



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

MAR 5 1992
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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: SACB Review of Interim Report Submitted by Mycogen Corporation on Monitoring of MVP Bioinsecticide Production Batches. (Caswell No. 067B; EPA ID No. 053219-00003; Submission: S286037; HED Project No. 2-0489)

TO: Willie Nelson/P. Hutton (PM-18)
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., Senior Science Advisor
Health Effects Division (H7509C)

Action requested: As a condition of Registration for MVP Bioinsecticide, the Agency has requested that Mycogen Corporation confirm cell kill in production batches of the product.

Summary of data presented. Four production batches (F673, F674, F677, and F678) were analyzed. In the confirmation test the

[REDACTED]

The results were reported as follows. No growth on P Isolation Agar; growth on positive control plates; pH [REDACTED] (F673, F674, and F678) or pH [REDACTED] (F677); and no Pseudomonas fluorescens colonies.

Microbial growth occurred on L-agar plates from batches F673, F677, and F678. "Mold" contamination, possibly from pouring of the plates, was believed to explain the contaminant of batch F673. Cocci and bacilli (numbers/plate not specified) and cocci (numbers/ plate not specified) were observed growing on L-agar for batch F677 and F678 respectively.

SACB Discussion: There was no mention of the analysis or disposition of batches F675 and F676, or if these were produced. SACB does not believe that [REDACTED]

[REDACTED] The submitted data did not mention whether the positive control plates contained unfixed bacteria which were subject to the exact

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

same treatment as the fixed bacteria, [REDACTED] SACB believes that this issue should be addressed, if Mycogen has not already addressed it in earlier submitted data.

Mycogen should discuss also the apparent source of the "cocci" and "bacilli" appearing on the L-Agar plates, and record the numbers/plate. Specifically, it should be addressed whether these organisms are contaminants of the production batches that can survive the fixation procedure.

Finally, SACB is not sure of the extent of data that is being recorded, nor whether it is sufficient to address the killing effectiveness of the fixation treatment. It appears that the interim report represents a "summary" table. All pertinent examinations and measurements, and colony counts/plate, etc. should be presented.

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED