

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

JAN 28 1992

Subject: Review of honeybee study for Oxytetracycline (906304)
From: Doug Urban, Acting Branch Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C) *Douglas J. Urban 1/23/92*
To: Walter Waldrop, PM 71
Reregistration Branch
Special Review and Reregistration Division (H7508C)

The Ecological Effects Branch (EEB) has completed its review of the study submitted by Pfizer Incorporated for Oxytetracycline. The following is a brief summary of the data reviewed.

CITATION: Winter, Patricia A., Kimberly A. Hoxter, Gregory J. Smith. 1991. Oxytetracycline Calcium Complex: An acute contact toxicity study with the honey bee Wildlife International Ltd. Project No. 260-107. Submitted by Pfizer Incorporated. Performed by Wildlife International Ltd., Easton, Maryland. MRID No. 417778-04.

CONCLUSIONS: This study is not scientifically sound and does not fulfill the data requirements for an acute contact toxicity test to the honeybee. Oxytetracycline Calcium Complex tested practically non-toxic to honeybees. The LD₅₀ for worker honeybees exposed to Oxytetracycline Calcium Complex is greater than 100 µg per bee. The NOEC is 100 µg a.i./bee. The registrant must submit another study in order to fulfill guideline requirements.

If there are any questions please contact Renee Lamb at 305-5294.

DATA EVALUATION RECORD

1. **CHEMICAL:** Oxytetracycline Shaughnessey Number: 006304
2. **TEST MATERIAL:** Oxytetracycline Calcium Complex, 60.4% active ingredient.
3. **STUDY TYPE:** Acute contact toxicity to the Honey bee Apis mellifera L.
4. **CITATION:** Winter, Patricia A., Kimberly A. Hoxter, Gregory J. Smith. 1991. Oxytetracycline Calcium Complex: An acute contact toxicity study with the honey bee Wildlife International Ltd. Project No. 260-107. Submitted by Pfizer Incorporated. Performed by Wildlife International Ltd., Easton, Maryland. MRID No. 417778-04.
5. **REVIEWED BY:**
 Renee Lamb
 Biologist
 Ecological Effects Branch (H7507C)
 Environmental Fate & Effects Division
 Signature: *Renee Lamb*
 Date: 9/30/91
6. **APPROVED BY:**
 Ann Stavola
 Head Section 5
 Ecological Effects Branch (H7507C)
 Environmental Fate & Effects Division
 Signature: *Ann Stavola*
 Date: 1/17/92
7. **CONCLUSIONS:** This study is not scientifically sound and does not fulfill the data requirements for an acute contact toxicity test to the honeybee. Oxytetracycline Calcium Complex tested practically non-toxic to honeybees. The LD₅₀ for worker honeybees exposed to Oxytetracycline Calcium Complex is greater than 100 µg per bee. The NOEC is 100 µg a.i./bee.
8. **RECOMMENDATIONS:** Submit another study to fulfill guideline requirements.
9. **BACKGROUND:** N/A
10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A
11. **MATERIALS AND METHODS:**
 A. **TEST ANIMALS:** Adult (1 to 7 days old) worker honey bees, Apis mellifera, obtained from hives maintained at the testing facility were used in this study.

B. **TEST SYSTEM:** The chambers used in the test were disposable one pint rolled paper containers which measured 87 mm in diameter and 85 mm high. Each one was covered with a disposable plastic petri dish (90 mm in diameter) through which a 20 ml glass vial was inserted (containing 50% sugar/water). This was covered with cheesecloth, the food source was available ad libitum throughout the test. A sponge was attached to the top of the container which was misted daily to increase humidity.

The photoperiod was maintained at 8 hours of light per day. Ambient room temperatures at the time of observations ranged from 21°C to 22°C. Mean relative humidity was 86%.

C. **DOSAGE:** There were five (nominal) treatment solutions of 13, 22, 36, 60 and 100 µg a.i. per bee. The test compound was dissolved in pesticide grade acetone. All doses were adjusted to 100% a.i. based on the purity of the test substance. There was also a solvent and a negative control.

D. **DESIGN:** There were 25 bees per treatment and there were two replicates of each treatment. The bees were immobilized using nitrogen and laid out on paper. 25 bees were individually dosed on the thorax and/or abdomen with 2 µl of the test solution using a digital pipette. The negative controls were handled identically to all other bees, but not dosed with any substance. The acetone controls were dosed with acetone only.

E. **STATISTICS:** The LD₅₀ value was determined by visual inspection of the data.

12. **REPORTED RESULTS:** At test termination there was 0% mortality in the negative control and 24% in the solvent control.

There was no mortality in any treatment group except at the 22 µg/bee level, which had a 16% mortality. This was not considered treatment related. Two immobile bees were noted at the 13 and 36 µg levels approximately 50 minutes after dosing, however, they were completely recovered by Day 1.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:**

"The acute contact LD₅₀ value for honey bees exposed to Oxytetracycline Calcium Complex was determined to be greater than 100 µg a.i./bee, the highest dose tested." The NOEC was 100 µg a.i./bee.

The report has a QA statement signed by a QA officer.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:

- A. TEST PROCEDURE: This test is in accordance with EPA's SEP protocol. However, there was high mortality in the solvent control (24%).
- B. STATISTICAL ANALYSIS: No analysis was required.
- C. DISCUSSION/RESULTS: This study is not scientifically sound and does not fulfill the guideline requirements for an acute contact study with the honeybee based on the high mortality in the solvent control. Oxytetracycline Calcium Complex tested practically non-toxic to honeybees. The LD₅₀ for worker honeybees exposed to Oxytetracycline Calcium Complex is greater than 100 µg per bee. The NOEC is 100 µg a.i./bee.
- D. ADEQUACY OF STUDY:
- (1) CLASSIFICATION: Invalid
 - (2) RATIONALE: High mortality in the solvent control.
 - (3) REPAIRABILITY: Irreparable