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

NOTICE OF PESTICIDE: [X] REGISTRATION [ ] REREGISTRATION

(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

EPA REGISTRATION NO.	DATE OF ISSUANCE
58998-16	MAY 08 1992

TERM OF ISSUANCE

NAME OF PESTICIDE PRODUCT

Novodor Flowable Concentrate

NAME AND ADDRESS OF REGISTRANT *(Include ZIP code)*

Reg #

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

PM 18

166 | 40,134

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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 returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his 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 this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

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. 58998-16" 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 at (703) 305-7783.

[ ] ATTACHED IS [illegible]

SIGNATURE OF APPROVING OFFICIAL	DATE
[signature]	5/7/92

EPA Form 8570-6 (Rev. 5-76) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED

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.

5. Although you perform bioassay's on the subject product, only toxin percentage is declared in your label ingredients statement. You must add product potency directly below your product's ingredient statement. 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.

6. In the ingredients statement of your label, change "active crystal protein" to read "Coleopteran active toxin."

7. Modify the Hazards to Humans and Domestic Animals statements to read as follows. "Causes moderate eye injury (irritation). Harmful if absorbed through the skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling."

8. Add a Statement of Practical Treatment block 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.

9. Modify the statements "If in eyes, flush with plenty of water." and "If in eyes ... Get medical attention if irritation persists." to read "If in eyes, flush with plenty of water and call a physician if irritation persists." **and** add the if on skin statement to both the oral and written portions of the reentry section in order to provide consistency with the Statement of Practical Treatment.

10. Ad the statement "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." after "...mixing all components in a small..." in compliance with PR Notice 82-1."

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

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)

NOVODOR

FLOWABLE CONCENTRATE

BIOLOGICAL INSECTICIDE

For the Control of Colorado Potato Beetle on Potatoes, Tomatoes, and Eggplant, and Elm Leaf Beetle on Shade Trees and Ornamentals.

ACTIVE INGREDIENT:

Bacillus thuringiensis subspecies tenebrionis Active Crystal Protein.....	3 %
INERT INGREDIENTS.....	97 %
TOTAL. ..	100 %

EPA Reg. No. 58998-
EPA Est. No. 58998-DN-001

Net Contents
___ Gallons

KEEP OUT OF REACH OF CHILDREN

ACCEPTED
with COMMENTS
In EPA letter dated

MAY

...insecticide,
...nticide Act
... the pesticide
... under EPA Reg. No.
58998-16

CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Avoid contact with eyes, skin, or clothing.

In case of contact immediately flush eyes or skin with plenty of water.

Get medical attention if irritation persists.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwaters.

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.

Reentry
NOVODOR FC may be applied up to and on the day of harvest.

Because certain states may require more restrictive reentry intervals for various crops treated with this product, consult your State Department of Agriculture for further information.

Do not apply this product in such a manner as to directly or through drift expose workers or other persons. The area being treated must be vacated by unprotected persons.

Written or oral warnings must be given to workers who are expected to be in a treated area or in an area about to be treated with this product. Oral warnings must include the following information:

> Inform workers of area of fields that must not be entered without appropriate protective clothing until sprays have dried. In case of accidental exposure, wash thoroughly with soap and water. If in eyes, flush with plenty of water.

When oral warnings are given, warnings shall be given in a language customarily understood by workers. Written warnings must include the following information:

> CAUTION: Area treated with Novodor Flowable Concentrate on (date of application). Do not enter without appropriate protective clothing until sprays have dried. In case of accidental exposure, wash thoroughly with soap and water. If in eyes, flush with plenty of water. Get medical attention if eye irritation persists.

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, Pyrrhalta 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 a 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.

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 fahrenheit is recommended for maximum product stability. Storage at temperatures above 90 degrees fahrenheit 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 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.

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, 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