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

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

TO: Bruce Sidwell, PM 53
Reregistration Division

FROM: Douglas Urban, Acting Chief
Ecological Effects Branch
Environmental Fate and Effects Division

SUBJECT: Review of Studies for Oxyfluorfen (Goal)

Douglas Urban
6/9/92

BACKGROUND

As part of the reregistration process of the List B chemical Oxyfluorfen (Goal), Rohm and Haas Company submitted studies for guidelines 72-1(a) and 72-1(c). The studies are the following:

Graves, William C. and Gregory J. Smith, 1991. Goal Technical Herbicide: a 96-Hour Static Acute Toxicity Test with the Bluegill (Lepomis macrochirus). MRID NO. 421298-01.

Graves, William C. and Gregory J. Smith, 1991. Goal Technical Herbicide: a 96-Hour Static Acute Toxicity Test with the Rainbow Trout (Oncorhynchus mykiss). MRID NO. 421298-02.

SUMMARY

Guide. Ref.	Test Species	% A.I.	Test Type	Test Results	Study Status	MRID NO
72-1 (a)	<u>Lepomis macrochirus</u>	71.4	Acute Toxicity Static	LC50 0.21 mg a.i./L	Core	421298-01
72-1 (c)	<u>Oncorhynchus mykiss</u>	71.4	Acute Toxicity Static	LC50 0.25 mg a.i./L	Core	421298-02

The attached data evaluation records will provide the necessary information regarding the classification of the studies. If you have any questions contact Concepción Rodríguez 308-2805 or Harry Craven 305-5320.

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DP Barcode : D174148
 PC Code No : 111601
 EEB Out : 6/12/92

To: Bruce Sidwell, 53\Mark White
 Product Manager
 Special Review and Reregistration Division (H7508W)

From: Douglas J. Urban, Acting Chief
 Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 111601-000707
 Chemical Name : Oxyfluorfen
 Type Product : Herbicide
 Product Name : Goal
 Company Name : Rohm & Haas
 Purpose : Generic Data Submission

Action Code : 627 Date Due : 6/05/92
 Reviewer : Concepcion Rodriguez

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)	421298-01	Y	72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)	421298-02	Y	72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
 P=Partial (Study partially fulfilled Guideline but additional information is needed)
 S=Supplemental (Study provided useful information but Guideline was not satisfied)
 N=Unacceptable (Study was rejected)/Nonconcur

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DATA EVALUATION RECORD

1. **CHEMICAL:** Oxyfluoren (Goal)
Shaughnessey No. 111601
2. **TEST MATERIAL:** Goal Tech 70; Lot No. 2-0956; a brown speckled solid; 71.4% a.i.
3. **STUDY TYPE:** Acute Fish Toxicity to Bluegill Sunfish
4. **CITATION:** Graves, William C. and Gregory J. Smith, 1991. Goal Technical Herbicide: A 96-Hour Static Acute Toxicity Test with the Bluegill Sunfish (Lepomis macrochirus). Prepared by Wildlife International LTD, Easton, Maryland Project Number 129A-103A. Submitted by Rohm and Haas Company, Spring House, Pennsylvania. MRID NO. 421298-01.
5. **REVIEWED BY:** Concepción Rodríguez, Biologist *Concepción Rodríguez*
Ecological Effects Branch *6/5/92*
Environmental Fate and Effects Division
6. **APPROVED BY:** Harry Craven, Head Section 4 *Harry T. Craven*
Ecological Effects Branch *6/5/92*
Environmental Fate and Effects Division
7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guidelines requirements for an acute toxicity test for freshwater fish. The 96-hour LC50 for rainbow trout is 0.21 mg a.i./L which classifies Goal Herbicide as highly toxic.
8. **RECOMMENDATIONS:**
9. **BACKGROUND:**
10. **DISCUSSION OF INDIVIDUAL TEST OR STUDY:**
11. **MATERIALS AND METHODS:**
 - A. **Test Animals:** Juveniles bluegill Sunfish, Lepomis macrochirus, were obtained from Delmarva Ecological Laboratories, Middletown, DE. During the 14 day holding period, water temperature ranged from 20.4-21.6 °C, water hardness was 148 mg/L as CaCO₃, alkalinity was 194 mg/L as CaCO₃, and pH ranged from 7.4 to 8.5.

All fishes were from the same year class. The average length of 10 control fishes at the end of the test was 23 mm (22-26 mm). The average wet weight for 10 control fishes was 0.3 grams (0.23-0.43 grams). Loading was 0.20 grams/L.

Organisms were feed flaked fish food salmon smash and/or salmon starter supplied by Zeigler Brothers Inc. Gardners, PA and live Artemia supplied by Artemia Inc., Newark, California. They were not feed 48 hours before the test nor during test period. Fish were acclimated for 51 hours before the test and no mortalities or signs of stressed were shown.

B. Test System: Test chambers were Teflon-lined, 25-L polyethylene aquaria filled up to 15 liters. Depth of test solution was 17 cm. Aquaria were randomly positioned in a temperature controlled environmental chamber to maintain a temperature of approximately 22°C. A photoperiod of 16 hours light 8 hours dark and a 30 minute transition period was provided.

The stock solution was prepared at a concentration of 0.008 g Goal/ml, by dissolving Goal in acetone (≤ 0.08 ml/L). The stock solution was mixed in the test chamber with the dilution water.

Dilution water was obtained from a well 45 meters deep located on Wildlife International. Water characterization is presented in Appendix III. The water was filtered, aerated and filtered again prior delivery to test chambers.

C. Dosage: Based on a preliminary test, the five nominal test concentrations are: 0.062, 0.103, 0.171, 0.286 and 0.476 mg ai/L. A negative control and a solvent control (0.08 ml/L acetone) were used.

D. Design: The test begin with the impartial addition of fish from holding tanks to test chambers. Fish are added in groups of two until each chamber contained 10 fishes (20 per concentration).

Biological observations, such as mortality and treatment - related effects, were made at 4.5, 24, 48, 72 and 96 hours. The concentration of Goal in water was measured at the beginning of the test in each replicate, and at 48 and 96 hours in replicate A. Hardness, alkalinity, conductivity and pH were measured at the beginning of the test in the negative control. pH and dissolved oxygen were measured every 24 hours in alternate replicates. Temperature was continuously monitored in one negative control replicate.

E. Statistics: The LC50 value and its 95% confidence interval were determined using probit analysis. The no

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mortality concentration and the no effect concentration were determined by visual interpretation of the data.

12. **REPORTED RESULTS:** Mean measured concentrations were 0.029, 0.054, 0.093, 0.175, 0.346 mg a.i./L which ranged from 47 to 73% nominal (Table 1). One solvent control replicate was found to be contaminated with Goal (0.013 mg ai/L). This sample was not used in any calculations.

Fish in the solvent control and negative control appeared normal, as well as in the 0.029, 0.05 and 0.093 mg a.i./L treatments. Effects were observed in concentrations of 0.175 mg a.i./L and higher (Table 3).

Dissolved oxygen concentrations were below 60% of saturation in the 0.093 and 0.175 mg a.i./L treatments at 72 hours. It was also below 60% in the negative control, 0.029, 0.093, 0.175 and 0.346 mg a.i./L at the end of the test. It appears that the low levels of oxygen did not affected the results of the study (Table 2).

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

The 96-hour LC50 was calculated to be 0.021 mg a.i./L. The 95% confidence interval was 0.18-0.35 mg a.i./L. The no mortality concentration and no observed effects concentration was 0.093 mg a.i./L.

The study was conducted in compliance with Good Laboratory Practices as promulgated by the US EPA, Office of Pesticides Programs in 40 CFR Part 160, 17 August 1989; OECD, ISBN 92-8-12367-9, Paris 1982; and Japan MAFF, 59 NohSan, Notification No 3850, Agricultural Production Bureau, 10 August 1984.

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

- A. **Test Procedure:** Test procedures were in accordance with the SEP and ASTM.
- B. **Statistical Analysis:** Using the Binomial Test the 96-hours LC50 was calculated to be 0.21 mg a.i./L. The 95% confidence interval was calculated as 0.175-0.346 mg a.i./L.
- C. **Discussion And Results:** The results of the study show a dose response of bluegill to Goal Herbicide. The calculated LC50 was the same as the author's. The no effect concentration and no mortality concentration was calculated to be 0.093 mg a.i./L based on visual interpretation of the data.

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The low levels of dissolved oxygen during the last 72 hours, have no important effects in the results of this study.

This study is scientifically sound and fulfill the guidelines requirements for an acute toxicity test for freshwater fish. The 96-hour LC50 for bluegill sunfish is 0.21 mg a.i./L which classifies Goal Herbicide as highly toxic.

D. Adequacy of the Study:

(1) **Classification:** Core

(2) **Rationale:** N/A

(3) **Repairability:** N/A

15. **COMPLETION OF ONE-LINER FOR STUDY:** YES

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Conchi Rodriguez Gaol Acute Toxicity LC50 Bluegill Sunfish

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
.346	20	20	100	9.536742E-05
.175	20	5	25	2.069473
.093	20	0	0	9.536742E-05
.054	20	0	0	9.536742E-05
.029	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .175 AND .346 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .2102209

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

Handwritten initials/signature

RIN 0637-00

EFED Review - Oxyfluorfen

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Pages 8 through 13 are not included.

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.
- 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.

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DATA EVALUATION RECORD

1. **CHEMICAL:** Oxyfluoren (Goal)
Shaughnessey No. 111601
2. **TEST MATERIAL:** Goal Tech 70; Lot No. 2-0956; a brown speckled solid; 71.4% a.i.
3. **STUDY TYPE:** Acute Fish Toxicity to Rainbow Trout
4. **CITATION:** Graves, William C. and Gregory J. Smith, 1991. Goal Technical Herbicide: A 96-Hour Static Acute Toxicity Test with the Rainbow Trout (Oncorhynchus mykiss). Prepared by Wildlife International LTD, Easton, Maryland Project Number 129A-102. Submitted by Rohm and Haas Comapany, Spring House, Pennsylvania. MRID NO. 421298-02.
5. **REVIEWED BY:** Concepción Rodríguez, Biologist *Concepción Rodríguez*
Ecological Effects Branch *6/5/92*
Environmental Fate and Effects Division
6. **APPROVED BY:** Harry Craven, Head Section 4 *Henry T. Craven*
Ecological Effects Branch *6/5/92*
Environmental Fate and Effects Division
7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guidelines requirements for an acute toxicity test for freshwater fish. The 96-hour LC50 for rainbow trout is 0.25 mg a.i./L which classifies Goal Herbicide as highly toxic.
8. **RECOMMENDATIONS:**
9. **BACKGROUND:**
10. **DISCUSSION OF INDIVIDUAL TEST OR STUDY:**
11. **MATERIALS AND METHODS:**
 - A. **Test Animals:** Rainbow trout, Oncorhynchus mykiss, eggs and sperm were obtained from Mount Lasson Trout Farm, Red Bluff, CA. The eggs were fertilized in the lab. Fish were held for 31 days prior to test. During the 14 day acclimatation period, water temperature ranged from 10.7-11.7 °C, water hardness ranged from 144-160 mg/L as CaCO₃, alkalinity was 194 mg/L as CaCO₃, and pH ranged from 7.0 to 8.0.

All fishes were from the same year class. The average length of 10 control fishes at the end of the test was 30 mm (27-31 mm). The average wet weight for 10 control fishes was 0.5 grams (0.37-0.63 grams). Loading was 0.34 grams/L.

Organisms were feed with salmon mash and or salmon starter supplied by Zeigler Brothers Inc. Gardners, PA during holding period. They were not feed 48 hours before the test nor during test period. Fish were acclimated for 52 hours before the test and no mortalities or signs of stressed were shown.

B. Test System: Test chambers were Teflon-lined, 25-L polyethylene aquaria filled up to 15 liters. Depth of test solution was 17 cm. Aquaria were randomly positioned in a temperature controlled environmental chamber to maintain a temperature of approximately 12°C. A photoperiod of 16 hours light 8 hours dark and a 30 minute transition period was provided.

The stock solution was prepared at a concentration of 0.020 g Goal/ml, by dissolving Goal in acetone (≤ 0.10 ml/L). The stock solution was mixed in the test chamber with the dilution water.

Dilution water was obtained from a well 45 meters deep located on Wildlife International. Water characterization is presented in Appendix III and IV. The water was filtered, aerated and filtered again prior delivery to test chambers.

C. Dosage: Based on a preliminary test, the five nominal test concentrations are: 0.089, 0.179, 0.357, 0.714 and 1.3 mg ai/L. A negative control and a solvent control (0.10 ml/L acetone) were used.

D. Design: The test begin with the impartial addition of fish from holding tanks to test chambers. Fish are added in groups of two until each chamber contained 10 fishes (20 per concentration).

Biological observations, such as mortality and treatment - related effects, were made at 4.5, 24, 48, 72 and 96 hours. The concentration of Goal in water was measured at the beginning of the test in each replicate, and at 48 and 96 hours in replicate A. Hardness, alkalinity, conductivity and pH were measured at the beginning of the test in the negative control. pH and dissolved oxygen were measured every 24 hours in alternate replicates. Temperature was continuously monitored in one negative control replicate.

E. Statistics: The LC50 value and its 95% confidence interval were determined using probit analysis. The no

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mortality concentration and the no effect concentration were determined by visual interpretation of the data.

12. **REPORTED RESULTS:** Mean measured concentrations were 0.037, 0.083, 0.175, 0.398, 1.09 mg a.i./L which ranged from 42 to 76% nominal (Table 1). Temperature, dissolved oxygen and ph measurements made during the study are presented in Table 2.

Fish in the solvent control and negative control appeared normal. As well as in the 0.037 mg a.i./L chambers. Effects were observed in concentrations of 0.083 and higher. See Table 3.

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

The 96-hour LC50 was calculated to be 0.025 mg a.i./L. The 95% confidence interval was 0.19-0.36 mg a.i./L. The slope of the concentration effect curve was 2.38. The no mortality concentration and no observed effects concentration was 0.037 mg a.i./L.

The study was conducted in compliance with Good Laboratory Practices as promulgated by the US EPA, Office of Pesticides Programs in 40 CFR Part 160, 17 August 1989; OECD, ISBN 92-8-12367-9, Paris 1982; and Japan MAFF, 59 NohSan, Notification No 3850, Agricultural Production Bureau, 10 August 1984.

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

- A. **Test Procedure:** Test procedures were in accordance with the SEP and ASTM.
- B. **Statistical Analysis:** Using the probit analysis the 96-hours LC50 was calculated to be 0.25 mg a.i./L. The 95% confidence interval was calculated as 0.186-0.355 mg a.i./L.
- C. **Discussion And Results:** The results of the study show a dose response of rainbow trout to Goal Herbicide. The calculated LC50 was the same as the author's. The no effect concentration and no mortality concentration was calculated to be 0.037 based on visual interpretation of the data.

This study is scientifically sound and fulfill the guidelines requirements for an acute toxicity test for freshwater fish. The 96-hour LC50 for rainbow trout is 0.25 mg a.i./L which classifies Goal Herbicide as highly toxic.

- D. **Adequacy of the Study:**

(1) **Classification:** Core

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(2) Rationale: N/A

(3) Repairability: N/A

15. COMPLETION OF ONE-LINER FOR STUDY: YES

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Conchi Rodriguez Goal Acute Toxicity LC50 Trout

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
1.09	20	19	95	2.002716E-03
.398	20	14	70	5.765915
.175	20	4	20	.5908966
.083	20	5	25	2.069473
.037	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .175 AND 1.09 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .2886253

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	.179521	.272125	.176046	.4269567

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H
4	.1050206	1

GOODNESS OF FIT PROBABILITY
.1390067

SLOPE = 2.378198
95 PERCENT CONFIDENCE LIMITS = 1.607498 AND 3.148898

LC50 = .2533354
95 PERCENT CONFIDENCE LIMITS = .1863608 AND .3550675

LC10 = .0740761
95 PERCENT CONFIDENCE LIMITS = 3.909731E-02 AND .1084315


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RIN 0637-00

EFED Review - Oxyfluorfen

Page is not included in this copy.

Pages 19 through 24 are not included.

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.
- FIFRA registration data.
- The document is a duplicate of page(s) .
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