5-5-83
(12-3a)

012301
SHAUGHNESSEY NO.

REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 3/18/83 OUT 5-5-83

FILE OR REG. NO. 352-325

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 3/10/83

DATE RECEIVED BY HED 3/16/83

RD REQUESTED COMPLETION DATE 5/16/83

EEB ESTIMATED COMPLETION DATE 5/9/83

RD ACTION CODE/TYPE OF REVIEW 660/Registration Standard

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

DATA ACCESSION NO (S).

PRODUCT MANAGER NO. R. Taylor (25)

PRODUCT NAME(S) Bromacil

COMPANY NAME Dupont

SUBMISSION PURPOSE Registrant Response to Registration Standard
48-h LC5Ø killi Fish
96-h LC5Ø mysid shrimp } All are not acceptable studies
48-h LC5Ø water fleas

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
012301	Bromacil (5-bromo-3-sec-butyl-6-methyluracil)	95

1

100 Pesticide Name

Bromacil

100.3 Submission Purpose

Registrant response to registration standard

101 Chemical and Physical Properties

101.1 Chemical Name

5-Bromo-3-$EC-butyl-6-methyluracil

101.2 Common Name

Bromacil

103 Toxicological Properties

48-hour LC50 for killifish
96-hour LC50 for mysid shrimp
48-hour LC50 for water fleas
Estimation of no effect concentrations (EE section # 11) in freshwater organisms

107 Conclusions

1. The 48 hour killifish study is not scientifically sound with an LC50 of 10-40 ppm of bromacil. This study does not fulfill the requirement for a 96-hour LC50 fish study.

2. The 96-hour mysid shrimp study is not scientifically sound with an LC50 >1.0 ppm of bromacil. This study does not fulfill the requirement for a 96-hour aquatic invertebrate study.

3. The 48 hr aquatic invertebrate (water flea) study is not scientifically sound with a 3-hour LC50 > 40 ppm. This study does not fulfill the requirement for an aquatic invertebrate study.

4. Ecological Effect Section # 11

   The material submitted in the ecological effects section # 11 were third quarter progress report (January 1 to March 31, 1979) findings or results instead of complete studies. EEB is unable to utilize the submitted material to determine the no effect concentration of bromacil to freshwater organisms because pertinent ecological effects data are lacking:

   a. First, second and obvious fourth quarter test material are missing.
   b. The no effect concentrations can not be determined until all studies are completed.

2

c. The fourth quarter finding can supersede either or all three previous quarters finding.

d. Further, In order for EEB to make a risk assessment for bromacil in support of the registration standard the technical grade material should be used.

The analytical method used in the fathead minnow bioconcentration test should be deferred to Environmental Fate Branch for their review.

EEB has reviewed the data submitted in response to the Registration Standard. EEB is unable to assess the Risk of bromacil to fish and aquatic invertebrates because pertinent ecological effects data are lacking. In order to assess the risks associated with this use, EEB requires the following studies:

a. the avian acute oral LD50 for one species of waterfowl (Mallard Duck, preferably) or one species of upland game bird (Bobwhite Quail or Ring-necked Pheasant);

b. the 96-hour LC50's for a coldwater species (Rainbow Trout) and a warmwater species (Bluegill Sunfish) of fish;

c. the acute 48-hour LC50 for an aquatic invertebrate (Daphnia sp., preferably).

107.1 Toxicology Finding

Organisms	Results(ppm)	Status
Killifish	10-40	Invalid
Mysid Shrimp	>1.0	Supplemental
Water Fleas	>40	Invalid
No effect concentrations	Not determined	Invalid

107.4 Data adequacy conclusions

Test Species	LC50 value ppm	Test Status
Mallard Duck Dietary	>10,000 (80% WP)	Core
Bobwhite Quail Dietary	>10,000 (80% WP)	Core

See validation by R.M. Matheny on 11-23-77

107.5 Data Requests

a. the avian acute oral LD50 for one species of waterfowl (Mallard Duck, preferably) or one species of upland game bird (Bobwhite Quail or Ring-necked Pheasant);

b. the 96-hour LC50's for a coldwater species (Rainbow Trout) and a warmwater species (Bluegill Sunfish) of fish;

d. the acute 48-hour LC50 for an aquatic invertebrate (Daphnia sp., preferably).

107.7 Recommendation

Six basic studies are required using the technical grade material as a minimum data requirement to support a registration. The two avian dietary studies have been acceptable as core. Therefore, the above four basic studies (107.7, a,b and c) are still required to support bromacil registration and should be submitted to this office (EEB).

Curtis E. Laird 5-4-83
Curtis E. Laird
Fishery Biologist
EEB/HED

Norman Cook 5.6.83
Norman Cook
Head, Section #2
EEB/HED

Clayton Bushong 5/6/83
Clayton Bushong, Chief
EEB/HED

MRID 00126345

1. Chemical: Bromacil

2. Formulation: Unknown

3. Citation: Yoshida, K., Nishiuchi, Y. (1970) Toxicity of Pesticide To Killifish; Bulletin Agriculture Inspection Stn; No 12: 122~128 (1972); ACC. # 249679.

4. Reviewed By: Curtis E. Laird
Fishery Biologist
Ecological Effects Branch

5. Date Reviewed: 4-7-83

6. Test Type: 48-hour LC50

A. Test Species: Killifish

7. Reported Results: The reported 48-hour LC50 value was 10-40 ppm.

8. Reviewer's Conclusion: This study appears to indicate bromacil is slightly toxic to killifish with an LC50 10-40 ppm for a 48 hours test. This study, however, does not fulfill the requirement in support of registration.

Material/Methods

Test Procedure

The test procedure did not comply with the recommended EPA protocol of April 1975.

Statistical Analysis

Unknown

Discussion/Results

The reported 48-hour LC50 value was 10-40 ppm.

Reviewer's Evaluation

A. Test Procedure

The test procedure did not comply with the recommended EPA protocol of April 1975 for the following reasons:

a. the test was 48 hours instead of 96.
b. scientific name of fish unknown
c. statistical method unknown
d. pH unknown
e. D.O. unknown
f. % active ingredient unknown
g. secondary source of information was used

B. Statistical Analysis

No statistics were performed due to lack of mortality data.

C. Conclusions

1. Category: Invalid

2. Rationale: See test procedure above

3. Repairability: Not repairable to core

MRID 00126346

Later study in 1989 had an LC50 of 112.9 ppm

1. Chemical: Bromacil (H-11,229)

2. Formulation: 95% (technical a.i.)

3. Citation: Hollister, T. (1980) Acute Toxicity of Fifteen Chemicals to Mysid Shrimp (Mysidopsis bahia); Project No. L 27; Report No. BP-80-2-43; Prepared by EG&G Bionomics for E. I. du Pont de Nemours & Company, Wilmington, Delaware; acc. No. 249679.

4. Reviewed By: Curtis E. Laird
Fishery Biologist
Ecological Effects Branch

5. Date Reviewed: 4-5-83

6. Test Type: 96-hour LC50

A. Test Species: Mysid Shrimp

7. Reported Results: Because the test material was insoluble in test concentrations $\geq$ 1,000 ppb during a 96-hour range-finding test, 1,000 ppb was the highest concentration tested in the definitive test. After 12 hours of exposure, no mortality had occurred in any test concentration or in the control. After 96 hours, the maximum mortality was 10% in 200 ppb; there was no control mortality. The estimated 96-hour LC50 was >1,000 ppb. A no-discernible-effect concentration was not determined. Salinity was 26±3 °/oo and temperature was 24±1°C. Dissolved oxygen concentrations ranged from 86-103% of saturation throughout the test. The pH was 7.9 in all test concentrations and in the control after 96 hours.

8. Reviewer's Conclusions: This study indicates bromacil is moderately toxic to mysid shrimp with an LC50 >1.0 ppm. However, this study does not fulfill the guideline requirement in support of registration because there is a lack of regression relationship between dosage tested and mortalities response (curve almost flat). Also, the solubility of bromacil in water is unclear; it is unclear to the reviewer whether it is 1.0 ppm or 815 ppm.

Material/Methods

Test Procedure

The test procedure did not complied with the recommended EPA protocol of April 1975.

Statistical Analysis

Stephan's computer program

Discussion/Results

The reported 96-hour LC50 value was >1000 ppb and the no-discernible-effect concentration was not determined.

Reviewer's Evaluation

A. Test Procedure

The test procedure did not comply with the recommended EPA protocol of April 1975 for the following reasons:

a. under declaration and certification of ingredient on page #3 (part 1) bromacil solubility is presented as 815 ppm in water. Therefore, the statement on page #4 of the mysid shrimp study which states the highest soluble concentration of bromacil was 1,000 ppb is incorrect.

b. there was a lack of a regression relationship between dosages tested and mortalities response (low or near harizonal curve).

c. neither the 96-hour LC50 value or the no effect level was established for bromacil in this study.

Further, EEB is requesting a clarification of bromacil solubility in water and the # of days the test ran. It appears it was run for 46 days, (1-9-80 to 2-24-80).

B. Statistical Analysis

The probit analysis should not be used with this set of data because the % of mortality did not exceed 50% of the test organisms for the highest or lowest concentration tested due to lack of regression relationship between dosages tested and mortalities response. See attached sheet.

C. Conclusion

1. Category: Supplemental
2. Rationale: See test procedure above
3. Repairability: Before EEB will consider changing the status of this study from supplemental to core, the following information is required:

   a. a clarification of bromacil solubility in water.
   b. no. of days this test ran.

Mysid Shrimp
4-5-83

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	8.08874	1	.558517

SLOPE = -.34941
95 PERCENT CONFIDENCE LIMITS =-1.34316 AND .644338

LC50 = 4.34477E-03
95 PERCENT CONFIDENCE LIMITS = 0 AND 14.1533

LC 10 = 18.7354
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY
****

Dead

(2) RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
7	8.08864	1	.558513

SLOPE = .34941 1
95 PERCENT CONFIDENCE LIMITS =-.644332 AND 1.34315

LC50 = 4.34484E-03
95 PERCENT CONFIDENCE LIMITS = 0 AND 14.1531

LC 10 = 1.00759E-06
95 PERCENT CONFIDENCE LIMITS = 0 AND 1.51777
****

(2) I entered the Number of live, instead of the Number of dead Organisms.

1. Chemical: Bromacil

2. Formulation: Unknown

3. Citation: Yoshida, K. Nishiuchi, Y. (1970) Toxicity of Pesticide To Some Water Organisms; Bulletin Agriculture Inspection Stn; No. 12:122~128 (1972) (Water Fleas); Acc. #249679.

4. Reviewed By: Curtis E. Laird
Fishery Biologist
Ecological Effects Branch

5. Date Reviewed: 4-7-83

6. Test Type: 48-hour LC50 water fleas

A. Test Species: unknown (adults)

7. Reported Results: The reported 3-hour LC50 value was >40 ppm.

8. Reviewer's Conclusions: This study appears to indicate bromacil is slightly toxic to water fleas with an LC50 >40 ppm for 3-hours. This study, however, does not fulfill the guideline requirement in support of registration.

Material/Methods

Test Procedure

The test procedure did not comply with the recommended EPA protocol of April 1975.

Statistical Analysis

Unknown

Discussion/Results

The reported 3-hours LC50 value was >40 ppm.

Reviewer's Evaluation

A. Test Procedure

The test procedure did not comply with the recommended EPA protocol of April 1975 for the following reasons:

a. test was 3 hours instead of 48-hours
b. adults were used instead of 1st instar <24 hrs old
c. % of active ingredient is unknown
d. statistical method unknown
e. pH unknown
f. D.O. unknown
g. scientific name unknown
h. secondary source of information

B. Statistical Analysis

No statistics were performed due to lack of mortality data

C. Conclusions

1. Category: Invalid

2. Rationale: See test procedure above

3. Repairability: Not repairable to core

Third Quarter Progress Report

Ecological Effects Section # 11 is a third quarter progress report and EEB is not considering the information contained therein to support this submission.