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DP BARCODE (RECORD)

109701
SHAUGHNESSEY NO.

REVIEW NUMBER

ECOLOGICAL EFFECTS BRANCH REVIEW

SEP 10 1991

DATE: IN 8/21/91 **OUT**

CASE # : 816291
SUBMISSION # : S400500
ID # : 109701-010182

REREG CASE # : 2510
LIST A, B, C, D

DATE OF SUBMISSION 5/20/91

DATE RECEIVED BY EFED 8/5/91
SRRD/RD REQUESTED COMPLETION DATE 10/14/91
EEB ESTIMATED COMPLETION DATE 10/14/91

SRRD/RD ACTION CODE/TYPE OF REVIEW Data review
MRID #(S) 418884-01, -02, -03

DP TYPE

PRODUCT MANAGER, NO. Christine Rice, 52

PRODUCT NAME(S) Permethrin

TYPE PRODUCT: I, D, H, F, N, R, S

COMPANY NAME ICI Americas, Inc.

SUBMISSION PURPOSE Review of avian studies required in Phase IV

INCLUDE USE(S)

COMMON CHEMICAL NAME Permethrin

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Subject: Review of data for Permethrin, submitted by ICI Americas Inc. (ID No. 109701-10182)

From: Doug Urban, Acting Branch Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

9/5/91

To: Christine Rice, PM 52
Reregistration Branch
Special Review and Reregistration Division (H7508C)

The Ecological Effects Branch (EEB) has completed its review of the studies submitted by ICI Americas, Inc. for Permethrin. The following is a brief summary of the data reviewed.

1. **CITATION:** Hakin, B., M. Rodgers, A. Anderson, and I.S. Dawe. 1991. Permethrin: Acute oral toxicity (LD_{50}) to mallard duck. Guideline Ref. 71-1(b). Study performed by Huntingdon Research Centre, Ltd., Huntingdon, Cambridgeshire, PE18 6ES UK. Study submitted by ICI Americas Inc. Ag Products, Wilmington, DE 19897. MRID No. 418884-01.

   CONCLUSIONS: This study appears to be scientifically sound and meets the guideline requirements for an avian acute oral study. The LD_{50} was determined to be greater than 2000 mg/kg. Therefore, Permethrin Technical, 94.4%, is practically non toxic to waterfowl.

2. **CITATION:** Hakin, B., M. Rodgers, A. Anderson, and I.S. Dawe. 1991. Permethrin: Subacute dietary toxicity (LC_{50}) to bobwhite quail. Guideline Ref. 71-2(a). Study performed by Huntingdon Research Centre, Ltd., Huntingdon, Cambridgeshire, PE18 6ES UK. Study submitted by ICI Americas Inc. Ag Products, Wilmington, DE 19897. MRID No. 418884-02.

   CONCLUSIONS: This study appears to be scientifically sound and meets the guideline requirements for an avian subacute dietary study. The LC_{50} was determined to be greater than 5200 ppm. The NOEL is greater than 5200 ppm. Therefore, Permethrin Technical, 93.43% active ingredient, is practically non toxic to upland game birds.

3. **CITATION:** Hakin, B., M. Rodgers, A. Anderson, and I.S. Dawe. 1991. Permethrin: Subacute dietary toxicity (LC_{50}) to mallard duck. Guideline Ref. 71-2(b). Study performed by Huntingdon Research Centre, Ltd., Huntingdon, Cambridgeshire, PE18 6ES UK. Study submitted by ICI Americas Inc. Ag Products, Wilmington, DE 19897. MRID No. 418884-03.

CONCLUSIONS: This study appears to be scientifically sound and meets the guideline requirements for an avian subacute dietary study. The LC_{50} was determined to be greater than 5200 ppm. The NOEL is greater than 5200 ppm. Therefore, Permethrin Technical, 93.43%, is practically non toxic to waterfowl.

If you have any questions concerning this, please feel free to contact Renee Lamb at 557-0294.

DATA EVALUATION RECORD

1. **CHEMICAL:** Permethrin
   Shaughnessey Number 109701

2. **TEST MATERIAL:** Permethrin Technical, 94.4% purity, clear amber liquid.

3. **STUDY TYPE:** Acute oral toxicity (LD_{50}) with the mallard duck

4. **CITATION:** Hakin, B., M. Rodgers, A. Anderson, and I.S. Dawe. 1991. Permethrin: Acute oral toxicity (LD_{50}) to mallard duck. Guideline Ref. 71-1(b). Study performed by Huntingdon Research Centre, Ltd., Huntingdon, Cambridgeshire, PE18 6ES UK. Study submitted by ICI Americas Inc. Ag Products, Wilmington, DE 19897. MRID No. 418884-01.

5. **REVIEWED BY:**

   Renee Lamb
   Biologist
   Ecological Effects Branch (H7507C)
   Environmental Fate & Effects Division

   Signature: Renée Lamb
   Date: 8/28/91

6. **APPROVED BY:**

   Ann Stavola
   Head Section 5
   Ecological Effects Branch (H7507C)
   Environmental Fate & Effects Division

   Signature: Ann Stavola
   Date: 8/30/91

7. **CONCLUSIONS:** This study appears to be scientifically sound and meets the guideline requirements for an avian acute oral study. The LD_{50} was determined to be greater than 2000 mg/kg. Therefore, Permethrin Technical, 94.4%, is practically non toxic to waterfowl.

8. **RECOMMENDATIONS:** N/A

9. **BACKGROUND:** N/A

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A

11. **MATERIALS AND METHODS:**

A. **TEST ANIMALS:** The birds, adult Mallards Anas platyrhynchos were 19 months old at test initiation and phenotypically indistinguishable from wild birds. They were obtained from John Coles of the County Game Farms in Ashford, Kent, England. All birds were previously unmated and not in a reproductive state.

The birds were identified using numbered metal wing tags. They were acclimated for 14 days prior to dosing.

B. **TEST SYSTEM:** All birds were housed indoors in pens of polyethylene coated steel wire mesh measuring 1.44 x .55 x .50 m. Average ambient room temperature ranged from 14°C ± 1.4°C to 17°C ± 1.1°C with an average relative humidity of 74% ± 12.9%. The photoperiod was 10 hours of continuous light and 14 hours dark.

C. **DOSAGE:** The treatment levels, 0, 500, 1000, and 2000 mg/kg bodyweight, were based on range finding tests where there was no mortality at 2000 mg/kg bodyweight. The dose concentrations were 0, 10, 20, and 40% w/v.

D. **DESIGN:** Each test group, and the control, were assigned 5 female ducks and 5 male ducks. They were acclimated for 14 days prior to dosing. The birds were allotted to groups on the basis of body weight with the intent of having similar mean body weights in all groups. The groups were then randomly assigned treatment levels.

The birds were given a single dose of the test material or vehicle by oral intubation. Corn oil was used as the vehicle and as a control. All birds were dosed at a rate of 5 ml/kg bodyweight.

The birds were fed a standard HRC layer diet ad libitum throughout the test except for the 21 hour period prior to dosing.

Birds were observed daily for signs of toxicity and abnormal behaviors. Individual body weights were measured on day -14, day -7, day 0, day 7, and on day 14. Group mean feed consumption was determined weekly on days, -14 to -8, -7 to -1, 1 to 7 and days 8 to 14.

At test termination, necropsies were performed on the 10 birds from the highest 2 surviving dose groups and the controls.

E. **STATISTICS**: The data was not analyzed using statistics due to the lack of mortality.

12. **REPORTED RESULTS**:

There were 0 mortalities at any test concentration. Male birds in the 2000 mg/kg group were subdued on days 1 and 2. All other birds were in good health throughout the study.

All control and test groups showed variable bodyweight changes throughout the study and there appeared to be no treatment related effect.

Food consumption was variable in all groups and there appeared to be no treatment related effect.

At the 2000 mg/kg treatment level, a single female bird had an abnormal liver. The surface was covered in yellow/white patches extending beneath the surface. Clear fluid was also found in the abdominal cavity of this bird. No other abnormalities were found from the necropsies, although a single bird in the 2000 mg/kg group had more subcutaneous fat then normal.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES**:

The reported LD_{50} was determined to be greater than 2000 mg/kg.

The report stated that the study was conducted under good laboratory practice standards and is signed be a quality assurance officer.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS**:

A. **TEST PROCEDURE**: This test is in accordance with EPA's SEP protocol with the following exceptions:

o Source of illumination was not reported.

o The birds were acclimated to the facilities for 14 days, SEP recommends at least 15 days.

B. **STATISTICAL ANALYSIS**: No statistics were used to analyze the data.

C. **DISCUSSION/RESULTS**: This study appears to be scientifically sound and meets the guideline requirements for an avian acute oral study.

The LD_{50} was determined to be greater than 2000 mg/kg.

D. **ADEQUACY OF STUDY:**

(1) **CLASSIFICATION:** Core

(2) **RATIONALE:** N/A

(3) **REPAIRABILITY:** N/A

15. **COMPLETION OF ONE-LINER:** Yes, August 28, 1991.

MRID No. 418884-02

DATA EVALUATION RECORD

1. **CHEMICAL:** Permethrin
Shaughnessey Number 109701

2. **TEST MATERIAL:** Permethrin Technical, 93.43% purity, clear yellow liquid.

3. **STUDY TYPE:** Subacute dietary LC_{50} with the bobwhite quail

4. **CITATION:** Hakin, B., M. Rodgers, A. Anderson, and I.S. Dawe. 1991. Permethrin: Subacute dietary toxicity (LC_{50}) to bobwhite quail. Guideline Ref. 71-2(a). Study performed by Huntingdon Research Centre, Ltd., Huntingdon, Cambridgeshire, PE18 6ES UK. Study submitted by ICI Americas Inc. Ag Products, Wilmington, DE 19897. MRID No. 418884-02.

5. **REVIEWED BY:**

Renee Lamb
Biologist
Ecological Effects Branch (H7507C)
Environmental Fate & Effects Division

Signature: Renee Lamb
Date: 8/28/91

6. **APPROVED BY:**

Ann Stavola
Head Section 5
Ecological Effects Branch (H7507C)
Environmental Fate & Effects Division

Signature: Ann Stavola
Date: 8/30/91

7. **CONCLUSIONS:** This study appears to be scientifically sound and meets the guideline requirements for an avian subacute dietary study. The LC_{50} was determined to be greater than 5200 ppm. The NOEL is greater than 5200 ppm. Therefore, Permethrin Technical, 93.43% active ingredient, is practically non toxic to upland game birds.

8. **RECOMMENDATIONS:** N/A

9. **BACKGROUND:** N/A

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A

11. **MATERIALS AND METHODS:**

A. **TEST ANIMALS:** The birds, Bobwhite quail, Colinus virginianus were obtained from D.R. and R.E. Wise in Monkfield, Bourn, England. They were one day old upon arrival and phenotypically indistinguishable from wild type birds. The chicks were 10 days old at test initiation and appeared to be in good health.

B. **TEST SYSTEM:** The birds were housed in wooden pens of approximately 83 x 52 x 51 cm, with wire mesh lids. The boxes were housed in a building designed to provide suitable environmental conditions. 300-watt bulbs were suspended over each box to provide extra heating. Illumination was continuous, and ventilation was adjusted as needed. The temperature ranged from 31°C ± 1.1°C to 27°C ± 1.8°C throughout the study with a mean relative humidity of 33% ± 4.9%.

C. **DOSAGE:** There were 9 test groups, 3 controls and 6 treatments of 163, 325, 650, 1300, 2600, and 5200 ppm.

D. **DESIGN:** Birds were assigned to groups on the basis of body weights, in order for each group to have similar group mean body weights. The groups of 10 birds were randomly assigned to treatment levels. Food and water were fed ad libitum throughout the test. No vehicle was used in the test diet.

Group body weights were measured on day -3 , day 0, 5 and 8. Group mean food consumption was measured on days -3 to -1, 1 to 5 (daily), and 6 to 8. Observations were made daily.

The birds were fed a standard HRC chick diet in meal form throughout the test.

The test diets were prepared by mixing the test substance into the basal diet to form a pre-mix from which the required nominal concentrations were formulated.

E. **STATISTICS:** The data was not analyzed using statistics due to the lack of mortality.

12. **REPORTED RESULTS:**

All birds seemed normal in appearance and behavior throughout the test. There were 0 mortalities at any test concentration.

All control and test groups showed continued bodyweight increase throughout the study and there appeared to be no treatment related effect.

Food consumption was similar in all groups and there appeared to be no treatment related effect.

Nothing abnormal was noted from the gross necropsies performed.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:**

The reported LC_{50} was determined to be greater than 5200 ppm. The NOEL was also determined to be greater than 5200 ppm.

The report stated that the study was conducted under good laboratory practice standards and is signed be a quality assurance officer.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **TEST PROCEDURE:** This test is in accordance with EPA's SEP protocol with the following exceptions:

o Group body weights were measured at test initiation and termination, SEP recommends individual body weights at these times.

o Temperatures inside the brooding chambers were not reported.

o Source of illumination was not reported.

o Temperatures outside the brooder ranged from 27 to 31°C, SEP recommends a range of 22 to 27°C.

B. **STATISTICAL ANALYSIS:** No statistics were used to analyze the data.

C. **DISCUSSION/RESULTS:** This study appears to be scientifically sound and meets the guideline requirements for an avian subacute dietary study.

The LC_{50} was determined to be greater than 5200 ppm. The NOEL is greater than 5200 ppm.

D. **ADEQUACY OF STUDY:**

(1) **CLASSIFICATION:** Core

(2) **RATIONALE:** N/A

(3) **REPAIRABILITY:** N/A

15. **COMPLETION OF ONE-LINER:** Yes, August 26, 1991.

MRID No. 418884-03

DATA EVALUATION RECORD

1. **CHEMICAL:** Permethrin
Shaughnessey Number 109701

2. **TEST MATERIAL:** Permethrin Technical, 93.43% purity, clear yellow liquid.

3. **STUDY TYPE:** Subacute dietary toxicity (LC_{50}) with the mallard duck

4. **CITATION:** Hakin, B., M. Rodgers, A. Anderson, and I.S. Dawe. 1991. Permethrin: Subacute dietary toxicity (LC_{50}) to mallard duck. Guideline Ref. 71-2(b). Study performed by Huntingdon Research Centre, Ltd., Huntingdon, Cambridgeshire, PE18 6ES UK. Study submitted by ICI Americas Inc. Ag Products, Wilmington, DE 19897. MRID No. 418884-03.

5. **REVIEWED BY:**

Renee Lamb
Biologist
Ecological Effects Branch (H7507C)
Environmental Fate & Effects Division

Signature: Renee Lamb
Date: 8/28/91

6. **APPROVED BY:**

Ann Stavola
Head Section 5
Ecological Effects Branch (H7507C)
Environmental Fate & Effects Division

Signature: Ann Stavola
Date: 8/30/91

7. **CONCLUSIONS:** This study appears to be scientifically sound and meets the guideline requirements for an avian ~~acute oral~~ dietary study. The LC_{50} was determined to be greater than 5200 ppm. The NOEL is greater than 5200 ppm. Therefore, Permethrin Technical, 93.43%, is practically non toxic to waterfowl.

8. **RECOMMENDATIONS:** N/A

9. **BACKGROUND:** N/A

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A

11. **MATERIALS AND METHODS:**

A. **TEST ANIMALS:** The birds, Mallard ducklings Anas platyrhynchos were 1 day old and phenotypically indistinguishable from wild birds when obtained from John Coles of the County Game Farms in Ashford, Kent, England. The ducklings were 7 days old at test initiation and appeared to be in good health.

B. **TEST SYSTEM:** All birds were housed indoors in brooding pens of galvanized steel with wire mesh floors measuring approximately 84 x 57 x 27 cm.

C. **DOSAGE:** Each of 9 groups were fed diets containing either 0, 163, 325, 650, 1300, 2600, or 5200 ppm of the test substance. The control birds received basal diet alone.

D. **DESIGN:** Each test group, and the controls, were assigned a pen containing 10 ducklings. The ducklings were immature and were not differentiated by sex. They were acclimated for 4 days prior to test initiation. The birds were allotted to groups on the basis of body weight with the intent of having similar mean body weights in all groups. The groups were then randomly assigned treatment levels.

The birds were fed a standard HRC chick diet ad libitum throughout the test. Average ambient room temperature ranged from 30°C ± .8°C to 26°C ± 2.1°C with an average relative humidity of 51% ± 7.3%. The photoperiod was continuous illumination.

Birds were observed daily for signs of toxicity and abnormal behaviors. Body weights by group were measured on day -4, day 0 and on day 5, and at termination on day 8. Average estimated feed consumption was determined for each group on days, -4 to -1, 1 to 5 (daily), and for the post-exposure period days 6-8. At test termination, necropsies were performed on 10 birds from the highest surviving dose group.

The test diets were prepared by mixing the test substance into the basal diet to form a pre-mix from which the required nominal concentrations were formulated.

E. **STATISTICS:** The data was not analyzed using statistics due to the lack of mortality.

12. **REPORTED RESULTS:**

All birds seemed normal in appearance and behavior throughout the test. There were 0 mortalities at any test concentration.

All control and test groups showed continued bodyweight increase throughout the study and there appeared to be no treatment related effect.

Food consumption was similar in all groups and there appeared to be no treatment related effect.

Nothing abnormal was noted from the gross necropsies performed.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:**

The reported LC_{50} was determined to be greater than 5200 ppm. The NOEL was also determined to be greater than 5200 ppm.

The report stated that the study was conducted under good laboratory practice standards and is signed be a quality assurance officer.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **TEST PROCEDURE:** This test is in accordance with EPA's SEP protocol with the following exceptions:

o Group body weights were measured at test initiation and termination, SEP recommends individual body weights at these times.

o Temperatures inside the brooding chambers were not reported.

o Source of illumination was not reported.

B. **STATISTICAL ANALYSIS:** No statistics were used to analyze the data.

C. **DISCUSSION/RESULTS:** This study appears to be scientifically sound and meets the guideline requirements for an avian acute oral dietary study.

The LC_{50} was determined to be greater than 5200 ppm. The NOEL is greater than 5200 ppm.

D. **ADEQUACY OF STUDY:**

(1) **CLASSIFICATION:** Core

(2) **RATIONALE:** N/A

(3) **REPAIRABILITY:** N/A

15. **COMPLETION OF ONE-LINER:** Yes, August 23, 1991.