D-7918 / LINURON SR UNDATED 11-25-85

DATA EVALUATION RECORD

Releasable

1. Chemical: Linuron

2. Test Material: Unknown percent active ingredient

3. Study Type: Avian Acute Oral Toxicity Study on a Upland Game Species
   Species Tested: Bobwhite Quail (Colinus virginianus)

4. Study ID: Beavers, J.B. (August 1985) H 15,651. An Acute Oral Toxicity Study with the Bobwhite. Final Report Project No. 112-164. Prepared by Wildlife International Ltd., St. Michaels, MD. Submitted to E.I. du Pont de Nemours and Co. Newark, DE. EPA Accession No. 259296.

5. Reviewed by: Elizabeth E. Zucker, Wildlife Biologist, EEB/HED — Signature: — Date:

6. Approved by: David Coppage, Supervisory Biologist, EEB/HED — Signature: — Date:

7. Conclusions:

This study cannot be used to fulfill a guidelines requirement for an avian acute oral toxicity test on an upland game species. This is mainly because the percent active ingredient of the test material was not reported.

8. Recommendations:

If the registrant submits information on the test material and it is found acceptable, this study can be used to fulfill the guideline requirement for an avian acute oral study.

9. Background:

This study was submitted to fulfill guideline requirements outlined in the Registration Standard for Linuron.

10. Discussion of Individual Study:

N/A

4 pages

1/7

51

11. Materials and Methods:
(from test report)

a. Test Procedures - Bobwhite were 17 weeks of age at initiation of the study. The birds were obtained from Fritt's Quail Farm, Phillipsburg, NJ. Birds were assigned to five test groups and one control group. Each treatment or control group contained five males and five females. All birds were acclimated for 40 days prior to testing.

The birds were fasted for at least 15 hours prior to dosing. At initiation of the test, a single dose of the test material in diluent was orally intubated directly into the crop or proventriculus of each bird using a stainless steel catheter. Each bird was individualy weighed and dosed on the basis of milligrams of test substance per kilogram of body weight. The control birds received a corresponding volume of corn oil only.

Test birds were housed indoors by dosage group. Birds were assigned to pens by random draw. Each pen had floor space that measured approximately 78 x 51 cm. Floors were sloped so that ceiling height ranged from approximately 20 to 25 cm. Birds were maintained at ambient room temperature. Average temperature for this study was 74 °F + 3 °F (SD) with a relative humidity of 47 percent. Food and water were available ad libitum.

Birds were observed at least twice daily. Individual body weights were measured at initiation of the test and by group on Days 3, 7, 14, and 21 of the test. Average estimated feed consumption was determined for each dosage group and the control for Days 0 to 3, 4 to 7, 8 to 14, and 15 to 21.

b. Statistical Analysis - An LD_{50} value along with 95 percent confidence limits was calculated using the computer program of C. E. Stephan.

12. Reported Results:

Mortality, food consumption and body weight data are appended.

Signs of toxicity included depression or lethargy, reduced reaction to external stimuli, wing droop, loss of coordination, prostrate posture, loss of righting reflex, shallow and rapid respiration, a ruffled appearance, lower limb weakness, and coma. At all test dosages signs of toxicity were apparent within 1 1/4 to 2 1/2 hours after dosing.

all treatment groups (see appended data).

13. Study Author's Conclusions:

"The bobwhite LD_{50} value for H 15,651 was 940 mg/kg with 95% confidence limits of 712 mg/kg to 1263 mg/kg. The no mortality dosage was 292 mg/kg. The no observed effect dosage was less than 292 mg/kg, the lowest dosage tested, based upon overt signs of toxicity as well as effects upon body weight gain and feed consumption."

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

a. Test Procedures - This study was performed under conditions that comply substantially with current testing standards with the notable exception that percent active ingredient of test material was not reported.

b. Statistical Analysis - Data were confirmed through utilization of Stephan's computerized program.

c. Results/Discussion: The LC_{50}, based on data from 21 days of observation, is 712 mg/kg (assuming technical ingredient was used). This indicates that linuron is slightly toxic to bobwhite quail on an acute oral basis. However, these data should not be used in a hazard assessment until it is confirmed that the technical product was utilized.

d. Adequacy of Study:

1. Category: Invalid

2. Rationale: The percent active ingredient of the test material was not reported.

3. Repairability: If the registrant submits the information on the test material and it is found to by acceptable, this study can be upgraded to core.

TABLE 1

CUMULATIVE MORTALITY OF BOBWHITE

GAVAGED WITH H 15,651 BY SEX

Number Dead/Number Exposed

Dosage mg/kg		Day of Study										
		0	1	2	3	4	5	6	7	8	9	10
Control	M	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
	F	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
292	M	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
	F	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
486	M	0/5	0/5	0/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5
	F	0/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5
810	M	0/5	0/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5
	F	0/5	0/5	2/5	3/5	3/5	3/5	3/5	3/5	3/5	3/5	3/5
1350	M	0/5	1/5	4/5	4/5	4/5	4/5	4/5	4/5	4/5	4/5	4/5
	F	0/5	0/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5
2250	M	0/5	1/5	3/5	3/5	3/5	3/5	3/5	3/5	3/5	3/5	3/5
	F	0/5	2/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5

TABLE 1

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CUMULATIVE MORTALITY OF BOBWHITE

GAVAGED WITH H 15,651 BY SEX

Number Dead/Number Exposed

Dosage mg/kg		Day of Study 11	12	13	14	15	16	17	18	19	20	21	Total
Control	M	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/10
	F	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	
292	M	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/10
	F	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	
486	M	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	2/10
	F	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	
810	M	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	4/10
	F	3/5	3/5	3/5	3/5	3/5	3/5	3/5	3/5	3/5	3/5	3/5	
1350	M	4/5	4/5	4/5	4/5	4/5	4/5	4/5	4/5	4/5	4/5	4/5	6/10
	F	1/5	1/5	1/5	1/5	1/5	1/5	1/5	2/5	2/5	2/5	2/5	
2250	M	3/5	4/5	4/5	4/5	4/5	5/5	5/5	5/5	5/5	5/5	5/5	10/10
	F	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	

S The LD50 value was determined to be 940 mg/kg, with confidence limits (95%) of 712 mg/kg to 1263 mg/kg.

TABLE 3

AVERAGE BODY WEIGHT AND ESTIMATED FEED CONSUMPTION OF BOBWHITE

GAVAGED WITH H 15,651

Dosage mg/kg		Average Body Weight in Grams										Estimated Feed Consumption Grams/Bird/Day			
		Day 0	Change	Day 3	Change	Day 7	Change	Day 14	Change	Day 21	Total Change	Days 0-3	Days 4-7	Days 8-14	Days 15-21
Control	M	193	6	199	1	200	- 2	198	0	198	5	22	11	14	11
	F	182	6	188	0	188	- 3	185	1	186	4	15	11	12	10
292	M	184	- 7	177	7	184	4	188	3	191	7	7	16	16	13
	F	187	-10	177	7	184	- 4	180	13	193	6	5	12	11	13
486	M	174	-20	154	3	157	12	169	10	179	5	3	10	13	13
	F	194	-15	179	12	191	6	197	5	202	8	3	13	12	12
810	M	181	-25	156	- 5	151	14	165	20	185	4	2	8	16	15
	F	182	0	182	0	182	11	193	6	199	17	7	24	16	19
1350	M	185	-44	141	-38	103	23	126	23	149	-36	2	12	13	27
	F	195	-16	179	-17	162	- 3	159	36	195	0	3	4	9	18
2250	M	191	-38	153	-25	128	-15	113	*	*	*	2	1	5	4
	F	182	*	*	*	*	*	*	*	*	*	2	*	*	*

*Data not available due to total mortality.

LINURON ACUTE ORAL 21 DAY LD50 BOBWHITE

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
2250	10	10	100	.0976563
1350	10	6	60	37.6953
810	10	4	40	37.6953
486	10	2	20	5.46875
292	10	0	0	.0976563

THE BINOMIAL TEST SHOWS THAT 292 AND 2250 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 1045.71

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	.114382	910.888	722.512	1183.73

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
9	.203889	1	.500776

SLOPE = 4.0146
95 PERCENT CONFIDENCE LIMITS = 2.20185 AND 5.82736

LC50 = 940.292
95 PERCENT CONFIDENCE LIMITS = 712.104 AND 1262.71

LC10 = 453.856
95 PERCENT CONFIDENCE LIMITS = 233.351 AND 618.178