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

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CONFIDENTIAL

MAR - 4 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: SACB review of supplemental data/information submitted by Mycogen Corporation to resolve outstanding toxicity/exposure issues related to MYX 7275 (MVP Bioinsecticide). [EPA ID No. 053219-G and 9F03744; Submission Nos. S384201 and S384202; MRID Nos. 416520-01, -02, -03, -04, -05; Caswell No. 714G; HED Project No. 0-2027].

TO: Willie Nelson/Phil Hutton (PM-17)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

FROM: Roy D. Sjoblad, Ph.D., Microbiologist
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

THROUGH: Reto Engler, Ph.D., Chief
SACB, HED (H7509C)

Background: On 10/16/90, SACB received information from Mycogen, Corp. for the purpose of resolving outstanding SACB issues for an EUP with the chemically-fixed and killed genetically engineered microbial pesticide, MVP. The following information was submitted: Description of technique used to quantify the fixative material, determination of amount of fixative material in the product and use of this datat to estimate dietary exposure, worker exposure data, an intravenous injection study with [redacted] fixed and chemically fixed bacterial preparations, and a storage stability study. Copies of the proposed label also were submitted. OREB is reviewing the worker exposure data.

SACB Conclusions: The concentration of [redacted] in the product, the description of the analytical method, and estimation of dietary exposure to [redacted] are adequate to show that under the proposed use there would be no expected concerns for exposure to the fixative material. The intravenous toxicity in rats appeared to be related to a shock response to the test material. The data support the EUP request, under non-crop destruct conditions. The intravenous study is an Acceptable study.

Data/information Submitted:

1. Method used to quantify the level of chemical fixative in the samples, and results of sample analysis.

[redacted]

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

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Bacillus Thuringiensis AI. 6409

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Pages _____ through _____ are not included in this copy.

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.

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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.

[redacted]

3. Storage stability data.

Three batch samples of MVP Bioinsecticide were stored in high-density polyethylene containers at 20°C for up to one-year, and no corrosivity was noticed. Stability of MVP was determined by bioassay with the diamondback moth done at 3, 6, 9, and 12 months after study initiation. There was no significant loss in bioactivity of MVP after 1 year storage under the above conditions. Initial activity was recorded at about 14,000 to 16,000 IU/mg, and final activity was determined to be about 13,000 IU/mg.

[redacted]

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g) Label Statements.

SACB would recommend that appropriate respiratory tract coverings (in this case a particle dust mask would be appropriate) should be worn by applicators/other exposed workers during application of aerosols of the bioinsecticide. SACB believes that it is prudent to minimize exposure of the respiratory tract to aerosols containing Gram-negative bacterial cell wall components. The label also states that repeat applications of the bioinsecticide are to be done as necessary, and thus there may be repeated exposure to the bacterial cell wall components. The label should be amended to reflect the potential for pulmonary exposure, and wearing of appropriate protective clothing.

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