DATE OF ISSUANCE EPA REGISTRATION US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS THAT U & 1994 REGISTRATION DIVISION (75-767) TERM OF ISSUANCE WASHINGTON, DC 20460 NAME OF PESTICIDE PRODUCT NOTICE OF PESTICIDE: REGISTRATION (Under the Federal Insecticide, Fungicide, Novodor Technical and Rodenfielde Aci, as amended) NAME AND ADDRESS OF REGISTRANT (Include ZIP code) Novo Nordisk A/S c/o Ms. Janet M. Overholt. Novo Nordisk Bioindustrials, Inc. 33 Turner Road Danbury, Ct. 06813 NOTE: Changer in labeling formula difference in substance from that accepted in connection with this registration must be submitted to and ancepted by the Reportration Division prior to use of the label in commerce. In an ecorrespondence on this product always refer to the above U.S. EIA reprotration number. On the basic of information for inherd to the reprotrant, the above named posticide in hereby Pegistered/Peregistered under the Federal Incominate, Europede, and Rosenticide Act. A cray of the 1 matery accepted an expectation with this Regultration/Reregistration is returned herewith. Permitted, and the country of the large information approval of this production Areany, In order to protect Bouted as the second to dismost the configuration, may at any time suspend or cancel the repostration of a perta-doctor of the repost of the discount of the second of the configuration of a product under this A right to the research of the real to the real part to exclusive our of the removal to stouch it has been covered. This product is conditionally registered in accordance with FIFRA sec. 3(c, (7)(A) provided that you: 1. Subrit and/or cite all data required for registration/ reregistration of your product under FIFPA sec. 3(c)(5) or FIFPA section 4 when the Agency requires all registrants of similar products to submit such data. 2. Add the phrase, "EPA Registration No. 58998-15" to your label before you release the product for shipment. 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 The ose level used in the dermal toxicity study registration. submitted and the surface area to which the test material was applied were both insufficient to resolve dermal 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 Peview Section

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- 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 bioassays 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 <u>Bacillus thuringiensis</u> 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. Delete the phrase "General Classification." from the label.
- 8. Add "In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists." after "...eyes or clothing." in the Hazards to Humans and Domestic Animals section of your label.
- 9. 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)

FOR MANUFACTURING USE ONLY

THE BUILDING

FOR USE IN MANUFACTURING OR FORMULATING REGISTERED PESTICIDE PRODUCTS. NOT TO BE USED DIRECTLY FOR TREATMENT OF PESTS.

NOVODOR™ TECHNICAL

For the control of Colorado potato beetle larvae (Leptinotarsa decemlineata)

ACTIVE INGREDIENT

Bacillus thuringiensis subsp. active crystal protein		33%
INERT INGREDIENTS		67%
TOTAL	:	100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

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

MANUFACTURED BY:

Novo-Nordisk A/S

Novo Alle

2880 Bagsvaerd

Denmark

EPA Reg. No.

58998-

EPA Est. No.

11636-DN-001

ACTION FOR MARKET IN STATE

Net Contents:

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STORE IN A COOL PLACE

5.8778-15

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals:

Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

Environmental Hazards:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE - General Classification

FOR MANUFACTURING USE ONLY

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Mode of Action
Novodor Technical contains the active protein crystal produced by <u>Bacillus thuringiensis</u> subsp. <u>tenebrionis</u> (<u>Btt</u>). The mode of action of Novodor Technical is similar to that of other <u>Bt</u> products. Novodor Technical must be INGESTED by the target insect larvae. Upon ingestion, the protein is activated under the specific gut conditions of the target insect. The gut of the target insect is paralyzed and feeding ceases almost immediately. Death occurs 2 - 5 days later.

Novodor™ Technical may be used in formulating any recistered pesticide. Prior approval of the formulation by the U.S. Environmental Protection Agency is required.



Storage and Disposal Do not contaminate water, food or feed by storage or disposal.

Storage: Store in a cool dry place. Keep containers of partially used Novodor Technical tightly closed. Store at temperatures below 90 degrees F. Storage at temperatures below 50 degrees F is recommended for optimal shelf life.

Pesticide

Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

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

All goods supplied by Novo-Nordisk A/S are of high grade and are believed to be suitable for the recommended purposes, but as control cannot be exercised over their storage or use, no responsibility will be accepted for any damage or injury whatsoever arising from their storage, handling, application or use.