

SHAUGHNESSEY NO.
036101

REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 9-27-83 OUT 1-9-84

FILE OR REG. NO. 1471-70

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 9-20-83

DATE RECEIVED BY HED 9-27-83

RD REQUESTED COMPLETION DATE 1-17-84

EEB ESTIMATED COMPLETION DATE 1-10-84

RD ACTION CODE/TYPE OF REVIEW 400/Data

TYPE PRODUCT(S): I, D, H, F, N, R. S Herbicide

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. R. Mountfort (23)

PRODUCT NAME(S) Treflan (Trifluralin)

COMPANY NAME Elanco Products Company

SUBMISSION PURPOSE Submission of data to support registration

| SHAUGHNESSEY NO. | CHEMICAL, & FORMULATION | % A.I. |
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Pesticide Name Trifluralin

100 Submission Purpose

Avian reproduction toxicity studies are submitted in support of current registrations.

101.4 Adequacy of Toxicity Data

The two avian reproduction studies (Acc. No. 251256) meet the requirements for acceptable studies. The results of the two studies are as follows:

| <u>Species</u> | <u>Material</u> | <u>Category</u> | <u>Summary</u> |
|----------------|-----------------|-----------------|--|
| Mallard Duck | 99.6% a.i. | Core | Slight reproductive impairment at 50 ppm. Increased incidence of eggs cracked. |
| Bobwhite Quail | 99.6% a.i. | Core | No effect observed at 5 or 50 ppm. |

103 Conclusions

The two studies submitted under Acc. No. 251256 are sufficient to satisfy the guidelines requirements for acceptable avian reproduction tests.

Leslie Touart 1/10/84

Leslie Touart, Fisheries Biologist, Sec. 4

H.T. Craven 1/10/84

H.T. Craven, Head, Sec. 4

Clayton Bushong 1/11/84
Clayton Bushong, Chief
Ecological Effects Branch

DATA EVALUATION RECORD

1. CHEMICAL: Trifluralin
2. FORMULATION: Technical (99.6% a.i.)
3. CITATION: Beavers, J.B. and R. Fink (1978) One - Generation Reproduction Study - Bobwhite Quail, Compound 36352, Trifluralin Final Report. Unpublished Study prepared by Wildlife International Ltd. for Lilly Research Laboratories. [Acc. No. 251256]
4. REVIEWED BY: Les Touart
Fisheries Biologist
EEB/HED
5. DATE REVIEWED: 1/9/84
6. TEST TYPE: Avian Reproduction Study
 - A. TEST SPECIES: Bobwhite Quail
7. REPORTED RESULTS: Trifluralin was fed to mature Bobwhite Quail at dietary concentrations of 5 ppm and 50 ppm throughout a one - generation reproduction study and had no effect on the reproductive success of the birds.
8. REVIEWERS CONCLUSIONS: The study is scientifically sound and fulfills the requirements of an acceptable avian reproductive study with an upland gamebird. Based on the results of this study, long-term exposure to Trifluralin at levels below 50 ppm will not significantly affect reproductive success.

Materials/Methods

Test Procedures

The test methods are consistent with current EPA guidelines for conducting an avian reproduction study. Specifically: Age - 5 months; experimental design - 12 pens/level, 1 male and 2 females/pen; levels - 5 ppm and 50 ppm with a control; treatment - 10 weeks prior to egg production and 8 weeks during egg production; temperature - 68°F; photoperiod - 9 hours of light for first 6 weeks of the study increased to 18 hours for remainder of the study; observations - egg laid, eggs cracked, egg set, viable embryos, live 3-week embryos, hatchlings, 14-day old survivors and eggshell thickness.

Statistical Analysis

The Student's t-test was utilized to evaluate the differences between each of the observed reproductive parameters.

Discussion/Results

Refer to attached tables.

Evaluation of the reproductive data and statistical analysis of the reproductive parameters demonstrate that Trifluralin caused no reproductive impairment at the dose levels tested.

Reviewer's Evaluation

A. Test Procedure

The test methods are consistent with current EPA guidelines for conducting and avian reproduction toxicity study.


B. Statistical Analysis

The analysis given in the study is sufficient to indicate no statistical significance for any parameter tested.

C. Discussion/Results

The conclusions drawn are consistent with the data presented. No reproductive impairment is observed in Bobwhite Quail exposed to levels of Trifluralin up to 50 ppm

D. Conclusions

1. Category: Core
 2. Rationale: N/A
 3. Repairability: N/A
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Trifluralin Science Reviews

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Pages 5 through 10 are not included in this copy.

The material not included contains the following type of information:

- _____ Identity of product inert ingredients.
- _____ Identity of product inert impurities.
- _____ Description of the product manufacturing process.
- _____ Description of product 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.

DATA EVALUATION RECORD

1. CHEMICAL: Trifluralin
2. FORMULATION: Technical (99.6% a.i.)
3. CITATION: Beavers, J.B. and R. Fink. (1978) One - Generation Reproduction Study - Mallard Duck, Compound 36352, Trifluralin Final Report. Unpublished Study prepared by Wildlife International Ltd. for Lilly Research Laboratories. [Acc. No. 251256]
4. REVIEWED BY: Les Touart
Fisheries Biologist
EEB/HED
5. DATE REVIEWED: 1/9/84
6. TEST TYPE: Avian Reproduction Study
 - A. TEST SPECIES: Mallard Duck
7. REPORTED RESULTS: Trifluralin was fed to mature mallard ducks at dietary concentrations of 5 ppm and 50 ppm throughout a one - generation reproduction study and had no effect on the reproductive success of the birds.
8. REVIEWERS CONCLUSIONS: The study is scientifically sound and fulfills the requirements of an acceptable avian reproduction study with a waterfowl subject to the following re-interpretation of the data. Trifluralin increases the incidence of cracked eggs at 50 ppm exposure levels.

Materials/Methods

Test Procedures

The test methods are consistent with current EPA guidelines for conducting an avian reproduction study. Specifically: Age - 6 months; experimental design - 5 pens/level, 2 males and 5 hens/pen; levels - 5 ppm and 50 ppm with a control; treatment - 10 weeks prior to egg production and 8 weeks during egg production; temperature - allowed to fluctuate with ambient temperature; photoperiod - 9 hours of light for first 7 weeks then increased to 16 hours of light and increased by 15 minutes every 2 weeks for the duration of the study; observations - eggs laid, eggs cracked, eggs set, viable embryos, live 3-week embryos, hatchlings, 14-day old survivors and eggshell thickness.

Statistical Analysis

The Student's t-test was utilized to evaluate the differences between each of the observed reproductive parameters.

Discussion/Results

Refer to attached tables.

Evaluation of the reproductive data and statistical analysis of the reproductive parameters demonstrate that Trifluralin caused no reproductive impairment at the dose levels tested.

Reviewer's Evaluation

A. Test Procedure

The test methods are generally consistent with current EPA guidelines for conducting an avian reproduction toxicity study, with the exception that temperatures (undocumented) were allowed to fluctuate with ambient levels.

B. Statistical Analysis

Anova were performed on all parameters. (see attached)

C. Discussion/Results

A significant ($p = 0.05$) difference was demonstrated only for eggs cracked at the highest treatment level versus control. All other parameters demonstrated no statistical differences although eggs laid per group and eggshell thickness per group were both depressed with increasing concentration.

The data indicate, contrary to the study report, that Trifluralin has slight effect on reproductive success at a level of 50 ppm.

D. Conclusions

1. Category: Core.
2. Rationale: N/A.
3. Repairability: N/A.

Trifluralin Science Reviews

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