label. No person shall be liable for any consequential or incidental damages resulting from the use of this product. All such risks shall be assumed by the user.