



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

MAR 23 1994

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Janet M. Overholt  
NOVO NORDISK A/S  
AGENT FOR: NOVO NORDISK A/S  
33 Turner Road - Box 1907  
Danbury, CT 06813

Subject: Label Amendment Submission of 07/26/93 in Response to PR Notice 93-7  
EPA Reg. No. 58998-16  
NOVODOR FLOWABLE CONCENTRATE

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.



**Recycled/Recyclable**  
Printed with Soy/Canola Ink on paper that  
contains at least 50% recycled fiber

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division

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

Comment for: EPA Reg Nr.58998-16  
NOVODOR FLOWABLE CONCENTRATE

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.

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

# KEEP OUT OF REACH OF CHILDREN CAUTION

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

ACCEPTED  
with COMMENTS  
in EPA Letter Dated  
MAR 23 1994

**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. Wash thoroughly with soap and water after  
handling.

**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 12 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, *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 insect. Applications should  
be followed by close scouting for signs of infestations. 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. 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 old 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 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.

**NOTICE OF 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.