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MEMORANDUM

TO: George LaRocca, Product Manager (15)
Insecticide and Rodenticide Branch
Environmental Fate and Effects Division (H-7507-C)

FROM: James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H-7507-C)

SUBJECT: EEB reconsideration of FMC fathead minnow life-cycle study conducted with Capture 2EC

EEB recommends that the fathead minnow life-cycle study submitted by FMC (for bifenthrin as Capture 2EC; EPA Accession No. 407913-01) be upgraded from invalid to valid. Based on this upgrade, the study fulfills Guideline data requirement §72.5.

The reason for this upgrade is based upon a review of control fathead minnow life-cycle data. Based on studies submitted by several government and private laboratories, the high variability observed for 30 day survival and reproductive data in this study are comparable to the variability observed in other studies.

No dose-dependent effects of bifenthrin were noted for egg production or spawning. The most sensitive indicator of toxicity was fry (F_0) survival which was significantly reduced after 30 days of exposure to the highest test concentration of 0.095 µg/L. The no observed effect concentration was 0.040 µg/L. Based on these data, the MATC was calculated to be 0.062 µg/L. An application factor of 0.295 for freshwater fish was calculated by dividing the MATC by the 96-hr LC50 of 0.21 µg/L.

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

TO: James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H-7507-C)

FROM: Arthur L. Buikema, Jr., PhD. 11/9/89
Aquatic Ecologist
Ecological Effects Branch
Environmental Fate and Effects Division (H-7507-C)

SUBJECT: FMC fathead minnow life-cycle study conducted with Capture 2EC (bifenthrin)

100 Historical Perspective

FMC submitted a fathead minnow full life-cycle (LC) study on May 27, 1988 (Record Numbers 230311 and 230312). The study was conducted by Analytical Bio-Chemistry Laboratories, Inc (EPA Accession No. 407913-01).

According to the study authors:

> "Whole body residues of parental (F_0) fish ranged from 21,000 to 28,000 times higher than the water concentrations. Bioconcentration factors for newly fertilized embryos and 96-hr 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 µg/L concentration.
>
> The most sensitive indicator of ^{14}C-FMC 54800 toxicity was fry (F^0) survival which was significantly reduced ($p<0.05$) after 30 days of exposure to the highest test concentration of 0.090 µg/L. Fathead minnow growth and reproduction was not significantly reduced at any test concentration when compared to the control. Based on these data, the MATC was calculated to be 0.060 µg/L as ^{14}C-FMC 54800. The no observed effect concentration was

requirements for a valid study.

101 Evaluation of Control Fathead Minnow Data

Methodology

I requested fathead minnow control data from several contract and governmental laboratories for early life stage and full life cycle studies conducted with fathead minnows. Additional information has been requested from other contract laboratories to make the analyses more complete. However, I feel that I have sufficient data to re-evaluate the original FMC study for fathead minnows chronically exposed to bifenthrin.

The data obtained from the laboratories included hatching and survival data for approximately 30 days post-hatch and for 30 day intervals thereafter. In addition, data were also available for body length and weight for these time intervals. Adult fish data included information on survival at the end of the experiment, body length and weight as a function of sex, number of spawns per female, total number of eggs per female and number of eggs per spawn.

The reproductive data varied in usefulness because the parameters that were measured differed over a 15+ year period of time and experimental methods also changed over time, e.g., life cycle studies were conducted with isolated spawning pairs or several pairs in a single aquarium.

For the ELS studies, hatchability and 30-day survival data were available for 254 and 347 sets of control data, respectively. For the full LC, hatchability and 30-day survival data were available for 14 and 34 sets of control data, respectively. Nineteen sets of data were available to evaluate survival of the F_1 generation. For reproductive data, information was available for 32 sets of data.

Hatchability and 28-35 day Survival

The data obtained for ELS studies were variable. Hatchability averaged 89 ± 12% (range 43 to 100%) and survival after 28 to 35 days averaged 91 ± 11% (range 30 to 100%). For the life cycle studies (both the F_0 and F_1 generations), hatchability averaged 80 ± 14% (range 50 to 100%) and survival averaged 82 ± 17% (range 40 to 100%). When the data were separated for the F_0 and F_1 generations, the data were comparable. For the F_0, the mean survival for 28 to 30 day post-hatch fish is 83 ±

18% (range 40 to 100%). For the F_0, the mean survival for 28 to 30 day post-hatch fish is 80 ± 14% (range 46 to 99%).

Reproductive Parameters

The data used in this analysis were averages for multiple breeding pairs/aquarium (17 data sets) and data for individual breeding pairs (15 data sets). These data were also variable. Based on these 32 data sets, the number of eggs per female averaged 1397 ± 1266 (CV = 0.91; range 169 to 5330). The number of spawns per female averaged 8.2 ± 6.4 (CV = 0.78; range 2.1 to 25.8). The number of eggs per spawn averaged 165.5 ± 81 (CV = 0.49; range 63.2 to 475.2).

Variability for Multiple Spawning Groups

Reproduction data for multiple spawning pairs are highly variable. Evaluation of reproductive data for multiple spawning groups per aquarium was examined for several studies. In three studies conducted by one laboratory, the mean ± standard deviation number of eggs per spawn for control fish was 131 ± 120 (CV = 0.92), 136 ± 107 (CV = 0.79), and 94 ± 91 (CV = 0.97). In another study, the mean ± standard deviation for number of eggs per spawn was 279 ± 260 (CV = 0.93) for one tank and 281 ± 233 (CV = 0.83) for a second tank.

Variability for Individual Spawning Pairs

Again these data were variable. In one study which ran for ran for 200 days, the number of spawns per female was 8 ± 1.4 (CV = 0.18) and the number of eggs per spawn was 150 ± 57 (CV = 0.38). In a second study which was terminated after spawning ceased, the average number of spawns per female was 22.3 ± 7.4 (CV = 0.33), the average number of eggs per female was 4066 ± 2733 (CV = 0.60), the average number of eggs per spawn was 172 ± 92 (CV = 0.53), and the average number of eggs per female reproductive day was 48.4 ± 36.8 (CV = 0.76).

102 Re-Evaluation of FMC Data

In a previous review, it was concluded that the FMC study was not scientifically sound and was insufficient to fulfill Guideline requirements for an acceptable freshwater finfish LC toxicity test. The study was deemed invalid because of the high variability of reproductive parameters, lack of raw data for individual spawning

pairs and unacceptable survival of the control fish. Based on my review of control fish data, I do not feel that these reasons are sufficient to classify the study as invalid.

Survival

In the FMC study, survival of control fish was 77% (range 71 to 83%) after 30 days and 66% (range 63 to 66%) after 60 days. Survival of solvent-control fish was 75% (range 71 to 77%) after 30 days and 71% (all replicates were 71%) after 60 days. After reduction in fish numbers, control and solvent-control survival was 100% up through 204 days.

I do not feel that the control survival values should be used to classify this study as invalid. Based on the ASTM criteria for the fathead minnow and my analysis of control fish data, I feel that the control survival values reported by FMC after 30 days are consistent with other fathead minnow studies.

Reproduction

In the FMC study, control reproduction data varied. The average number of spawns per female ranged from 2.8 to 5.5, and the average number of eggs per female ranged from 787 to 1671. From the raw data provided by the contractor, the average number of eggs per spawn in replicate CE was 304 ± 257 (CV = 0.93) and in replicate CF was 281 ± 233 (CV = 0.83).

The solvent used in this experiment had an effect on reproduction. Compared to the non-solvent controls, fish in the solvent controls exhibited decreases in total egg production, number of spawns per female, number of eggs per spawn.

I do not feel that the variability in control fish reproduction data should be used to classify this study as invalid. Based on my review of control fish data, the variability in reproductive parameters noted in this study is comparable to those observed in other studies.

Multiple Spawning Groups versus Spawning Pairs

I do not feel that the experimental design used in this study should be used to classify this study as invalid. The protocol for this study was apparently approved by EEB using multiple spawning groups instead of individual spawning pairs. The contract laboratory had a generic

protocol approved by EPA prior to submitting a chemical specific protocol through the registrant (W. McAllister, ABC Laboratories, pers. comm.). The protocol was submitted to the Agency before the SEP documents were available to the public in 1986. In subsequent protocol submissions by the contractor, EPA has requested the use of individual spawning pairs in life-cycle studies. The use of multiple spawning groups is consistent with earlier studies conducted by EPA-Duluth and other facilities.

103 Recommendation

I feel that the fathead minnow LC study submitted by FMC (for bifenthrin as Capture 2EC) should be considered a valid fathead minnow life cycle study; based on this upgrade, the study fulfills data requirement §72.5.

The reasons for this upgrade are based upon a review of control fathead minnow LC data. Based on studies submitted by several government and private laboratories, the variability observed for 30 day survival and long-term reproductive data in this study are comparable to the variability observed in other studies.

104 Calculation of MATC

No dose-dependent effect due to bifenthrin was noted using egg production, spawning, etc. The most sensitive indicator of toxicity was fry (F^0) survival which was significantly reduced ($p<0.05$) after 30 days of exposure to the highest test concentration of 0.095 µg/L. The no observed effect concentration was 0.040 µg/L. Based on these data, the MATC was calculated to be 0.062 µg/L. An application factor of 0.295 for freshwater fish was calculated by dividing the MATC by the 96-hr LC50 of 0.21 µg/L.