1-29-82

028201
SHAUGHNESSEY NO.

21
REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 1/8/82 OUT 1/29/82

FILE OR REG. NO. 707-75

PETITION OR EXP. PERMIT NO.

DATE RECEIVED BY HED 1/6/82

DATE OF SUBMISSION 12/16/82

RD REQUESTED COMPLETION DATE 4/26/82

EEB ESTIMATED COMPLETION DATE

RD ACTION CODE/TYPE OF REVIEW 400/Data Submission

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 3E Herbicide

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%
	"Both white goose only"	

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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: Avian dietary (EPA Acc. # 246413)

Test organism: Bobwhite quail

		95% C. I.
Results:	LC50 = 2311.1 ppm	(1297.4 - 4116.8)

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. Eight day dietary LC50 study in bobwhite quail with STAM (EPA Acc. # 246413).

107.5 Additional Data Required**

The following data are required to support to conditional registration of Stampede 3E on wheat:

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

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

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

3. 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 2 should be conducted with technical propanil.

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Chemical: STAM

Formulation: Technical (88% active ingredient)

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

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: bobwhite quail (Colinius virginianus)

Reported Results:

The LC_{50} of STAM is estimated to be greater than 2311.1 (95% C.I 1297.4 - 4116.8) ppm. Body weight losses ranged from 2.5 - 3.7 g/bird in treatment groups 1000-2510 ppm during the 5 day treatment period compared to a gain of 8.6 g/bird in the control group.

Reviewer's Conclusions:

This bioassay is scientifically sound and demonstrates that STAM (88% active ingredient) is slighty toxic to ~~water~~fowl. This study can be used to support product registration.

OK

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 14 day-old bobwhite quail 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, necropsied, and examined for gross pathology.

Author's Results:

Based on the results of this study, the LC_{50} of STAM in bobwhite quail is 2311.1 ppm with 95% confidence Limits of 1297.4 to 4116.8 ppm (Litchfield and wilcoxin, 1949)

Cumulative mortality data are summarized in Table 1. Mortalities occurred in the following groups: one death in Group 1 (0 ppm), five deaths in Group 2 (1000 ppm), three deaths in Group 3 (1260 ppm), three deaths in Group 4 (1780 ppm), five deaths in Group 5 (2510 ppm), ten deaths in Group 6 (3550 ppm), and nine deaths in Group 7 (5000 ppm).

Table 2 summarizes group and individual body weight and food consumption data and estimated compound intakes.

Slight body weight losses (-2.5 to -3.7 grams/bird) were observed in Groups 2 (1000 ppm), 3 (1260 ppm), 4 (1780 ppm), and 5 (2510 ppm) during the five-day treatment period when compared to a gain of 8.6 gm/bird in the control group. These birds showed body weight gains similar to control during the three-day post treatment period. Food consumption per bird for Groups 2, 3, 4, and 5 were lower than the control during the treatment phase and similar to the control during the post treatment phase.

A severe body weight loss was noted for the surviving bird in Group 7 (5000 ppm) during the treatment period. A slight gain in body weight and low food consumption was noted in this bird during the post treatment phase.

Gross Pathology

One bird receiving 1780 ppm had a pale liver at necropsy. No other birds showed any pathological changes at necropsy.

EEB Statistical Validation:

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
5000	9	8	88.8889	1.953125
3550	9	9	100	0.1953125
2510	9	4	44.4444	50
1780	9	2	22.2222	8.984375
1260	9	2	22.2222	8.984375
1000	9	4	44.4444	50

THE BINOMIAL TEST SHOWS THAT 0 AND 3550 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 LC_{50} FOR THIS SET OF DATA IS 2575.751

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
5	0.8184408	1858.803	296.8056	3595.209

RESULTS CALCCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
5	0.3196449	1	0.05588601

SLOPE = 2.811639
95 PERCENT CONFIDENCE LIMITS = 1224192 AND 4.409087

LC50 = 1923.589
95 PERCENT CONFIDENCE LIMITS = 1292.785 AND 2682.906

LC10 = 681.1148
95 PERCENT CONFIDENCE LIMITS = 150.7353 AND 1087.567

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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 subacute avian bioassays. The author's conclusions are supported by the dose-related mortality data cited earlier (See Author's Results).

Category Repairablity: N.A.

TABLE 1
CUMULATIVE MORTALITY
EIGHT-DAY DIETARY LC_{50} STUDY IN BOBWHITE QUAIL WITH STAM TECHNICAL

TREATMENT GROUP	DIETARY LEVEL (ppm)	NUMBER OF SURVIVORS PER GROUP							
		On Day 1	On Day 2	On Day 3	On Day 4	On Day 5	On Day 6	On Day 7	On Day 8
1	0	10	10	10	9	9	9	9	9
2	1000	10	10	9	9	7	6	5	5
3	1260	9	9	9	8	7	7	7	7
4	1780	10	10	8	8	7	7	7	7
5	2510	10	9	9	6	6	5	5	5
6	3550	10	10	5	3	0	0	0	0
7	5000	10	10	10	2	1	1	1	1

TABLE 2

BODY WEIGHT, BODY WEIGHT CHANGE, FOOD CONSUMPTION AND ESTIMATED COMPOUND INTAKE (PER GROUP)

EIGHT-DAY DIETARY LC_{50} STUDY IN BOBWHITE QUAIL WITH STAM TECHNICAL

		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 Day 1-5	Daily Average During Days 1-5	Total During Days 6-8	Daily Average During Days 6-8	Total Consumed Per Group (gm)	Average Consumed (gm/kg/day)
1	0	180	239[a]	298[a]	59[a]	59[b]	240	48.0	191	63.7	0	0
2	1000	231	136[a]	140[b]	-95[a]	4[b]	142	28.4	105	35.0	0.142	.155
3	1260	198	121[a]	157[b]	-77[a]	36[b]	155	31.0	95	31.7	0.195	.245
3	1780	195	117[a]	165[b]	-78[a]	48[b]	143	28.6	201	67.0	0.255	.327
5	2510	193	101[a]	124[b]	-92[a]	23[b]	155	31.0	81	27.0	0.389	.529
6	3550	201	-[a]	-[b]	-[a]	-[b]	70[c]	17.5	-	-	0.249	.619
7	5000	199	11[a]	14[b]	-188[a]	3[b]	69	13.8	3	1	0.345	.657

[A] Group 1 N=9
Group 2 N=7
Group 3 N=7
Group 4 N=7
Group 5 N-6
Group 6 N=0
Group 7 N=1

[b] Group 1 N=9
Group 2 N=5
Group 3 N=7
Group 4 N=7
Group 5 N=5
Group 6 N=0
Group 7 N=1

[c] All birds dead by Day 5. Data based on four days of food consumption.
[d] Sum of birds surviving oneach day for that interval (1-5 or 6-8).
[e] Based on average body weights between Day 1 and Day 5.