1-6-82

028201
SHAUGHNESSEY NO.

20
REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 10/27/81 OUT 1/06/82

FILE OR REG. NO. 707-75

PETITION OR EXP. PERMIT NO.

DATE RECEIVED BY HED 10/27/81

DATE OF SUBMISSION 10/7/81

RD REQUESTED COMPLETION DATE 2/27/82

EEB ESTIMATED COMPLETION DATE

RD ACTION CODE/TYPE OF REVIEW 400/Data Submission -- Not 6(a)(2)

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

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. R. Taylor (25)

PRODUCT NAME(S) Stampede

COMPANY NAME Rohm and Haas Company

SUBMISSION PURPOSE Submission of Data in Support of Conditional Registration

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
028201	Propanil: 3', 4'-Dichloropropanilide	88%

100.0 Purpose of Submission

Validation of toxicity studies required for the Conditional Registration of Stampede 3E herbicide on wheat.

103.0 Toxicological Properties

Chemical: STAM

Formulation: Technical (88% active ingredient)

Test type: Fish acute (EPA Acc. # 246087)

Test organism: Rainbow trout

		95 % C. I.
Results:	LC50 = 2.3 mg/l	(1.8 - 3.0)

Validation Status: Core

Comments: See attached validation sheets.

Chemical: STAM

Formulation: Technical (88% active ingredient)

Test type: Avian dietary (EPA Acc. # 246087)

Test organism: Mallard duck

		95% C. I.
Results:	LC50 = >5,000 ppm	(N. A.)

Validation Status: Core

Comments: See attached validation sheets.

104.0 Discussion

Stampede 3E Herbicide (EPA Reg. 707-75) was conditionally registered on April 30, 1980. Toxicity studies required by EEB as a condition of the registration were (Leitzke 4/11/80):

1. Two avian subacute LC50 dietary studies (preferably, mallard duck and bobwhite quail).

2. A 96-hour acute LC50 for a coldwater fish species (rainbow trout).

3. A field residue monitoring study.

In a subsequent review concerning the registration of Stampede 3E on barely and oats this Branch also noted that the registrant's data base was deficient in the following basic studies (Johnston 8/27/81):

1. A 96-hour acute LC50 for a warmwater fish species (bluegill sunfish).

2. An acute 48-hour LC50 for an aquatic invertebrate species (preferably, Daphnia sp.).

Since the above requirements were overlooked in the initial review, data requirements cited in Section 107.5 are now required to support the Conditional Registration of Stampede 3E on wheat.

107.0 Conclusions

107.1 Classification

No classification will be suggested until all data gaps have been filled.

107.2 Data Adequacey

The following bioassays have been classified as acceptable and can be used in support of the Conditional Registration of Stampede 3E on wheat:

1. The acute toxicity of STAM to rainbow trout (EPA Acc. # 246087).

2. Eight day dietary LC50 study in mallard duck with STAM (EPA Acc. # 246087).

107.5 Additional Data Required**

The following data are required to support to Conditional Registration of Stampede 3E on wheat:

1. An 8-day dietary LC50 study for an upland gamebird (preferably the bobwhite quail).

2. A 96-hour LC50 study for a warmwater fish species (preferably the bluegill sunfish).

3. A 48-hour LC50 study for an aquatic invertebrate (preferably Daphnia sp.)

4. Field residue monitoring study; the general protocol for this (as cited in the Leitzke 4/11/80 review) calls for triplicate water and hydrosoil samples (for propanil, 3,4-DCA and TCAB) pre- and post application for enough time to establish a decline curve; at least one of the experimental ponds must be immediately adjacent to and downwind of a large wheat field being treated; since propanil can be applied either aerially or on the ground, two sets of experimental ponds for these two uses must be sampled.

Conditions 1 through 3 should be conducted with technical propanil

**Note to PM 25- See Section 104 for changes in data required to support Conditional Registration.

Charles A Bowen II 1/6/82
Charles A. Bowen II
Fisheries Biologist, Section I
Ecological Effects Branch / HED

for Dennis McLane 1/6/82
Raymond Matheny
Head, Section I
Ecological Effects Branch / HED

Clayton Bushong Clayton Bushong 1/6/82
Chief
Ecolgical Effects Branch / HED

Chemical: STAM

Formulation: Technical (88% active ingredient)
Lot #2-3634

Citation: LeBlanc, G.A. 1980. Acute toxicity of STAM technical (TD No. 80-198) to Rainbow trout. EG&G, Bionomics, Wareham, Massachusetts. EPA Acc. #246087.

Reviewed by: Charles A. Bowen II
Title: Fish and Wildlife
Organization: EEB/HED
Telephone: 557-5651

Test Type: 96-hour Static Freshwater Bioassay

A. Test Organism: Rainbow trout (Salmo gairdneri)

Reported Results:

The 96-hour LC_{50} of STAM technical to Rainbow trout is 2.3 mg/l (95% C.I. 1.3-3.0 mg/l). The 96-hour no discernible effect concentration was estimated to be 1.8 mg/l active ingredient per liter.

Reviewer's Conclusions:

This bioassay is scientifically sound and demonstrates that STAM (88% A.I.) is moderately toxic to coldwater fishes. This study can be used to support product registration.

Materials and Methods:

Unless otherwise stated, procedures used in this acute toxicity test followed those described in "Methods for acute toxicity tests with fish, macroinvertebrates, and amphibians" (U.S. EPA, 1975) and the "EG&G, Bionomics Protocol for Freshwater Static Acute Toxicity Tests with Fish" (1979).

Methods specific to this bioassay are as follows:

1. All test solution temperatures were controlled by a system designed to maintain temperature at 12 $\pm$ 1°C. Test solutions were not aerated. The photoperiod during testing was 16 hours light and 8 hours darkness.

2. Ten Rainbow trout with a mean (range, N=30) wet weight and total length of 1.0 (0.64-1.52) g and 49 (43-55) millimeters (Fish Weights and Lengths Log) were randomly distributed to each test jar within 15 minutes after the test solutions had been prepared.

Author's Results:

The 96-hour LC_{50} with 95% confidence intervals for STAM to Rainbow trout is 2.3 mg/l (1.8-3.0 mg/l). Percent mortalities and LC_{50} values with their respective confidence intervals are shown below:

Nominal concentration (mg/l)	xxx Percentage mortality			
	24 hour	48 hour	72 hour	96 hour
5.0	100	100	100	100
3.0	0[a,b,c]	70[a,d]	100	100
1.8	0	0	0	0
1.1	0	0	0	0
0.65	0	0	0	0
0.39	0	0	0	0
control	0	0	0	0
control (TEG)[e]	0	0	0	0

xxx Ten fish were exposed to each concentration.
[a] Some fish exhibited a complete loss of equilibrium.
[b] One fish was at the surface.
[c] Some fish exhibited dark pigmentation.
[d] Some fish were lethargic.
[e] triethylene glycol (TEG).

V

		LC50 Values Estimated by binomial probability method			
		24 hour	48 hour	72 hour	96 hour
LC50 mg/l		3.9	3.0	2.3	2.3
95% Confidence Interval	Low	3.0	1.8	1.8	1.8
	High	5.0	5.0	3.0	3.0

The 96-hour no-effect level was observed to be 1.8 mg/l.

EEB Statistical Validation:

Conc.	Number Exposed	Number Dead	Percent Dead	Binomial Prob. (Percent)
5	10	10	100	0.09765625
3	10	10	100	0.09765625
1.8	10	0	0	0.09765625
1.1	10	0	0	0.09765625
0.65	10	0	0	0.09765625
0.39	10	0	0	0.09765625

The binomial test shows that 1.8 and 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 2.32379.

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.

Statistical Conclusions:

LC50 values calculated by the above methods do not differ significantly from the value reported by the author.

Validity of Author's Conclusions:

The conclusions drawn by the author are supported by the dose related mortality data cited under Author's Results.

Validation Status: Core

Validation Rationale:

The methods employed by the registrant's testing facility adhere to EPA's current guidelines for static freshwater testing. The author's conclusions are supported by the dose related mortality data cited earlier (See Author's Results).

Category Repairability: N.A.

Chemical: STAM

Formulation: Technical (88% active ingredient)

Citation: Piccirillo, V.J. 1981. Eight-day dietary LC_{50} study in mallard ducks with STAM. Borriston Research Laboratories, Inc., Temple Hills, Maryland. EPA Acc. #246087.

Reviewed by: Charles A. Bowen II
Title: Fish and Wildlife
Organization: EEB/HED
Telephone: 557-5651

Test Type: Eight-day Subacute Avian Bioassay

A. Test Organism: Mallard duck (Anas platyrhynchos)

Reported Results:

The LC_{50} of STAM is estimated to be greater than 5000 ppm. Birds in all treated groups exhibited dose-related loss of body weight (40-60%) and depressed food consumption (65-90%) from day 1 through 5 of the study.

Reviewer's Conclusions:

This bioassay is scientifically sound and demonstrates that STAM (88% active ingredient) is practically non-toxic to waterfowl. This study can be used to support product registration.

Materials and Methods:

Bioassay protocols used by Borriston Laboratories are outlined in detail in the review cited below:

Piccirillo, V.J. 1980. Eight-day dietary LC_{50} study in bobwhite quail with RH-8817. (Bowen 12/15/81)

Methods specific to this bioassay are cited below:

1. STAM technical, lot 2-3634, 88% active ingredient, TD 80-198 was incorporated into the diets of 17 day-old mallard ducklings Anas platyrhynchos and fed for 5 consecutive days, ad libitum, at concentrations of 1000, 1260, 1780, 2510, 3550, and 5000 ppm (active ingredient).

2. Food consumption was recorded on days 5 and 8 and group body weights were measured on days 1, 5 and 8. All birds were sacrificed on day 8 and those from the control, 1780, 2510, and 5000 ppm level were necropsied and observed for gross pathology.

Author's Results:

Based on the results of this study, the LC_{50} of STAM in Mallard ducks is estimated to be greater than 5000 ppm.

Table 1 summarizes body weight, body weight changes, food consumption, and estimated compound intake per group and per bird.

All groups, except Group 1 (0 ppm) exhibited loss of body weight and depressed food consumption from Day 1 thru Day 5 of the Study. Both the body weight losses and food consumption decreases followed a dose related pattern. During the three-day recovery period all groups except Group 1 (0 ppm) showed a marked increase in both food consumption and body weight. The effect of body weight and food consumption indicates a lack of acceptance of the treated diets by the birds.

Mortalities occurred in the following groups: one death in Group 4 (1780 ppm) on Day 3, one death in Group 5 (2510 ppm) on Day 5, and one death in Group 7 (5000 ppm) on Day 5. No dose-related pattern of death was observed.

Gross Pathology - One bird in Group 4 (1780 ppm) showed pale viscera at necropsy. Two birds, one in Group 4 and one in Group 5, had whitish material in the stomach. An additional bird in Group 5 showed pale viscera and was very thin at necropsy and one bird in Group 7 had a paler than normal liver and was very thin at necropsy. All other birds undergoing gross necropsy appeared normal.

EEB Statistical Validation:

NEITHER THE BINOMIAL TEST NOR THE MOVING AVERAGE METHOD CAN GIVE ANY RESULTS FOR THIS DATA SET SINCE THE HIGHEST CONCENTRATION TESTED (5000 PPM) KILLED LESS THAN 50 PERCENT OF THE ORGANISMS EXPOSED.

Statistical Conclusions: N.A.

Validation of Author's Conclusions:

The conclusions drawn by the author are supported by the dose mortality data cited under Author's Results.

Validation Status: Core

Validation Rationale:

The methods employed by the registrant's testing facility adhere to EPA's current guidelines for subacute avian bioassays. The author's conclusions are supported by the dose-related mortality data cited earlier (See Author's Results).

Category Repairability: N.A.

TABLE 1

BODY WEIGHT, BODY WEIGHT CHANGE, FOOD CONSUMPTION, AND ESTIMATED COMPOUND INTAKE (PER BIRD)
EIGHT-DAY DIETARY LC_{50} STUDY IN MALLARD DUCKS WITH STAM TECHNICAL (Project #202-P)

		BODY WEIGHTS (gms)					FOOD CONSUMPTION (gms)				TEST MATERIAL CONSUMPTION (100% A.I.)	
Treatment Group	Dietary Level (ppm)	On Day 1	On Day 5	On Day 8	Change During Days 1-5	Change During Days 6-8	Total During Days 1-5	Daily Average During Days 1-5	Total During Days 6-8	Daily Average During Days 6-8	Total Consumed Per Bird (mg)	Average Consumed (mg/kg/day)
1	0	270.0	422.5	515.0	152.5	92.5	350.0	70.0	285.0	95.0	0	0
2	1000	257.5	252.0	367.5	-5.5	115.5	125.0	25.0	295.0	98.0	125	98
3	1260	265.0	225.0	355.0	-40.0	130.0	77.5	15.5	315.0	105.0	98	80
4	1780	260.0	222.2[a]	363.9[a]	-37.8[a]	141.7[a]	74.5	14.9	336.1[a]	112.0[a]	133	110
5	2510	270.0	213.9[a]	350.0[a]	-56.1[a]	136.1[a]	69.4	13.9	322.2[a]	107.4[a]	174	144
6	3550	295.0	205.0	365.0	-90.0	160.0	35.0	7.0	325.0	108.3	124	99
7	5000	262.5	183.3[a]	319.4[a]	-79.2[a]	136.1[a]	33.2	6.64	297.2[a]	99.1[a]	166	149

All groups have an n=10 except

[a] Group 4 N=9
Group 5 N=9
Group 7 N=9