6-13-89
3

DATA EVALUATION RECORD

1. Chemical: RE-45601 (Clethodim)

2. Test Material: RE-45601 Technical (83.3% purity specified in protocol).

3. Study Type: Coldwater Fish LC_{50}
   Species Tested: Rainbow Trout (Salmo gairderi)

4. Study ID: Swigert, J.P. 1986. Acute Toxicity of Chevron RE-45601 Technical to Rainbow Trout in a Static Test System. Prepared by Analytical Biochemistry Laboratories, Inc., Columbia, MO (ABC Laboratory Project ID #34968). Study Sponsor: Chevron Environmental Health Center, Inc., Richmond, CA. EPA Accession No. 409745-28.

5. Reviewed By: David Warburton
   Wildlife Biologist
   EEB/EFED
   Signature: Dave Warburton
   Date: 6/8/89

6. Approved By: Douglas J. Urban
   Supervisory Biologist
   EEB/EFED
   Signature: Douglas J. Urban
   Date: 6/13/89

7. Conclusions:

The study is scientifically sound and documents a 96-hour LC_{50} of 18 mg/l for rainbow trout exposed to RE-45601 Technical. This value differs from that obtained by the study authors for reasons discussed in Section 14C. However, the study still fulfills the Guidelines requirement for acute toxicity testing for a coldwater freshwater fish using the technical grade active ingredient.

8. Recommendations: N/A.

9. Background:

The study was submitted to support, in part, a proposed Experimental Use Permit for Select 2EC herbicide to control annual and perennial grasses in cotton (EPA Record No. 238236).

10. Discussion of Individual Test: N/A.

11. Materials and Methods (Excerpted in part from submission):

a. Test Animals - Rainbow trout used in the test were obtained from Mt. Lassen Trout Farm, Red Bluff, California. All test fish were held in culture tanks on a 16 hour daylight photoperiod and observed for at least 14 days prior to testing. During this period the fish received a standard commercial fish food occasionally

31

supplemented with brine shrimp daily until 48-96 hours prior to testing at which time feeding was discontinued. The trout used as the controls for this experiment had a mean weight of 0.67 (±0.24) g and a mean standard length of 35 (±3.5) mm. This gave a test chamber loading biomass of 0.45 g/l for the definitive study.

b. System - The static fish bioassay was conducted in five gallon glass vessels containing 15 liters of soft reconstituted water prepared to yield a total hardness of 40-45 mg/l as $CaCO_3$, a total alkalinity of 30-35 mg/l as $CaCO_3$ and an initial pH of 7.2 to 7.6. Test vessels were kept in a water bath at 12°C (±1.0).

c. Dose - Definitive test concentrations were obtained by transferring appropriate weights of test compound directly to the test chambers. All test concentrations were corrected for sample purity (83.3%). Before addition to the test chambers, 1.5 ml of dimethylformamide (DMF) was added to each sample weight to increase dispersion of the compound in the dilution water. Test solutions were stirred vigorously after compound addition. The solvent control chamber received a 1.5 ml aliquot of DMF, which was equivalent to the highest amount used in any test solution. The fish were added to the test chambers by random assignment within 30 minutes after addition of test material.

A RE-45601 primary standard of 2.06 mg/ml in acetone was prepared; subsequent dilutions were prepared in 2% acetic acid in HPLC-grade acetonitrile for chromatography standards. Analysis of water samples for RE-45601 Technical at 0-, 48-, and 96-hours of testing were accomplished according to a method provided by the study sponsor. Prior to the initiation of the definitive study, a method validation in aged well water was conducted to determine the extractability of RE-45601 from aquatic test water.

d. Design - Based on the results of preliminary testing, five duplicate concentrations of the test compound, ranging in a geometric series from 10 to 100 mg/l, with 10 fish per replicate concentration were selected for the definitive bioassay. Also included were duplicate dilution water controls and solvent control chambers. Randomization was done by sequentially adding one fish per test container until all containers had their complement of test organisms. All test organisms were observed after 3 and 6 hours and once every 24 hours thereafter for mortality and abnormal (sub-lethal) effects. Any dead individuals were removed from the test chambers after each 24-hour observation.

e. Statistics - Concentration vs. effect data (generally mortality) was analyzed by a computerized LC_{50} program developed by Stephan et al. (1978).

12. Reported Results (Excerpted in part from submission):

Results of the 96-hour static toxicity test with rainbow trout

exposed to RE-45601 Technical are presented in attached Table 2. The 24-, 48-, and 96-hour LC_{50} values for RE-45601 Technical (active ingredient) were >100, 72 and 56 mg/l, respectively. On a total product basis, these LC_{50} values correspond to >120, 86, and 67 mg/l. All results were based on the active ingredient (83.3%) nominal concentrations of 10, 18, 32, 56 and 100 mg/l. The 10 and 18 mg/l solutions had a light surface film at 0- and 96-hours of testing. The 32, 56 and 100 mg/l solutions had a surface film and yellow oil drops which increased with increasing concentration at 0-hour. The 56 and 100 mg/l solutions still had surface film and large yellow oil drops on the surface at 96 hours. The 100 mg/l solutions also had oil drops at the bottom of the chambers.

The 96-hour no-observed effect concentration was estimated to be 18 mg/l, based on the lack of mortality or observed abnormal (sub-lethal) effects. The abnormal effects of mortality, surfacing, loss of equilibrium, dark discoloration, fish on the bottom of test chamber and/or quiescence were observed in the 32, 56 and 100 mg/l test concentrations during the 96-hour exposure period.

Results of the determination of RE-45601 Technical in the static toxicity test are presented in attached Table 3. The measured concentrations yielded an average percent recovery of 78 $\pm$4.2% of nominals for the low test level, 56 $\pm$7.9% of nominals for the middle test level, and 33 $\pm$4.2% of nominals for the high test level. The average concentration of RE-45601 Technical for the low, middle and high test levels measured at 0-, 48- and 96-hours were 7.8, 18 and 33 mg/l, respectively. Fortification samples analyzed with each sample day ranged from 86 to 100%. Recoveries for the fortification levels conducted with well water were 86 to 110% for a range of 1.0 to 100 ppm RE-45601.

Nominal test concentrations, mortality rates, and water quality data are presented in attached Table 6. The dissolved oxygen concentrations ranged from 7.4 to 9.5 mg/l during the test. These values represented 70 and 88% saturation at 13 and 12^{o}C, respectively, and were considered adequate for testing. The pH values ranged from 6.9 to 7.5. Conductivity, hardness and alkalinity were measured at 0- and 96-hours and are also reported in Table 6.

13. Study Author's Conclusions/QA Measures:

The 96-hour static fish toxicity LC_{50} was determined to be 56 mg/l (32-100 mg/l 95% c.i.) on an active ingredient basis for rainbow trout exposed to RE-45601 Technical. Also, the results indicated a 96-hour, no-observed effect concentration could be estimated at 18 mg/l nominal concentration.

The study was conducted following the intent of the Good Laboratory Practice Regulations and the final report was reviewed by Analytical Bio-Chemistry Laboratories' Quality Assurance Unit.

83

14. Reviewer's Discussion and Interpretation of Study:

a. Test Procedures - The study was conducted according to Agency recommended procedures.

b. Statistical Analysis - Statistical analysis was appropriate.

c. Discussion/Results - Based on the results of the measured concentrations of RE-45601 Technical in the test chambers, exposure of fish at the highest nominal test level (100 mg/l) was actually 33 mg/l, apparently due to technical substance solubility limitations. Because of this, EEB conservatively estimates that the mean actual exposure concentration at the LC_{50} level (i.e. 56 mg/l) was also 33% of nominal, or 18 mg/l. EEB does not concur with the study author's conclusions of the LC_{50} being 56 mg/l due to maximum actual (measured) exposure of 33 mg/l at the 100 mg/l test level. It is EEB's view that this study adequately documents a 96-hour LC_{50} of 18 mg/l for rainbow trout exposed to RE-45601 Technical (clethodim); this value may be used in hazard assessments where appropriate.

d. Adequacy of Study -

1) Classification - Core for RE-45601 technical.
2) Rationale - Conducted according to recommended protocol.
3) Reparability - N/A.

CLETHODIM

Page _____ is not included in this copy.

Pages 5 through 9 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 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.