1-9-91

124474
MRID No.

112701
Shaughnessy No.

Data Evaluation Record

BRODIFACOUM

Acute toxicity for freshwater fish (TEP)

GUIDELINE NUMBER: 72-1 (b)

CITATION: Hill, R.W. 1978. Brodifacoum: Determination of the acute toxicity of a 0.25% W/W formulation to Bluegill sunfish *Lepomis macrochirus*. Submitted by ICI Americas, Inc., Agricultural Products, Wilmington, Delaware 19897. Report No. BL/B/1879. Study No. E/038/B.

REASON FOR SUBMISSION:

FIFRA '88 Reregistration.

RESULTS-	Valid _____	Invalid X	Supplemental _____
GUIDELINE-	Satisfied _____	Partially Satisfied _____	Not Satisfied X

DISCUSSION:

The LC_{50} was calculated with two sets of measured concentrations that were done in two series. Since Brodifacoum degrades, the calculation based upon the nominal concentrations is not acceptable.

There were "On" and "Off" measurements of the concentration:

'ON' measured immediately after test concentration is prepared.
'OFF' measured 24 hours after preparation.

Because of the phrasing of these definitions, EEB infers that the chemical analysis was not done on aquarium water, but was done on the stock solutions instead. This is inappropriate because of the changes in the concentrations that may be brought about by the fishes' metabolism.

ICI never calculates the LC_{50} based upon measured concentrations, but it does offer a table that would allow the calculation to be made using the "OFF" data. The "OFF" data is more appropriate than the "ON" data, but if there is little variation, mean levels can also be accepted.

Little explanation is given for the two "series" of groups. "Series II" appears to have been designed to "Fill-in" gaps in the range of concentrations used. The dates of the test (April 3 to 14) lead EEB to infer that the test were conducted separately then their results were combined in order to calculate the LC_{50}. This is not statistically acceptable.

EEB has made it's calculations by using the "OFF" data and combining the two series and converting the results to "percent active ingredients." If the results are accepted, the LD_{50}=0.009 mg/kg (CI 0.000 to 0.002). The relation of the nominal to the measured concentrations and to

the mortality is not linear. The report states, "Problems occurred due to low oxygen levels which were recorded at the end of each 24 hours period." These low oxygen levels were enough to cause the unexpected results and to permanently classify the study as "Invalid."

CONCLUSIONS: Change classification to "Invalid".

REVIEWED BY:

James J. Goodyear
Biologist, Section 1
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

Signature: James J. Goodyear
Date: Jan 4, 1991

APPROVED BY:

Leslie W. Touart
Acting Head, Section 1
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

Signature: L. W. T.
Date: 1-9-91

VALIDATION SHEET CRF #_____PAGE_____OF_____

FORMULATION: JFU 5074	IA	IB	T	FW	EC	R		
% a. i. SC# CHEMICAL NAME	Validator: Larry Turner					Date: April 17, 1979		
0.25% brodifacoum	Test Type: Fish acute 96 hour LC_{50} Bluegill sunfish							
	Test ID.# ES-I1							

CITATION: Hill, R. W. 1978. Determination of the acute toxicity of formulation JFU 5074 to bluegill sunfish (Lepomis macrochirus). 19 p. Study conducted by Imperial Chemical Industries, Ltd., Brixham Laboratory. Submitted by ICI Americas, 10182-26; Acc. No. 234655, Report 10I; 8/15/78.

RESULTS: Bluegill sunfish 96 hour LC_{50}= 12.89 mg/l (95% c.i. 10.68-15.56 mg/l). No mortality occurred at the lowest level of 4.2 mg/l; 100% mortality occurred at the four highest levels of 32 mg/l and up. Toxic symptoms included darkness and weakness and were observed at all levels above 4.2 mg/l. Control mortality was 5%. (See note at end for values based on measured concentrations).

VALIDATION CATEGORY: Supplemental

CATEGORY RATIONALE: Although two series of dose levels were tested at different times, there appears to be no intent to hide this fact. Statistical analyses indicated that LC_{50} for the combined series was about midway between the values for each separate series, both of which generally approximated the combined value. 0_2 levels rapidly lowered to less than acceptable values, but fresh concentrations were mixed daily. Toxicant concentrations were extremely low in some concentrations and controls just prior to renewal. The formulated product was tested. Basically the test appeared good, but not precise due to the above factors.

CATEGORY REPAIRABILITY: No repair is possible. Even if a test is required on the formulated product, the factors noted above appear to be significant enough to preclude upgrading this test.

ABSTRACT: Bluegill sunfish were exposed for 96 hours to formulation JFU 5074 of brodifacoum in two series of concentrations, as given below:

Series	Date Started	Concentration	96-Hour Mortality
I	4/3/78	100	10/10
		75	10/10
		56	10/10
		32	10/10
		10	0/10
		5.6	1/10
		Control	1/10
II	4/10/78	21	9/10
		15.5	8/10
		4.2	0/10
		Control	0/10

Because of degradation and/or precipitation of the test materials concentrations were renewed each day. Fresh concentrations were measured at 66-112% of nominal. When measured just prior to renewal, measured concentrations were 3-60% of nominal. The investigator commented on the latter results as being quite erratic and probably unrealistic, as were controls. But no data were given for controls in order to evaluate investigator's comments. Oxygen determinations just prior to renewal showed notably low levels, especially in series II where 5 of 16 measurements indicated less than 20% 0_2 saturation in spite of high initial levels. This reviewer considers that the high temperature, loading of .82 g/l, use of formulated product, and test material breakdown could be potential causes of low, final 0_2 levels.

Procedures generally followed Stephan (USEPA, 1975). Procedural discrepancies included use of formulated product, two different series of tests, and water temperature of 23 ± 1 C°. Results discrepancies are noted in the above paragraph or in the following paragraph on statistics.

Statistical analysis was conducted according to the Finney probit method, combining the data from both test series. When checked on the EEB calculator, an LC_{50} value of 12.88 mg/l - essentially the same as reported - was obtained. Each of the separate series were also analyzed by this reviewer. For Series I, a Spearman-Karber analysis yielded an LC_{50} value of 17.35 mg/l. For Series II, a Spearman-Karber analysis and Finney probit analysis yielded LC_{50} values of 9.58 and 11.76 mg/l, respectively. Both Spearman-Karber values were outside the confidence limits reported for the combined series.

NOTE: In Accession 237703, additional information on this test was supplied. The LC_{50} values for 24, 48, 72, and 96 hours were calculated, apparently by probit analysis, based on (a) measured fresh concentrations, (b) measured concentrations just prior to renewal, and (c) mean values of the above two. These 96-hour values are given below.

Bluegill 96-hour LC_{50} (.25%) = (a) 10.5 ppm (b) 1.7 ppm, (c) 7.5 ppm

96 hr LC_{50} - bluegill
Finney probit
brodifacoum 0.25%

L.Turner
4/17/79

Series II doses only

4.2	
0.	
10.	
15.5	
8.	
10.	
21.	
9.	
10.	
5.815	M
-1.224	YINT
1.486	LW M
0.268	CHI^2
11.756	LD50
8.136	LDCL
16.987	UPCL
7.077	LD10
3.460	LDCL
14.474	UPCL
19.531	LD90
14.356	LDCL
26.570	UPCL

96 hr LC_{50} - bluegill
α-Trimmed Spearman-Kärber
brodifacoum 0.25%

L.Turner
4/17/79

Series II doses only

4.2	
0.	
10.	
15.5	
8.	
10.	
21.	
9.	
10.	
10.	%TRM
9.58	LC50
7.39	LDCL
12.43	UPCL

96-hour LC_{50} - bluegill
α-Trimmed Spearman-Kärber
brodifacoum 0.25%

L.Turner
4/17/79

Series II doses only

5.6	
1.	
10.	
10.	
0.	
10.	
32.	
10.	
10.	
56.	
10.	
10.	
75.	
10.	
10.	
100.	
10.	
10.	
10.	%TRM
17.35	LC50
15.87	LDCL
18.96	UPCL

96-hour LC_{50} - bluegill
brodifacoum 0.25%
Finney probit

L.Turner
4/16/79

Series I and II doses combined.

4.2	
0.	
10.	
5.6	
1.	
10.	
10.	
0.	
10.	
15.5	
8.	
10.	
21.	
9.	
10.	
32.	
10.	
10.	
56.	
10.	
10.	
75.	
10.	
10.	
100.	
10.	
10.	
5.946	M
-1.601	YINT
1.473	LW M
8.788	CHI^2
12.884	LD50
10.678	LDCL
15.545	UPCL
7.842	LD10
5.744	LDCL
10.707	UPCL
21.166	LD90
16.156	LDCL
27.729	UPCL

ENVIRONMENTAL FATE AND EFFECTS DIVISION

ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

CHEMICAL AI NAME: Brodifacoum **CASE NO.:** 2755
CHEMICAL NO.: 112701

REVIEWER'S NAME: James J. Goodyear
TELEPHONE NUMBER: 703-557-7726
DATE: January 4, 1991

USE PATTERN(S): In and around buildings.

GUIDELINE NO.: 72-1 (b). Acute toxicity for freshwater fish (TEP).

TITLE: Brodifacoum: Determination of the acute toxicity of a 0.25% W/W formulation to Bluegill sunfish *Lepomis macrochirus*. Submitted by ICI Americas, Inc., Agricultural Products, Wilmington, Delaware 19897. Report No. BL/B/1879. Study No. E/038/B.

MRIDS AND DATES OF STUDIES REVIEWED: MRID 124474 (1978) in 92195-009 (1990).

MRIDS AND DATES OF FULLY ACCEPTABLE STUDIES: None.

COMMENTS: Invalid.

The LC_{50} was calculated with two sets of measured concentrations that were done in two series. Since Brodifacoum degrades, the calculation based upon the nominal concentrations is not acceptable. EEB infers that the chemical analysis was not done on aquarium water, but was done on the stock solutions instead. This is inappropriate because of the changes in the concentrations that may be brought about by the fishes' metabolism.

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U.S. Environmental Protection Agency

Office of Pesticide Programs Information Network

Results

1 Items Found

MRID
1) 124474

Back to Query

Summary Information For *Study 124474*

MRID: 124474

Citation Reference: Hill, R. (1979) PP 581: Determination of the Acute Toxicity of Formulation JFU 5074 to Bluegill Sunfish ...: BL/B/1879. (Unpublished study received Feb 27, 1979 under 10182-26; prepared by Imperial Chemical Industries, Ltd., Eng., submitted by ICI Americas, Inc., Wilmington, DE; CDL:237703-E)

Author: Hill, R.

Content Category: Incomplete or summarized -- experimental research

Receipt Date: 27-Feb-1979

Laboratory Project #: NO PROJNR

Accession #: 237703 E

Products Tested:

Status: Acceptable (07-Jun-1991)

DP #:

Ingredients

PC Code	CAS #	Ingredient Name
112701	56073-10-0	Brodifacoum
Total Rows: 1		

Laboratory

Laboratory #	Laboratory Name
959804	Imperial Chemical Industries, Ltd./Zeneca
Total Rows: 1	