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). 406607-05

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 15G

Terbufos	15 W/W %
Inert ingredients	85
	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 15G in Mallard ducks. Bio-Life Associates, Ltd. Submitted by American Cyanamid Company, Princeton, NJ MRID 406607-05.

5. REVIEW BY:

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

   Signature: Goodyear
   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 meets the requirements of the Avian Single-Dose Oral LD_{50} guidelines. Because the Terbufos formulated product has an LD_{50} of 88.1 mg/kg it would be considered to be moderately toxic to mallard ducks.

It does not, however, meets the requirements for the registration of Counter 20P since it was done with Counter 15G.

8. RECOMMENDATIONS- N/A.

9. BACKGROUND:

The study was submitted to meet the requirements of registration for 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 15G in five dosages (46.4, 68.1, 100, 147 and 215 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} = 83.0 mg/kg 95% C.I. = 59.7 - 115.40 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 15G in Mallard ducks showed the acute oral median lethal dose (LD_{50}) to be 83.00 mg/kg

of body weight with 95% confidence limits of 59.7 and 115.4 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, the per cent of active ingredient in the test substance was not given and it is not stated if the LD_{50} is in milligrams of ai or end-use product. 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 formulated product was found to be 88.1 (0 - 215) mg/kg.

C. Discussion/Results:

Counter 20P formulated product can be characterized as being moderately toxic orally to mallard ducks.

D. Adequacy of the Study:

Classification- Core.

Rational- The study is scientifically sound and meets the requirements of the guidelines. It does not meet the requirements of any Registration Standard since there are no current outstanding requirements for Counter 15G.

Repair- This study may be used to meet requirements of a Second Round Review, should one be initiated.

15. COMPLETION OF ONE-LINER FOR STUDY:

Yes, see the attached sheets.

16. CBI APPENDIX- N/A.