

06.28.94

DP Barcode : D196150  
PC Code No : 043901  
EEB Out :

JUN 28 1994  
JUN 28 1994

To: John Lee  
Product Manager 31  
Registration Division (H7505C)

From: Anthony F. Maciorowski, Chief  
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 010352-00021  
Chemical Name : Glutaraldehyde  
Type Product : Microbiocide  
Product Name : Ucarcide 250 Antimicrobial  
Company Name : Union Carbide Chemicals and Plastics Co., Inc.  
Purpose : Submission of data to support registration.  
(Mysid shrimp toxicity study.)

Action Code : 321 Date Due : 01/03/94  
Reviewer : C. Laird Date In : 10/28/93

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)	429523-01	Y	122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur  
P=Partial (Study partially fulfilled Guideline but additional information is needed)  
S=Supplemental (Study provided useful information but Guideline was not satisfied)  
N=Unacceptable (Study was rejected)/Nonconcur

DP BARCODE: D196150

CASE: 019101  
SUBMISSION: S451575

DATA PACKAGE RECORD  
BEAN SHEET

DATE: 10/25/93  
Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION      ACTION: 321      RESUBMISSION  
CHEMICALS: 043901 Glutaral      50.0000%

ID#: 010352-00021      UCARCIDE 250 ANTIMICROBIAL  
COMPANY: 010352 UNION CARBIDE CHEMICALS & PLASTICS CO INC  
PRODUCT MANAGER: 31 JOHN LEE      703-305-5675      ROOM: CM2      270  
PM TEAM REVIEWER: VELMA NOBLE      703-305-7441      ROOM: CM2      268  
RECEIVED DATE: 10/05/93      DUE OUT DATE: 01/23/94

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 196150      EXPEDITE: N      DATE SENT: 10/25/93      DATE RET.: / /  
CHEMICAL: 043901 Glutaral  
DP TYPE: 001 Submission Related Data Package

CSF: N      LABEL: N

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 01/03/94
DIV : EFED	10 / 28 / 93	/ /	NEGOT DATE: 01/03/94
BRAN: EEB	10 / 27 / 93	/ /	PROJ DATE: / /
SECT:	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Please review data. Glutaraldehyde MRID# 42952301

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package.

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
-------	----------------	----------	----------	-----	-----	-------



UNION CARBIDE CHEMICALS AND PLASTICS COMPANY INC.  
SPECIALTY CHEMICALS DIVISION

September 27, 1993

Mr. John H. Lee (PM-31)  
Registration Division (H7505C)  
Antimicrobial Program Branch  
Environmental Protection Agency  
401 M St. S.W.  
Washington, DC 20460

429523-00

Subject: UCARCIDE® 250 Antimicrobial  
EPA Registration Number 10352-21  
Aquatic Toxicity Study

Dear Mr. Lee:

In accordance with the above subject, Union Carbide  
Chemicals & Plastics Company Inc. submits the following study:

Vol. 1: Machado, Mark (1993) Glutaraldehyde - Acute  
Toxicity Study. Prepared by Springborn  
Laboratories, Inc., Environmental Sciences  
Division, Wareham, MA, 66 pages.

42952301

I trust that you will find this study to be in good  
order. Any questions or problems, please do not hesitate to  
call.

Very truly yours,

  
Joan E. Young

JEY/f  
Att.  
springborn.stdy

cc: L. DeLuise - EPA

- 100.0 Pesticide Name  
Glutaraldehyde
- 100.3 Submission Purpose  
Submission of 96-hour LC<sub>50</sub> study for mysid shrimp
- 101.0 Chemical and Physical Properties
- 101.1 Common Name  
Glutaraldehyde
- 103.0 Toxicological Properties  
96-hour LC<sub>50</sub> for mysid shrimp
- 105.0 Conclusions

This study is scientifically sound and meets the guideline requirements for an acute flow-through toxicity study using mysids. Based on mean measured concentrations, the 96-hour LC<sub>50</sub> was 7.1 mg ai/l, which classifies glutaraldehyde as moderately toxic to mysids. The NOEC was 0.78 mg ai/L.

*Curtis E. Laird 6-23-94*  
Curtis E. Laird, Fishery Biologist  
Ecological Effects Branch  
Environmental Fate and Effects Division (7507C)

*Norman J. Cook 06.27.94*  
Norman J. Cook, Head-Section 2  
Ecological Effects Branch  
Environmental Fate and Effects Division (7507C)

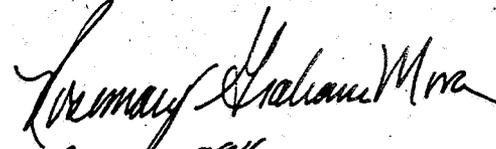
*Anthony F. Maciorowski 6/28/94*  
Anthony F. Maciorowski, Chief  
Ecological Effects Branch  
Environmental Fate and Effects Division (7507C)

DATA EVALUATION RECORD

1. **CHEMICAL:** Glutaraldehyde. Shaughnessey No. 043901.
2. **TEST MATERIAL:** Glutaraldehyde; CAS No. 111-30-8; IS No. 566756; 51% active ingredient; a clear liquid.
3. **STUDY TYPE:** 72-3. Marine/Estuarine Shrimp Acute Flow-Through Toxicity Test. Species Tested: Mysids (*Mysidopsis bahia*).
4. **CITATION:** Machado, M.W. 1993. Glutaraldehyde - Acute Toxicity to Mysid Shrimp (*Mysidopsis bahia*) Under Flow-Through Conditions. SLI Report No. 92-11-4496. Performed by Springborn Laboratories, Inc., Wareham, MA. Submitted by Union Carbide Chemicals and Plastics Company Inc., South Charleston, WV. EPA MRID No. 429523-01.

5. **REVIEWED BY:**

Rosemary Graham Mora, M.S.  
Associate Scientist  
KBN Engineering and  
Applied Sciences, Inc.

Signature: 

Date: 10 Jan 1994

6. **APPROVED BY:**

Mark A. Mossler, M.S.  
Associate Scientist  
KBN Engineering and  
Applied Sciences, Inc.

Signature: 

Date: 1/10/94

James J. Goodyear, Ph.D.  
Project Officer, EEB/EFED  
USEPA

Signature: 

Date: 6 17 94

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for an acute flow-through toxicity study using mysids. Based on mean measured concentrations, the 96-hour LC<sub>50</sub> was 7.1 mg ai/l, which classifies glutaraldehyde as moderately toxic to mysids. The NOEC was 0.78 mg ai/l.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

**11. MATERIALS AND METHODS:**

- A. **Test Animals:** The mysids (*Mysidopsis bahia*) used in this study were originally obtained from a commercial supplier in Fort Collins, CO. Prior to testing, the mysids were maintained in a 500-l tank under recirculating conditions with a 16-hour light photoperiod (light intensity of 320-1100 lux). The culture water was natural seawater and had a temperature of 24-26°C and a salinity of 24-26 parts per thousand (ppt). Mysids were fed live *Artemia salina* nauplii twice daily.
- B. **Test System:** The test system was a constant-flow serial diluter. The test vessels were 19.5-l glass aquaria (39 X 20 X 25 cm) with self-starting siphons which maintained a solution volume of 7-11 l. Each replicate aquarium contained 2 retention chambers (10-cm Petri dishes with 15-cm high Nitex® screen collars) which housed five mysids each. The flow rate to each aquarium (50 ml/minute) provided 6.5 volume replacements every 24 hours.
- The aquaria were impartially positioned in the waterbath which was designed to maintain the test temperature at 25 ±1°C. The photoperiod during the test was the same as that used for culturing with a light intensity of 220-470 lux. Sudden transitions from light to dark and dark to light were avoided.
- The dilution water was filtered (20 and 5 µm) natural seawater collected from the Cape Cod Canal, Bourne, MA. The seawater had a salinity of 31-32 ppt and a pH of 8.0-8.1.
- Based on a specific gravity of 1.1306 g/ml and an active ingredient of 51% , the concentration of test material was calculated to be 576.606 mg ai/ml. The exposure solutions were prepared by injecting the test material directly into the diluter system's chemical mixing chamber.
- C. **Dosage:** Ninety-six-hour flow-through test. Based on the results of preliminary testing, six nominal concentrations (0.78, 1.3, 2.2, 3.6, 6.0, and 10.0 mg ai/l) were selected for this study. A dilution water control was also included.
- D. **Design:** Ten mysids (<24 hours old) were impartially loaded into each of two replicate aquaria per treatment

(i.e., 20 mysids/treatment). During the test, the organism loading rate was 0.000139 g/l/day. Live brine shrimp nauplii were added twice daily during the study.

Biological observations and observations of physical characteristics of the test solutions were noted at test initiation and every 24 hours. Dead mysids were removed at each observation interval.

The dissolved oxygen concentration (DO), pH, salinity, and temperature were measured daily in each replicate chamber. The temperature in one replicate of the dilution water control was monitored continuously using a Min/Max thermometer.

Chemical analysis of glutaraldehyde was performed using high performance liquid chromatography on each test solution collected on days 0 and 4 from each replicate vessel.

**E. Statistics:** The authors used a computer program by Stephan (1977, 1982) to calculate LC<sub>50</sub> values. The probit analysis was used to calculate the 96-hour LC<sub>50</sub>.

12. **REPORTED RESULTS:** Mean measured concentrations were 0.78, 1.5, 2.5, 3.9, 6.8, and 12 mg ai/l and averaged 112% of the nominal concentrations (Table 2, attached). The coefficients of variation averaged 8.9% for all mean measured concentrations.

No mortality or sublethal effects were observed in the control or the lowest test concentration (Table 3, attached). The 96-hour LC<sub>50</sub> for *Mysidopsis bahia* exposed to glutaraldehyde was 7.1 mg ai/l (95% confidence interval of 6.0-8.6 mg ai/l). The slope of the probit curve was 3.9. The NOEC was 0.78 mg ai/l.

During the study, the test solutions had a temperature of 24-26°C, a pH of 8.0-8.2, a DO of 6.9-7.3 mg/l (99-104 % of saturation), and a salinity of 31-32 ppt.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:**  
Based on criteria established by U.S. EPA, glutaraldehyde would be classified as moderately toxic to mysids.

A Good Laboratory Practice Compliance statement and a Quality Assurance statement were included in the report, indicating that the study was in accordance with GLP regulations (40 CFR, Part 160).

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

- A. Test Procedure: The test procedures were generally in accordance with the SEP, except for the following deviations:

The test material was <80% purity and no inert ingredients control(s) was included in the study design as recommended.

During the study, the temperature of the test solutions ranged from 24 to 26°C. The SEP recommends a temperature at or around 22°C and it should not deviate more than 1°C during the test.

- B. Statistical Analysis: The reviewer used EPA's Toxanal computer program to calculate the LC<sub>50</sub> value and obtained the same results as those of the author, except that the slope of the dose response-curve was 5.2 (printout, attached).
- C. Discussion/Results: This study is scientifically sound and meets the guideline requirements for an acute flow-through toxicity study using mysids. Based on mean measured concentrations, the 96-hour LC<sub>50</sub> was 7.1 mg ai/l, which classifies glutaraldehyde as moderately toxic to *Mysidopsis bahia*. The NOEC was 0.78 mg ai/l.
- D. Adequacy of the Study:
- (1) Classification: Core for a formulated product.
  - (2) Rationale: N/A.
  - (3) Repairability: N/A.

15. COMPLETION OF ONE-LINER FOR STUDY: Yes; 28 December 1993.

---

GLUTARALDEHYDE

---

Page      is not included in this copy.

Pages   9   through  10  are not included.

---

The material not included contains the following type of information:

- Identity of product inert ingredients.
  - Identity of product impurities.
  - Description of the product manufacturing process.
  - Description of quality control procedures.
  - Identity of the source of product ingredients.
  - Sales or other commercial/financial information.
  - A draft product label.
  - The product confidential statement of formula.
  - Information about a pending registration action.
  - FIFRA registration data.
  - The document is a duplicate of page(s)     .
  - The document is not responsive to the request.
- 

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

---

Rosemary Graham Mora Glutaraldehyde Mysids

\*\*\*\*\*

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
12	20	19	95	2.002716E-03
6.8	20	7	35	13.1588
3.9	20	1	5	2.002716E-03
2.5	20	1	5	2.002716E-03
1.5	20	0	0	9.536742E-05
.78	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 3.9 AND 12 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 7.698931

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
2	8.711716E-02	7.378248	6.382508	8.658256

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
7	.1292016	1	.1869227

SLOPE = 5.237453  
 95 PERCENT CONFIDENCE LIMITS = 3.35487 AND 7.120036

LC50 = 7.127366  
 95 PERCENT CONFIDENCE LIMITS = 6.028321 AND 8.596831

LC10 = 4.077977  
 95 PERCENT CONFIDENCE LIMITS = 2.900241 AND 4.956517

\*\*\*\*\*