DP Barcode : D177826
PC Code No : 111601
EEB Out : JUN 5 1992

To: Bruce Sidwell, 53\Mark Wilhite
Product Manager
Special Review and Reregistration Division (H7508W)

From: Douglas J. Urban, Acting Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 111601-000707
Chemical Name : Chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluor
Type Product : HERBICIDE
Product Name : OXYFLUORFEN
Company Name : ROHN & HASS COMPANY
Purpose : UPGRADE OF STUDY

Action Code : 606 Date Due : 7/16/92
Reviewer : Concepción Rodríguez

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)	422559-01	Y	72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

JUN 5 1992

To: Bruce Sidwell, 53\Mark Wilhite
Special Review and Reregistration Division

From: Doug Urban, Acting Chief
Ecological Effects Branch
Environmental Fate and Effects Division
(H7507C)

Douglas J. Urban 6/4/92

Subject: Review of Additional Data for REREG CASE 2490

Rohm and Hass submitted additional data to upgrade an avian single dose study on the bobwhite quail. The study is the following:

Fletcher, D.W., 1987. 21-Day Acute Oral Toxicity Study with Goal Technical Herbicide in Bobwhite Quail. MRID No. 92136102

EEB has reviewed the study and the additional data and concluded that the study is scientifically sound and fulfills the guideline requirements for an avian single dose oral LD50. The LD50 was greater than 2150 mg a.i./kg, which classifies Oxyflourfen as practically non-toxic to the bobwhite quail. Please refer to the enclosed Data Evaluation Record for the details of the study. If you have any questions please contact Concepción Rodríguez (308-2805) or Harry Craven (305-5320)

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MEMORANDUM

JUN 5 1992

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Special Review and Reregistration Division

From: Doug Urban, Acting Chief
Ecological Effects Branch
Environmental Fate and Effects Division
(H7507C)

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CONCURRENCES

SYMBOL	H7507C	H7507C	H-7507C					
SURNAME	C. Rodriguez	Craven	D. Urban					
DATE	6/4/92	6/4/92	6/4/92					

EPA Form 1320-1A (1/90)

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*U.S. Government Printing Office: 1992 — 620-856/40672

DP BARCODE: D177826 REREG CASE # 2490

CASE: 816380 DATA PACKAGE RECORD DATE: 05/07/92
SUBMISSION: S417358 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 606 DATA PACKAGE REVIEW
CHEMICALS: 111601 Chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromet 100.00 %

ID#: 111601-000707
COMPANY: 000707 ROHM & HAAS COMPANY
PRODUCT MANAGER: 53 BRUCE SIDWELL 703-308-8078 ROOM: CS1 3E3
PM TEAM REVIEWER: MARK WILHITE 703-308-8586 ROOM: CS1 3RD FL
RECEIVED DATE: 04/02/92 DUE OUT DATE: 07/01/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 177826 EXPEDITE: N DATE SENT: 05/07/92 DATE RET.: / /
CHEMICAL: 111601 Chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benze
DP TYPE: 999 Miscellaneous Data Package
ADMIN DUE DATE: 07/16/92 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	05/12/92	/ /
BRAN: EEB	05/12/92	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

Upgrade of a study called for in Phase 4 DCI. Please review and indicate wether this study satisfies the requirement. gdln 71-1(a) MRid 42255901 [orig. MRID is 42142301].

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

4

DATA EVALUATION RECORD

1. **CHEMICAL:** Oxyfluorfen
   Shaughnessey Number: 111601

2. **TEST MATERIAL:** Goal Technical Herbicide, Lot No. 8159, TD No. 86-134, 70.2% active ingredient.

3. **STUDY TYPE:** Avian single dose oral LD_{50} test.
   Species Tested: Bobwhite Quail (Colinus virginianus)

4. **CITATION:** Fletcher, D.W. 1987. 21-Day Acute Oral Toxicity Study with Goal Technical Herbicide in Bobwhite Quail. Study performed by Bio Life Associates, Ltd., Neillsville, Wisconsin. Laboratory Identification Number 86 QD 76. Submitted by Rohm and Haas Company, Spring House, Pennsylvania. MRID No. 92136102.

5. **REVIEWED BY:**

   Concepcion Rodriguez — **Signature:** Concepcion Rodriguez
   Biologist — **Date:** 6/4/92
   Ecological Effects Branch
   Environmental Fate and Effects Division

6. **APPROVED BY:**

   Henry T. Craven, M.S. — **Signature:** Henry T. Craven
   Supervisor, EEB/HED — **Date:** 6/4/92
   USEPA

7. **CONCLUSIONS:** The study is scientifically sound and meets the requirements for an avian single dose oral LD_{50} test. With an LD_{50} greater than 2150 mg a.i./kg, the test material is considered to be practically non-toxic. The NOEL could not be determined.

8. **RECOMMENDATIONS:** N/A.

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5. **REVIEWED BY:**

   Rosemary Graham Mora, M.S.
   Associate Scientist
   KBN Engineering and Applied Sciences, Inc.

   Signature: Rosemary G. Mora
   Date: 4/30/91

6. **APPROVED BY:**

   Michael L. Whitten, M.S.
   Wildlife Toxicologist
   KBN Engineering and Applied Sciences, Inc.

   Signature: Michael L. Whitten
   Date: 4/30/91

   Henry T. Craven, M.S.
   Supervisor, EEB/HED
   USEPA

   Signature: Henry T. Craven 6/4/92
   Date: Concur/Residues 6/4/92

7. **CONCLUSIONS:** The study is scientifically sound and meets the requirements for an avian single dose oral LD_{50} test. With an LD_{50} greater than 2150 mg a.i./kg, the test material is considered to be practically non-toxic. The NOEL could not be determined.

8. **RECOMMENDATIONS:** N/A.

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6 hrs

9. **BACKGROUND:**

~~10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.~~

11. **MATERIALS AND METHODS:**

A. **Test Animals:** The birds used in the study were 25 to 34 week old bobwhite quail obtained from Oak Ridge Game Farm, Gravette, Arkansas. Each treatment group and the control group contained five males and five females. All birds were acclimated to the caging and facilities for 16 weeks prior to test initiation. All birds were suitable for this study.

B. **Test System:** All birds were housed indoors in wire pens with dimensions 53.3 cm X 45.7 cm X 38.1 cm. Fluorescent lights provided 8 hours of light per day. The temperature range was 64°F to 80°F. The relative humidity range was 64% to 86%.

C. **Dosage:** Single dose oral LD_{50} test. Based upon a toxicity range study, nominal dosages selected for the study were 1470 and 2150 mg a.i./kg.

D. **Design:** Groups of ten birds (five males and five females) were randomly assigned to each of two treatment groups and one control vehicle group. Each dosage group was assigned one pen, containing five males and five females. All bird were fed Ralston Purina GameBird Flight Conditioner. Food and water were supplied ad libitum during acclimation and during the test, except for a 19.25 hour period prior to dosing, when feed was withheld.

The test substance was administered via gavage after mixing with corn oil. Each bird was individually weighed and dosed on the basis of milligrams of active ingredient per kilogram of body weight. The control birds were administered 4 mL of corn oil.

All birds were observed at least daily for mortality and signs of intoxication. The birds were individually weighed on days 1, 3, 7, 14, and 21 (Table IV, attached). Group food consumption was determined on days 3, 7, 14, and 21 (Table V, attached).

E. **Statistics:** The LD_{50} was greater than 2150 mg a.i./kg, since only 10% mortality was demonstrated in the 2150 mg a.i./kg by the end of the test. Statistical analysis of body weight data was conducted using

analysis of variance.

12. ~~REPORTED RESULTS: There was no mortality in the control~~ group. All birds were normal in appearance and behavior throughout the test period.

Birds in the 1470 mg/kg and 2150 mg a.i./kg dosage groups demonstrated signs of intoxication including weakness, anorexia, piloerection, and abnormal cage droppings. All bird had completely recovered by day 7 and were normal in appearance and behavior until test termination, except one bird at 2150 mg a.i./kg which showed signs of weakness and piloerection again on day 13. This bird died on day 14 (attached, Table III). A necropsy performed on this bird revealed gas-filled intestines and severe emaciation. Other necropsies revealed only one abnormality which was, in the opinion of the author, non-treatment related.

No significant differences in group body weights were noted. Food consumption was severely depressed in the 1470 mg a.i./kg group during the first three days of the study, and in the 2150 mg a.i./kg group during the first seven days of the study.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:**

The acute LD_{50} for bobwhite exposed to Goal Technical Herbicide was greater than 2150 mg a.i./kg.

The report stated that the study was conducted in conformance with Good Laboratory Practice regulations. The Compliance Statement was signed by the Study Director.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **Test Procedure:** The test procedures were in accordance with Subdivision E and SEP guidelines with the following exceptions:

Birds were not of the same hatch. Ages of birds ranged from 25 to 34 weeks old.

A photoperiod of 10 hour light/14 hour dark was not provided. They provided 8 hour light.

Amounts of test material and diluent administered to each bird were not presented in the report. But was submitted in a later response.

B. **Statistical Analysis:** The LD_{50} could not be calculated

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and is assumed to be greater than 2150 mg a.i./kg.

C. **Discussion/Results:** With an LD_{50} greater than 2150 mg a.i./kg the test material is considered practically non-toxic. Behavioral signs of toxicity were noted in birds from both treatment groups. Although not clear from the report, apparently all birds dosed with the test chemical displayed the noted signs of toxicity. Furthermore, food consumption and group body weights appear to have been reduced in both treatment groups. The author reported no significant differences in body weights, but failed to comment on the fact that 19 to 20 treatment group birds lost weight during the first three days of the study, while none of the control birds lost weight during the same period (Table IV, attached). Due to behavioral signs of toxicity, reduced body weight, and reduced food consumption in both treatment groups, the NOEL could not be determined.

The study is scientifically sound and meets the requirements for an avian single dose oral LD_{50} study.

D. **Adequacy of the Study:**

(1) **Classification:** Core.

(2) **Rationale:** N/A

(3) **Repairability:** N/A

15. **COMPLETION OF ONE-LINER:** Yes; March 27, 1991.

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RIN 0637-00

EFED Review - Oxyfluorfen

Page____ is not included in this copy.

Pages 10 through 12 are not included.

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 quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

__X__ 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.

Shaughnessey No. 111601 Chemical Name Oxyfluorfen Chemical Class ____ Page 1 of 1

Study/Species/Lab/ Accession	Chemical % a.i.	Results	Reviewer/ Date	Validn Stat
14-Day Single Dose Oral LD_{50}		LD50 > 2150 a.i. mg/kg (95% C.L. NA) Contr. Mort.(%) = 0%		
Species Colinus virginianus	72150 mg a.i./ Kg	Slope = — # Animals/Level = 10 Age(Days) = 182-238 Sex = 5♂ 5♀	MM	Core
Lab BioLife Ltd.		14-Day Dose Level mg/kg/(% Mortality) 1470 (0%), 2150 (10%), ( ), ( ), ( )		3/27/91
Acc. MRID 92136102		Comments: Age of birds indicate that test birds not of same hatch.		
14-Day Single Dose Oral LD_{50}		LD50 = mg/kg. (95% C.L.) Contr. Mort.(%) =		
Species		Slope = # Animals/Level = Age(Days) = Sex =		
Lab		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L.) Contr. Mort.(%) =		
Species		Slope = # Animals/Level = Age(Days) = Sex =		
Lab		8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L.) Contr. Mort.(%) =		
Species		Slope = # Animals/Level = Age(Days) = Sex =		
Lab		8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
48-Hour LC_{50}		LC50 = pp__ (95% C.L.) Contr. Mort.(%) = Sol. Contr. Mort.(%) =		
Species		Slope = # Animals/Level = Temperature =		
Lab		48-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
96-Hour LC_{50}		LC50 = pp__ (95% C.L.) Con. Mor.(%) = Sol. Con. Mor.(%) =		
Species		Slope = # Animals/Level = Temp. =		
Lab		96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
96-Hour LC_{50}		LC50 = pp__ (95% C.L.) Con. Mort.(%) = Sol. Con. Mort.(%) =		
Species		Slope = # Animals/Level = Temp. =		
Lab		96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		