107401

IBT DATA GAP EVALUATION FORM

28 APR 1981

Shaughnessy No. 107401

Chemical D.C. 5700

EEB File Reviewed for Supportive F & W Studies:

Test Material		Species	Test	IBT Test #	Test Status Valid	Test Status Invalid	Major IBT Gap
?	%	Bluegill Sunfish	LC50	A-1904		X	X†
?	%	Rainbow Trout	LC50	A-1904		X	X†

Uses: Industrial preservative finish for textiles.

Data Gaps: Missing valid studies for all six basic Fish and Wildlife tests

Six Basic Studies on Technical Material	Technical Have	Technical Major Data Gap	Formulations Powder Have	Formulations Powder Data Gap	Formulations Granular Have	Formulations Granular Data Gap	Formulations Concentrate Have	Formulations Concentrate Data Gap
Avian Acute Oral LD50								
Avian Upland Game LC50								
Avian Waterfowl LC50								
Warm-water Fish LC50		X						
Cold-Water Fish LC50		X						
Aquatic Invert. EC50								
Additional Studies:								
Estuarine Fish LC50								
Estuarine Shrimp EC50								
Molluscan Larvae EC50								
Shell Deposition EC50								
Estuarine Algae EC50								
Fish Accumulation								
Avian Accumulation								
Avian Field Study								
Upland Game Species								
Waterfowl Species								
Avian Reproduction								
Upland Game Species								
Waterfowl Species								

† We suggest that the replacement studies for these two fish studies be conducted on the technical material, rather than the formulated product.

Reviewer: William S. Rabert

William S. Rabert, Biologist
Ecological Effects Branch, HED

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Data Evaluation Record

1. Chemical: TX-793 or Dow Corning X-9-5700
(3- (Trimethoxysilyl)propyl dimethyl octadecyl ammonium chloride)

2. Formulation: Unknown

3. Citation: Report to Dow Corning Corporation - Four Day Static Fish Toxicity Studies with Tx-793 in Rainbow Trout and Bluegills; IBT Report A-1904 submitted 9/29/72.

4. Reviewed By: T. B. Johnston
Biologist, EEB/HED
June 18, 1980

5. Test Type: 96-hr LC50s to rainbow trout and bluegill sunfish

6. Reported Results: The 96-hour LC50 of TX-793 (also known as Dow Corning X-9-5700 and 3-(Trimethoxysilyl)propyl dimethyl octadecyl ammonium chloride) was 0.56 ppm for rainbow trout, and 0.51 ppm for bluegill sunfish.

7. Reviewer's Conclusions: The studies are not scientifically sound and do not fulfill the requirements for acute toxicity tests on coldwater and warmwater fish.

Materials/Methods

Protocol generally followed EPA guidelines, but several important deviations were noted. First, the control and solvent control tests were run one week earlier than the toxicant tests. Therefore, test and control animals could not have been randomly chosen from the same population. Second, the raw data sheets showed 10% mortality among the rainbow trout controls, and 70% mortality among the bluegill solvent controls, but these data went unmentioned in the final report. Apparently IBT simply ignored any results that were inconvenient. Third, IBT used polyethylene liners in all test chambers. Many toxicants can adsorb to polyethylene surfaces, reducing the actual test concentrations well below the nominal levels. Where such bags are used, the Agency requires post-test measurements of the actual toxicant concentrations. There is no indication in the reports that such measurements were made.

Statistical Analysis

The LC50s and 95% confidence limits were calculated according to the methods of Litchfield Wilcoxon. This reviewer's analysis (by the Finney probit method) gives slightly different results when applied to the final report data.

Apparently, an error was made during the transfer of trout mortality data from the raw data sheets to the final report tables. The raw data sheets are difficult to read, but they appear to indicate only 4 trout mortalities at the 0.56 ppm level, rather than the 5 that were reported.

Results/Discussion

Concentration (ppm)	No. Mortalities/No. in Group
Rainbow Trout	
Control	0/10 (2/20*)
Solvent control	Not given (0/10*)
0.10	0/10
0.18	2/10
0.32	1/10
0.56	5/10 (4/10*)
1.00	10/10

LC50 = 0.56 ppm (95% C.I. = 0.34 - 0.92 ppm)
LC50 = 0.50 ppm** (95% C.I. = 0.36 - 0.73 ppm)**

Bluegill	
Control	0/10
Solvent control	Not given (7/10*)
0.10	0/10
0.18	1/10
0.32	1/10
0.56	6/10
1.00	10/10

LC50 = 0.51 ppm (95% C.I. = 0.38 - 0.69 ppm)
LC50 = 0.46 ppm** (95% C.I. = 0.35 - 0.62 ppm)**

*As recorded on raw data sheets
**As calculated by the reviewer from data on raw data sheets.

Reviewer's Evaluation:

Validation Category: Invalid
Category Nationale: The test substance may have adsorbed to the polyethylene liners used in the test vessels. Such adsorption could reduce toxicant concentrations in the test vessels to levels well below the nominal concentrations given. Also, IBT (the testing lab) used fish from different groups for the control, solvent control, positive control, and toxic materials tests. Good laboratory practice demads that control and experimental animals be randomly selected from a single group.

Category Repairability: The trout test may be upgraded to Supplemental if the laboratory can show evidence that they measured ambient toxicant levels in each test vessel at the conclusion of each test, and that these levels approximated the nominal concentrations. The test cannot be upgraded to Core because the control and experimental fish were not taken from the same group.

The bluegill test may not be upgraded, because 70% of the solvent control fish died. Such a high mortality rate among control animals indicates problems with test conditions, water quality, and/or the fish themselves.

	EXPOSED	DEAD	DEAD	PROB.(PERCENT)
1	10	10	100	9.76563E-2
.56	10	5	50	62.3047
.32	10	1	10.	1.07422
.18	10	2	20.	5.46875
.1	10	0	0	9.76563E-2

THE BINOMIAL TEST SHOWS THAT .1 AND 1 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.

96-HR LC50
RAINBOW TROUT TEST
IBT REPORT A-1904
2/29/72
(REPORTED MORTALITIES USED)

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .56

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

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	.218715	.493996	.363545	.731881

--------RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	.226161	1	9.14559E-2

SLOPE = 3.67321
95 PERCENT CONFIDENCE LIMITS = 1.92637 AND 5.42006

LC50 = .466178
95 PERCENT CONFIDENCE LIMITS = .344017 AND .66301

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
1	10	10	100	9.76563E-2
.56	10	4	40.	37.6953
.32	10	1	10.	1.07422
.18	10	2	20.	5.46875
.1	10	0	0	9.76563E-2

THE BINOMIAL TEST SHOWS THAT .1 AND 1 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.

96-HR LC50
RAINBOW TROUT TEST
IBT REPORT A-1904
2/29/72
(RAW DATA SHEET MORTALITIES USED)

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .602724

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

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	.218109	.52307	.387217	.795134

--------RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	.236619	1	5.63889E-2

SLOPE = 3.50858
95 PERCENT CONFIDENCE LIMITS = 1.80188 AND 5.21528

LC50 = .496139
95 PERCENT CONFIDENCE LIMITS = .363792 AND .726713

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
1	10	10	100	9.76563E-2
.56	10	5	50	62.3047
.32	10	1	10.	1.07422
.18	10	2	20.	5.46875
.1	10	0	0	9.76563E-2
0	20	2	10.	

96-HR LC50
RAINBOW TROUT TEST
IBT REPORT A-1969
2/24/72
(REPORTED MORTALITIES USED) - USING ABBOTT'S CORRECTION FOR CONTROL MORTALITY

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .56

THE BINOMIAL TEST SHOWS THAT .1 AND 1 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.

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

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	.218715	.493996	.363545	.731882

--------RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	CHI-SQUARE	PROBABILITY
6	.226161	1	6.45496	9.14559E-2

SLOPE = 3.67321
95 PERCENT CONFIDENCE LIMITS = 1.92637 AND 5.42006

LC50 = .466178
95 PERCENT CONFIDENCE LIMITS = .344017 AND .66301

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RESULTS USING ABBOTT°S FORMULA-----TENTATIVE VERSION-----
CONTACT CHARLES STEPHAN IF YOU HAVE QUESTIONS OR COMMENTS

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
1	9	9	100	.195313
.56	9	4	44.4444	50
.32	9	0	0	.195313
.18	9	1	11.1111	1.95313
.1	9	-1	-11.1111	0
0	20	2	10.	

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .584751

THE BINOMIAL TEST SHOWS THAT .32 AND 1 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.

THE MOVING AVERAGE METHOD CANNOT BE USED WITH THIS SET OF DATA BECAUSE NO SPAN WHICH PRODUCES MOVING AVERAGE ANGLES THAT BRACKET 45 DEGREES ALSO USES TWO PERCENT DEAD BETWEEN 0 AND 100 PERCENT.

THE PROBIT METHOD PROBABLY CANNOT BE USED WITH THIS SET OF DATA SINCE CONVERGENCE WAS NOT ACHIEVED IN 100 ITERATIONS.

COMPARE ALL RESULTS WITH ORIGINAL DATA TO BE SURE THE RESULTS ARE REASONABLE.

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
1	10	10	100	9.76563E-2
.56	10	4	40.	37.6953
.32	10	1	10.	1.07422
.18	10	2	20.	5.46875
.1	10	0	0	9.76563E-2
0	20	2	10.	

96-HR LC50
RAINBOW TROUT TEST
IBT REPORT A-1404
2/24/72
(RAW DATA SHEET MORTALITIES USED)
-USING ABBOTT'S CORRECTION FOR CONTROL MORTALITIES

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .602724

THE BINOMIAL TEST SHOWS THAT .1 AND 1 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.

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

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	.218109	.523071	.387217	.795134

--------RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	CHI-SQUARE	PROBABILITY
7	.236619	1	7.54597	5.63891E-2

SLOPE = 3.50858
95 PERCENT CONFIDENCE LIMITS = 1.80188 AND 5.21528

LC50 = .496139
95 PERCENT CONFIDENCE LIMITS = .363792 AND .726713

AAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAA
RESULTS USING ABBOTT°S FORMULA----TENTATIVE VERSION----
CONTACT CHARLES STEPHAN IF YOU HAVE QUESTIONS OR COMMENTS

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
1	9	9	100	.195313
.56	9	3	33.3333	25.3906
.32	9	0	0	.195313
.18	9	1	11.1111	1.95313
.1	9	-1	-11.1111	0
0	20	2	10.	

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .627764

THE BINOMIAL TEST SHOWS THAT .32 AND 1 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.

THE MOVING AVERAGE METHOD CANNOT BE USED WITH THIS SET OF DATA BECAUSE NO SPAN WHICH PRODUCES MOVING AVERAGE ANGLES THAT BRACKET 45 DEGREES ALSO USES TWO PERCENT DEAD BETWEEN 0 AND 100 PERCENT.

THE PROBIT METHOD PROBABLY CANNOT BE USED WITH THIS SET OF DATA SINCE CONVERGENCE WAS NOT ACHIEVED IN 100 ITERATIONS.

COMPARE ALL RESULTS WITH ORIGINAL DATA TO BE SURE THE RESULTS ARE REASONABLE.

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
1	10	10	100	9.76563E-2
.56	10	6	60.	37.6953
.32	10	1	10.	1.07422
.18	10	1	10.	1.07422
.1	10	0	0	9.76563E-2

THE BINOMIAL TEST SHOWS THAT .32 AND 1 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.

96-HR LC50 BLUEGILL SUNFISH TEST FBT REPORT A-1104 2/24/72

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .505705

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

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	.170737	.476606	.363493	.656191

--------RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
7	.234863	1	.297866

SLOPE = 4.69405
95 PERCENT CONFIDENCE LIMITS = 2.41918 AND 6.96891

LC50 = .46382
95 PERCENT CONFIDENCE LIMITS = .352798 AND .620211