224446
Record No.

Review No.

105001
Shaughnessey No.

EEB REVIEW

DATE: IN August 3, 1988 OUT December 15, 1988

FILE OR REG. NO. 241-GRU

PETITION OR EXP. NO.

DATE OF SUBMISSION June 10, 1988

DATE RECEIVED BY EFED August 2, 1988

RD REQUESTED COMPLETION DATA August 29, 1988

EEB ESTIMATED COMPLETION DATE August 29, 1988

RD ACTION CODE/TYPE OF REVIEW 165

TYPE PRODUCTS(S): I, D, H, F, N, R, S Insecticide/Nematicide

DATA ACCESSION NO(S). 406607-06

PRODUCT MANAGER NO. J. Tice / M. Mautz

PRODUCT NAME(S) Counter XL

COMPANY NAME American Cyanamid Company

SUBMISSION PURPOSE Proposed new formulation (20G) for use on corn, sorghum and sugar beets. Response to previous EEB review

SHAUGHNESSEY NO.	CHEMICAL AND FORMULATION	% A.I.

DATA EVALUATION RECORD

1. TEST MATERIAL

Terbufos

(S-[[(1,1-dimethylthyl)thio]methyl]0,0-diethyl phosphorodithioate)

2. STUDY MATERIAL - Counter 20P

Terbufos	20 W/W %
Inert ingredients	80
	100%

3. STUDY TYPE- Avian Dietary Single-dose Oral LD_{50}.

Species tested-

Mallard Duck Anas platyrhynchos.

4. STUDY IDENTIFICATION:

Fletcher, D.W. 1987. 21-day acute oral toxicity study with Counter 20P in Mallard ducks. Bio-Life Associates, Ltd. Submitted by American Cyanamid Company, Princeton, NJ MRID 406607-06.

5. REVIEW BY:

James J. Goodyear
Biologist
Ecological Effects Branch
Environmental Fate and
Effects Division (TS-796C)

Signature: JGoodyear

Date: Sept 30, 1988

6. APPROVED BY:

Raymond W. Matheny
Head, Section 1
Ecological Effects Branch
Environmental Fate and
Effects Division (TS-796C)

Signature: Ray W. Matheny

Date: SEP 30 1988

7. CONCLUSIONS:

The study is scientifically sound and meets Avian Single-Dose Oral LD_{50} guidelines for the registration of Counter 20P. Because the study found an LD_{50} of

160.9 mg/kg, Terbufos 20P is considered to be moderately toxic to mallard ducks.

8. RECOMMENDATIONS- N/A.

9. BACKGROUND:

The study was submitted for the registration of Counter 20P.

10. DISCUSSION OF INDIVIDUAL TEST- N/A.

11. MATERIALS AND METHODS:

A. Test animals:

Mallard ducks (23 weeks old) from Whistling Wings, 113 Washington Street, Hanover, Ill. 61041

B. Dose:

Counter 20P in five dosages (68.1, 100, 147, 215 and 316 mg/kg).

C. Design:

There were five test groups of five male and five females each (one for each test level) plus a control group of five males and five females housed in 4'x 4'x 4' pens in a heated room in which lighting "was provided by fluorescent lights which were left on eight hours per day". The birds were observed and acclimated for 24 days and fasted for 21 hours before the dosing with gelatin capsules.

D. Statistics:

Litchfield, J.T., Jr. and F. Wilcoxon. 1949. A simplified method of evaluating dose-effect experiments. J. Pharmacology and Experimental Therapeutics. Vol. 96.

12. REPORTED RESULTS:

LD_{50} = 160.9 mg/kg 95% C.I. = 68.1 - 316 mg/kg

The NOEL was not given.

13. STUDY AUTHORS' CONCLUSIONS/QA MEASURES:

"The results of the 21-day Acute Oral toxicity Study conducted with Counter 20P in Mallard ducks showed the acute oral median lethal dose (LD_{50}) to be 182.0 mg/kg of body weight with 95% confidence limits of 121.3 and 273.0 mg/kg of body weight." and that,

"In accordance with Bio-Life Associates, Ltd. Laboratories' intent that all toxicity tests conducted by our facility follow good laboratory practices, Bio-Life Associates, Ltd's study director for the above test herein confirms that the study was conducted in compliance with the US EPA Good Laboratory Practice Regulations; Pesticide Programs (40 CFR 160)."

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF THE STUDY:

A. Test Procedures:

The procedures were not in complete accordance with the guidelines for testing avian single-dose oral LD50.

Errors include; the chemical names of the pesticide were not given, it was not specifically stated if the test was done with the end-use product or the technical grade chemical and the per cent of active ingredient in the test substance was not given. However, Marilyn Mautz of the Registration Division contacted the Cyanimid Company and found that all dosages and the LD_{50} are in milligrams of Terbufos end-use product.

Only eight, rather that ten, hours of light was provided. The report only states that lighting was provided for eight hours per day, not that an 8 hour light / 16 hour dark photoperiod was provided. This leaves open the possibility that the room had natural light and, therefore, the ducks had a natural photoperiod. This might be of major importance in an avian dietary study but it is considered to be of minor importance in this acute toxicity study.

B. Statistical Analysis:

The LD_{50} was calculated from the registrant's data using a computer program from "Stephan, et al. 1978. Computer program for calculating LD_{50}; probit method". The LD_{50} of the end-use product was found to be 160.9 (68.1 - 316) mg/kg.

C. Discussion/Results:

Counter 20P may be characterized as being "moderately toxic" orally to mallard ducks.

D. Adequacy of the Study:

Classification- Core.

Rational- The study was scientifically sound and fulfills the guideline requirements for the registration of Counter 20P.

Repair- N/A.

15. COMPLETION OF ONE-LINER FOR STUDY:

Yes, see attached sheets.

16. CBI APPENDIX- N/A.