SHAUGHNESSEY NO.
105001

REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 9-29-83 OUT 10/20/83

FILE OR REG. NO. 241-241

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 9-16-83

DATE RECEIVED BY HED 9-27-83

RD REQUESTED COMPLETION DATE 10-27-83

EEB ESTIMATED COMPLETION DATE 10-26-83

RD ACTION CODE/TYPE OF REVIEW 485/IBT Data

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

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. W. Miller (16)

PRODUCT NAME(S) Terbufos

COMPANY NAME American Cyanamid Company

SUBMISSION PURPOSE Request by RD for review of IBT data on terbufos (Avian dietary)

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.

Terbufos (Shaughnessy No. 105001)

Sections 100 to 103.1 are not applicable to RD request.

103.2 Minimum Requirements

103.2.1 Avian Acute Oral LD_{50}

See Registration Standard

103.2.2 Avian Dietary LC_{50}'s

	LC_{50} (ppm)	Reviewer	Category
Mallard Duck	185	Farringer	Core
Ringneck pheasant	145	Farringer	Invalid

103.2.3 to 106 see previous Reviews and Registration Standards

107 Conclusions

EEB has reviewed the two IBT studies as per RD's request. EEB has determined that the mallard duck study would support registration, however, the ringneck pheasant study was unacceptable in support of registration. The high control mortality in ringneck pheasants (up to 80%) indicates that either the birds or the test conditions were not suitable.

Russel T. Farringer, III 10/24/83
Wildlife Biologist
Ecological Effcts Branch/HED

Raymond Matheny Raymond Matheny 10/24/83
Head, Review Section 1
Ecological Effects Branch/HED

Clayton Bushong 10/24/83
Branch Chief
Ecological Effects Branch/HED

DATA EVALUATION RECORD

1. CHEMICAL: Terbufos

2. FORMULATION: 96.7% pure

3. CITATION: "8-day dietary LC_{50} study with AC-92100, 96.7% pure in Ring-necked Pheasants" by IBT for American Cyanamid Acc. # IBT J-1778. August 24, 1972.

4. REVIEW BY: Russel Farringer
Wildlife Biologist
EEB/HED

5. DATE REVIEWED: 10/20/83

6. TEST TYPE: Avian dietary LC_{50} (upland gamebird)

Test Species: Ring-neck pheasants (Phasianus colchicus)

7. REPORTED RESULTS: The avian dietary LC_{50} of terbufos for the upland game species (Ring-neck pheasants) was reported as 145 ppm (no confidence interval given).

8. REVIEWER'S CONCLUSIONS: This study is not scientifically sound. Control mortality ranged from 0% to 80% with a mean of 30%. This study does not satisfy the requirement for an upland gamebird dietary LC_{50}.

Materials and Methods

Test Procedures

1) Age - 10 to 15 days old

2) Controls (negative) - 5 groups of 10 birds with 0%, 10%, 20%, 40%, and 80% mortality, respectively.

3) History of rearing and source

   a) photoperiod - not given
   b) medication - no information available
   c) type of food - Purina Gamebird Conditioner
   d) preconditioning - unknown

4) Selection - Birds appear to be of uniform weight by the means of each group's body weight.

5) Housing condiltions - not given

6) Weights - reported at beginning and end of study and depicts a general 20 gram weight gain for controls and treatment groups.

7) Vehicle - not given

8) Number of concentrations - 6: 21.5, 31.6, 68.1, 147, 2.5, 316 ppm

9) Number of birds - 10/pen 5 control pens, 6 treatment pens

10) Duration of test - 5 days on toxicant, 3 days observation on clean feed

11) Raw mortality - reported in laboratory sheets
    21.5 ppm (10%), 31.6 ppm (10%), 68.1 ppm (20%)
    147 pm (40%), 215 ppm (50%), 316 ppm (100%)

12) Food consumption - reported in text for each group similar

13) Necropsy - reported for survivors which were sacrificed: no abnormalities were observed.

    - no necropsies reported for toxicant affected birds

Statistical Analysis

The laboratory reported that the data was analyzed by the methods described by Litchfield - Wilcoxin.

Reviewer's Evaluation

Test procedures

This study generally follows the procedures as outlined in EPA's guidelines. However, the report failed to provide the following data: photoperiod, any medication given to the birds prior to or during the study, the source from which the birds were obtained, preconditioning of the birds to the maintenance diets, the vehicle or carrier that was used to prepare the test diet and the confidence interval for the statistical analysis.

Statistical Analysis

First, statistical analysis was performed even though the control mortality was in excess of ten percent.

Second, an Abbot's correction for control mortality was utilized using the mean (e.g., 30%) of the control mortality (N = 5).

Third, the Stehans computer program with Abbots correction for control mortality when used with the six treatments given in the laboratory record book gave LC_{50} values from 177 ppm (moving average method) to 236 ppm (binomal test). (See attached computer print out).

Conclusions

Category: Invalid

Rationale: The negative control groups (N = 5) had an average of 30% mortality (range = 0-80%). This high control mortality could indicate that the treatment birds that died may not have been appropriate test subject.

Repairability: None

NOTE: BECAUSE THERE WAS CONTROL MORTALITY, AND NONE
OF THE LOWER CONCENTRATIONS PRODUCED ZERO MORTALITY,
THE DATA HAS BEEN SUBJECTED TO ABBOTT'S CORRECTION.

PHEASANT ACUTE DIETARY LC50

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
316	7	7	100	0.78125
215	7	2	28.5714	22.65625
147	7	1	14.2857	6.25
68.1	10	2	20	5.46875
31.6	10	1	10	1.074219
21.5	10	1	10	1.074219

THE BINOMIAL TEST SHOWS THAT 31.6 AND 316 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 236.0873

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	0.1884479	177.0804	140.5785	238.88

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
5	0.3819498	1	0.08440918

SLOPE = 1.668178
95 PERCENT CONFIDENCE LIMITS = 0.6372093 AND 2.699147

LC50 = 206.7383
95 PERCENT CONFIDENCE LIMITS = 117.788 AND 843.944

LC10 = 35.81882
95 PERCENT CONFIDENCE LIMITS = 5.121321 AND 66.74944

DATA EVALUATION RECORD

1. CHEMICAL: Terbufos

2. FORMULATION: 96.7% pure

3. CITATION: "8-day dietary LC_{50} study with AC 92100, 96.7% pure in mallard ducks." by IBT for American Cyanamide, Acc. # IBTJ-1777. August 24, 1972.

4. REVIEW BY: Russel Farringer
Wildlife Biologist
EEB/HED

5. DATE REVIEWED: 10/20/83

6. TEST TYPE: Avian dietary LC_{50} (waterfowl)

Test Species: Mallard ducks (Anas platyrhynchos)

7. REPORTED RESULTS: The avian dietary LC_{50} of terbufos for the waterfowl species (Mallard duck) was reported as 185 pm. (No confidence interval was given.)

8. REVIEWER'S CONCUSIONS: This study is scientifically sound. The dietary LC_{50} value of 185 ppm indicates that this product is highly toxic to waterfowl. This study fulfills the requirement for a waterfowl dietary LC_{50}.

Materials/Methods

Test Procedure

1) Age of birds - 10 to 15 days old

2) Controls - 5 groups of 10 birds with no mortality

3) History of rearing and source

   a) photoperiod - not given
   b) medication - no information available
   c) type of food - Purina Gamebird Conditioner
   d) preconditioning - unknown

4) Selection - Birds appear to be of uniform weight based on the mean weights for each group.

5) Housing conditions - not given

6) Weights - Reported at beginning and end of study and depicts a general weight gain of 100 grams for each group.

7) Vehicle - corn oil

8) Number of concentrations and mortality - 5: 46.4ppm (0%), 68.1ppm (10%), 147ppm (20%), 316ppm (90%), 464ppm (90%)

9) Number of birds - 10/pen, 5 control pens, 5 treatment pens

10) Duration of test - 5 days on toxicant, 3 days observation on clean feed

11) Raw Mortality - reported in laboratory sheets

12) Food Consumption - reported in text for each group and appears consistant between groups, averaging 45 g during 8 day test.

13) Necropsy - reported for dead birds and survivors which were sacrificed: no abnormalities were observed.

Statistical Analysis

The laboratory reported that the data was analyzed by the methods described by Litchfield - Wilcoxin.

Reviewer's Evaluation

Test Procedure

This study generally follows EPA's guidelines for the conduct of an eight day avian dietary LC_{50} study. However, the following parameters were not reported: source of birds, photoperiod, medication the birds received prior to and during the study, and preconditioning of the birds to the diet and laboratory conditions.

Statistical Analysis

The Stephans Computer program was utilized on the reported raw data. The moving average method gave a value of 180 ppm (C.L. 134.7 - 254.3) which is very close to the 185 ppm reported by the testing laboratory. (See attached computer printout).

Conclusions

Category: Core - This study will support the registration of Terbufos technical.

AVIAN LC50

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
464	10	9	90	1.074219
316	10	9	90	1.074219
147	10	2	20	5.46875
68.1	10	1	10	1.074219
46.4	10	0	0	0.09765625

THE BINOMIAL TEST SHOWS THAT 68.1 AND 316 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 201.713

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	0.1144934	180.932	134.7151	254.3486

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
14	0.1888043	1	0.4899014

SLOPE = 3.817787
95 PERCENT CONFIDENCE LIMITS = 2.158897 AND 5.476677

LC50 = 190.9723
95 PERCENT CONFIDENCE LIMITS = 137.472 AND 263.0237

LC10 = 88.78035
95 PERCENT CONFIDENCE LIMITS = 43.50371 AND 125.7555