DP Barcode : D198422
PC Code No : 043901
EEB Out :
JUL 21 1994

To: Linda Deluise
Product Manager 50
Special Review and Reregistration Division (7508W)

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch/EFED (7507C)

Attached, please find the EEB review of...

Reg./File # : 043901-010352
Chemical Name : Glutaraldehyde
Type Product : Microbiocide
Product Name : Ucaracide 250 Antimicrobial
Company Name : Union Carbide Corporation
Purpose : Submission of data in support of reregistration for Case No. 2315.

Action Code : 627 Date Due : 07/17/94
Scientist : N. Cook Date In : 01/25/94

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)	427532-01	Y[1]	122-1(A)		
71-2(B)			72-3(B)	429521-01	Y[1]	122-1(B)		
71-3			72-3(C)			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)	429523-01	Y[1]	123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)	125515	Y[1]	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
Y[1]=Acceptable for a formulated product.

DP BARCODE: D198422 REREG CASE # 2315

CASE: 804947 DATA PACKAGE RECORD DATE: 01/19/94
SUBMISSION: S456635 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 627 CORE DATA
CHEMICALS: 043901 Glutaral 100.00 %

ID#: 043901-010352
COMPANY: 010352 UNION CARBIDE CHEMICALS & PLASTICS CO INC
PRODUCT MANAGER: 50 JAY ELLENBERGER 703-308-8085 ROOM: CS1 4J1
PM TEAM REVIEWER: LINDA DELUISE 703-308-8065 ROOM: CS1 4N6
RECEIVED DATE: 01/13/94 DUE OUT DATE: 07/22/94

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 198422 EXPEDITE: N DATE SENT: 01/18/94 DATE RET.: / /
CHEMICAL: 043901 Glutaral
DP TYPE: 999 Miscellaneous Data Package
CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	01/25/94	08/15/94
BRAN: EEB	01/25/94	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 07/17/94
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

PLEASE REVIEW MRID 125515 FOR 72-1B
MRID 42753201 FOR 72-3A AND D
MRID 42952101 FOR 72-3(B) AND E
MRID 42952301 FOR 72-3F

* * * 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
198421	TB-2	01/18/94	07/17/94	Y	N	N

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

JUL 21 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Submission of Four Aquatic Studies in Support of Reregistration of Glutaraldehyde, Barcode D198422

FROM: Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (7507C) 7/21/94

TO: Linda DeLuise, Chemical Review Manager 50
Accelerated Reregistration Branch
Registration Division (7508W)

The Ecological Effects Branch (EEB) has completed a review of a package containing four aquatic studies, MRID Nos. 125515, 427532-01, 429521-01, and 425523-01. These studies were submitted by Union Carbide Chemicals & Plastics Company, Inc. in support of reregistration of Glutaraldehyde, ID. No. 043901-010352. Studies 427532-01, 429521-01, and 429523-01 were reviewed previously under barcodes D191342, D196151, and D196150, respectively. Copies of these prior reviews are attached.

EEB has rereviewed MRID No 125515, which was previously reviewed in 1978 under Accession Number 233936. We conclude that this study fulfills the guideline requirement for a 96-hour static acute LC_{50} study for a warmwater fish using 50 % active ingredient (ai) formulated product. Further, this study can be considered as supporting a 100 % ai (i.e., TGAI) provided the composition of the formulation is identified and EEB determines the inerts are not likely to influence the toxicity. Based on the conditions of this study the 96-hour LC_{50} is 22.6 (18.0 - 32.0) mg product/L. The 96-hour NOEC is 10.0 mg product/L. This classifies glutaraldehyde as slightly toxic to bluegill sunfish.

If you have any questions on the above, please contact Norm Cook (305-5322) of my staff.

Attachments

DATA EVALUATION RECORD

1. CHEMICAL: Glutaraldehyde 043901

2. TEST MATERIAL: 50 % a.i. glutaraldehyde

3. STUDY TYPE: §72-1(b)

4. CITATION:

Author:	Algirdas G. Vilkas
Title:	The Acute Toxicity of 50 % Glutaraldehyde to Bluegill Sunfish, Lepomis macrochirus Rafinesque
Date:	January 6, 1978
Laboratory Report #:	11506-61-06
Any Other Study #:	N/A
Sponsor:	Union Carbide Corporation, Chemicals and Plastics Division
Sponsor #:	Chemical Lot No. IS-147958
Laboratory:	Union Carbide Corporation Environmental Services
MRID No.:	125515 (formerly Acc. No. 233936)

5. REVIEWED BY:

Norman J. Cook, Supervisory Biologist
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

Signature: Norman J. Cook
Date: 07.21.94

6. APPROVED BY:

Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

Signature: Douglas D. Urban (Signature)
Date: 7/21/94

7. CONCLUSION: This study is scientifically sound and fulfills the guideline requirement for a 96-hour static acute LC_{50} study for a warmwater fish using 50 % ai formulated product. This study indicates this formulation is slightly toxic to bluegill sunfish with a 96-hr LC_{50} of 22.6 (18.0 - 32.0) ppm (product - 50 % ai) based on nominal concentrations. The 96-hr NOEC is 10.0 ppm product. This study can be considered in fulfilling the guideline requirement for glutaraldehyde TGAI provided: the registrant identifies the composition of this formulation and EEB determines the inerts are not likely to influence the toxicity.

8. RECOMMENDATIONS: N/A

9. BACKGROUND: This study was submited in support of glutaraldehyde reregistration.

10. MATERIALS AND METHODS

A. Test Organisms:

Guideline Criteria	Reported Information
Species (Scientific Name)	Lepomis macrochirus Rafinesque
Mean Weight (0.5-5 grams)	0.39 gms
Mean Length(S.L. longest not > 2x shortest	32 mm
Supplier	Nebraska commercial hatchery
All fish from same source (yes or no)	Yes
Al fish from the same year class (yes or no)	Yes
Other Comments	N/A

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period (minimum 14 days)	30 Days
Wild caught 7 day quarantine (yes or no)	N/A
Check for signs of disease or injury (yes or no, if yes describe)	Mortalities in stock culture < 2 % over month period.
If diseased it can be treated in 48-hr pretest no sign of the disease remains (Report hours prior to test in which no sign of disease or N/A)	Not Stated
No feeding during the study (When last fed)	Taken of feed 48-hrs before start of exposure to pesticide.
<3% mortality 48 hours prior to testing (% mortality, if any)	Not Stated

C. Test System:

Guideline Criteria	Reported Information
Describe source of dilution water (prefer soft reconstituted water)	Well on Tarrytown, NY, site (soft reconstitued water).
Does water support test animals without observable signs of stress?	Yes
Was dechlorinated water used (not recommended)	No
Water Temperature (Warm water-17°C or 22°C) (Cold water-12°C)	22° C ± 2° C
pH	7.56
Dissolved Oxygen (Static 1st 48 hrs 60%; 2nd 48 hrs 40%; Flow-through 60%) (% of lowest conc. & hour)	1st 48 hrs: 72 - 79 % 2nd 48 hrs: 69 - 70 %
Total hardness (40 to 48 mg/L as $CaCO_3$ well water)	34 mg/l
Total Alkalinity	35 mg/l
Specific Conductance	160 umhos/cm
Total Organic Carbon	Not Stated
Test Aquaria 1. Material (glass or stainless steel) 2. a. Static volume (18.9 L (5 gal or 19000 cc) with 15 L solution) b. Static or flow-through volume (300x600x300 = 54000 cc.)	5 gallon glass aquaria containing 15 liters of water. Static set up.
Type of Dilution System (Reproducible supply of toxicant)	Test material diluted to volume in volumetric glassware.

Flow rate Consistent flow rate-meter systems calibrated before study and checked 2*24 hours - 5 to 10 vol/24 hours	N/A
Biomass Loading Rate (Static no > 0.8 g/L ≤ 17°C; >17°C 0.5g/L; Flow-through 1 g/L/24	0.26 g/l
Photoperiod (16 L & 8 D)	Not stated
Solvents 1. (Do not exceed 0.5 ml/L for static tests) 2. (Do not exceed 0.1 ml/L for flow-through)	Deionized water used as solvent.
Other Comments	N/A

D. Test Design:

Guideline Criteria	Reported Information
Range Finding Test (LC_{50} >100 mg/L with 30 fish, no definitive test required.)	N/A
Definitive Test	
Nominal Concentrations (control+5 treatment levels; dosage should be 60% of the next highest concentration; concentrations should be geometric series)	Control plus nominal concentrations of 5.6, 10.0, 18.0, 32.0, and 56.0 ppm product (50 % ai)
Controls (Minimum control mortality; static 10%; flow-through 5%	0 %
Number of Test Organisms; (Minimum 10/level can be divided among containers)	10/concentration
All organisms must be randomly assigned to test vessels. (yes or no, describe if no)	Assume yes

Biological Observations (yes or no)	Yes (limited)
Water Parameter Measurements 1. Temperature - record every 6 hrs;>1°C. 2. D.O. beginning,48 hrs,end for control high, medium, and low dose. 3. pH beginning,48 hrs, end for control, high, medium, and low dose.	Temperature: Beginning and at 96 hrs. D.O.: Beginning, 48 hrs, and 96 hrs. pH: Beginning and at 96 hrs.
Chemical Analysis (needed if aeration, volatile, insoluble, precipitate, not steel or glass, known to adsorb, and flow-through) (yes or no)	None
Other Comments	None

11. REPORTED RESULTS:

Guideline Criteria	Reported Information
Mean Measured Concentrations (report conc.)	N/A
Recovery of Chemical (% recovery)	N/A
Mortality & Observations (Describe observations & attach mortality tables)	Fish exposed to >=32.0 ppm became "excitable and were sounding".
Author's Comments	No additional comments.

12. STUDY AUTHOR'S CONCLUSIONS / QUALITY ASSURANCE MEASURES: The 24-hr, 48-hr, and 96-hr LC_{50} values with 95 % confidence limits were: 29.8 (24.7 - 36.0) ppm, 23.7 (20.1 - 27.9) ppm, and 22.4 (19.9 - 25.1) ppm, respectively, based on nominal concentrations for 50 % ai glutaraldehyde. The 96-hr NOEC is 10.0 ppm product. Quality assurance measures were not discussed.

13. REVIEWER'S DISCUSSION AND INTERPRETATION

A. Test Procedure:

The following items did not meet the guideline criteria: **The test procedures appeared adequate for this study.**

1.

2.

3.

4.

5.

B. Statistical Analysis

Guideline Criteria	Reported Information
Binomial (yes, no, or not reported)	24-hr LC_{50}: 29.8 (18.0 - 56.0) ppm product 48-hr LC_{50}: 25.5 (18.0 - 32.0) ppm product 96-hr LC_{50}: 22.6 (18.0 - 32.0) ppm product
Moving Average Angle (yes, no, or not reported)	Not calculated.
Probit (yes, no, or not reported)	Not calculated.
Other Comments	None

C. Discussion/Results: Glutaraldehyde 50 % ai product is slightly toxic to bluegill sunfish with a 96-hr LC_{50} of 22.6 (18.0 - 32.0) ppm. The 96-hr NOEC is 10.0 ppm product. These results support those of the author.

D. Adequacy of the Study:

1. Classification: Core for a formulated product of 50 % ai.

2. Rationale: Testing generally followed Agency-recommended protocol.

3. Reparability: This study can be considered in fulfilling the guideline requirement for glutaraldehyde TGAI provided: the registrant identifies the composition of this formulation and EEB determines the inerts are not likely to influence the toxicity.

14. COMPLETION DATE OF ONE-LINER FOR STUDY: Yes. 07/21/94.

NORM COOK GLUTARALDEHYDE BLUEGILL STATIC ACUTE LC50 STUDY - 24 HRS.

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
56	10	10	100	9.765625E-02
32	10	6	60.00001	37.69531
18	10	0	0	9.765625E-02
10	10	0	0	9.765625E-02
5.6	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 18 AND 56 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 29.74847

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

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NORM COOK GLUTARALDEHYDE BLUEGILL STATIC ACUTE LC50 - 48HRS.

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
56	10	10	100	9.765625E-02
32	10	9	90	1.074219
18	10	0	0	9.765625E-02
10	10	0	0	9.765625E-02
5.6	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 18 AND 32 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 25.50135

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE
PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE
NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

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NORM COOK GLUTARALDEHYDE BLUEGILL STATIC ACUTE LC50 - 96 HRS.

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
56	10	10	100	9.765625E-02
32	10	10	100	9.765625E-02
18	10	1	10	1.074219
10	10	0	0	9.765625E-02
5.6	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 18 AND 32 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 22.58704

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

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Oneliner Database Entry Form for Multiple Acute or Chronic Toxicity Data

Chemical Glutaraldehyde Shaughnessy 043901 Use Pattern Microbiocide Todays Date 07/21/94

Species Tested	Age or Mean Wt.	Study Type, ie. Static	Study Duration	Toxicity (CLs)	NOEL	%AI	Slope	Study/Review Dates	Lab Code	MRID	Category	Rev. By
Bluegill Sunfish	0.39 gms	Static	96-hrs	22.6(18-32)ppm product	10 ppm product	50.0	N/A	01/06/78 / 07/21/94	Union Carbide	125515	Core for a formulated product	N. Cook
Chronic Effects MATC Range-(cont. from above)	Eggs Cracked	Viable Eggs	Live Embryos	# Eggs Hatched	14 Day Survival	Feed	Time to Swim-up	Growth Wt/Length	Larval surv.			

Comments: This is a new entry form which allows multiple entries to be entered into the oneliner database - your comments are welcome on improving it