



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

JUL 5 1990

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Product Chemistry Review of Novodor™ Technical
(EPA File No. 58998-RL)

FROM: Alfred Smith, Chemist *Alfred Smith*
Product Chemistry Review Section
Registration Support Branch
Registration Division (H7505C)

TO: Phil Hutton, PM 17
Insecticide-Rodenticide Branch
Registration Division (H7505C)

THRU: Donald Stubbs, Acting Chief *Donald Stubbs*
PCRS/RSB/RD (H7505C)

Applicant: Novo-Nordisk A/S

EPA File No: 58998-RL

MRID No: 414127-03

Product Name: Novodor™ Technical

Biological Name: Bacillus thuringiensis subsp. tenebrionis

Use: Insecticide

Introduction

Novo-Nordisk A/S has submitted an application for registration of the manufacturing-use product (MP) Novodor™ Technical containing Bacillus thuringiensis subsp. tenebrionis as the active ingredient (a.i.). The PM Team 17 has

asked the PCRS/RSB to review the Confidential Statement of Formula (EPA Form 8570-4) and the Physical and Chemical Properties (GRN 151A-16). PM Team 17 has indicated that the remainder of the product analysis data are being reviewed by HED since this is a microbial.

For a discussion of the CSF, see Confidential Appendix A.

151A-16: Physical and Chemical Properties (MRID 414127-03)

<u>Property</u>	<u>Description</u>
Color	Light brown to brown
Physical State	Solid, powder
Odor	Characteristic of fermented bacterial products
Melting Point	Decomposes upon heating
Boiling Point	Decomposes upon heating
Bulk Density	0.1-0.4 gm/cc at 25 °C
Solubility	Insoluble in distilled water and in nonaqueous solvents. But goes readily into suspension in water.
pH	5.0-6.0 at 25 °C (10% suspension in distilled water).
Stability	No loss of potency after 15 months storage at 4 °C and 38-48% relative humidity in sealed polyethylene containers.
Corrosion Characteristics	No corrosion of the plastic containers used for product storage has been noted. (See <u>Stability</u> above.)

No additional data are needed for this section.

Note to PM:

The applicant is requesting a "me too" registration based on their claim that EPA has reviewed a pesticide containing the active ingredient Bacillus thuringiensis

subsp. tenebrionis and granted a registration to Sandoz Crop Protection Corp. in December, 1988 (see Novo-Nordisk's letter of 3/6/90, Janet M. Overholt). However, Novo does not provide a reference for the CSF of Sandoz to be used as a basis of comparison to demonstrate a substantial similarity which is needed for a "me too" registration.

Attachment:

Confidential Appendix A

BACILLUS THURINGIENSIS (TENEBRIONIS)

Page 4 is not included in this copy.

Pages _____ through _____ are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
 - A draft product label.
 - The product confidential statement of formula.
 - Information about a pending registration action.
 - FIFRA registration data.
 - The document is a duplicate of page(s) _____.
 - The document is not responsive to the request.
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
