

7-6-88

## DATA EVALUATION RECORD

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CASE: GS0058

BENEFIN

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CONT-CAT: 02      GUIDELINES:    121-1      71-1      72-4  
                                 81-3      81-4      81-5  
                                 82-1  
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Accession No. 234214; Prepared by C. C. Kehr,  
H. C. West, J. L. Hamelink, L. T. Kile, W. D.  
Braddle, D. R. Brannon, and D. M. Morton,  
Toxicology Division, Lilly Research Laboratories,  
Study No. 2057-77; Dated: July 19 to August 16,  
1977; Title: The Toxicity of Benefin in Bluegills  
(Lepomis macrochirus): A Twenty-Eight Day Con-  
tinuous Flow-through Study; Submitted by  
Elanco Products Co., A Division of Eli Lilly and  
Co., Indianapolis, Indiana 46206.

## REVIEW RESULTS:

VALID ☒INVALID ☐INCOMPLETE ☐

## GUIDELINE:

SATISFIED ☒PARTIALLY SATISFIED ☐ NOT SATISFIED ☐

DIRECT RVW TIME = 1 Hour

START DATE: 7-6-88      END DATE: 7-6-88

REVIEWED BY: Charles Lewis

TITLE: Agronomist

ORG: EE's/HED

LOC/TEL: C m II, 552-7463

SIGNATURE: Charles Lewis

DATE: 7-6-88

## APPROVED BY:

TITLE:

ORG:

LOC/TEL:

SIGNATURE:

DATE:

# VALIDATION SHEET

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FORMULATION:	CHEMICAL NAME:	VALIDATOR:	DATE:
% a.i.	N-butyl-N-ethyl a,a,	D. J. Urban	8/4/78
96.4%	a,a-trifluoro-2,6-	TEST TYPE:	
	dinitro-p-toluidine.		
Compound 54521		Fish Acute 96-hour LC <sub>50</sub> Bluegill sunfish ( <u>Lepomis macrochirus</u> ).	

TEST ID#: ES-F1

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VALIDATION CATEGORY: Core

- RESULTS:
1. The 96-hour and 28-day LC<sub>50</sub> values of Benefin on Bluegill sunfish are: 65 ppb and 29 ppb, respectively. These values were based on mean assay concentrations, and estimated by graphical interpolation.
  2. Analysis of Benefin showed that the average assay concentrations were about 50% of the nominal concentrations.
  3. The 20 and 36 ppb nominal concentrations (6.6 and 13.6 ppb mean assay concentrations) produced no observable effects.
  4. Observed intoxication responses at:
    - 64 ppb nominal (27.2 mean assay) - hypo-activity and prostration through the first 16 test days. Five fish were nearly

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normal for the test duration. Two fish continued to display signs of stress, i.e. tetany that resulted in a scoliosis-like curvature of the body.

- 112 ppb nominal (55.1 ppb mean assay) - fish did not respond to touch or food stimuli after 5 to 6 days of exposure, and remained prostrate and moribund until death. A state of tetany that produced a scoliosis-like curvature of the body was also observed.
- 200 ppb nominal (100.4 mean assay) - all fish died within 96 hours.

5. Control mortality - none.

VALIDATION CATEGORY RATIONALE:  $LC_{50}$  values "estimated by graphical interpolation" are normally inadequate. The use of "graphical interpolation" often indicates that the dose-response mortality pattern can be analysed by parametric statistical methods. This situation often arises when range findings tests are absent or inadequate. This appears to be the case for this study. Only one partial mortality was observed at 96-hours and at 28 days. This reviewer analysed the data by means of a non-parametric statistical method and the resultant  $LC_{50}$  values were very similar to the reported values (see Additional Information section that follows). The study is classified as "core" based on the above statistical confirmation.

It is important to note that the measured concentrations were only 50% of the nominal concentrations. If Benefin is ever considered for aquatic use(s), measurement of degradation products would be in order for all aquatic bioassays.

CATEGORY REPAIRABILITY RATIONALE: N.A.

ADDITIONAL INFORMATION:

TEST: A twenty eight-day continuous flow-through bioassay.

SUBSTANCE TESTED: Technical Benefin (96.4%)

PROTOCOL: Similar to Stephan (1975) EPA-660/3/75-009 (April)

TEST ORGANISM(S): Bluegill sunfish (Lepomis macrochirus)  
5.5 cm long at test termination.

Loading: ? - 10 fish per vessel.

Feeding: Master mix fish starter no. 2 fed for  
the first time on day 6, and daily  
thereafter.

WATER TEMPERATURE:  $22 \pm 1^{\circ}\text{C}$

STOCK SOLUTION PREPARATION:

Solvent: acetone

Toxicant Solubility: ?

1.862 g of Technical Benefin dissolved in  
3.785 liters acetone.

DILUTION WATER DESCRIPTION: Conditioned well water;  
total hardness of approximately 300 ppm.

DESCRIPTION OF TEST EQUIPMENT: Five 15 gallon (56 liter)  
aquaria with 10 fish each were connected to the  
diluta set to deliver 500 ml of the various  
toxicant-diluent concentrations.

Aeration: not during the test.

TOXICANT DELIVERY SYSTEM: Mount and Brungs simplified  
dosing apparatus for fish toxicology studies.

NOMINAL/MEASURED CONCENTRATIONS:

Nominal: 20, 36, 64, 112, 200 ppb.

Mean Measured: 6.6, 13.6, 27.2, 55.1, 100.4 ppb.

MORTALITY RESPONSE DATA:

<u>At 96 hours</u>		<u>At 28 days</u>	
Control	- 0%	Control	- 0%
20	- 0%	20	- 0%
36	- 0%	36	- 0%
64	- 0%	64	- 30%
112	- 10%	112	- 100%
200	- 100%	200	- 100%

OBSERVATIONS ON SIGNS OF INTOXICATION:

- hypoactivity
- scoliosis-like curvature of the body and red spots
- abnormal swimming behavior

STATISTICAL PROCEDURES FOR HANDLING DATA: graphical interpolation to provide an estimated LC<sub>50</sub> value.

OTHER COMMENTS: This reviewer analysed the data by the Spearman Karber non-parametric method. Results follow:

96 hour LC <sub>50</sub>		28 day LC <sub>50</sub>	
0.	%TRM	0.	%TRM
69.68	LC <sub>50</sub>	31.38	LC <sub>50</sub>
61.56	LOCL	25.63	LOCL
78.87	UPCL	38.44	UPCL

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