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9/24/91

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REVIEW NO.

EEB REVIEW

DATE IN: 09-09-91 OUT: _____

CASE # : 052578 REREG CASE # : _____
SUBMISSION # : S401997 LIST A B C D
ID # : 000707-00203

DATE OF SUBMISSION _____ 07-05-91

DATE RECEIVED BY EFED _____ 09-05-91

SRRD/RD REQUESTED COMPLETION DATE _____ 12-04-91

EEB ESTIMATED COMPLETION DATE _____ 12-04-91

SRRD/RD ACTION CODE/TYPE OF REVIEW _____ 410 - Data Call-In

MRID #(S) _____ 419340-01

DP TYPE _____ 001 - Submission Related Data Package

PRODUCT MANAGER, NO. _____ D. Edwards (19)

PRODUCT NAME(S) _____ Kelthane

TYPE PRODUCT F R I N H D _____ Miticide

COMPANY NAME _____ Rohm and Haas

SUBMISSION PURPOSE _____ Review reproduction study on

INCLUDE USE(S) _____ kestrels

COMMON CHEMICAL NAME _____ Dicofol

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41934001

ECOLOGICAL EFFECTS BRANCH

Chemical Name: Dicofol, Kelthane

100.0 Purpose of Submission

The Registrant (Rohm and Haas) has submitted a study entitled; "Dicofol (Kelthane)- Induced Eggshell Thinning in Captive American Kestrels" to satisfy data requirements as specified in the Dicofol Data Call-In Notice of April 16, 1986.

100.1 Background

The study submitted was sponsored and conducted by the U.S. Fish and Wildlife Service Patuxent Wildlife Research Center at Laurel, Maryland, according to its standard procedures and Investigative Research Plan, Study Plan No. 883.06.04, signed 5/16/86. The study was approved by the EPA for compliance with the Data Call-In Notice in a letter dated June 24, 1987.

The study has been published in Environmental Toxicology and Chemistry, Vol. 9, pp. 1063-1069, 1990.

101.0 Data Adequacy

The following is the abstract for the article as published in the journal:

" Reproductive parameters of American kestrels (*Falco sparverius*) were measured through two breeding seasons. Exposure to Kelthane (containing no DDT-related compounds) at dietary concentrations of 0 (control), 1.0, 3.0, 10 and 30 ug/g (wet weight) began in late November before, and continued through, the second breeding season. Kelthane thinned eggshells and lowered the thickness index at dietary concentrations ≥ 3 ug/g and it reduced shell weight at ≥ 10 ug/g when comparisons to concurrent controls. Kelthane reduced the thickness index at ≥ 3 ug/g and it reduced shell thickness and weight at ≥ 10 ug/g when comparisons were to the same birds during the previous season. All changes were dose-related. It was not previously known that as little as 3 ug/g dicofol could cause these effects. Kestrels resembled previously studied eastern screech owls (*Otus asio*) in that 10 ug/g reduced hatchability of eggs. Both of these raptors showed eggshell changes without the serious effects on production of young. Available data show Dicofol only equal to or less effective than DDE as a shell-thinning agent. Also, DDE may have more impact than dicofol on such critical aspects of reproduction as egg hatchability and survivability of hatchlings. Field

studies of dicofol residues in food chains and of the concentrations in eggs vs. nesting success from areas of heavy dicofol use are needed to judge this chemical's ecological impact."

The EEB believes that the study design and methods used in the study were appropriate for testing to determine if Dicofol induces eggshell thinning in kestrels. The EEB also concurs with the results and discussion of the study provided by the authors (See DER).

102.0

Results

The following is a bullet summary of the results of the study:

1. Kelthane thinned eggshells and lowered the thickness index at concentrations ≥ 3 ug/g (ppm) and reduced shell weight at ≥ 10 ug/g (ppm).
2. Kelthane reduced the thickness index at ≥ 3 ug/g and it reduced shell thickness and weight at ≥ 10 ug/g when comparisons were to the same birds during the previous season.
3. All changes were dose related.

103.0

Discussion

Based upon the results of this study as well as other studies (Wiemeyer et al., 1889, Schwartzbach, et al. 1988, Bennett et al. 1990, and Beavers et al. 1989), dicofol can reduce eggshell thickness, shell weight and/or strength depending upon the species. The issue is whether such effects occur under field conditions and, if so, will they effect other reproductive factors such as hatchability and survivability.

104.0

Conclusions

It is EEB's conclusion that the only way to determine if dicofol causes reproductive impairment to avian species is through the conduct on field tests under actual use conditions. It is important to note that such field testing must be designed to encompass numerous avian species in that the data suggest effects are species specific.

The EEB suggests the Registrant prepare field study protocols for the conduct of these studies as soon as possible. The EEB recommends that the Registrant refer to USEPA publication "Guidance Document for Conducting Terrestrial Field Studies" for guidance on the design and conduct of these studies.

Richard W. Felthousen 9/23/91
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DATA EVALUATION RECORD

- 1. CHEMICAL: Dicofol, Kelthane
- 2. TEST MATERIAL: (4-chloro-alpha(-chlorophenyl)-alpha trichloromethyl)benzenemethanol)
- 3. STUDY TYPE: Eggshell thinning study
- 4. CITATION AND MRID NO: "Dicofol (Kelthane)-Induced Eggshell Thinning in Captive American Kestrels" MRID# 419340-01
- 5. AUTHORS, STUDY DATE, TEST LABORATORY :

Clark, Donald L., Jr., James W. Spann, and Christine M. Bunck, (1990), U.S. Fish and Wildlife Service Patuxent Wildlife Research Center, Laurel, Md.

6. REVIEWED BY:

Richard W. Felthousen
Wildlife Biologist
EEB/EFED

Signature: *Richard W. Felthousen*
Date: 9/23/91

7. APPROVED BY:

Al Vaughan
Acting Section Head
EEB/EFED

Signature: *Allen W. Vaughan*
Date: 9.24.91

8. CONCLUSIONS:

Based upon the results of this study, dicofol can reduce eggshell thickness and shell weight in the kestrel. The issue is whether or not such effects occur under field conditions and, if so, will they effect other reproductive parameters such as hatchability and survivability. It is EEB's opinion that the only way to satisfactorily address this issue is to conduct actual field tests where heavy use of dicifol is likely to occur.

9. RECOMMENDATIONS: See above

10. BACKGROUND: The study was required to satisfy data requirements as specified in the Dicofol Data Call-In Notice of April 16, 1986. The study was sponsored and conducted by the U.S. Fish and Wildlife Service Patuxent Research Center and was approved by EPA for compliance with the Data Call-In Notice in a letter dated June 24, 1987.

11. DISCUSSION OF INDIVIDUAL TESTS: See attached copy of study reprint.

12. MATERIALS AND METHODS: See attached copy of study reprint.

A. Test Animals: American kestrels (Falco sparverious)

B. Dosage: control, 1.0, 3.0, 10 and 30 ug/g (ppm)

C. Test System: Laboratory pen

13. REPORTED RESULTS:

The following is the abstract for the article as published in the journal:

" Reproductive parameters of American kestrels (Falco sparverious) were measured through two breeding seasons. Exposure to Kelthane (containing no DDT-related compounds) at dietary concentrations of 0 (control), 1, 3, 10 and 30 ug/'g (wet weight) began in late November before, and continued through the second breeding season. Kelthane thinned egg shells and lowered the thickness index at dietary concentrations ≥ 3 ug/g and it reduced shell weight at ≥ 10 ug/g when comparisons to concurrent controls. Kelthane reduced the thickness index at ≥ 3 ug/g and it reduced shell thickness and weight at ≥ 10 ug/g when comparisons were to the same birds during the previous season. All changes were dose-related. It was not previously known that as little as 3 ug/g dicofol could cause these effects. Kestrels resembled previously studied eastern screech owls (Otus asio) in that 10 ug/g reduced hatchability of eggs. Both of these raptors showed eggshell changes without the serious effects on production of young. Available data show Dicofol only equal to or less effective than DDE as a shell-thinning agent. Also, DDE may have more impact than dicofol on such critical aspects of reproduction as egg hatchability and survivability of hatchlings. Field studies of dicofol residues in food chains and of the concentrations in eggs vs. nesting success from areas of heavy dicofol use are needed to judge this chemical's ecological impact."

14. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:

15. REVIEWER'S DISCUSSION:

A. Test Procedure: The test procedure was adequate for determining if dicofol is capable of inducing eggshell thickness in the kestrel.

B. Discussion/Results: Based upon the results of this study dicofol can reduce eggshell thickness and shell weight in the kestrel. The issue is whether or not such effects occur under field conditions and, if so, will they effect other reproductive parameters such as hatchability and

survivability. It is EEB's opinion that the only way to satisfactorily address this issue is to conduct actual field tests where heavy use of dicofol is likely to occur.

D. Adequacy of the Study: The EEB believes that the study design and methods used in the study were appropriate for testing to determine if Dicofol induces eggshell thinning in kestrels. The EEB also concurs with the results and discussion of the study provided by the authors.

(1) Classification: CORE

(2) Rationale: The study is scientifically sound and satisfies the requirement as set forth in the Data Call-In Notice.

(3) Repairability: N/A