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

CONFIDENTIAL

53219-2

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MAR 25 1991

MEMORANDUM

SUBJECT: SACB Re-review of Data/Information Submitted by the Mycogen Corporation to Support the Registration of MYX7275, a Killed Pseudomonas spp. Genetically Engineered to Contain the Delta-Endotoxin of Bacillus thuringiensis var. kurstaki (MRID No. CA408974-28 and 408974-28-C)

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

FROM: J. Thomas McClintock, Ph.D., Microbiologist
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Health Effects Division (H7509C)

THROUGH: Reto Engler, Ph.D., Chief
Science Analysis and Coordination Branch
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BACKGROUND INFORMATION: In an effort to expedite the registration of MYX7275, a killed bioinsecticide containing the delta-endotoxin of B. thuringiensis and in response to a recent meeting with the Mycogen Corporation, SACB has re-reviewed portions of a previous submission (MRID Nos. CA408974-28 and 408974-28-C) to determine if several outstanding issues have been resolved. These issues included, but were not limited to, an adequate method to evaluate the effectiveness of the killing/fixation process with an appropriate validation procedure, the degree of sampling necessary during large-scale production of fermentation batches, and data, previously agreed to be submitted to the Agency, from Mycogen's monitoring of their previous 30 batches (see 4/4/91 memorandum from R.D. Sjoblad to W. Nelson/P. Hutton). In response to these deficiencies the Mycogen Corporation stated that the pertinent data/information was provided in previous submissions on MYX7275. The following data/information were reviewed based on the above-referenced issues.

SACB CONCLUSION: Based on the data review in this submission, SACB would conclude that given the set of defined parameters [redacted] that there will be a reasonable probability that all cells will be killed, provided all cells are exposed to these conditions. In lue of the fact that no data was provided on the effectiveness of cell kill using a pH [redacted] or lower SACB would

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

recommend that the correct pH range be limited to [redacted] Mycogen should also specify the protocol and quality control/assurance procedure to ensure the final pH and [redacted] concentration and validation that all cells will be equally exposed to these components during the killing/fixation process.

MANUFACTURING PROCESS. [redacted]

Formulation and Quality Control. Mycogen stated that the purity and quality "...of the manufacturing and end-use products is monitored and maintained throughout the manufacturing process by strict adherence to quality control procedures." Quality control of the product(s) is administered by a "Products Standard Board" which ensures regulatory compliance.

Verification of Cell Kill. [redacted]

Bacillus Thuringiensis N.I. 6409

Page _____ is not included in this copy.

Pages 3 through 5 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.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

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]

In a recent meeting with OPP (3/13/91) J. Panetta of Mycogen stated that following the killing/fixation procedure that approximately 30 large-scale production batches have been analyzed for the presence of viable Pseudomonas spp. Mycogen stated that in each instance complete kill was demonstrated in all batches. SACB has not yet received this data. Interestingly, Mycogen had agreed to submit this data last year. If Mycogen has truly analyzed this number of batches the procedures for detecting viable cells should be sufficiently reliable not to warrant a "Products Standard Board." No method or procedure(s) were submitted to confirm the presence of not only viable Pseudomonas spp. (i.e. by colonial morphology and/or biochemical analyses) but the presence of the genetically engineered bacterium.