

1-27-97



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Isoxaflutole Herbicide Degradate. Bobwhite Quail LC50 study. DP Barcode D224163. Sponsor: Rhone-Poulenc Ag Company. PRAT Case No. 286745. (The PC Code for Isoxaflutole parent is 123000).

FROM: Robert K. Hitch, Ecologist, *Robert K. Hitch Jun 17 97*
Environmental Risk Characterization Branch
Environmental Fate and Effects Division (7507C)

THRU: Dr. F. Nicholas Mastrotta, Biologist, *F. Nicholas Mastrotta*
Peer Reviewer, ERCB
Environmental Fate and Effects Division *1-27-97*

THRU: Elizabeth Leovey, Ph.D. Chief,
Environmental Risk Characterization Branch
Environmental Fate and Effects Division. *[Signature]*
12/67

TO: Joanne Miller (PM 23) or Danniel Kenny
PM Team Reviewer
Reregistration Division (7505C)

Rhone-Poulenc Corporation has submitted an 8-day dietary LC50 test with the bobwhite quail FIFRA 71-2(A) with RPA 202248 degradate of isoxaflutole. The study is judged "Core" as it determines that the LC50 is greater than 5200 ppm a.i. A Data Evaluation Record (DER) is attached and the citation for the study is as follows:

M. Rodgers (Study Director). 1995. Subacute dietary toxicity (LC50) to the bobwhite quail. Huntingdon Life Sciences Ltd. Lab Report no. RNP 479/9525517.

Attachment: Data Evaluation Record for Bowwhite Quail Study.

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DATA EVALUATION RECORD
§ 71-2(A) -- UPLAND GAME BIRD DIETARY LC₅₀ TEST

1. CHEMICAL: RPA 202248 PC Code No.: None. The PC code
for isoxaflutole
is 123000

Hydrolysis degradate of
Isoxalutole herbicide. RPA 202248 is Isoxaflutole with the
isoxazole ring opened.

2. TEST MATERIAL: RPA 202248 Purity: 99.9%

3. CITATION

Authors: Study Director: M. Rodgers.
Title: Subacute dietary toxicity (LC50) to the
bobwhite quail.
Study Completion Date: 8 December 1995.
Laboratory: Huntingdon Life Sciences Ltd.
Sponsor: Rhone Poulenc Ag Company
Laboratory Report ID: RNP 479/952517
MRID No.: 439403-02

4. REVIEWED BY: Robert K. Hitch, Ecologist,
Environmental Risk Characterization Branch
Environmental Fate and Effects Division

Sign: Robert K. Hitch Date: Jan 20 1997

5. APPROVED BY: Dr. F. Nicholas Mastrotta, Biologist
Peer Reviewer
Environmental Risk Characterization Branch

Sign: F. Nicholas Mastrotta Date: Jan. 21, 1997

6. STUDY PARAMETERS

Scientific Name of Test Organism: Colinus virginianus
Age of Test Organisms at Test Initiation: 10 days
Definitive Study Duration: 8 days

7. CONCLUSIONS:

Results Synopsis

LC₅₀: >5200 ppm ai
NOEL: 5200 ppm ai

95% C.I.: Not Appropriate
Probit Slope: Not Determined

8. ADEQUACY OF THE STUDY

A. Classification: Core.

B. Rationale: It was determined that the LC50 exceeds 5200 ppm. FIFRA Subdivision E does not normally require testing above 5000 ppm a.i.

C. Repairability: N. A.

9. GUIDELINE DEVIATIONS

None..

10. SUBMISSION PURPOSE:**11. MATERIALS AND METHODS****A. Test Organisms**

Guideline Criteria	Reported Information
Species: An upland game bird species, preferably the bobwhite (<i>Colinus virginianus</i>).	Bobwhite
Age at beginning of test: 10-14 days old.	10 Days old
Supplier	D.R. and R.E. Wise Monkfield, Bourn, Cambridgeshire, England
Chicks appeared healthy and did not have excessive mortality before the test?	Yes
Acclimation period: As long as possible.	Yes

B. Test System

Guideline Criteria	Reported Information
Pen size: about 35 x 100 x 24 cm.	50 x 80 x 60 cm
Brooder temperature: about 35°C (95°F)	NA
Room temperature: 22-27°C (71-81°F)	26-28 Degrees C.
Relative humidity: 30-80%	63%
Adequate ventilation?	Yes
Photoperiod Minimum of 14 h of light.	14 h of light
Diet: A commercial diet for game birds.	Standard HRC (Huntington Research Center) Chick Feed

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Not reported
<u>Definitive Test</u> Nominal concentrations: Four minimum, 5 or 6 strongly recommended, in a geometric scale, unless $LC_{50} > 5000$ ppm.	6 concentrations
Controls: Control group tested with diet containing the maximum amount of vehicle used in treated diets?	No vehicle was utilized.
Number of birds per group: 10 (strongly recommended)	10

Guideline Criteria	Reported Information
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	None
Vehicle amount (% of diet by weight): Not more than 2%	NA
Test durations: 5 days with treated feed and at least 3 days observation with "clean" feed.	Five Days with treated feed and 3 days with clean feed
No mortality during last 72 hr of observations?	No mortality observed during this period.

12. REPORTED RESULTS

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Body weights measured at beginning and end of study?	Yes
Estimated consumption per pen reported for pretreatment, treatment, and observation periods?	Yes
Control Mortality: Not more than 10%	0 %
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Mortality

Conc. (ppm)		No. of Birds	Cumulative Number of Dead							
Nominal	Mean Measured		Day of Study							
			1	2	3	4	5	6	7	8
Control		10	0	0	0	0	0	0	0	0
Control		10	0	0	0	0	0	0	0	0
163		10	0	0	0	0	0	0	0	0
325		10	0	0	0	0	0	0	0	0
650		10	0	0	0	0	0	0	0	0
1300		10	0	0	0	0	0	0	0	0
2600		10	0	0	0	0	0	0	0	0
5200		10	0	0	0	0	0	0	0	0

Other Significant Results:Statistical Results

Statistical Method:

LC₅₀: >5200 ppm

95% C.I.: Not Appropriate

NOEL: 5200 ppm

Probit Slope: Not Appropriate

13. Verification of Statistical Results

Statistical Method: No sign of mortality occurred at any dose including 5200 ppm, the highest.

LC₅₀: >5200 ppm

95% C.I.: Not Appropriate

NOEL: 5200 ppm

Probit Slope: Not Appropriate

- 14. REVIEWER'S COMMENTS:** This study is judged to be core and acceptable for the purposes of filling FIFRA guideline 71-2 with an upland game bird.