7-8-87

DATA EVALUATION REPORT

1. Chemical: Cyfluthrin - Cyano(4-fluoro-3-phenoxyphenyl) methyl-3-(2,2-dichloroethenyl)-2,2-dimethyl-cyclopropanecarboxylate

2. Test Material: Cyfluthrin (Baythroid) Technical 96 percent.

3. Study Type: Early Life Stage of Rainbow Trout Salmo gairdneri

4. Study ID: Carlisle, J.C. (1985) Toxicity of Cyfluthrin (Baythroid) Technical to early life stages of Rainbow Trout. Study No. 85-666-01. Prepared by Mobay Chemical Company, Stilwell, KS; submitted by Mobay Chemical Company, Kansas City, MO 64120 Accession No. 262443.

5. Reviewed By: Candy Brassard
EEB/HED
Signature: Candy Brassard
Date: 6/30/87

6. Approved By: Douglas J. Urban
Head-Section III
EEB/HED
Signature: Douglas J. Urban
Date: 7/8/87

7. Conclusions:

The study is scientifically sound; however, there are discrepancies that detract from the study, therefore, this study is classified as "supplemental". The study results indicate that, based on analytical measured concentrations, the maximum acceptable toxicant concentration (MATC) was 14 ng/L ($\geq$ 10 ng/l and $\leq$ 17.7 ng/l) and the no-observed-effect level (NOEL) was 10 ng/L. The requirement for a freshwater fish early life stage study is still pending.

8. Recommendations:

There were many discrepancies, but the major concern was the fluctuations of the measured concentrations within the same treatment levels. In addition, the company should identify in writing the reason for the discrepancy in the reported measured concentrations in the raw data, and the Table 1 data summary.

9. Background:

EEB determined that a fish early life stage study on coldwater species with cyfluthrin (Baythroid) Technical was needed prior to registration of this chemical. This decision was based on the use pattern, number of applications, low water solubility, and high acute toxicity to aquatic organisms.

1

10. Discussion of Individual Test: N/A.

11. Materials and Methods:

a. Test Animals: Rainbow trout (Salmo gairdneri) eggs from Mount Lassen Trout Farms, Red Bluff, California. The eggs were incubated to the eyed stage prior to testing.

b. Test System: Each of 12 test vessels consisted of a 20 L stainless steel tank with a perforated stainless steel tray divided into 12 incubation chambers. The temperature during the study ranged from 8.3 to 11.9 °C and the maximum variation between chambers at a given time was 2.5 °C. The pH ranged from 6.5 to 7.8. The length of the study was 58 days. A 16-hour photoperiod was used. The dissolved oxygen concentration ranged from 6.5 to 11.9 ppm, except on three occasions when it went above the range.

c. Dose: The nominal concentration levels were measured a total of 17 times from day 3 to day 58 of the study. Hexane was first used then evaporated off and the DMF was added as a solvent at the same rate as the 400 ng/L group.

d. Design: There were 100 fish eggs with 50 "eyed"-stage per replicate and two replicates per concentration, five doses total with one solvent control (control < 2.5 ng/L, a total of 10 eggs per chamber).

e. Statistics: The Waller-Duncan k-ratio t-test was used to compare the control with each concentration for percent hatch, swimup and survival to term, mean fish weight, mean chamber biomass, behavioral signs of intoxication, and incubation period. For dose-response analysis, cumulative mortality was analyzed by the probit method. Weight data were compared using Cochran's approximation of the t distribution test with the significance level at $p < 0.05$.

2

12. Reported Results:

The study authors found the 58-day LC50 active ingredient was 69 ng/L. Growth as measured by biomass and mean fish weight was significantly reduced in 50, 100, and 200 ng/L groups. A number of fish showed behavioral signs at concentrations of 50 ng/L (nominal concentrations) and higher. The NOEL was 25 ng/L (nominal concentrations). The MATC was 37 (25 to 50 ng/L) (nominal concentrations). Based on analytical measured concentrations, the NOEL was 10 ng/L and the MATC was 14 (10 to 18) ng/L. See Attachment A for hatching and mortality summaries. 13.

Study Author's Conclusions/QA Measures:

The NOEL was 10 ng/L and the MATC was 14 (10 to 18) ng/L.

In compliance with the Good Laboratory Practice regulations, this final report for study number 85-666-01 has been reviewed by the Ouality Assurance Unit. The results presented in this report accurately describe the methods and standard procedures and reflect the raw data collected during the conduct of the study.

14. Reviewer's Discussion and Interpretation of the Study:

a. Test Procedures: There were several discrepancies that were found in this study. They are listed as follows:

- The recommended water hardness of 40 to 48 mg/L $CaCO_3$ was exceeded. The levels in the study ranged from 94 to 138 mg/L $CaCO_3$.

- The pH ranged from 6.5 to 7.8. The pH is recommended to range from 7.2 to 7.6.

- The photoperiod was 16 hours light/8 hours dark. The recommended photoperiod is 12 hours light/12 hours dark.

- The total length of the study was 58 days. The recommended length is 31 days prior to hatching and then an additional 60 days posthatch for an approximate total exposure of 90 days.

- Using the reported temperatures of 8.3 to 11.9 °C and the dissolved oxygen levels of 6.5 to 11.9 ppm, the saturation could have been as low as 57 percent. The recommended saturation level is greater than 75 percent.

- The study reported that the control tank received DMF at the same rate as the 400 ng/l group. It was never stated what the rate of DMF was in the 400 ng/l group.

- It appears the controls were contaminated with Baythroid 2. Three days prior to the start of the test, Baythroid 2 was detected at 6.7 ng/L. One day prior to the start, the controls reported levels of 12.1 ng/L and 9.4 ng/L.

- The mortality was summed, when the mortality of embryos, larvae, and juveniles should be delineated.

- Clinical signs of abnormality and numbers of survivors were only rated on a weekly basis for 5 weeks. The recommended rate for observing numbers and abnormalities is 4, 11, 18, 25, and 32 days after hatching.

- The study did not indicate if the dilution water was free of pesticides. A negative control was not used. A negative control and solvent control are recommended.

- According to the submitted raw data, the temperature varied within the same treatment level by as much as 3.3 °C. EEB did not receive the reported temperatures of the test vessels from June 15, 1985 through July 1, 1985, so the temperatures may have varied even more. In addition, the submitted summary indicated temperatures were as low as 8.3 °C, which indicates there could be 3.6 °C deviation. All treatment levels exceeded the recommended 1°C deviation from 10° C for rainbow trout.

- The diluter apparatus delivered six chamber volumes daily. The flow rate through the test chambers should be at least 10 volume additions every 24 hours (ASTM 1982).

- The reported concentrations of cyfluthrin in the replicate test tanks appear to be extremely erratic. The diluter may not have been operating properly.

- For each treatment, the highest of all the measured concentrations obtained during the test divided by the lowest should be less than 2 (ASTM 1982). EEB estimated that within the treatment levels, the highest measured concentrations were as high as 37.2 times the lowest measured concentration.

- The reported measured concentrations in the raw data were significantly different from Table 1 in the summary. The Company should identify in writing why these values are so different. These measured concentrations of the test material in any chamber should be no more than + 30% of the nominal concentration. The reported measured concentrations exceeded the nominal concentrations by as much as 137% in one treatment level.

- The dilution water was run through the test system for 3 days prior to the start of the test. Therefore, there should be little or no fluctuations in measured concentrations. However, based on the raw data, it is evident that the concentrations varied so greatly that it is impossible to accurately ascertain the true concentration at which these test organisms were affected.

5

- The recovery rate was only 32 to 48% of cyfluthrin. Where it should have been at least 80%.

- The study author reported (in the raw data only) that when the tanks were cleaned weekly, the trays were placed in an extra tank containing clean water at the same temperature. Even 5 minutes causes concern. The embryos/fish must always be exposed to the same dilution water.

- The study author indicated that the edema and deformity signs (in Clinical Signs section) were not associated with the treatment. The study author should indicate what caused these adverse effects.

b. Statistical Analysis: Based on analytical measured concentrations, the reported NOEL was 10 ng/L and the MATC was 14 (10 to 18) ng/L. There was significant mortality at the 100, 200, and 400 ng/L treatment levels (nominal) during larvae exposure. Growth was significantly reduced in the 50, 100, and 200 ng/L treatment levels. There was a significant increase in behavioral changes in fish at levels > 50 ng/L (nominal concentration). An ANOVA was conducted on the mean fish weight/tretment level. The results indicate that the NOEL is $\leq$ 10 ng/l (mean measured concentrations) and the MATC is $\geq$ 10 ng/l and $\leq$ 17.7 ng/l.

c. Discussion/Results: There was significant variation of the measured concentrations within each treatment level to cause concern. The exact concentration that causes adverse effects on the test organism cannot be accurately ascretained from these data.

d. Adequacy of Study:

1) Classification - Supplemental for 96% ai.

2) Rationale - The study appears to be scientifically sound. However, there are major discrepancies that detract from the study. The study cannot be upgraded to Core unless it is run again.

6

15. Completion of One-Liner for Study: September 9, 1986.

16. CBI Appendix: N/A.

7

Bifenthrin ecological effects review

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