1-9-91

124473
MRID No.

112701
Shaughnessy No.

Data Evaluation Record

BRODIFACOUM

Acute toxicity for freshwater fish

GUIDELINE NUMBER: 72-1 (d)

CITATION: Hill, R.W. 1978. Brodifacoum: Determination of the acute toxicity of a 0.25% w/w formulation to Rainbow trout *Salmo gairdneri*. Submitted by ICI Americas, Inc., Agricultural Products, Wilmington, Delaware 19897. Report No. BL/B/1874. Study No. E038/A.

REASON FOR SUBMISSION:

FIFRA '88 Reregistration.

RESULTS-	Valid _____	Invalid _____	Supplemental X
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 variation is small, means could be used.

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 (March 6 to 19) lead EEB to infer that the test were conducted separately then their results were combined in order to calculate the LC_{50}.

EEB has made it's calculations by using the "OFF" data and combining the two series. The study could be upgraded to "Core" by explaining the points discussed here and/or recalculating

the data. Since LC_{50}s should be reported as "percent active ingredient," EEB has converted the ICI's figures to %ai.

CONCLUSIONS: Change the classification to- "Supplemental" LC_{50} = 0.02 mg/kg (0.01 - 0.03), NOEL <0.01 mg/kg.

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VALIDATION SHEET CRF #_____PAGE_____OF_____

FORMULATION: JFU 5074			IA	IB	T	FW	EC	R		
% a.i.	SC #	CHEMICAL NAME	Validator: Larry Turner					Date: April 16, 1979		
0.25%		brodifacoum	Test Type: Fish acute 96 hour LC_{50} Rainbow Trout							
			Test ID.# ES-J1							

CITATION: Hill, R. W. 1978. Determination of the acute toxicity of formulation JFU 5074 to rainbow trout (Salmo gairdneri). 19 p. Study conducted by Imperial Chemical Industries, Ltd., Brixham Laboratory. Submitted by ICI Americas, 10182-26; Acc. No. 234655, Report 9I; 8/15/78.

RESULTS: Rainbow trout 96 hour LC_{50} - 17.36 mg/l (95% c.i. 15.86-19.01 mg/l). No mortality occurred at the 3 lowest levels up to 10.0 mg/l; 100% mortality occurred at the 5 highest concentrations of 24.0 mg/l and up. Toxic symptoms included swimming at the surface, weakness, and darkened coloration. There was no observed effect on controls or fish treated at 4.2 and 5.6 mg/l. (See note at end for values based on measured concentrations.)

VALIDATION CATEGORY: Supplemental (core for formulated Product)

CATEGORY RATIONALE: Although two series of dose levels were run at separate times, there appeared to be no intent to hide this fact. Statistical analyses showed that the LC_{50} was approximately the same for either series or for the combination. The test appeared to meet or exceed all other standards and protocol recommendations except that the formulated product was tested.

CATEGORY REPAIRABILITY: No repair is possible, although this test can be considered core if a test on the formulated product is required.

ABSTRACT: Rainbow trout 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	3/6/78	75	10/10
		56	10/10
		32	10/10
		18	6/10
		10	0/10
		Control	0/10
II	3/10/78	42	10/10
		24	10/10
		15.5	2/10
		5.6	0/10
		4.2	0/10
		Control	0/10

Because of degradation and/or precipitation of the test material, concentrations were renewed each day. Fresh concentrations were measured at 67-120% of nominal, while just prior to renewal concentrations were measured at 42-82% of nominal.

Procedures very closely followed Stephan (USEPA, 1975), except that the formulated product was tested, water temperature was $13\pm1^{o}C$, and two different dose series were tested at different times. Statistical analysis was conducted according to the Finney probit method, combining both of the dose series. When checked on the EEB calculator, the data would not run with all 0% and 100% mortality levels included. When the lowest 0% and the three highest 100% mortality levels were excluded, an LC_{50} value of 17.31 mg/l was obtained, with an acceptable chi square value. Each of two separate series was analyzed according to the Spearman-Karber method because the individual series had only one partial mortality level each. Comparable LC_{50} values of 16.75 mg/l and 17.75 mg/l were obtained for Series I and II, respectively.

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.

Rainbow 96-hour LC_{50} (.25%) = (2) 12.3 ppm, (b) 8.7 ppm, (c) 10.6 ppm

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

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4/16/79

Series I and II combined with the lowest 0% mortality and the three highest 100% mortality levels dropped.

5.6	
0.	
10.	
10.	
0.	
10.	
15.5	
2.	
10.	
18.	
6.	
10.	
24.	
10.	
10.	
32.	
10.	
10.	
18.551	M
-17.973	YINT
1.132	LW M
0.077	CHI²
17.314	LD50
16.090	LOCL
18.632	UPCL
14.767	LD10
12.960	LOCL
16.826	UPCL
20.301	LD90
17.483	LOCL
23.573	UPCL

96-hour LC_{50} - rainbow trout
α-trimmed Spearman-Kärber
brodifacoum 0.25%

L. Turner
4/16/79

Series I doses only

10.	
0.	
10.	
18.	
6.	
10.	
32.	
10.	
10.	
56.	
10.	
10.	
75.	
10.	
10.	
10.	%TRM
16.75	LC50
13.42	LOCL
20.90	UPCL

96-hour LC_{50} - rainbow trout
α-trimmed Spearman-Kärber
brodifacoum 0.25%

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4/16/79

Series II doses only

4.2	
0.	
10.	
5.6	
0.	
10.	
15.5	
2.	
10.	
24.	
10.	
10.	
42.	
10.	
10.	
10.	%TRM
17.75	LC50
13.56	LOCL
23.24	UPCL