7-11-88

221409
221410
RECORD NO.

128701
SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 6/27/88 OUT 7/11/88

FILE OR REG. NO 8340-GL, 8340-GU

PETITION OR EXP. NO

DATE OF SUBMISSION: 4/28/88

DATE RECEIVED BY HED: 6/08/88 resubmitted 6/27/88 because registrant's data were not included

RD REQUESTED COMPLETION DATE: originally 7/5/88

EEB ESTIMATED COMPLETION DATE: 7/27/88

RD ACTION CODE/ TYPE OF REVIEW: 160

TYPE PRODUCT(S): Herbicide

ACCESSION NUMBER(S): 406066--10-16

PRODUCT MANAGER: E. Wilson (10)

PRODUCT NAME(S): Super Whip and Super Acclaim

COMPANY NAME: Hoechst

PURPOSE OF SUBMISSION: Proposed new formulation of 85:15 ratio of D and L enantiomers

SHAUGHNESSEY NO.	CHEMICAL AND FORMULATION	%A.I.
	fenoxyprop ethyl d isomer	6.5% (d isomer)

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: New formulation of fenoxyprop ethyl

FROM: David Johnson, Ph.D.
Fishery Biologist

David Johnson 11 July 88

THROUGH: Henry Craven, Head-Section 4
Ecological Effects Branch

Henry F. Craven 7/12/88

THROUGH: James Akerman, Chief
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

James Akerman 7/12/88

TO: Richard Mountford, Product Manager (27)
Registration Division

Hoechst-Celanese has requested a review of a new formulation of fenoxpprop ethyl. The proposed new products, Super Whip and Super Acclaim, like the presently registered products, Whip and Acclaim, are identical formulations with different uses. Whip and Acclaim contain a racematic mixture of fenoxyprop ethyl, while the new products contain a different racematic mixture. In support of the registration, the company has submitted three toxicity studies for review. Our reviews are summarized below.

1. Fisher, R. 1987. The effect of HOE-046360 oil in water emulsion (75 g/l) to Daphnia magna in a static acute toxicity test. Hoechst AG Laboratory Frankfurt. Submitted by Hoechst Celanese Corporation, Somerville, NJ. Assession number: 406066-13.

The formulated product of fenoxyprop ethyl (Super Whip/Super Acclaim) was found to be moderately toxic to Daphnids. This study was performed under conditions that generally comply with current Guideline standards, and is acceptable for use in a hazard assessment.

2. Fisher, R. 1987. The effect of HOE-046360 oil in water emulsion (75 g/l) to Lepomis macrochirus in a static acute toxicity test. Hoechst AG Laboratory Frankfurt. Submitted by Hoechst Celanese Corporation, Somerville, NJ. Assession number: 406066-12.

The formulated product of fenoxyprop ethyl (Super Whip/Super Acclaim) was found to be moderately toxic to bluegill. This study was performed under conditions that generally comply with current Guideline standards, and is acceptable for use in a hazard assessment.

3. Fisher, R. 1987. The effect of HOE-046360 oil in water emulsion (75 g/l) to Salmo gairdneri in a static acute toxicity test. Hoechst AG Laboratory Frankfurt. Submitted by Hoechst Celanese Corporation, Somerville, NJ. Assession number: 406066-11.

The formulated product of fenoxyprop ethyl (Super Whip/Super Acclaim) was found to be moderately toxic to rainbow trout. This study was performed under conditions that generally comply with current Guideline standards, and is acceptable for use in a hazard assessment.

Conclusions

Super Whip and Super Acclaim, like the presently registered products, are identical formulations with different uses. The presently registered products, Whip and Acclaim, contain a 50:50 ratio racematic mixture of the d and l enantiomers, and the proposed new product would contain a 85:15 ratio of enantiomers. Whip/Acclaim contains a 12.5% solution of the d and l enantiomer, whereas Super Whip/Super Acclaim are identified as a 6.5% solution of d enantiomer. Implicit in this action, and the listing of the d enantiomer as the sole active ingredient, is the assumption that the l enantiomer is biologically inactive; otherwise, the l enantiomer must be listed as an active ingredient. Thus, the new formulation will be more efficacious because it contains a higher percentage of the d enantiomer. Mr. Victor Dorr of Hoescht misrepresents the product when he states that the use rates, on the basis of active ingredient per acre, will be almost one half of the presently labelled rates. If both the old and the new use rates are calculated on the same basis, namely the amount of the d enantiomer, the proposed use rate for the new product is in fact slightly higher.

The three studies included with this submission allow a partial comparison of the toxicities of the old and the new formulations. The following data represent validated studies for the 50:50 ratio of d and l enantiomers.

Species	% AI*	LD50/LC50
Mallard (dietary)	96.6%	>5620ppm
Bobwhite (dietary)	96.6	>5620ppm
" acute oral	96.6%	>2510mg/kg
brown trout	96	0.48ppm
rainbow trout	12.5 fp	3.38ppm
bluegill	95.8	0.31ppm
Daphnia	96	3.18ppm
"	12.5 fp	11.5ppm
fathead minnow	12.5 fp	7.12ppm
mysid shrimp	96.5	0.098ppm
"	9.7 fp	1.71ppm
eastern oyster	96.5	0.25ppm
	9.7 fp	2.0

*fp=formulated product (Whip) 12.5% d&l fenoxyprop ethyl, or 6.25% d fenoxyprop ethyl.

The studies included with the present submission for the 85:15 ratio show that the new formulation is slightly more toxic than the previous formulation.

Species	%AI	LD50/LC50
rainbow trout	6.5%**	2.4 mg/L
bluegill	"	4.7 mg/L
Daphnia	"	6.0 mg/L

**formulated product (Super Whip and Super Acclaim) 6.5% d fenoxyprop ethyl.

The data to support this use of the dextrorotatory enantiomer of fenoxyprop ethyl should include all tests needed to support the previous racematic mixture. However, if no substantial difference in toxicity is found between the old and new formulations for the most sensitive organisms, EEB will waive the basic tests, and will apply all available data on the old formulation to hazard assessments of the new formulation.

Because previously submitted studies indicated that fenoxyprop ethyl is practically nontoxic to birds, EEB will waive the avian acute oral and dietary testing.

The newly reviewed aquatic studies indicate the new formulation is slightly more toxic, but the toxicities are above the mysid EC50 tested with the d and l formulation. Because mysids are the most sensitive species tested with the old formulation and therefore serve as the basis for our marine/estuarine hazard assessments, EEB will require that the mysid test be repeated with the new formulation. EEB will waive

aquatic tests using the active ingredient consisting of the d enantiomer pending the outcome of the mysid test.

EEB also notes that phytotoxicity testing as required for the previous formulation (Mountford letter dated 01/11/87) has not been reviewed. Those studies should now test the new formulation.

Summary

Prior to the registration of this new formulation of the d enantiomer of fenoxyprop ethyl, EEB requires the following.

1. Because the mysid (estuarine shrimp) is the most sensitive species tested with the previous formulation, EEB requires that the acute mysid shrimp study be repeated using the new formulation.

2. We also note that aquatic plant growth Tier I studies as described at 40 CFR 158.150 were previously required for the 50:50 racematic mixture, but have not been reviewed by EEB. EEB will require that these studies be performed on the new 85:15 racematic formulation.

3. EEB will also require Tier I/Tier II phytotoxicity testing for the new formulation, as previously required for the presently registered product.

ADDENDUM

Using the maximum application rate of 0.1 lbs/acre for rice, the estimated environmental concentration of product in six inches of water is 73.4 ppb. The toxicity values for the formulated product on trout and mysid are listed in the following table along with restricted use and endangered species triggers. The restricted use trigger is EEC $\geq$ 1/10 LC50 of the most sensitive aquatic species. The endangered species trigger is EEC $\geq$ 1/20 LC50 of the most sensitive aquatic species. Because the toxicities of the new formulation are approximately one half the concentrations of the old formulation in the only two tests that can serve as a comparison, we have estimated the LC50 for mysid shrimp with the new formulation by halving the LC50 of the old formulated product.

EEC=73.4ppb

Species	LC50 for formulation	Triggers exceeded?	
trout	2400ppb (Super Whip)	EEC < 1/10 LC50	no
mysid	1710ppb (Whip)	EEC < 1/10 LC50	no
		EEC ≈ 1/20 LC50	*
mysid	855ppb (Super Whip, est.)	EEC ≈ 1/10 LC50	*
		EEC > 1/20 LC50	yes

*= For those situations where the EEC approximates the trigger, additional information is required to identify any mitigating circumstances.

From the above table it is clear that additional information on the toxicity of the Super Whip/Super Acclaim formulation will allow EEB to make a more informed decision concerning the criteria for restricted use and possible adverse effects to endangered species.

DATA EVALUATION RECORD

1. CHEMICAL: fenoxyprop (Super Whip) SN: 128701

2. TEST MATERIAL: formulated product may be expressed as 7.4% a.i. as 85:15 racematic mixture of d and l enantiomers, or 6.5% a.i. as d enantiomer only.

3. STUDY/ACTION TYPE: Acute Toxicity on Freshwater Invertebrate species: Daphnia magna

4. STUDY IDENTIFICATION:

Fisher, R. 1987. The effect of HOE-046360 oil in water emulsion (75 g/l) to Daphnia magna in a static acute toxicity test. Hoechst AG Laboratory Frankfurt. Submitted by Hoechst Celanese Corporation, Somerville, NJ. Assession number: 406066-13.

5. REVIEWED BY:

David Johnson, Ph.D.
Fishery Biologist

Signature: David Johnson
Date: 11 July 88

6. APPROVED BY:

Henry Craven, Head Section 4
Ecological Effects Branch
Hazard Evaluation Division

Signature: Henry T. Craven
Date: July 12/88

7. CONCLUSIONS:
This study is scientifically sound and is acceptable for use in hazard assessments. These data indicate that Super Whip and Super Acclaim are likely to be moderately toxic to daphnids.

8. RECOMMENDATION: N/A

9. BACKGROUND: N/A

Sum

10. DISCUSSION OF INDIVIDUAL STUDIES OR TESTS: N/A

11. METHODS AND MATERIALS:

Species. Daphnia magna

Size/Age/Physical Condition. Daphnids less than 24h in age were selected from an established culture.

Source. The Daphnids were cultured from laboratory stock.

Food. Prior to testing, the Daphnids were fed green algae.

Test water

Temperature: 20±1°C

Water source and chemistry: Fortified well water.

The properties of the water are: Hardness- 43mg/L $CaCO_3$, pH- 7.6

Aeration: Test solutions were not aerated.

Solvent: water

Controls: Controls were run concurrent with the test.

Test System.

Vessel Size/Volume: 200ml/300ml of test solution

Vessel Construction: Glass

Photoperiod: 16h-light/8h-dark

Number of Daphnids/concentration. 10/vessel x 2reps =20

Test Levels: nominal: 1, 1.8, 3.2, 5.6, 10, 32, 56, 100 mg/L

Toxic signs. mortality, inability to swim

Statistical analysis.
The modified Stephan's program was used to estimate the LC50 and confidence interval.

12. REPORTED RESULTS:

Chemical analysis of dilution water not included

Raw data

The raw data were not included with the study report.

Analysis of Test Concentrations Chemical analyses of the test concentrations were not performed.

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

48h EC50(95%CL): 6.0 mg/L (7.9-12) Slope: not specified
NOEL: 48h EC0: 3.2 mg/L

24h EC50: 9.7 ppm

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

A. Test Procedure.
This study was performed under conditions that generally comply with current Guideline standards.

B. Statistical Analysis.

EEB agrees with the statistical method. The study author's calculations match the reviewer's. The calculations are appended.

C. Results/Discussion.

The study is judged to be scientifically sound and acceptable for use in a hazard assessment.

D. Adequacy of the Study.
1. Category: core

2. Rationale: N/A

3. Remedy: N/A

15. COMPLETION OF ONE LINER 01 July 1988

D JOHNSON fenoxyprop ethyl (+) daphnia 06-27-88

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
100	20	20	100	9.536742E-05
56	20	20	100	9.536742E-05
32	20	20	100	9.536742E-05
18	20	20	100	9.536742E-05
10	20	20	100	9.536742E-05
5.6	20	8	40	25.17223
3.2	20	0	0	9.536742E-05
1.8	20	0	0	9.536742E-05
1	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 3.2 AND 10 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 6.018772

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.

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DATA EVALUATION RECORD

1. CHEMICAL: fenoxyprop ethyl SN: 128701

2. TEST MATERIAL: formulated product 6.5% a.i. of d enantiomer of fenoxyprop ethyl (Super Whip & Super Acclaim)

3. STUDY/ACTION TYPE: Acute Toxicity on Freshwater Fish species: Bluegill sunfish Lepomis macrochirus

4. STUDY IDENTIFICATION:
Fisher, R. 1987. The effect of HOE-046360 oil in water emulsion (75 g/l) to Lepomis macrochirus in a static acute toxicity test. Hoechst AG Laboratory Frankfurt. Submitted by Hoechst Celanese Corporation, Somerville, NJ. Assession number: 406066-12.

5. REVIEWED BY:

David Johnson, Ph.D.
Fishery Biologist
Ecological Effects Branch

Signature: David Johnson
Date: 11 July 88

6. APPROVED BY:

Henry Craven, Head Section 4
Ecological Effects Branch
Hazard Evaluation Division

Signature: Henry Craven
Date: 7/12/88

7. CONCLUSIONS:
This study is scientifically sound, and was performed under conditions that comply with current Guideline standards. These data indicate that Super Whip and Super Acclaim are likely to be moderately toxic to bluegill.

8. RECOMMENDATION:

9. BACKGROUND: n/a

10. DISCUSSION OF INDIVIDUAL STUDIES OR TESTS: n/a

11. METHODS AND MATERIALS:

Species. Bluegill sunfish Lepomis macrochirus

Size/Age/Physical Condition. Bluegill sunfish of a mean length <5.0cm and weight of <2.0g were selected. The fish were held 14d with < 1% mortality.

Source. The source of Bluegill sunfish was Osage Catfisheries, Osage Beach, Missouri.

Food. The food source was Tetra Min standard trout food.

Test water

Temperature: 21±1°C

Water source and chemistry: Deionized water was reconstituted to freshwater.

The properties of the adjusted water are:
Hardness= 42.6 mg/L total, pH= 7.2 - 8.1.

Aeration: The test solutions were not aerated.

Solvent: water

Controls: A Control was run concurrent with the test.

Test System.

Vessel: Stainless Steel

Photoperiod: 16h-light/8h-dark

Loading: 0.121g fish/L solution

Number of Bluegill/concentration: 10/vessel, 10 total

Test Levels: nominal: 0, .56, 1, 1.8, 3.2, 5.6, 10, 18 mg/L

Toxic signs. mortality

Statistical analysis. A modified Stephan's program was used to calculate the LC50 values and the confidence limits.

12. REPORTED RESULTS:

Chemical analysis of dilution water not included

Data
The data were included with the study report.

Analysis of Test Concentrations n/a

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:
Discussion was not included with the report.
96h LC50 (95%CL)= 4.7 mg/l (3.2-10)mg/L NOEL=1.8 mg/L

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

A. Test Procedure.
This study was performed under conditions that generally comply with current Guideline standards.

B. Statistical Analysis. A modified Stephan's program was run, the results are attached.

C. Results/Discussion.
The Ecological Effects Branch concurs with the study authors' conclusions.

D. Adequacy of the Study.

1. Category: core

2. Rationale: n/a

3. Remedy: n/a

15. COMPLETION OF ONE LINER 27 June 1988

D JOHNSON FENOXYPROP ETHYL BLUEGILL 27 JUNE 88

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
18	10	10	100	9.765625E-02
10	10	10	100	9.765625E-02
5.6	10	8	80	5.46875
3.2	10	0	0	9.765625E-02
1.8	10	0	0	9.765625E-02
1	10	0	0	9.765625E-02
.56	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 3.2 AND 10 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 4.69561

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.

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DATA EVALUATION RECORD

1. CHEMICAL: Fenoxyprop-ethyl (Super Whip & Super Acclaim) SN: 128701

2. TEST MATERIAL: formulated product: 6.5% a.i. of d enantiomer only

3. STUDY/ACTION TYPE: Acute Toxicity on Freshwater Fish
species: Salmo gairdneri

4. STUDY IDENTIFICATION:

Fisher, R. 1987. The effect of HOE-046360 oil in water emulsion (75 g/l) to Salmo gairdneri in a static acute toxicity test. Hoechst AG Laboratory Frankfurt. Submitted by Hoechst Celanese Corporation, Somerville, NJ. Assession number: 406066-11.

5. REVIEWED BY:

David Johnson, Ph.D.
Fishery Biologist
Ecological Effects Branch

Signature: David Johnson
Date: 11 July 88

6. APPROVED BY:

Henry Craven, Head Section 4
Ecological Effects Branch
Hazard Evaluation Division

Signature: Henry Craven
Date: 7/12/88

7. CONCLUSIONS: This study is scientifically sound. The study is appropriate for use in a hazard assessment, and the data indicate that fenoxyprop ethyl (Super Whip & Super Acclaim) is likely to be moderately toxic to fish.

8. RECOMMENDATION:

9. BACKGROUND: n/a

10. DISCUSSION OF INDIVIDUAL STUDIES OR TESTS: n/a

11. METHODS AND MATERIALS:

Species. Salmo gaidneri

Size/Age/Physical Condition. Rainbow trout of a mean length 5.9cm and weight of 2.7g were selected.

Source. The supplier of the Rainbow trout was Trout Lodge, Inc., McMillin, WA.

Food. Tetra Min, frozen fly larvae, frozen Daphnids.

Test water

Temperature: 12±1°C

Water source and chemistry: Deionized water was reconstituted to freshwater with the addition of carbonates and salts.

The properties of the adjusted water are: Hardness- 36-39 mg/L, pH- 7.0-8.4.

Aeration: The test solutions were not aerated.

Solvent: water

Controls: A Control was run concurrent with the test.

Test System.

Vessel Size/Volume: 300L stainless steel aquarium/100L solution

Vessel Construction: stainless steel

Photoperiod: 16h-light/8h-dark

Loading: 0.27g fish/L solution

Number of Rainbow trout/concentration. 10 fish/ concentration

Test Levels: nominal: 0.56, 1, 1.8, 3.2, 5.6, 10, 18, 32, 56 mg/L

Toxic signs. mortality

Statistical analysis. Stephan's program was used in the analysis of the data, the results are appended.

12. REPORTED RESULTS:

Chemical analysis of dilution water not included

Data
The data were included with the study report.

Analysis of Test Concentrations n/a

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:
The study was conducted in compliance with GLP. One fish died (10%) in the control group after 72 hours.

96h & 72h EC50(95%CL): 2.4 (1.8-3.2) mg/L NOEL: 1mg/1
48h EC50(95%CL): 2.6 (1.8-3.2)
24h EC50(95%CL): 4.2 (3.5-5.2) 24h slope: 10.6

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

A. Test Procedure.
The formulated product of fenoxyprop ethyl (Super Whip) was found to be moderately toxic to rainbow trout. This study was performed under conditions that generally comply with current Guideline standards.

B. Statistical Analysis. A modified Stephan's program was run, the results are attached.

C. Results/Discussion.
The Ecological Effects Branch concurs with the study authors' conclusions.

D. Adequacy of the Study.
1. Category: core

2. Rationale: n/a

3. Remedy: n/a

15. COMPLETION OF ONE LINER 28 June 1988

12/10

21 May 85

Attn: Richard Mountford

As per our telephone conversation of today, I am returning this Super Whip submission because it is missing the Ecological Effects Data. Please return the submission to me when you have located the data. Since I have now reviewed our file on this chemical, I should be able to return it to you fairly quickly.

David Johnson, EEB
557-7725 Rm 811