? 1-23-87

RECORD NO.

128701
SHAUGHNESSY NO. REVIEW NO.

EEB REVIEW

DATE: IN 10/09/86 OUT 1-23-87

FILE OR REG. NO. 8340-EG

PETITION OR EXP. NO.

DATE OF SUBMISSION 10/02/86

DATE RECEIVED BY HED 10/07/86

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RD ACTION CODE/TYPE OF REVIEW 111

TYPE PRODUCT(S): I, D, H, F, N, R, S Herbicide

DATA ACCESSION NO(S). 265260

PRODUCT MANAGER NO. R. Mountfort (23)

PRODUCT NAME(S) WHIP 1EC

COMPANY NAME American Hoechst Corporation

SUBMISSION PURPOSE Registrant response with submission of data to previous Agency reviews of rice and soybeans uses.

SHAUGHNESSY NO.	CHEMICAL & FORMULATION	% A.I.
128701	Whip (technical)	96.5
128701	Whip (formulated	9.7

Fenoxaprop-ethyl scientific review

Page _____ is not included in this copy.

Pages 2 through 7 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 product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commercial/financial information

X 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.

EEB REVIEW

PESTICIDE NAME: Fenoxaprop-ethyl (HOE-33171)

100.0 Submission Purpose and Label Information:

100.1 Submission Purpose and Pesticide Use:

Review of additional data (marine/estuarine studies) to support the proposed registration of WHIP^{R} 1EC Herbicide for selective postemergence annual and perennial grass control in rice and soybeans.

100.2 Formulation Information:

ACTIVE INGREDIENT:	
Fenoxaprop-ethyl: (±)-ethyl 2-[4-[6-chloro-2-benxoxazolyl)oxy]phenoxy] propanoate	12.50%*
INERT INGREDIENT:	87.50%
	100.0%

100.3 Application Methods, Direction, Rates:

See following pages. Soybeans, label pages 1-2; rice, pages 7-8.

100.4 Target Organisms:

Annual and perennial grass.

100.5 Precautionary Labeling:

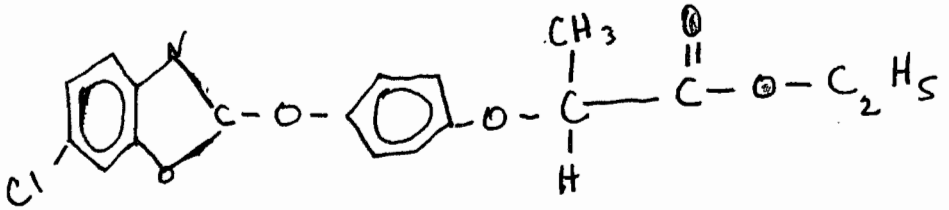
ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not apply directly to a body of water outside of the treated rice field. Do not apply when weather conditions favor runoff or drift. Do not contaminate land/or water by cleaning of equipment/disposal of waste.

101.0 Physical and Chemical Properties

101.1 Chemical Name

101.2 Structural Formula



101.3 Common Name

HOE - 33171
Fenoxaprop-ethyl(proposed name)

101.4 Trade Name

Whip

101.5 Molecular Weight

361.8

101.6 Physical State

Coarse powder, flakes or solidified melt, beige to brown in color, weak aromatic odor. Melting point: 358-36 KO (85-87 °C). Boiling point > 300 °C. Density: 1.3 gm/cm^3 at 293 K (20 °C).

101.7 Properties

101.7.1 Solubility (at 20 °C, except where noted)

Water (at 25 °C):	0.9	mg/L (pH 7)
Acetone:	51	mg/100 mL
Ethanol:	2	gm/100 mL
Toluene:	34	gm/100 mL
Cyclohexane:	1.5	gm/100 mL
Hexane:	0.5	gm/100 mL
Ethylacetate:	24	gm/100 mL
1-Octanol:	2	gm/100 mL
Sesamoil:	2.5	gm/100 mL

101.7.2 Octanol/Water Partition Coefficient

P = 19,100 (18,800-19,300)

101.7.3 Soil Adsorption Coefficient K_d

101.7.4 Vapor Pressure

0.187×10^{-7} mbar at 20 °C
0.406×10^{-6} mbar at 40 °C
0.609×10^{-5} mbar at 60 °C
0.672×10^{-4} mbar at 80 °C
0.573×10^{-3} mbar at 100 °C

102 Behavior in the Environment:

102.1 Soil

Aerobic soil metabolism studies indicated half-lives for the parent of < 1 day and 5 to 14 days for the major metabolite. Three different soils were used. The solvent extracted ^{14}C decreased to 37.1% to 10.9% by day 32 (expressed as % of applied), while the residues bound to soil increased at each sampling, with a range for the soils of 43.1% to 64.6% on day 32.

HOE-033171 in soil TLC was found to range from immobile to intermediate mobility with respect to its capacity to leach in the soil types tested (two silt loam soils and one silty clay). (From EAB review November 3, 1983.)

A rotational crop study performed with radio-labeled HOE-033171 showed measurable activity present in the soil (0-2" segment) 480 days (16 months) after treatment. (From EAB review January 4, 1984.)

102.2 Water

HOE-33171 was found to be stable to hydrolysis at 20 °C in pH 5 and pH 7 solutions, but rapidly hydrolyzed in pH 9 buffer. (From EAB review November 3, 1983.)

Aerobic Aquatic Metabolism: A system consisting of Erlenmayer flasks and a carbosorb CO_2 trap was used to test the aerobic aquatic metabolism of soil and water from a rice field (Mississippi Research Farm of American Hoechst). The soil/sediment was at pH 6.4 and 1.6% O.M., 7.2% sand, 70.4% silt, 22.4% clay. Under the experimental conditions of the study, HOE 033171 degraded rapidly to the acid and ultimately to mineralization (CO_2 evolution) of the chlorophenyl ring. While no half-life was given for the parent, it was possible to use a linear/log regression analysis program to obtain a half-life of 3.8 days. (From EAB Review April 10, 1984.)

102.3 Plant

Samples of representative rotation crops did not show significant uptake of radiolabeled HOE-33171 after 120 and 364 days. (From EAB review January 4, 1984.)

102.4 Animal

A nonradiolabeled study using pumpkinseed sunfish in a flow-through system indicated a maximum bioaccumulation factor of 384. (From EAB review February 17, 1984.) A new, radiolabeled study will be submitted at a later date.

In this nonradiolabeled study, pumpkinseed sunfish rapdily reached maximum accumulation by day 3 and declined to plateau levels thereafter. Depuration resulted in loss of residues. (From EAB review April 10, 1984.)

103.0 Toxicological Properties:

103.1 References from Toxicology Branch

No references from Toxicology Branch.

103.2 Fish and Wildlife Toxicology

103.2.5 Fish Acute LC_{50}

Species	Formulation	LC_{50} (ppm)	Category
Sheepshead minnow	96.5% Tech.	> 1.0	Supplemental
Sheepshead minnow	9.7% EC	5.6	Supplemental

103.2.6 Aquatic Invertebrate LC_{50}

Species	Formulation	LC_{50} (ppm)	Category
Mysid shrimp	96.5% Tech.	0.098 ppm	Core
Mysid shrimp	9.7% EC	1.71 ppm	Core
Eastern Oyster	96.5% Tech.	0.25 ppm	Supplemental
Eastern Oyster	9.7% EC	2.0 ppm	Supplemental

103.4 Additional Aquatic Laboratory Tests

103.4.1 Toxicity to Estuarine and Marine Animals

96-hour LC_{50} for sheepshead minnow (using technical and formulated product) (§72-3).

103.4.2 Embryo-Larvae

48-hour embryo-larvae study (using technical and formulated product) (§72-3).

104.0 Discussion:

Based upon the available data, technical Whip is very highly toxic to mysid shrimp (0.098 ppm), highly toxic to eastern oysters (0.25 ppm), and moderately toxic to sheepshead minnow (< 1.0 ppm). One must keep in mind that only the mysid shrimp studies are of Core status.

Whip is very highly toxic to marine/estuarine invertebrates, with an LC_{50} of 0.098 ppm to mysid shrimp (the most sensitive species).

104.2 Likelihood of Adverse Effects to Nontarget Organisms:

A single application of Whip 1 EC applied to rice field at the rate of 1.6 pt ai/A will produce the following concentrations after 26 days:

1.6 pt (appl. rate) x 0.125 (12.50% ai) x 1.3 (spec. density density = 1.3) x 8.33 lb = 8 pt (pt-lb conversion) = 0.27 lb (per A)

$$K = \text{(hyrolysis breakdown rate)} = \frac{\ln Co - \ln Ct}{t} = \frac{\ln(1) - \ln(0.5)}{t_{1/2}} = \frac{0.693}{5} = 0.1386$$

$$\ln Ct = \ln Co - k.t = \ln(0.27) - (0.1386)(26) = -1.309 - 3.604 = -4.913$$

$$Ct = C \text{ 26 days} = \ln^{-1} Ct = \ln^{-1}(-4.913) = 0.0074\text{-lb (residue on the 26th day)}$$

Conc. in rice field	EEC in Bayou	EEC in River
4-lbs*	25.1 ppb	10.5 ppb
0.0074-lb	0.046 ppb*2	0.019 ppb*3
0% breakdown after 26 days (0.27 lb)	1.6 ppb*4	0.7 ppb

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*1From actual field monitoring study (See review by C. Natella dated February 12, 1986).

*2EEC in bayou = 25.1 ppb x $\frac{0.0074 \text{ lb}}{4 \text{ lb}}$ = 0.046 ppb

*3EEC in river = 10.5 ppb x $\frac{0.0074 \text{ lb}}{4 \text{ lb}}$ = 0.019 ppb

*40% breakdown in rice field after 26 days = 0.7 ppb.

The mysid shrimp is the most sensitive aquatic organism to technical Whip with an LC_{50} of 98 ppb which is 2130 times greater than the concentration of Whip 1 EC in bayou and 5,157 times greater than the concentration of Whip 1 EC in a river after 26 days (If

rice is greater than 8 inches in height, the field can be reflooded in 4 to 5 days following application. The water depth (flush or flood) should not exceed 3 inches for at least 21 days after the Whip 1 EC herbicide application). The 0% breakdown after 26 days is 1.69 ppb for bayou and 0.7 ppb for river. The mysid shrimp LC_{50} (98 ppb) is 61.25 and 140 times greater than the concentration of Whip 1 EC in bayous and rivers after 26 days. These values are well below the aquatic hazard trigger of 1/2 the LC_{50} for the most sensitive species (1/2 98 ppb = 46 ppb) and indicate a lack of acute hazard to marine/estuarine invertebrates.

For additional information, see the review by C. Natella dated February 2, 1986 for freshwater species.

104.3 Endangered Species Consideration:

The endangered species consideration for both freshwater and marine/estuarine species will not be addressed until the required marine/estuarine studies are re-done, submitted and meet guideline requirement.

105.0 Conclusions:

Ecological Effects Branch (EEB) has reviewed the additional data (marine/estuarine studies) submitted by the registrant in support of rice and soybeans registration. EEB is unable to complete a full risk assessment (3)(c)(5) finding for these uses because pertinent ecological effects data are lacking. In order to assess the risk associated with these uses, EEB has concluded the following:

1. Four of the six estuarine studies were supplemental and will have to be reconducted (§72-3);

2. Phytotoxicity data are required;

3. Residue monitoring is not necessary; and

4. Endangered species concerns are not indicated at this time. However, results of re-doing the oyster studies will have to be evaluated before endangered species issues are completely eliminated.

Estuarine Studies

Of the estuarine studies submitted, 4 were supplemental;

shrimp are most sensitive of the three species tested. The supplemental studies should be reconducted. However, the problems with the supplemental studies still allow us to draw some conclusions on acute effects to estuarine fish and mollusks. That is, new studies would probably not change our conclusions that shrimp are most sensitive and the expected levels are far below the lowest NOEL of shrimp, 50 ppb. If the results of the oyster study indicate possible effects to endangered mussel species, consultation with USFWS and possibly labeling restrictions may be required.

The registrant:

a. Knew these estuarine studies were a requirement; and
b. Should know the appropriate protocol and guideline requirements for such studies.

The studies submitted (on both the technical and formulated product) for sheepshead minnow and oyster embryo larvae were unacceptable for the following reasons:

a. The sheepshead minnow study cannot be used to support registration because the LC_{50} was not established as outlined in Subdivision E section 72-3(3)(i)(A) and the fish were fed prior and during the test; and

b. The oyster embryo larvae study cannot be used to support registration because the dose levels used were too high to establish the no-observable effect level as outlined in Subdivision E Section 70-4(7)(iii) and the control mortality was greater than 30%.

Phytotoxicity Data

Phytotoxicity data are needed so we can assess potential impact to nontarget plants and habitat. This includes both terrestrial and aquatic phytotoxicity studies. This is aimed at precluding an incident such as occurred with Command. Phototoxicity testing guidelines are being modified to avoid future "Command" incidents, thus the registrant would not have known that such testing would be required.

Residue Monitoring

The expected environmental concentrations (EEC) predicted by EEB indicate that at worst, concentrations in bayous adjacent to rice fields would not exceed 6.6 ppb. This EEC is based on the assumption that 0.27 lbs ai is applied and the field flooded to 3" 5 days later. The concentration would be 22 ppb.

110 ppb X 0.2 = 22 ppb

(potential conc.) (20% in water col.)

If 2" rainfall occurred at day 7, concentration in field would be 13.2 ppb.

22 ppb X 3/5 = 13.2 ppb out flow
(dilution of 3" by 2 inches of rain)

This 13.2ppb would be diluted by the receiving bayou.

13.2 ppb X 0.5 = 6.6ppb in adjacent bayou
(estimated dilution)

This concentration is the maximum that could be in the adjacent bayou, and would only occur without any dilution from the receiving water. This level is below the lowest LC50 available (shrimp) and below the shrimp NOEL of 50 ppb. Therefore, based on our criteria for requesting monitoring, no additional field monitoring is necessary. It is unlikely that the results of new, core estuarine studies (oyster and fathead minnow) would trigger monitoring requirement because of Whip's short halflife (<4 days) in both water and sediment, and low use rate (0.27 lb. ai/acre).

Endangered Species

The only endangered species occurring within rice use areas is the fat pocketbook pearly mussel (Potamilus capax) which is in the St. Francis River in Arkansas. The supplemental data indicate that mussels are probably not sensitive enough to Whip to be adversely affected by expected exposure levels. If the new, core mussel data show that mussels are more sensitive than expected, consultation with USFWS may be required. The outcome of a jeopardy opinion would likely result in the need for labeling restrictions to protect this endangered mussel species.

Curtis E. Laird 1-30-87
Curtis E. Laird, Fishery Biologist
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

Norman Cook 2.3.87
Norman Cook, Head-Section II
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

Michael Slimak 2/4/87
Michael Slimak, Chief
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

DATA EVALUATION RECORD

1. Chemical: Whip

2. Test Material: 9.7% ai (formulation)

3. Study Type: 96-hour LC_{50}

   Species tested: Sheepshead Minnow

4. Study ID: Ward, G.S. (1986) Acute Toxicity of HOE 033171 to the Sheepshead Minnow (Cyprindon variegatus); ESE No. 86-341; Prepared by Environmental Science and Engineering, Inc. for Hoechst-Roussel Agri-Vet Company, Somerville, NJ; Accession No. 265260.

5. Reviewed by: Curtis E. Laird, Fishery Biologist, EEB/HED — Signature: Curtis E. Laird — Date: 1-21-87

6. Approved by: Norman J. Cook, Supervisory Biologist, EEB/HED — Signature: Norman J. Cook — Date: 2.3.87

7. Conclusions:

This study appears to indicate Whip is moderately toxic to sheepshead minnow with an LC_{50} of 5.6 ppm. However, this study does not fulfill the requirement in support of registration for a marine/estuarine fish study because the fish were fed prior to and during the acute toxicity test (see ASTM p. 13 Feeding 11.6 and Methods for Acute Toxicity Tests With Fish, Macroinvertebrates, and Amphibians p. 37; section 7 Feeding).

8. Recommendations:

Another study must be conducted using the sheepshead minnow weighing in the range of 0.5 to 5.0 grams. The test "organisms should not be fed while in test chambers. If cannibalistic organisms cannot be physically restrained or separated, however, minimal feeding is necessary. Organisms should not be fed during acute toxicity tests or for a time before then when possible (10.7.3), because fecal matter and uneaten food will decrease the oxygen concentration and alter the biological activity of some toxicants (ASTM p. 13; E729).

9. Background:

This study was requested by EEB to support rice and soybeans registration.

10. Discussion of Individual Test: N/A

11. Materials and Methods:

a. Test Animals: Test animals were sheepshead minnow (Cyprindon variegatus) from laboratory culture; mean weight = 0.028 g; mean SL = 11 ± 1 mm; age 2 to 3 weeks old.

b. Test System: 1.6 liter (L) glass test container with 1 L of test solution; static exposure to test solution at 22 °C; 96 hours duration.

c. Dose: Static bioassay using nominal concentration; no solvent used.

d. Design: 10 fish per level; 5 dose levels plus control (0, 1.34, 2.77, 3.71, 6.8, 10.3 ppm).

e. Statistics: Stephan et al. 1982 (binomial).

12. Reported Results:

The study author found that the 96-hour LC_{50} was 5.6 ppm for whip 9.7% EC. The no-effect concentration was 3.71 ppm.

13. Study Authors' Conclusions:

The 96-hour LC_{50} was 5.6 ppm. This study was conducted and complies with published Good Laboratory Practices (GLP) for tests or substances regulated under the Toxic Substances Control Act and the Federal Insecticide, Fungicide, and Rodenticide Act. The test data were reviewed by the Quality Assurance Unit to assure that standard operating procedures and protocol used in the conductance of this test were followed.

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

a. Test Procedures: The test procedures complied with the recommended EPA protocol of October 1982 except for the following reasons:

1. Fish weight was 0.028 g instead of from 0.5 to 5.0 g;

2. Fish were fed during the test; and

3. Food was not withheld prior to testing.

b. Statistical Analysis: The binomial test shows the 96-hour LC_{50} to be approximately 5.6 ppm.

c. Discussion/Results: With the 96-hour LC_{50} of 5.6 ppm indicates Whip is moderately toxic to sheepshead minnow.

d. Adequacy of Study:

1. Category: Supplemental.

2. Rationale: See test procedure above.

3. Repairability: Not repairable to core.

15. Completion of One-Liner: Yes.

16. CBI Appendix: N/A.

LAIRD WHIP 96-HOUR LC_{50} FOR SHEEPSHEAD MINNOW

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
10.3	10	10	100	9.765625E-02
6.8	10	8	80	5.46875
3.71	10	0	0	9.765625E-02
2.77	10	0	0	9.765625E-02
1.34	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 3.71 AND 10.3 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 5.619367

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: Whip

2. Test Material: 96.5% (technical ai)

3. Study Type: 96-hour LC_{50}

   Species Tested: Sheepshead minnow

4. Study ID: McAllister, W.A. (1986) Acute Toxicity of HOE-33171 Technical Substance (Code: HOE 033171 OHZD98 0001) to Sheepshead Minnow (Cyprinodon variegatus): Report No. 33977; Prepared by Analytical Bio-Chemistry Laboratories, Inc. for Hoechst-Roussel Agri-Vet Company, Route 202-206 North Somerville, NJ 08876; Accession No. 265260.

5. Reviewed by: Curtis E. Laird
   Fishery Biologist
   EEB/HED
   Signature: Curtis E. Laird
   Date: 1-21-87

6. Approved by: Norman J. Cook
   Supervisory Biologist
   EEB/HED
   Signature: Norman J. Cook
   Date: 2.3.87

7. Conclusions:

   It appears that Whip is moderately toxic to sheepshead minnow with an LC_{50} > 1.0 mg/L. However, this study does not fulfill the requirement in support of registration for a marine/estuarine fish study because the LC_{50} was not established as outlined in Subdivision E section 72-3(3)(i)(A).

8. Recommendations:

   Conduct another study using dose levels high enough to establish the LC_{50} value with 95% confidence intervals.

9. Background:

   This study was requested by EEB to support rice and soybean registration.

10. Discussion of Individual Test: N/A.

11. Materials and Methods:

a. Test Animals: Test animals were 0.63 g sheepshead minnows from Multiaqua Culture System, Amagansett, NY.

b. Test System: 5-gallon glass vessels with 15 L of test solution; static exposure to test solution at 22 °C; 96-hour duration.

c. Dose: Static bioassay using nominal concentrations plus negative and solvent controls.

d. Design: 10 fish per level; 5 levels plus negative and solvent controls (0, DMF, 0.1, 0.18, 0.32, 0.56, and 1.0 ppm).

e. Statistics: Stephan et al.

12. Reported Results:

The study author found that the 96-hour LC_{50} was > 1.0 mg/L for Whip 96.5% ai.

13. Study Authors' Conclusions:

The 96-hour LC_{50} was > 1.0 mg/L. The study was conducted in accordance with ABC Laboratories' intent that all studies conducted at their facilities are designed and functioned in conformance with good laboratory conductance. An inspection of the final report for HOE 33171 was conducted and found to be in an acceptable form by a member of Analytical Bio-Chemistry Laboratories, Inc. Quality Assurance Unit.

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

a. Test Procedures: The test procedures complied with the recommended EPA protocol of October 1982 (Part 158) except the 96-hour LC_{50} value was not established.

b. Statistical Analysis: No statistics were performed due to lack of mortality.

c. Discussion/Results: With an LC_{50} >1.0 ppm for Whip 96.5% ai is moderately toxic to sheepshead minnow.

d. Adequacy of Study:

1. Category: Supplemental.
2. Rationale: See section 7 above.
3. Rapairability: no repairable to core.

15. Completion of One-Liner: Yes.

16. CBI Appendix: N/A.

DATA EVALUATION RECORD

1. Chemical: Whip

2. Test Material: 9.7% ai (formulated)

3. Study Type: 96-hour LC_{50}

   Species Tested: Mysid Shrimp (Mysidopsis bahia)

4. Study ID: Ward, G.S. (1986) Acute Toxicity of HOE 033171 to the Mysid Shrimp (Mysidopsis bahia); ESE No. 86-341; Prepared by Environmental Science and Engineering, Inc. for Hoechst-Roussel Agri-Vet Company, Somerville, NJ; Accession No. 265260.

5. Reviewed by: Curtis E. Laird, Fishery Biologist, EEB/HED — Signature: Curtis E. Laird — Date: 1-21-87

6. Approved by: Norman J. Cook, Supervisory Biologist, EEB/HED — Signature: Norman J. Cook — Date: 2.3.87

7. Conclusions:

   This study indicates Whip is moderately toxic to mysid shrimp with an LC_{50} of 1.71 ppm. This study does fulfill the requirement in support of registration for a marine/estuarine invertebrate.

8. Recommendations: N/A.

9. Background:

   This study was requested by EEB to support rice and soybean registration.

10. Discussion of Individual Test: N/A.

11. Materials and Methods:

a. Test Animals: Test animals were 3 to 4-day old mysid shrimp from laboratory stock.

b. Test System: 1.6 L glass container with 1 L of test solution; static exposure to 21 ± 1 °C test solution; 96 hours duration.

c. Dose: Static bioassay using nominal concentration; no solvent was used.

d. Design: 10 shrimp per level; 6 levels plus control (0, 0.258, 0.515, 1.03, 2.06, 4.12, and 8.24 ppm).

e. Statistics: Stephan's et al (binomial)

12. Reported Results:

The study author found that the 96-hour LC_{50} was 1.71 ppm for Whip 9.7% ai. The no-effect level was 1.03 ppm.

13. Study Authors' Conclusions:

The 96-hour LC_{50} was 1.71 ppm. This study was conducted and complies with published Good Laboratory Practices (GLP) for tests of substances regulated under the toxic substance control act and the Federal Insecticide, Fungicide, and Rodenticide Act. The test data were reviewed by the Quality Assurance Unit to assure that standard operating procedures and protocol used in the conductance of this test were followed.

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

a. Test Procedures: The test procedure complied with the recommended EPA protocol of October 1982 (Part 158).

b. Statistical Analysis: The statistics were verified using the binomial test.

c. Discussion/Results: With the 96-hour LC_{50} of 1.7 ppm, Whip EC, a representative 9.7% ai formulation, is moderately toxic to mysid shrimp.

d. Adequacy of Study:

1. Category: Core.

2. Rationale: N/A.

3. Repairability: N/A.

15. Completion of One-Liner: Yes.

16. CBI Appendix: N/A.

LAIRD WHIP 9.7% A.AI. 96-HOUR LC_{50} FOR MYSID SHRIMP

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
8.24	10	10	100	.0976563
4.12	10	10	100	.0976563
2.06	10	8	80	5.46875
1.03	10	0	0	.0976563
.515	10	0	0	.0976563
.258	10	0	0	.0976563

THE BINOMIAL TEST SHOWS THAT 1.03 AND 4.12 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 1.65622

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: Whip

2. Test Material: 96.5% (technical ai) a white solid.

3. Study Type: 96-hour LC50

   Species Tested: Mysid Shrimp (Mysidopsis bahia)

4. Study ID: Forbis, A.D. (1986) Acute Toxicity of HOE-33171 Technical Substance (Code: HOE 033171 OH ZD 98 0001) to Mysid Shrimp (Mysidopsis bahia ; Report No. 33979; Prepared by Analytical Bio-Chemistry Laboratories for Hoechst-Roussel Agri-Vet Company, Route 200-206 North, Somerville, NJ 08876; Accession No. 265260.

5. Reviewed by: Curtis E. Laird, Fishery Biologist, EEB/HED — Signature: Curtis E. Laird — Date: 1-21-87

6. Approved by: Norman J. Cook, Supervisory Biologist, EEB/HED — Signature: Norman J. Cook — Date: 2.3.87

7. Conclusions:

This study indicates Whip is very highly toxic to mysid shrimp with an LC_{50} of 0.098 ppm. This study does fulfill the requirement in support of registration for a marine/estuarine invertebrate study.

8. Recommendations: N/A.

9. Background:

This study was requested by EEB to support rice and soybean registration.

10. Discussion of Individual Test: N/A.

11. Materials and Methods:

a. Test Animals: Test animals were 3 to 4-day old mysid shrimp from aquatic indicator.

b. Test System: 400 mL glass beakers with 300 mL of test solution; exposure to test solution at 22 ± 2 °C; 96 hours duration.

c. Dose: Static bioassay using nominal concentrations. Acetone was used as a solvent.

d. Design: 10 shrimp per level; 6 dose levels plus negative and solvent control.

e. Statistics: Stephans' et al program.

12. Reported Results:

The study author found the 96-hour LC_{50} to be 0.098 ppm for Whip 95.6% ai. The no-effect level was 0.05 ppm which was based on the lack of mortality and abnormal effects.

13. Study Authors' Conclusions:

The 96-hour LC_{50} was 0.098 (0.068 to 0.15) ppm. The no-effect level was 0.05 ppm. All studies conducted at their facilities are designed and functioned in conformance with Good Laboratory Practice regulations and the protocol for individual laboratory studies. An inspection of the amended final report for HOE-033171 was conducted and found to be in an acceptable form by a member of the Quality Assurance Unit.

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

a. Test Procedures: The test procedure complied with the recommended EPA protocol of October 1982 (Part 158).

b. Statistical Analysis: The statistics were verified with the moving average method.

c. Discussion/Results: With the 96-hour LC_{50} of 0.098 ppm indicates technical Whip is very highly toxic to mysid shrimp.

d. Adequacy of Study:

1. Category: Core

2. Rationale: N/A.

3. Repairability: N/A.

15. Completion of One-Liner: Yes

16. CBI Appendix: N/A.

LAIRD WHIP 1EC 48-HOUR EC_{50} FOR EASTERN OYSTERS

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
.4	10	10	100	.0976563
.2	10	10	100	.0976563
.1	10	3	30	17.1875
.05	10	0	0	.0976563
.025	10	1	10	1.07422
012	10	0	0	.0976563

THE BINOMIAL TEST SHOWS THAT .05 AND .2 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 .117143

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
5	.115988	.0981718	.0687296	.152833

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
7	1.52733	3.61492	5.96416E-03

SINCE THE PROBABILITY IS LESS THAN 0.05, RESULTS CALCULATED USING THE PROBIT METHOD PROBABLY SHOULD NOT BE USED.

SLOPE = 3.92779
95 PERCENT CONFIDENCE LIMITS = .92638 AND 8.78197

LC50 = .1019
95 PERCENT CONFIDENCE LIMITS = 0 AND INFINITY

LC10 = .0483989
95 PERCENT CONFIDENCE LIMITS = 0 AND .10714

DATA EVALUATION RECORD

1. Chemical: Whip 1 EC

2. Test Material: 96.5% (technical ai), a white powder

3. Study Type: 48-hour embryo-larvae

   Species Tested: Eastern Oyster

4. Study ID: Surprenant, D.C. (1986) Acute Toxicity of HOE-033171 Technical To Embryo-Larvae of Eastern Oysters (Crassostrea virginica); Report No. BW-86-8-2124; Prepared by Springborn Bionomics, Inc. for Hoechst-Roussel Agri-Vet Company, Somerville, NJ 08876; Accession No. 265260

5. Reviewed by: Curtis E. Laird, Fishery Biologist, EEB/HED — Signature: Curtis E. Laird — Date: 1-21-87

6. Approved by: Norman J. Cook, Supervisory Biologist, EEB/HED — Signature: Norman J. Cook — Date: 2.3.87

7. Conclusions:

This study appears to indicate Whip is highly toxic to Eastern oyster with an EC_{50} of 0.25 ppm. This study does not fulfill the requirement in support of registration for an Eastern oyster embryo-larvae study because the dosage levels were too high to establish the no-effect level and control mortality was greater than 30%. Test should be reevaluated based on modifications to SEP by D. Reid, Nov. 20, 1987.

8. Recommendations:

Conduct another study using [illegible] ough to establish the no-effect level.

9. Background:

This study was requested by [illegible] and soybean registration.

10. Discussion of Individual Test: N/A.

Ordered 265260 12-21-87

11. Materials and Methods:

a. Test Animals: Test animals were 2-hour-old fertilized Eastern oyster eggs.

b. Test System: 3 L test vessel with 1 L test solution at 20 °C, 48 hours duration.

c. Dose: Static bioassay to nominal concentration; DMF was used as a solvent.

d. Design: 26,400 oyster per level; 5 levels plus a negative and solvent control (0, DMF, 0.18, 0.32, 0.52, 0.87, and 1.4 ppm).

e. Statistics: Linear regression analysis.

12. Reported Results:

The study author found that the 48-hour EC_{50} was 0.25 (0.15 - 0.38) ppm for Whip 96.5% ai.

13. Study Authors' Conclusions:

48-hour EC_{50} was 0.25 ppm. This study was produced and complied in accordance with all pertinent EPA Good Laboratory Practice regulations except in the case of characterization and verification of the test substance identity. The data contained in this report were audited by the Quality Assurance Unit to assure compliance with the Protocols, standard operating procedures and pertinent EPA Good Laboratory Practice regulations.

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

a. Test Procedures: The test procedure complied with the recommended EPA protocol of October 1982 (Part 158) except the dose levels were too high to establish the no-effects level.

b. Statistical Analysis: Statistics were verified with probit method.

c. Discussion/Results: With the 48-hour EC_{50} of 0.25 (0.15 to 0.38) ppm indicates Whip is highly toxic to the Eastern oysters.

d. Adequacy of Study:

1. Category: Supplemental.

2. Rationale: See section 7 above.

3. Repairability: Not repairable.

15. Completion of One-Liner: Yes.

16. CBI Appendix: N/A.

LAIRD WHIP 1EC 48-HOUR EC_{50} FOR EASTERN OYSTERS

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
1.4	16467	15972	96.994	0
.87	16467	16137	97.996	0
.52	16467	16137	97.996	0
.31	16467	12679	76.9964	0
.18	16467	1976	11.9998	0

BECAUSE THE NUMBER OF ORGANISMS USED WAS SO LARGE, THE 95 PERCENT CONFIDENCE INTERVALS CALCULATED FROM THE BINOMIAL PROBABILITY ARE UNRELIABLE. USE THE INTERVALS CALCULATED BY THE OTHER TESTS.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .249711

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
2	1.00956E-04	.253826	.252653	.255196

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
7	4.92233	9797.9	0

SINCE THE PROBABILITY IS LESS THAN 0.05, RESULTS CALCULATED USING THE PROBIT METHOD PROBABLY SHOULD NOT BE USED.

SLOPE = 4.4299
95 PERCENT CONFIDENCE LIMITS = 5.39842 AND 14.2582

LC50 = .257319
95 PERCENT CONFIDENCE LIMITS = 0 AND INFINITY

LC10 = .132979
95 PERCENT CONFIDENCE LIMITS = 0 AND INFINITY

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DATA EVALUATION RECORD

1. Chemical: Whip 1 EC

2. Test Material: 9.7% formulated product

3. Study Type: 48-Hour EC_{50} for embryo-larvae

   Species Tested: Eastern Oysters

4. Study ID: Surprenant, D.C. (1986) Acute Toxicity of HOE-033171 EC10 To Embryo-Larvae of Eastern Oysters (Crassostrea virginica); Report No. BW-86-8-2123; Prepared by Springborn Bionomics, Inc. for Hoechst-Roussel Agri-Vet Company; Somerville, NJ 08876; Accession No. 265260.

5. Reviewed by: Curtis E. Laird, Fishery Biologist, EEB/HED — Signature: Curtis E. Laird — Date: 1-21-87

6. Approved by: Norman J. Cook, Supervisory Biologist, EEB/HED — Signature: Norman J. Cook — Date: 2.3.87

7. Conclusions:

This study appears to indicate Whip 1 EC is moderately toxic to Eastern oysters with an EC_{50} of 2.0 ppm. However, this study does not fulfill the requirement in support of registration for a marine/estuarine invertebrate study due to dose levels being too high to establish the no-observable-effect level.

8. Recommendations:

Conduct another study using lower dose levels in order to establish the no-effect level for Eastern oysters.

9. Background:

This study was requested by EEB to support rice and soybean registration.

10. Discussion of Individual Test: N/A.

11. Materials and Methods:

a. Test Animals: Test animals were oyster eggs released in the presence of viable sperm exercised from the gonad of a sexually matured male oyster. The oysters were obtained from Seapit River, Cape Cod, MA.

b. Test System: 1 L glass beakers with 900 mL of test solution; static exposure to 20 °C; 48-hour duraton.

c. Dose: Static bioassay using nominal concentration; no solvent was used.

d. Design: 26,400 embryos per level; 5 levels plus control (0, 2.0, 3.4, 5.7, 9.3, and 15.5 ppm).

e. Statistics: Linear regression analysis.

12. Reported Results:

The study author found that 48 EC_{50} was 2.0 ppm for Whip 9.7% 1 EC. The no-observable-effect level was not given.

13. Study Authors' Conclusions:

The 48-hour EC_{50} was 2.0 ppm. This study was produced and complied in accordance with all pertinent EPA Good Laboratory Practice regulations except in the case of characterization and verification of the test substance identity. The data contained in this report were audited by the Quality Assurance Unit to assure compliance with the protocols, standard operation procedures and the pertinent EPA Good Laboratory Practice Regulation.

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

a. Test Procedures: The test procedure complied with the recommended EPA protocol of October 1982 (Part 158) except the no-effect level was not established.

b. Statistical Analysis: The statistics were verified with probit analysis.

c. Discussion/Results: With the 48-EC_{50} of 2.0 ppm indicates that Whip 1 EC is moderately toxic to Eastern oysters.

d. Adequacy of Study:

1. Category: Supplemental.

2. Rationale: See section 7 above.

3. Repairability: Not repairable to core.

15. Completion of One-Liner: Yes

16. CBI Appendix: N/A.

LAIRD WHIP 1EC 48-HOUR EC_{50} FOR EASTERN OYSTERS

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
15.5	16933	16933	100	0
9.3	16933	16933	100	0
5.7	16933	16933	100	0
3.4	16933	15747	92.9959	0
2.	16933	8466	49.9971	0

BECAUSE THE NUMBER OF ORGANISMS USED WAS SO LARGE, THE 95 PERCENT CONFIDENCE INTERVALS CALCULATED FROM THE BINOMIAL PROBABILITY ARE UNRELIABLE. USE THE INTERVALS CALCULATED BY THE OTHER TESTS.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 2.00006

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
1	4.23503E-04	2.00006	1.98445	2.01534

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	.0113053	9.99772	0

SINCE THE PROBABILITY IS LESS THAN 0.05, RESULTS CALCULATED USING THE PROBIT METHOD PROBABLY SHOULD NOT BE USED.

SLOPE = 6.58057
95 PERCENT CONFIDENCE LIMITS = 5.88089 AND 7.28026

LC50 = 2.00507
95 PERCENT CONFIDENCE LIMITS = 1.93483 AND 2.06985

LC10 = 1.28569
95 PERCENT CONFIDENCE LIMITS = 1.18825 AND 1.37176