6-28-94

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

DP BARCODE: D204294
Case Number: 008246
Submissions: S462553
Chemical: 129090

MEMORANDUM

SUBJECT: EFED Biotechnology Team review of request for a waiver of the requirement for testing, plant studies, for the registration of 129090 codling moth granulosis virus.

TO: Phillip Hutton, PM-18
Registration Division (H7505C)

FROM: Leo R. LaSota, Ph.D.
Biologist
EFED Biotechnology Team
Environmental Fate and Effects Division (H7507C)

THRU: David C. Bays, Ph.D.
Plant Pathologist
EFED Biotechnology Team
Environmental Fate and Effects Division (H7507C)

Elizabeth Leovey, Ph.D.
Team Leader
EFED Biotechnology Team
Environmental Fate and Effects Division (H7507C)

EFED supports the request for a waiver of the requirement of nontarget plant studies for the registration package for *Baculovirus cydia pomella*. The applicant has submitted literature reviews in support of the host specificity of *Baculovirus cydia pomella*, its lack of reported phytotoxicity, or its ability to infect plants. The applicant also reported that no phytotoxicity related to the use of this baculovirus was reported during end use product testing.

EFED believes that the applicant's request reflects the consensus of current scientific opinion concerning the inability of baculoviruses to infect plant tissue. End use product testing did not result in any observed phytotoxicity to target plants (apple, pear, and walnut orchards) or to associated understory annual, biennial and perennial plants.

UNIVERSITY OF CALIFORNIA, BERKELEY

BERKELEY • DAVIS • IRVINE • LOS ANGELES • RIVERSIDE • SAN DIEGO • SAN FRANCISCO

SANTA BARBARA • SANTA CRUZ

COLLEGE OF NATURAL RESOURCES
DEPARTMENT OF ENVIRONMENTAL SCIENCE, POLICY & MANAGEMENT
DIVISION OF ENTOMOLOGY AND PLANT AND SOIL MICROBIOLOGY
201 WELLMAN HALL

BERKELEY, CALIFORNIA 94720
OFC: (510) 642-3327
FAX: (510) 642-7428

March 6, 1994

Phil Hutton
PM18
Insecticide/Rodenticide Branch
Office of Pesticide Programs - H7505C
U.S. Environmental Protection Agency
401 "M" Street (SW)
Washington, DC 20460

Dear Mr. Hutton:

RE: Your letter to Dr. Falcon, University of California of 7/28/93 on
Granulosis Virus of Cydia pomonella
Specific T-1
EPA File Symbol 58042-R
Registration Submission dated 12/16/92
PP 3E 4166 Amendment

This letter is in regard to EPA's letter of 7/28/93 (attached) in regard to the above information.

List of Studies Submitted in Support of Registration/Proposed Exemption from the requirements of a Tolerance for the Codling Moth Granulosis Virus

Volume No. and Title

Volume 1 -Baculovirus cydia pomonella - Product Identity and Disclosure of Ingredients, - Amendment No. 1 to MRID No. 42561101 - Revised Confidential Statement of Formula.

Volume 2 - Baculovirus cydia pomonella - Analysis of Samples and Certification of Ingredient Limits - Amendment No. 1 to MRID No. 42561102 - Analysis of 5 End-Use-Product Batches.

Volume 3 - Baculovirus cydia pomonella - Cell Culture Tests with Viral Pest Control Agents (Tier 1) Concurrent Dose Bioassays.

Volume 4- Baculovirus cydia pomonella - Hypersensitivity Incidents with Microbial Pest Control Agents - Statement of Finding of No Hypersensitivity.

Volume 5- Baculovirus cydia pomonella - Plants Studies - Request for Waiving of the Requirement for Testing.

Sincerely,

Louis A. Falcon, Ph.D.
University of California
and

H.M. Kaplan
Association for Sensible
Pest Control, Inc.

LAF:ab
Attachments (4)
cc: Hoyt Jamerson, EPA (w/o encl.)
W. Biehn, IR-4 (w/o encl.)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

JUL 28 1993

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

Louis A. Falcon
Professor of Entomology
Regents of the University of California
University of California @ Berkeley
201 Wellman Hall
Berkeley, California 94720

Subject: **Granulosis virus of Cydia pomonella**
Specific-T-1
EPA File Symbol 58042-R
Resubmission of data dated April 14 and 15, 1993

Dear Dr. Falcon:

The resubmission referred to above, submitted in connection with FIFRA, as amended is deficient at this time for the following reasons:

I. PRODUCT IDENTITY

Submit a five batch analysis as part of the analysis of samples and list the specific impurities separately (i.e., components of [redacted]

II. PRIMARY EYE IRRITATION STUDY

Submit clinical observation for the primary eye irritation study.

III. CELL CULTURE ASSAY

In accordance with 40 CFR 158.740, data from cell culture tests with viruses are required to support the registration of each manufacturing-use product and each end-use product. Therefore, you must evaluate the potential of the virus to infect, replicate, transform or cause toxicity, in a mammalian cell culture assay (refer to Subdivision M part 152A-15).

IV. HYPERSENSITIVITY INCIDENTS

Data on any incidents of hypersensitivity, including immediate and delayed type reactions of humans or domestic animals that occur during the production or testing of the technical grade of the active ingredients, the manufacturing-use product, or the end-use product must be submitted to the Agency.

V. ACUTE DERMAL TOXICITY

Pending review of data resubmitted on 5/21/93.

VI. NONTARGET PLANT STUDIES

Submit the data for nontarget plant studies or request a waiver for this study.

The following studies have been found acceptable:

VII. ACUTE ORAL TOXICITY

VIII. ACUTE INTRAVENOUS TOXICITY

This application will be kept open for a period for 75 days to give you an opportunity to correct the deficiencies listed above. If you find that you need more time to satisfy the requirements, you should request an extension and commit yourself to satisfy the deficiencies within a reasonable stated period of time. If you do not comply with this procedure, the Agency may administratively withdraw your application from further consideration, and retire this file without further notice to you in accordance with the policy established by PR Notice 75-4 of August 27, 1975. Once this is done, you will have to submit a complete new application should you wish to pursue the registration of your product after the application has been withdrawn.

Should you have any questions regarding this matter, please call Linda Hollis of my staff @ 703-305-6397.

Sincerely,

Phil Hutton, Product Manager 18
Insecticide/Rodenticide Branch
Registration Division H7505C