

US EPA ARCHIVE DOCUMENT



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

MEMORANDUM

MAR 22 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: BPPD Review of Data Submitted by Mycogen Corporation in Support of the Registration of MVPII Bioinsecticide, Which Contains the Active Ingredient: the Delta Endotoxin of *Bacillus thuringiensis* var. *kurstaki* Encapsulated in Killed *Pseudomonas fluorescens*). (I.D. No: 053219-RE; DP Barcode No: D212188; Submission No: S481959; Chemical No: 006410; MRID No.'s: 435090-01, 435090-02, 435090-03).

TO: Phillip Hutton, Team Leader
Biological and Pollution Prevention Division (H7501W)

FROM: Cindy Schaffer, Microbiologist *Cindy Schaffer*
Biological and Pollution Prevention Division (H7501W)

ACTION REQUESTED:

BPPD has been asked to review the product chemistry for MVPII Bioinsecticide, submitted by Mycogen Corporation, in support of registration.

BACKGROUND:

Mycogen Corporation has previously registered a similar product, MVP Bioinsecticide (EPA Registration No.: 53219-3), and wishes bridge the most of the data submitted for the prior registration to the present submission.

CONCLUSION:

This package is acceptable as reviewed. No additional mammalian toxicology data are needed on the new product because the active ingredient has not changed, except for a two-fold increase. The studies submitted on the earlier TGAI are adequate to support the new TGAI. Also, the new inerts are of a nature and are present in sufficiently low amounts so as not to increase the toxicity of the product. The current label precautionary statements and protective clothing statements derived from the earlier product are adequate for the new product.

NOTE: CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DATA EVALUATION REPORT

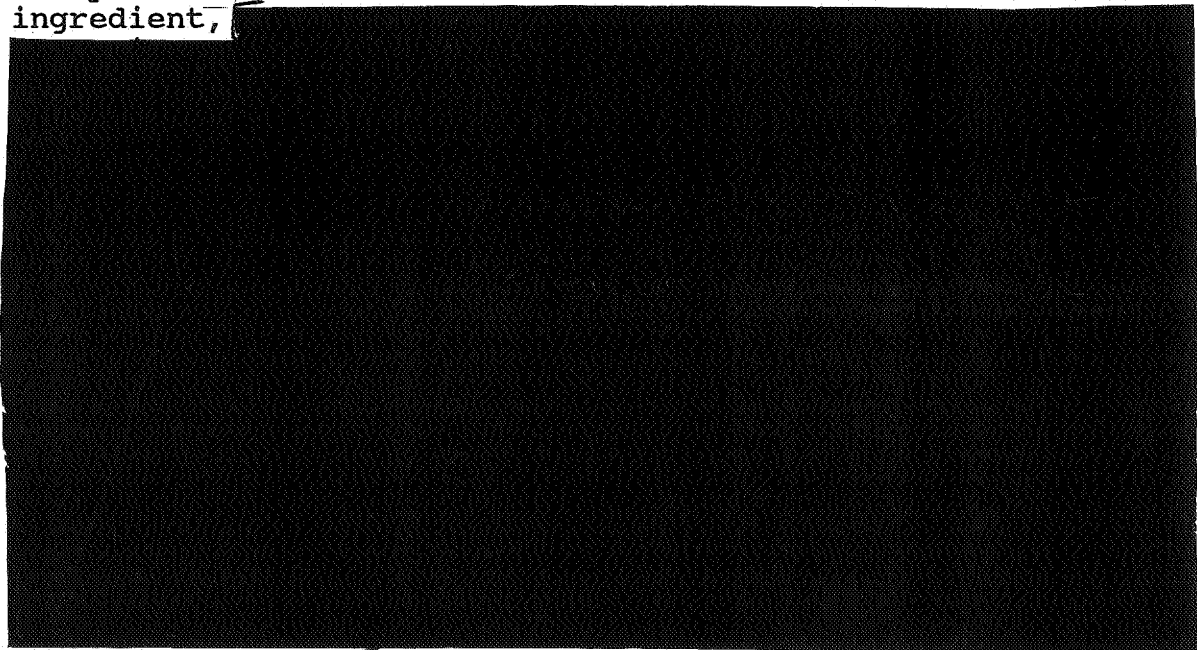
Primary Reviewer: Cindy Schaffer, Microbiologist BPPD
Secondary Reviewer: Roy Sjoblad, Ph.D., Microbiologist BPPD

CS
RSD

151A-10 Product Analysis and Disclosure of Ingredients

Identity: The active ingredient of MVPII Bioinsecticide is the delta endotoxin of *Bacillus thuringiensis* var. *kurstaki* encapsulated in killed *Pseudomonas fluorescens*. This product is similar to MVP Bioinsecticide (EPA registration No.: 53219-3) in that it contains the same active ingredient [at a higher concentration] and has similar inerts, with the addition of 4 new inerts (see below).

Confidential Statement of Formula has been submitted by the registrant. MPVII Bioinsecticide contains 20% Delta endotoxin of *Bacillus thuringiensis* var. *kurstaki* encapsulated in killed *Pseudomonas fluorescens* as the active ingredient,



INERT INGREDIENT INFORMATION IS NOT INCLUDED

* = new inerts not listed on CSF for MVP Bioinsecticide.

Manufacturing Process(151A-11):

MVPII Bioinsecticide has the identical manufacturing process as MVP Bioinsecticide, with the exception of the addition of different inert ingredients added during the final product formulation.

Quality Control:

MVPII Bioinsectice has the identical quality control procedures in place as MVP Bioinsecticide.

Discussion of the Formation of Impurities (151A-12):
Mycogen does not foresee any formation of unintentional ingredients during this formulation.

Analysis of Samples (151A-13):

A five batch analysis was performed for the product chemistry and potency of MVPII Bioinsecticide with the following batches: MYD 1765; MYD 1766; MYD 1767; MYD 1768; MYD 1769. Results are listed under Physical/Chemical Properties, see below.

Certification of Limits (151A-15):

The encapsulated delta endotoxins of *B.t.k.* will not fall below 14 mg/g in the final formulation of MVPII Bioinsecticide.

Physical/Chemical Properties (151A-16): (ave. of 5 batches)

	<u>MVPII Bioinsecticide</u>
Physical State	Homogenous, free flowing liquid
Density	1.062
pH	4.94
Viscosity	1052 CPS @ 10RPM
Purity (HPLC)	23.2 mg/g

BPPD DISCUSSION:

No additional mammalian toxicology data are needed on the new product because the active ingredient has not changed, except for a two-fold increase. The studies submitted on the earlier TGAI are adequate to support the new TGAI. Also, the new inerts are of a nature and are present in sufficiently low amounts so as not to increase the toxicity of the product. The current label precautionary statements and protective clothing statements derived from the earlier product are adequate for the new product.