

4-11-95



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

MEMORANDUM

APR 11 1995

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Subject: BPPD Review of Supplemental Product Characterization and Insect Bioassay Data Submitted by The University of California and the Association for Sensible Pest Control in Support of the Registration of Specific T-1 [Granulosis Virus of Cydia pomonella] (Submission No.: S478908; ID No.: 058042-2; DP Barcode No.: D212215).

To: Linda Hollis, Regulatory Action Leader
Biological and Pollution Prevention Division (H7501W)

From: Cindy Schaffer, Microbiologist *Cindy Schaffer 4/11/95*
Biological and Pollution Prevention Division (H7501W)

Through: Roy Sjoblad, Ph.D., Microbiologist *R. Sjoblad 4/11/95*
Biological and Pollution Prevention Division (H7501W)

Action: BPPD has been asked to review additional product analysis and insect bioassay data in support of the registration of The University of California and the Association for Sensible Pest Control's product, Specific T-1 [containing the Granulosis virus of Cydia pomonella].

Background:
The last review of this product (see 7/13/94 memorandum from J. Kough to L. Hollis) indicates a five batch analysis and an insect bioassay be submitted to verify the cell culture assay as a caviat for bringing the current studies up to acceptable levels. Both studies have been submitted.

Conclusion:
The data submitted is acceptable as reviewed. BPPD upgrade the product characterization studies from supplementary to acceptable and supports the registration of Specific T-1.

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

SUMMARY OF DATA:

Analysis of Samples:
The registrant submitted the methods used to evaluate each production batch. This bioassay evaluates the quantity (Gibs/ml) of Baculovirus cydia pomonella preparations by testing against the

neonate codling moth larvae looking for the dilution which will provide an LD₅₀ in 72 hours. A known purified standard is utilized as a positive control.

Confidential Statement of Formula:

A revised CSF was submitted stating that at least [REDACTED] GIB's/ml will be present as the active ingredient. Along with this came an explanation as to how the actual Gib's/ml were calculated.

Insect Bioassay:

[REDACTED]

The insect bioassay examines the activity of a specific amount of *Baculovirus cydia pomonella* which will produce an LD₅₀ in 72 hours, against the neonate codling moth larvae.

[REDACTED]

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED