1-25-89

230311,230312
Record No.

128825
Shaughnessey No.

Review No.

EEB REVIEW

DATE: IN 08-24-88 OUT 01-~~12~~25-89

FILE NUMBER 270-3055,279-3069

DATE OF SUBMISSION 07-27-88

DATE RECEIVED BY HED 08-24-88

RD REQUESTED COMPLETION DATE 10-21-88

EEB ESTIMATED COMPLETION DATE 10-21-88

RD ACTION CODE 575

TYPE PRODUCT Synthetic pyrethroid

DATA ACCESSION NO. 407913-01

PRODUCT MANAGER G. LaRocca(15)

PRODUCT NAME Bifenthrin (Capture, Talstar, Brigade)

COMPANY NAME FMC Corporation

SUBMISSION PURPOSE Submission of raw data for fathead minnow life-cycle study.

SHAUGHNESSEY NO.	CHEMICAL	%AI
128825	bifenthrin	

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JAN 27 1989

MEMORANDUM

SUBJECT: Submission of Fish Life Cycle Toxicity Test for Bifenthrin.

FROM: James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (TS-769C)

TO: George LaRocca (PM-15)
Registraion Division (TS-767C)

The fish life cycle toxicity test submitted by FMC to fulfill a condition imposed for conditional registration of bifenthrin has been determined to be scientifically unsound and therefore fails to fulfill this condition. High mortality in control fish, high variability in reproduction parameters and loss of pertinent reproduction data will not allow unequivocal determination of bifenthrin effect and no effect concentrations. No valid conclusions can be drawn from this test.

Shaughnessey # 128825

DATA EVALUATION RECORD

1. CHEMICAL: Bifenthrin

2. TEST MATERIAL: ^{14}C-FMC 54800, 5 mCi/vial 70% pure a.i.

3. TEST TYPE: Freshwater fish life-cycle toxicity test

4. STUDY IDENTIFICATION: McAllister, W. A., T. McLain and Tom Leak (1988) Full Life Cycle Toxicity of ^{14}C-FMC 54800 to Fathead Minnow (Pimephales promelas) in a Flow-Through System. Unpublished report prepared by Analytical Bio-Chemistry Laboratories, Inc. for FMC Corporation. [EPA Accession No. 407913-01]

5. REVIEWED BY:

Les Touart
Fisheries Biologist
Ecological Effects Branch

Signature: LT
Date: 1-25-89

6. APPROVED BY:

Raymond Matheny
Supervisory Biologist
Ecological Effects Branch

Signature: Raymond W Matheny
Date: 1-26-89

7. CONCLUSIONS:

The study is not scientifically sound and is insufficient to fulfill Guidelines requiremnts for an acceptable freshwater finfish life-cycle toxicity test.

8. RECOMMENDATIONS: N/A

9. BACKGROUND: This study was submitted to fulfill a requirement imposed for conditional registration.

10. DISCUSSION OF INDIVIDUAL TESTS: N/A

3

11. METHODS AND MATERIALS:

A. Test Organisms: Fathead minnow (Pimephales promelas)

Age/Size at test initiation: newly fertilized eggs (< 24 hours old)

Source: ABC Labs in-house culture

B. Dosage Form:

Solvents/Vehicles: acetone

C. Referenced Protocol:

Test Levels: 3.74, 9.02, 19.2, 40.5 and 90.5 ng/l mean measured, with appropiate controls

Number per level: 35 eggs/chamber, 4 chambers/level; 1st reduction - 15 fish/chamber, 4 chambers/level; 2nd reduction - 20 fish/chamber, 2 chambers/level; 3rd reduction - 17 fish/chamber, 2 chambers/level; 4th reduction - 10 fish/chamber, 2 chambers/level.

Temperature: 23 - 25 (24.7 mean) degrees C

Dissolved Oxygen: 5.6 - 8.4 ppm (7.1 mean)

pH: 7.9 - 8.2 (8.0 mean)

Source of Dilution Water: well water

Test Vessels/Test System: 2 liter proportional diluter flow through system receiving 68 ml of test water/replicate/minute (= 5 volume replacements/24 hr for 11-liter growth chambers). Test aquaria (14) were 32 cm X 75 cm X 33 cm tanks subdivided into 2 growth chambers (16 cm X 28 cm) and 1 spawning chamber (32 cm X 46 cm). Approximate volume for growth and spawning chambers was 11 and 35 liters, respectively.

Aeration: prior to delivery

Photoperiod: 16 hrs. light

Observation period: 368 days

Statistical Methods:

"Comparison analyses of data were performed between the control and test levels for the parental generation (Fo) fish from 0-120 days post-hatch and for the first filial generation (F1) fish 0-56 days post-hatch. Analyses included the measured parameters of hatchability, survival standard length, and wet weight. Also comparison analyses were performed between the control and test levels for the parental generation spawning data. Analyses include the measured parameters of number of spawns, number of eggs, number of eggs per spawn, number of spawns per female and number of eggs per female."

Data were generally analyzed using analysis of variance (ANOVA). Dichotomous data (e.g., survival) were transformed with an arcsine transformation. A secondary method of analysis was with the Kruskal-Wallis non-parametric test.

Biological Procedures:

Prior to test initiation, test solutions were allowed to flow through test aquaria for a 3-day equilibration (conditioning) period.

Eggs (< 24 hours) from spawns of over 50 eggs and from tiles with a male guarding the spawn were used for initiating the test. Eggs were incubated overnight and fertilized healthy embryos were collected and 35 placed in each incubation cup (140 embryos/concentration). Additional eggs from this group were reserved for acute toxicity testing. Hatching was 95% complete by study day 6. Fry were retained at least 2 days before release into growth chambers. All minnows were fed live brine shrimp nauplii in combination with standard commercial dry fish food.

At 121 days post-hatch, 20 minnows were randomly selected and placed in spawning chambers (2/level) along with 5 spawning tiles. At 150-151 days post-hatch the fish were sexed and reduced to 5 males and 12 females. at 198 days post-hatch, fish were reduced to 4 males and 6 females. Fish were then left for 6 days undisturbed with no observations after which tiles were checked regularly for eggs.

Spawns of less than 50 eggs were removed for residue analysis. Spawns of greater than 50 eggs were collected for use in hatching and growth determinations. Parental fish were terminated after spawning had declined and necessary spawning data had been collected.

12. REPORTED RESULTS:

Refer also to attached tables.

Hatchability of eggs were not significantly affected at any concentration of FMC 54800. Fry survival at 30 and 92 days was significantly reduced at the highest test concentration (0.090 ug/l). No significant differences were reported at 60 and 120 days exposure in any test concentration. Fry growth was significantly reduced only in solvent control fish. Reproduction parameters was not significantly affected at any treatment level. First filial generation fish were unaffected except for reduced growth in the lowest test level (0.0037 ug/l) after 56 days.

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

"Whole body residues of parental (Fo) fish ranged from 21,000 to 28,000 times higher than the water concentrations. Bioconcentration factors for newly fertilized embryos (<48 hours old) and 96-hour old embryos ranged from 83X to 4900X and 530X to 10000X, respectively. The bioconcentration factor for the 14-day old f_1 larval fathead minnows was 6000X for the 0.019 ug/l concentration.

The most sensitive indicator of ^{14}C-FMC 54800 toxicity was fry (Fo) survival which was significantly reduced ($p<0.05$) after 30 days of exposure to the highest test concentration of 0.090 ug/l. Fathead minnow growth and reproduction was not significantly reduced at any ^{14}C-FMC 54800 test concentration when compared to the control. Based on these data, the Maximum Acceptable Toxicant Concentration (MATC) was calculated to be 0.060 ug/l as ^{14}C-FMC 54800. The no observed effect concentration was 0.040 ug/l. An application factor of 0.29 for freshwater fish was calculated by dividing the MATC by the 96-hour LC50 of 0.21 ug/l."

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

A. Test Procedures: The test was generally performed according to acceptable methods and were consistent with an EEB accepted protocol. A descrepancy between the observational data entries and photographic measurements of fry taken 30 days post hatch (test day 36) suggest that data are entered as "number of fish dead" but observations are made as "number of fish alive". Data should be entered as observed. The total number of fish counted as dead (cumulative) in controls on day 35 were 32 (5,7,10, and 10 in each of four replicates, respectively) where photographic evidence indicated a

total on day 36 of 32 (6,8,8, and 10, respectively). These data raise a question as to the accuracy of the observational data.

B. Statistical Analysis: Appropriate, however, high variability in some parameters lowers the confidence or otherwise compromises the conclusions.

C. Discussion/Results: The data do not support the conclusions drawn, and are deemed equivocal due to the high variability in reproduction parameters, lack of raw data on individual spawning pairs and the unacceptable control survival. At 10 days post hatch cumulative control survival was 77%, at 31 days post hatch cumulative control survival was 65%, and by 60 days post hatch cumulative control survival was 63%. Cumulative survival in the lowest test concentration level at 60 days post hatch was 57%.

Control fish produced 13802 eggs in an average of 25 spawns, solvent control fish produced 7781 eggs in an average of 19 spawns, and treatment group 1 (3.74 ng/l) fish produced 3327 eggs in an average of 11.5 spawns. Egg production in solvent control fish was 56.4% of control fish and in low dose fish it was 42.8% of solvent control fish and only 24% of control fish. Data on individual spawning pairs was not available so these data cannot be evaluated statistically, though they are highly suggestive of a solvent and test material related effect. However, any conclusions on reproduction are unwarranted in light of the poor survival of control fish.

D. Adequacy of Test:

1. Validation Category: Invalid.

2. Rationale: High variability of reproduction parameters and unacceptable performance of controls.

3. Repairability: None.

15. COMPLETION OF ONE-LINER FOR TEST:

16. CBI APPENDIX: N/A

Bifenthrin ecological effects review

Page _____ is not included in this copy.

Pages 8 through 54 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 product 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

_X_ 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.