

214756
Record No.

Review No.

057801
Shaughnessey No.

EEB REVIEW

DATE: IN 02-25-88 OUT JAN 30 1990

FILE OR REG. NO. 100-524

PETITION OR EXP. NO. _____

DATE OF SUBMISSION 02-05-88

DATE RECEIVED BY EFED 02-23-88

RD REQUESTED COMPLETION DATA 04-22-88

EEB ESTIMATED COMPLETION DATE 04-22-88

RD ACTION CODE/TYPE OF REVIEW 660

TYPE PRODUCTS(S): I, D, H, F, N, R, S Insecticide

DATA ACCESSION NO(S). 405098-02

PRODUCT MANAGER NO. G. LaRocca (15)

PRODUCT NAME(S) Diazinon

COMPANY NAME Ciba-Geigy

SUBMISSION PURPOSE Submission of data in response to DCI
notice.

SHAUGHNESSEY NO.	CHEMICAL AND FORMULATION	% A.I.
------------------	--------------------------	--------

_____	<u>Diazinon</u>	_____
-------	-----------------	-------

_____	_____	_____
-------	-------	-------

_____	_____	_____
-------	-------	-------



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JAN 30 1990

MEMORANDUM

SUBJECT: Submission of Diazinon data in response to
DCI notice

FROM: James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division

TO: George T. LaRocca, (PM15)
Insecticide-Rodenticide Branch
Registration Division

Ecological Effects Branch has completed its review of ecotoxicity data for Diazinon AG 500 submitted by Ciba-Geigy Corporation. The following is a brief summary of the result of this review.

CITATION: Surprenant, D.C. 1987. Static Acute Toxicity of Diazinon AG 500 to Bluegill (Lepomis macrochirus). Prepared by Springborn Life Sciences, Inc. Wareham, Massachusetts. Submitted by CIBA-GEIGY Corporation, Greensboro, North Carolina. Report #87-12-2568. EPA Accession No. 405098-02.

CONCLUSIONS: This study is scientifically sound and meets the requirements for a freshwater fish acute toxicity test. The 96-hour LC_{50} of Diazinon AG 500 to bluegills is 0.22 mg a.i./L. Diazinon AG 500 is classified as highly toxic to Lepomis macrochirus. The NOEC was determined to be < 0.055 mg a.i./L.

If you have any any questions concerning this study, please contact Clyde Houseknecht at 557-4372.

DATA EVALUATION RECORD

1. CHEMICAL: Diazinon.
2. TEST MATERIAL: Formulation: Diazinon AG 500 (Lot #FL-861806); 48% active ingredient, a light yellow liquid.
3. STUDY TYPE: Freshwater Fish Static Acute Test.
Species Tested: Lepomis macrochirus.
4. CITATION: Surprenant, D.C. 1987. Static Acute Toxicity of Diazinon AG 500 to Bluegill (Lepomis macrochirus). Prepared by Springborn Life Sciences, Inc., Wareham, Massachusetts. Submitted by CIBA-GEIGY Corporation, Greensboro, North Carolina. Report #87-12-2568. Accession #405098-02. Shaughnessey #057801.

5. REVIEWED BY:

Prapimpan Kosalwat, Ph.D.
Staff Toxicologist
KBN Engineering and
Applied Sciences, Inc.

Signature: P. Kosalwat
Date: 7-6-88

6. APPROVED BY:

Isabel C. Johnson, M.S.
Principal Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Isabel C. Johnson
Date: 7-11-88

Henry T. Craven
Supervisor, EEB/HED
USEPA

Signature: Henry T. Craven
Date: 11/25/90

Clyde R. Householder

Clyde R. Householder 1-24-90

7. CONCLUSIONS: This study is scientifically sound and meets the guideline requirements for a freshwater fish acute test. With the LC50 value of 0.22 mg A.I./L, Diazinon AG 500 is considered highly toxic to Lepomis macrochirus. The NOEC was determined to be less than 0.055 mg A.I./L.
8. RECOMMENDATIONS: N/A.

9. BACKGROUND:
10. DISCUSSION OF INDIVIDUAL TESTS: N/A.
11. MATERIALS AND METHODS:

A. Test Animals: The bluegill (Lepomis macrochirus) were obtained from a commercial supplier in Nebraska and held in a 500-L fiberglass tank under a photoperiod of 16 hours light and 8 hours darkness. The well water which flowed into this tank had total hardness and alkalinity ranges as calcium carbonate of 30-34 mg/L and 26-30 mg/L, respectively. Other parameters monitored in the holding tank were a specific conductivity range of 90-140 umhos/cm, pH of 7.0, dissolved oxygen concentration of 93% of saturation, and a flow rate of 5.8 tank volume replacements/day.

Test fish were maintained under these conditions for a minimum of 14 days. The temperature range in the holding tank was 20-21°C during this period. The fish were fed a dry commercial pelleted food, ad libitum, daily except the 48 hours prior to testing. There was 0.3% mortality of the test fish population during this 48-hour period. The mean wet weight of the test fish population was 0.75 g (range of 0.27-1.36 g) and the mean total length was 40 mm (range of 34-47 mm).

B. Test System: The test system consisted of 18.9-L glass aquaria which contained 15 L of test solution. The test solution depth was 18.4 cm with a surface area of 816 cm². The dilution water used was soft water reconstituted from deionized water with a total hardness and alkalinity as CaCO₃ of 50 mg/L and 35 mg/L, respectively. The pH of the water was 7.6 and specific conductivity was 160 umhos/cm. A cloudy white stock solution of 7.2 mg A.I./mL was prepared using distilled water.

All test solution temperatures were controlled by a system designed to maintain temperatures at 22 ± 1°C. Aeration was initiated at 24 hours. The photoperiod during testing was the same as that provided in the fish culture area. Light at an intensity of 25 foot-candles was provided at the solution surface.

C. Dosage: 96-hour acute static test.

D. Design: Ten bluegill selected impartially from the holding tank were placed in each test aquarium (2 replicate aquaria per test concentration and the control) within twenty minutes after the test solutions had been prepared. The resulting test organism loading factor was 0.5 grams of biomass per liter of test solution. Fish were not fed during the exposure. The nominal test concentrations were 0.062, 0.11, 0.17, 0.29, and 0.48

mg A.I./L. The test concentrations were measured at test initiation and termination.

All aquaria were examined after 0, 24, 48, 72, and 96 hours of exposure as follows: mortalities were recorded, dead fish were removed, and observations of the fish and the physical characteristics of the test solutions were recorded. Dissolved oxygen concentrations, temperature, and pH were measured in the controls and all test concentrations.

E. Statistics: The LC50 values and their corresponding 95% confidence intervals were calculated using a computer program modified from C. Stephan's program.

12. **REPORTED RESULTS:** The pH ranged between 8.3 and 6.9 (appeared to decrease over time), while the temperature stayed between 21 and 22°C during the 96-hour test period.

Analyses of the exposure solutions at 0 hour resulted in measured concentrations which averaged 123% of the nominal levels. Measured concentrations at 96 hours established that the concentration of Diazinon in the exposure solutions generally decreased by an average of 50% between 0 and 96 hours. The mean measured test concentrations, the corresponding cumulative percent mortalities, and the observations made during the definitive test are presented in Table 2.

Table 3 summarizes the 0, 24-, 48-, 72-, and 96-hour LC50's and corresponding 95% confidence intervals, and presents the no-observed-effect concentration (NOEC).

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The 96-hour LC50 and 95% confidence interval (based on measured concentrations) was 0.21 (0.16-0.29) mg A.I./L. The NOEC was 0.055 mg A.I./L. Based on EPA (1985) criteria, the test material would be classified as highly toxic to Lepomis macrochirus.

The data and report were produced and compiled in accordance with all pertinent EPA Good Laboratory Practice regulations except in the case of characterization and verification of the test substance identity. The report was signed by Springborn Life Sciences' Quality Assurance Unit.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:

A. Test Procedure: The test procedure is generally in accordance with the SEP guidelines, except for the following deviations:

- o No inert control was included in the study.
- o The age of the test fish was not provided.
- o The temperature was measured every 24 hours instead of continuously (hourly) as recommended by the SEP.
- o There was no report on a range-finding test.

B. Statistical Analysis: The statistical analyses performed by the author were appropriate. However, the highest mean measured concentration used in the calculations was 0.40 mg/L, instead of 0.48 mg/L. The reviewer recalculated the 96-hour LC50 value using the reported highest concentration of 0.48 mg A.I./L (attached). The LC50 value obtained was 0.22 mg A.I./L (with 95% confidence limits of 0.17-0.32 mg A.I./L).

C. Discussion/Results: The author reported the NOEC as 0.055 mg A.I./L. According to the observation made at 96 hours (Table 2), there was 5% mortality in the 0.055-mg/L treatment level. Therefore, the NOEC should be reported as <0.055 mg A.I./L. With an LC50 value of 0.22 mg A.I./L, Diazinon AG 500 is considered highly toxic to Lepomis macrochirus.

D. Adequacy of the Study:

(1) Classification: Core.

(2) Rationale: Although the test procedure deviated from the SEP guidelines, the reviewer does not believe that it significantly affected the toxicity results.

(3) Repairability: N/A.

15. COMPLETION OF ONE-LINER: Yes, July 5, 1988.

Table 2. Concentrations tested, corresponding cumulative mortalities and observations made during the 96 hour static exposure of Diazinon AG 500 to bluegill (*Lepomis machirus*).

Mean Measured Concentration (mg A.I./L)	Cumulative Mortality (%)			
	24-hour	48-hour	72-hour	96-hour
Control	0	0	0	0
0.055	0	0	0	5
0.12	0	10 ^a	25 ^a	35 ^b
0.14	0	10 ^{ac}	15 ^b	40 ^d
0.26	15 ^{ae}	40 ^b	45 ^c	45 ^c
0.48	20 ^f	70 ^f	75 ^f	80 ^f

^a20-50% of the surviving fish exhibited a partial loss of equilibrium.

^b>50% of the surviving fish exhibited a partial loss of equilibrium.

^c>50% of the surviving fish exhibited a complete loss of equilibrium.

^dAll of the surviving fish exhibited a partial loss of equilibrium.

^e20-50% of the surviving fish exhibited a complete loss of equilibrium.

^fAll of the surviving fish exhibited a complete loss of equilibrium.

Table 3. The LC50 values, 95% confidence intervals and No Observed Effect Concentration for the 96-hour static exposure of Diazinon AG 500 bluegill (*Lepomis macrochirus*). Values presented are based on mean measured concentrations of active ingredient (Diazinon).

	LC50 (mg A.I./L)	Confidence Interval	
		Lower (mg A.I./L)	Upper (mg A.I./L)
24-hour ^a	>0.40	---	---
48-hour ^b	0.29	0.24	0.40
72-hour ^b	0.26	0.21	0.35
96-hour ^c	0.20	0.16	0.29

NOEC through 96 hours : 0.055 mg A.I./L.

^aLC50 value empirically estimated as being greater than the highest concentration tested.

^bLC50 value and 95% confidence interval calculated using probit analysis.

^cLC50 value and 95% confidence interval calculated using moving average angle analysis.

(SALWAT DIAZINON AG500 LEPOMIS MACROCHIRUS 6-24-88

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
.48	20	16	80	.5908966
.26	20	9	45	41.19014
.14	20	8	40	25.17223
.12	20	7	35	13.1588
.055	20	1	5	2.002716E-03

THE BINOMIAL TEST SHOWS THAT .055 AND .48 CAN BE
USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT
CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL
ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .2825165

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS
3	.772142	.2095139	8.555709E-02 .577533

RESULTS CALCULATED USING THE PROBIT METHOD

ATIONS	G	H	GOODNESS OF FIT PROBABILITY
3	.1777342	1	.4855933

SLOPE = 2.212466
95 PERCENT CONFIDENCE LIMITS = 1.279723 AND 3.145209

LC50 = .2191582
95 PERCENT CONFIDENCE LIMITS = .1651356 AND .3180552

LC10 = 5.844367E-02
95 PERCENT CONFIDENCE LIMITS = 2.396853E-02 AND 8.800556E-02

No. _____

Chemical Name Diazinon Chemical Class _____Page 1 of 1Study/Species/Lab/
Succession _____
Chemical
a.i.

(Diazinon AG 500)

Results

Reviewer/ Valid:
Date Stat:1 Day Single Dose Oral LD₅₀LD₅₀ = mg/kg (95% C.L.) Contr. Mort.(%) = _____

Species _____

Slope = _____ # Animals/Level = _____ Age (Days) = _____

Lab _____

14-Day Dose Level mg/kg/(% Mortality)

Acc. _____

Comments: _____

14-Day Single Dose Oral LD₅₀LD₅₀ = mg/kg (95% C.L.) Contr. Mort.(%) = _____

Species _____

Slope = _____ # Animals/Level = _____ Age (Days) = _____

Lab _____

14-Day Dose Level mg/kg/(% Mortality)

Acc. _____

Comments: _____

8-Day Dietary LC₅₀LC₅₀ = ppm (95% C.L.) Contr. Mort.(%) = _____

Species _____

Slope = _____ # Animals/Level = _____ Age (Days) = _____

Lab _____

8-Day Dose Level ppm/(Mortality)

Acc. _____

Comments: _____

8-Day Dietary LC₅₀LC₅₀ = ppm (95% C.L.) Contr. Mort.(%) = _____

Species _____

Slope = _____ # Animals/Level = _____ Age (Days) = _____

Lab _____

8-Day Dose Level ppm/(Mortality)

Acc. _____

Comments: _____

8-Day Dietary LC₅₀LC₅₀ = ppm (95% C.L.) Contr. Mort.(%) = _____
Sol. Contr. Mort.(%) = _____

Species _____

Slope = _____ # Animals/Level = _____ Temperature = _____

Lab _____

96-Hour Dose Level ppm/(Mortality)

Acc. _____

Comments: _____

96-Hour LC₅₀LC₅₀ = 0.22 ppm (95% C.L.) Contr. Mort.(%) = 0
Sol. Contr. Mort.(%) = N/ASpecies Lepomis macrochirusSlope = 2.2 # Animals/Level = 20Lab Springborn Life

96-Hour Dose Level ppm/(Mortality)

Temp. = 21-22°CPK CoreSciences, Inc.0.055 (5), 0.12 (35), 0.14 (40), 0.26 (45), 0.48 (80)Acc. 405098-02

Comments: * Mean measured conc. and recalculated by the reviewer

96-Hour LC₅₀LC₅₀ = ppm (95% C.L.) Contr. Mort.(%) = _____
Sol. Contr. Mort.(%) = _____

Species _____

Slope = _____ # Animals/Level = _____ Temp. = _____

Lab _____

96-Hour Dose Level ppm/(Mortality)

Acc. _____

Comments: _____

(10)