

US EPA ARCHIVE DOCUMENT

111801
SHAUGHNESSEY NO.

77
REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 9-3-80 OUT 11-21-80

FILE OR REG. NO. 10182-RO

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 8-27-80

DATE OF SUBMISSION _____

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCT(S): I, D, H, F, N, R, S Bacteria And Algae

DATA ACCESSION NO(S). 243099

PRODUCT MANAGER NO. A. Castillo (32)

PRODUCT NAME(S) Baquacil

COMPANY NAME ICI Americas, INC.

SUBMISSION PURPOSE Data Validation

SHAUGHNESSEY NO.

CHEMICAL, & FORMULATION

% A.I.

111801

Poly (iminoimidocarbonyiminoimicarbonyimino-
hexamethylene)

I talked to Norm Cook on 12/2/80, we
concluded that for a new chemical the
data needs to be complete, thus registration
should be withheld until deficiencies are
corrected

Rob Fyler

ECOLOGICAL EFFECTS BRANCH REGISTRATION DIVISION SUBMISSIONS

18

DATE INTO FILED	DATE PROJECTED RETURN TO RD	EEB ESTIMATED COMPLETION DATE	PRODUCT/REGISTRATION NUMBER/SECTION 3, 5, 18, 24(c), 6(a)(2)	TYPR OF REVIEW	REVIEWER ASSIGNED TO(SECTION)	DATE OF ASSIGNMENT	REVIEWER STARTING DATE	DATE OF REQUEST TO EFB AN/IV/OR TB	RECEIPT OF REQUEST FROM EFB AN/IV/OR TB	REVIEWER COMPLETION DATE(HAND-WRITTEN COPY)	DATE OUT OF EEB	COMMENTS
27/80	12/18/80			Sec. 3	2	8/28/80	9/1/80			10/14/80	11-24-80	

19

100.0 Pesticide Name: Baquacil

100.3 Submission Purpose

1. Submission of 96-hour LC50 Rainbow Trout to support registration
2. " " Bluegill Sunfish " registration
3. " 48-hour LC50 Daphnia Magna " registration

101.0 Chemical and Physical Properties

101.1 Chemical

Poly(iminoimidocarbonyiminoimicarbonyiminohexamethylenehydrochloride)

101.2 Common Name

Baquacil

103 Toxicological Properties

- 48-hour LC50 for Daphnia Magna Straus (0.18 ppm)
- 96-hour LC50 for Bluegill Sunfish (0.62 ppm)
- 96-hour LC50 for Rainbow Trout (3.2 mg/L)

105.0 Conclusion

The 48-hour aquatic invertebrate study is scientifically sound and with an LC50 of 0.18 ppm of Baquacil is highly toxic to Daphnia Magna. The study does fulfill the requirements for an aquatic invertebrate acute LC50.

The 96-hour warmwater fish study is not sound and does not fulfill the requirements for a warmwater fish acute LC50 for the following reason: A 21% dissolved oxygen does not meet the guideline requirements, which states the dissolved oxygen after 48 hour must be between 40% and 100% saturation.

The 96-hour coldwater fish study indicates Baquacil is moderately toxic to Rainbow Trout with an LC50 of 3.2 mg/L. This study does not fulfill the guidelines requirements for a coldwater fish study for the following reason:

- A. The fish weighed 16.4 g instead of 0.5 to 1.0 gram as outlined in EPA protocol of April 1975.
- B. The binomial is not an acceptable method in calculating fish LC50 values. One treatment other than the control must have killed or affected less than 35% of the organisms exposed to it,

20

and one treatment must have killed or affected more than 65% of the organisms.

Bluegill and Rainbow Trout studies are unacceptable to support registration. However, considering the use pattern EEB concurs with the proposed registration provided the registrant agrees to submit acceptable studies for trout and bluegill.

Environmental Hazard Statement: Treated pool effluent should not be discharged where it will drain into lakes, ponds, or streams.

Curtis Laird 11-20-80
Curtis Laird
Fishery Biologist
Ecological Effects Branch/HED

Norman Cook 11-20-80
Norm Cook
Head, Section #2
Ecological Effects Branch/HED

Clayton Busting 11/20/80
Clayton Busting
Chief
Ecological Effects Branch/HED

- 81
1. Chemical: Baquacil
 2. Formulation: 20% a.i.
 3. Citation: Brown, D. (1980) Acute toxicity of Vantocil P" to Rainbow Trout (Salmo Gairdneri), Test No. G 184/B, EPA Registration No. 10182-Ro, Product Name, Baquacil, Producer Name ICI Americas, Inc. Test by, Imperial Chemical Industries Ltd., Brixham Lab., Brixham, Devon.

4. Reviewed By: Curtis Laird
Fishery Biologist
EEB/HED

5. Date Reviewed: Aug. 25, 1980

6. Test Type: Fish acute 96-hour LC50
A. Test Species Rainbow Trout

7. Reported Result:

The 96-hour LC50 is 3.2 mg/L

8. Reviewer Conclusion

The study indicates Baquacil is moderately toxic to rainbow trout. This study does not fulfill the 96-hour acute LC50 requirements for fish. The binominal is not an acceptable statistical method.

82

Material/Methods

Test Procedures

The protocol generally followed the recommended EPA protocol of April 1975. The concentration for this particular study ranged from 1.0 to 13.0 mg/L.

Statistical Analysis

The ET50 method was used

Discussion/Results

The reported 96-hour LC50 was 3.2 mg/L

Reviewer's Evaluation

A. Test Procedures

The test procedure complies with the recommended US EPA 1978 protocol, except for statistics and weight.

B. Statistical Analysis

The LC50 value was verified with Stephan's computer program. Binomial shows an approximate LC50 value of 3.2 mg/L, but the moving average and probit method cannot be determined when there is less than two concentrations at which the percent dead is between 0 and 100.

C. Conclusions

1. Category: Invalid

2. Rationale: a. When there are less than two concentrations at which the percent dead is between 0 and 100, neither the moving average nor probit method can give statistically sound results. As outlined in Stephan's Methods for Acute Toxicity Tests With Fish Microinvertebrates, And Amphibians of April 1975 states one treatment other than the control must have killed or affected less than 35% of the organisms exposed to it, and one treatment must have killed or affected more than 65% of the organisms.

b. Fish with a mean weight of 16.4 g.

c. Bionomical is not an acceptable statistical method.

3. Repairability: Not repairable

- 83
1. Chemical: Baquacil
 2. Formulation: 20% a.i.
 3. Citation: Wheeler, A.G. (1980) Acute Toxicity of Vanticol^R IB to Bluegill (*Lepomis Macrochirus*), Mix No. 1857, EPA Registration No. 10182-Ro, Producer Name ICI Americas, Inc; Tested by EG&G Bionomics, Wareham, Mass. 02571.
 4. Reviewed By: Curtis Laird
Fishery Biologist
EEB/HED
 5. Date Reviewed: Aug. 26, 1980
 6. Test Type: Fish acute 96-hour LC50
 - A. Test Species: Bluegill Sunfish
 7. Reported Results: The 96-hour LC50 value was 0.62 ppm (0.46 to 0.83 ppm). There were no mortalities at any dose level after 24 hours.
 8. Reviewer's Conclusion: This study indicates that Baquacil is highly toxic to bluegill sunfish. However this study does not fulfill the guidelines requirements.

In regard to the registrant's letter dated July 17, 1980, with a saturation of 21% dissolved oxygen does not meet the guideline requirements according to the recommended EPA protocol (Method for Acute Toxicity Tests with Fish, Microinvertebrates and Amphibians) of April. Therefore, another study must be conducted and submitted to this office before it will meet the registration standard.

In regard to the registrant's letter dated August 29, 1980 concerning mortality after 24-hour. The Ecological Effects Branch realizes certain compounds reach their peak of toxicity around the 24-hour period, but there was no information in the submission indicating this process took place with Baquacil.

84

Material/Methods

Test Procedures

The test procedures generally complies with the EPA protocol of April 1975 (Stephan's); except for dissolved oxygen.

Statistical Analysis

Not given

Discussion Results

In addition to the 96-hour LC50 the author provided the following:

Organism	LC50 mg/L	95% Conf. Limit mg/L
Bluegill	24-h 0.62	(0.46-0.83)
	48-h 0.62	(0.46-0.83)
	96-h 0.62	(0.46-0.83)
	(No effect level 0.24 mg/L)	

Reviewer's Evaluation

Test Procedure

The test generally complies with the recommended US EPA 1975, except, for dissolved oxygen.

B. Statistical Analysis

The LC50 value was verified with Stephan's computer programs, binomial, moving average and probit method. See attached sheet.

C. Conclusion

1. Category: Supplementary
2. Rationale: A 21% dissolved oxygen after 48 hours.
3. Repairability: Not repairable

- 84
1. Chemical: Baquacil
 2. Formulation: 20% a.i.
 3. Citation: Sleight III, B.H. (1980) Daphnia Magna Exposure to Vantosil IB # 1857, EPA Registration No. 10182-EUP-11, Product Name: Baquacil, Producer Name, ICI Americas, Inc, tested by EG&G Bionomices; Wareham, Mass. 02571
 4. Reviewer: Curtis Laird
Fishery Biologist
EEB/HED
 5. Date Reviewed Aug. 25, 1980
 6. Test Type: Daphnia acute 48-hour LC50
 7. Reported Results:
The 48-hour acute LC50 is 0.18 (0.12 to 0.30)
 8. Reviewer's Conclusion:

The study is scientifically sound and indicates that Baquacil is highly toxic to Daphnia. The study does fulfill the requirements for an aquatic invertebrate acute 48-hour LC50.

Material/Methods

Test Procedures

The protocol generally followed the recommended EPA protocol of April 1975. For this study the concentration levels ranged from 0.024 to 0.75 ppm.

Statistical Analysis

Not given

Discussion/Results

The 48-hour LC50 value was 0.18 ppm.

Reviewer's Evaluation

A. Test Procedure

The test procedure complies with the recommended US EPA 1975 protocol.

B. Statistical Analysis

The 48-hour LC50 value was verified with Stephan's computer program. The probit method shows the LC50 value to be 0.219 ppm (0.178132 and 0.276 273)

C. Conclusion:

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

asic,old,s79lc50

ADY.

00 data 7

001 data .75,.32,.24,.18,.14,.087,.024

002 data 15,15,15,15,15,15,15

003 data 15,10,7,8,2,2,0

run

Daphnia

highly toxic

80/08/25. 09.20.10.

BASIC PROGRAM S79LC50

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
.75	15	15	100	3.05176E-3
.32	15	10	66.6667	15.0879
.24	15	7	46.6667	50
.18	15	8	53.3333	50
.14	15	2	13.3333	.369263
.087	15	2	13.3333	.369263
.024	15	0	0	3.05176E-3

THE BINOMIAL TEST SHOWS THAT .14 AND .75 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 .250768

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	.418646	.221238	.176389	.303335

RESULTS CALCULATED USING THE PROBIT METHOD

OPERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	.151429	1	.525389

SLOPE = 3.45595

95 PERCENT CONFIDENCE LIMITS = 2.1111 AND 4.80079

LC50 = .219311

95 PERCENT CONFIDENCE LIMITS = .178132 AND .276273

SRU 1.459 UNTS.

RUN COMPLETE.

EL-111

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basic,old,s79lc50
READY:
9000 data 5
9001 data 1.6,.75,.56,.42,.24
9002 data 10,10,10,10,10
9003 data 10,6,3,1,0
run

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80/08/27. 08.02.21.
BASIC PROGRAM S79LC50

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	EXPOSED	DEAD	DEAD	CONC.	PROB.(PERCENT)	B PERC
1.6	10	10		100	9.76563E-2	
.75	10	6		60.	37.6953	
.56	10	3		30.	17.1875	
.42	10	1		10.	1.07422	
.24	10	0		0	9.76563E-2	

THE BINOMIAL TEST SHOWS THAT .42 AND 1.6 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 .681216

-----RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	.274069	<u>.695051</u>	.556508	.941588

-----RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	.348393	1	.988398

SLOPE = 6.71453
 95 PERCENT CONFIDENCE LIMITS = 2.75129 AND 10.6778

LC50 = .671384
 95 PERCENT CONFIDENCE LIMITS = .563195 AND .891737

SRU 1.323 UNTS.
 RUN COMPLETE.

The 24, 48 AND 96-hour LC50 VALUE
 Are the same

Rainbow Trout

Moderately toxic
(Binomial Test method)

sic,old,s79lc50

ADY.

00 data 6

01 data 13,10,7.5,5.6,3.2,1

02 data 20,20,20,20,20,20

03 data 20,20,20,20,10,0,0

n

0/08/25. 09.31.42.

SIC PROGRAM S79LC50

NC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
3	20	20	100	9.53674E-5
0	20	20	100	9.53674E-5
.5	20	20	100	9.53674E-5
.6	20	20	100	9.53674E-5
.2	20	10	50	58.8099
	20	0	0	9.53674E-5

THE BINOMIAL TEST SHOWS THAT 1 AND 5.6 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.

APPROXIMATE LC50 FOR THIS SET OF DATA IS 3.2

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

U 1.263 UNITS.

N-COMplete.