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REVIEW NO.

EEB REVIEW

DATE IN: 09-09-91 OUT: _____

CASE # : 052578 REREG CASE #: _____
SUBMISSION # : S402171 LIST A B C D
ID # : 000707-00203

DATE OF SUBMISSION 09-03-91

DATE RECEIVED BY EFED 09-09-91

SRRD/RD REQUESTED COMPLETION DATE 12-25-91

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SRRD/RD **ACTION** CODE/TYPE OF REVIEW 400 - Data-Misc

MRID #(S) 420035-01, -02, -03 → 40042005 40042006 40042007
71-4a 72-2A → 72-3C

**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 data submitted to upgrade

INCLUDE USE(S) earlier studies

COMMON CHEMICAL NAME Dicofol

ECOLOGICAL EFFECTS BRANCH

Chemical Name: Kelthane

100.0 Purpose of Submission

In response to EEB Data Evaluation Reports (DERs) the Registrant (Rohm and Haas) has submitted supplemental data for up-grading the following studies to "Core" classification:

| Guideline No. | Title |
|---|---|
| 71-4 | Supplement to the Dicofol (Kelthane Technical Miticide): A one Generation Reproduction Study with the Bobwhite Quail (Rohm and Haas Report No. 86RC-0047 MRID 400420-55) |
| 72-2 A | Supplement to the Dicofol (Kelthane Technical Miticide): Acute toxicity of Kelthane Technical to Daphnia Magna (Rohm and Haas Report No. 85RC-0014 MRID 400420-57) |
| 72-3 C | Supplement to the Dicofol (kelthane Technical Miticide): Acute Toxicity to Mysid Shrimp (Rohm and Haas Report No. 85RC-0046 MRID 400420-60) |

101.0 Data Adequacy

| Guideline No. | |
|---|---|
| 71-4 | The supplemental data provided was a description, including analytical data, of Dicofol (<0.1% DDTr Kelthane Technical Miticide) Lot No. RS-4503, (TD No. 85-211)<br><br>The information provided satisfies the data requirement and has been appended to the original DER for the study. |
| 72-2 | The DER for this study was found to be invalid due to the poor fit of the dose response curve using the probit method (this method could not be used due to the probability of less than 0.05). The EEB calculated the EC50 to be 0.14 mg/l and stipulated that the study would satisfy the data requirement provided the Registrant agreed to this value. The |

supplemental data provided was recalculated using the binomial method. The EC50 calculated for this data set was 0.14 mg/l with a 95% confidence limit of 0.10 to 0.18 mg/l. The Registrant has agreed to the use of this value as the EC50 for dicofol. The statistical analysis will be appended to the original DER for this study along with an analysis conducted by the EEB.

72-3 The original DER stipulated that the study could be up-graded to "Core" provided certain additional information on the test system was reported. The Registrant has provided supplemental information relative to the test system as well as the test organisms (mysid shrimp) for review. This information will be appended to the original DER.

The EEB has found the supplemental information adequate to satisfy the test requirement.

102.0 Conclusions

The supplemental data submitted by the Registrant to support guideline requirements 71-4, 72-2 and 72-3 are adequate to up-grade the studies to "Core" classification. The supplemental information will be attached to the original DER.

Richard W. Feithousen 9/18/91
Richard W. Feithousen, Wildlife Biologist
EFED/EEB

Allen W Vaughan 9.23.91
Al Vaughan, Acting Head-Section 2
EFED/EEB

Douglas J. Urban 9/24/91
Doug Urban, Acting Chief
EFED/EEB