4-18-80
167

ECOLOGICAL EFFECTS BRANCH

REVIEW

DATE: IN 3-26-80 OUT 4-18-80

FILE OR REG. NO. 10182-RO, 10182-EUP-11

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED

DATE OF SUBMISSION

DATE SUBMISSION ACCEPTED

TYPE PRODUCTS(S): I, D, H, F, N, R, S

DATA ACCESSION NO(S).

PRODUCT MGR. NO. Castillo (32)

PRODUCT NAME(S) Baquacil

COMPANY NAME ICI American Inc.

SUBMISSION PURPOSE

CHEMICAL & FORMULATION

100.0 Pesticide Labeling Information

See review by A. Rosenkranz on 10-26-79

101.0 Physical and Chemical Properties

See review by A. Rosenkranz on 10-26-79

102.0 Behavior in Environment

See review by A. Rosenkranz on 10-26-79

103.0 Toxicological Properties

See review by A. Rosenkranz on 10-26-79

104.0 Hazard Assessment

104.1 Discussion

See review by A. Rosenkranz on 10-26-79

104.2 Adequacy of Toxicity Data

None of the fish studies submitted to date is acceptable to support registration. Aside from specific defects in each study, the major reason is that technical compound and not the formulated product must be used.

Furthermore, the protocols of the submitted studies should more closely comply with the ones recommended by the Agency, Methods for Acute Toxicity Tests with Fish, Macroinvertebrates, and Amphibians, EPA - 660/3-75-009, April, 1975. The major discrepancies with the rainbow trout study concern the large size of the fish, the short length of the acclimation period, a narrow range of test concentrations, and calculation of the LC50 values with a non-standard method. The major problem with the bluegill study is the low dissolved oxygen value. Two discrepancies with the Daphnia study concern the age of the Daphnia, which must be in the first instar and preferably 6 to 8 hours old at the start of the experiment, and failure to report the mortality data as a total value, not the mean value.

104.3 Additional Data Required

Hydrolysis and Volatility studies are needed.

107 Conclusion

107.1 Data Adequacy

The following studies are not adequate to support registration of Baquacil for the reasons listed.

(a) Acute toxicity of Vantocil 1B, mix No. 1857, to bluegill (lepomis macrochirus) and the water flea (Daphnia magna) dated June, 1977, is unacceptable because

Both studies tested the formulated product; tests on the technical material ~~is~~ are required for registration. If tests on the formulated product ~~is~~ are necessary, it may be used.

(b) Determination of the acute toxicity to rainbow trout of Vantocil IB in freshwater, February, 1975, by Brixham Laboratory, ICI, LTD. BL/B/1631. Study is unacceptable for the following reasons:

(1) Study tested the formulated product.

(2) Using the ET_{50} to determine LC_{50} is not an acceptable method. If the dose-response data are available to determine a 96 hr. LC_{50} value, the study will be reevaluated and may be used if an LC_{50} value for the formulated product is necessary.

107.2 Data Requests

Prior to registration of the product the following basic studies must be supplied or referenced for each active ingredient of the product:

1. Fish acute 96 hour LC_{50} studies for one species of warmwater (preferably bluegill sunfish) and for one species of coldwater (preferably rainbow trout) fish.

2. An aquatic invertebrate acute 48 hour LC_{50} study (preferably for Daphnia magna).

107.3 Environmental Fate and Toxicology

A 20% active ingredient poses no hazard to human health when used as directed in swimming pool (TB/HED).

EFB concluded that the study on the degradation of ^{14}C-Baquacil in soil was deficient. The tentative conclusions are that Baquacil appears to be stable to soil degradation and/or the compound adsorbs rapidly enough to sandy loam and loam soils to make it unavailable for degradative processes to occur. This conclusion is based upon results that indicate that over 50% of the biocide is bound to the soil (maybe to both mineral and organic soil surfaces) and that 30-40% of the bound radioactivity might still be present as the polymeric biguanide.

Water

The study that was submitted on the photodegradation of Baquacil in water was determined by EFB to not fulfill the data requirement.

107.4 Recommendations

The Ecological Effects Branch has no objection to the experimental use of Baquacil

See requirements noted in 107.2

108.0 Note to the P.M.

As noted in section 100.2 of this review, this chemical contains heavy metals. Because one of the metals, cadmium, has been "RPAR'ed" we believe SPRD should be notified.

109.0 The information contained in C-31 submission is of not sufficient to the reviewer to support the rainbow trout study. Based on review conducted by A Rosenkranz on 10-26-79, the study cannot be upgraded to Core. Therefore, another study must be conducted and submitted to EEB for review. See attached computer sheet for Probit Analysis result Contained in C-31

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 80/04/21. 07.59.07.
BASIC      PROGRAM   S79LC50

 ILLEGAL LINE NO    AT  9001
 ILLEGAL STATEMENT AT  9001
BASIC COMPILATION ERRORS

SRU       1.146 UNTS.

RUN COMPLETE.
basic,old,s791c50
READY.
9000 data 6
9001 data 68,47,33,22,15,20
9002 data 10,10,10,10,10,10
9003 data 10,10,10,10,9,0
run

 80/04/21. 08.01.39.
BASIC      PROGRAM   S79LC50


**************************************************************************
CONC.          NUMBER          NUMBER          PERCENT          BINOMIAL
               EXPOSED         DEAD            DEAD             PROB.(PERCENT)
 68             10              10              100              9.76563E-2
 47             10              10              100              9.76563E-2
 33             10              10              100              9.76563E-2
 22             10              10              100              9.76563E-2
 15             10              9               90.              1.07422
 10             10              0               0                9.76563E-2

THE BINOMIAL TEST SHOWS THAT  10  AND  15  CAN BE
USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT
CONFIDENCE LIMITS SINCE THE ACTUAL CONFIDENCE LEVEL
ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.


AN APPROXIMATE LC50 FOR THIS SET OF DATA IS  12.7825


WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT
DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE
PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.
**************************************************************************


SRU       1.250 UNTS.

RUN COMPLETE.
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1. Chemical: Baquacil

2. Formulation: Technical (20% a.i.)

3. Citation: Fink, R. (1979) Eight-Day Dietary LC50-Bobwhite Quail Final Report, Sample #5889, EPA Registration No. 10182-RO; Product Name, Wildlife International LTD for ICI Americas, Inc. Goldsboro, N.C. 27530

4. Reviewed By: C.E. Laird

5. Date Reviewed: April 8, 1980

6. Test Type: Avian Eight-Day Dietary LC50

   A. Test Species: Bobwhite Quail

7. Reported Results:

   There were three mortalities in the negative control groups, each the result of toe picking, and three mortalities occurred at the 3160 ppm dose level on day 4 due to nostril and toe picking.

8. Reviewer's Conclusion:

   The study is scientifically sound and indicates the Baquacil is practically non-toxic to bobwhile quail. The study does fulfill the requirements for an avian eight-day dietary LC50.

Material/Methods

Test Procedure

Not given

Statistical Analysis

Finney Probit

Discussion / Results

The LC50 value was greater than 5620 ppm. There were mortalities in the negative control and three mortalities at the 3160 ppm dosage level.

Reviewer's Evaluation

A. Test Procedure

Test procedure complies with the recommended EPA protocol of 1978.

B. Statistical Analysis

No statistical analysis was performed, because no mortalities occurred at any dosage level due to test chemical.

C. Conclusion

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

1. Chemical: Baquacil

2. Formulation: Technical (20% a.i.)

3. Citation: Fink, R. (1979) Eight-Day Dietary LC50 Mallard Duck Final Report, Sample # 5889, EPA Registration No. 10182-RO; Product Name, Baquacil; Producer Name, Wildlife International LTD for ICI Americas, Inc. Goldsboro N.C. 27530.

4. Reivewed By: C.E. Laird

5. Date Reviewed: April 7, 1980

6. Test Type: Avian Eight-Day Dietary LC50
   A. Test Species: Mallard Duck

7. Reported Results: No mortalities occurred in any Negative control or any dosage level, but there was a slight reduction in feed consumption at all dosage levels tested.

8. Reviewer's Conclusion: This study is scientifically sound and indicates Baquacil is practically non-toxic to mallard duck. The study does fulfill the requirements for an avian eight-day dietary LC50.

Material/Methods

Test Procedure

Not given

Statistical Analysis

Finney Probit

Discussion/Results

Baquacil #5889 did not cause overt symptoms of toxicity or behavioral abnormalities at any dosage level tested. The eight-day LC50 value was greater than 5620 ppm.

Reviewer's Evaluation

A. Test Procedure

Test procedure complies with the recommended EPA Protocol of 1978.

B. Statistical Analysis

No statistical analysis was performed, because no mortalities occurred at any dosage level or in the negative control.

C. Conclusion

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

1. Chemical: Baquacil

2. Formulation: Technical (20% a.i.)

3. Citation: Fink, R. (1979) Acute Oral LD50 for Mallard Duck final report, sample No. 5889, EPA Registration No. 10182-RO, Product Name, Baquacil; Producer Name, Wildlife International LTD for ICI Americas, Inc. Goldsboro, N.C. 27530

4. Reviewed By: C.E. Laird

5. Date Reviewed: April 7, 1980

6. Test Type: Avian Acute Oral LD50

   A. Test Species: Mallard Duck

7. Reported Results: No mortalities occurred in any negative control or any dosage level tested. The LD50 value was greater than 2510 mg/kg.

8. Reviewer's Conclusion:

   The study is acceptable and indicates the Baquacil is practically non-toxic to mallard duck. The study does fulfill the reqirements for an Avian Acute Oral LD50.

Material/Methods

Test Procedures

Not given

Statistical Analysis

Finney Probit Method

Discussion / Results

There was some fighting in the negative control group # five on Day 3. The acute oral LD50 value was greater than 2510 mg/kg.

Reviewer's Evaluation

A. Test Procedure

The test procedure complies with the recommended EPA protocal of 1978.

B. Statistical Analysis

No statistical analysis was performed, because no mortalities occurred at any dosage level or in the negative controls.

C. Conclusion

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