

Shaughnessy No.: 043901

Date Out of EAB: APR 14 1987

To: John Lee  
Product Manager #31  
Registration Division (TS-767)

From: Dr. Akiva D. Abramovitch, Acting Chief  
Environmental Chemistry Review Section 1  
Exposure Assessment Branch  
Hazard Evaluation Division (TS-769-C)

*A*

Attached, please find the EAB review of...

Reg./File # : 662-TL, 662-TU, 662-TG, 662-TE  
Chemical Name: Glutaraldehyde  
Type Product : Microbiocide  
Product Name : GDA-25, GDA-50, Sepacide-25, Sepacide-50  
Company Name : BASF Corp  
Purpose : Review fate studies.

Action Code: 160 EAB #(s): 70109-~~12~~ 70481-3  
Date Received: 11/24/86 TAIS Code: 302  
Date Completed: 4/10/87 Total Reviewing Time: 2.0 days  
Monitoring study requested: \_\_\_\_\_  
Monitoring study voluntarily: \_\_\_\_\_

Deferrals to: \_\_\_\_\_ Ecological Effects Branch  
\_\_\_\_\_ Residue Chemistry Branch  
\_\_\_\_\_ Toxicology Branch

19530 HEL  
11-24-86

**REGISTRATION DIVISION DATA REVIEW RECORD**  
Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME <i>Glutaraldehyde</i>			
2. IDENTIFYING NUMBER <i>662-TE</i>	3. ACTION CODE <i>160</i>	4. ACCESSION NUMBER <i>265 838</i>	TO BE COMPLETED BY PM
			5. RECORD NUMBER <i>184446</i>
			6. REFERENCE NUMBER

19530 HEL  
11-24-86

**REGISTRATION DIVISION DATA REVIEW RECORD**  
Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME <i>Glutaraldehyde</i>			
2. IDENTIFYING NUMBER <i>662-TG</i>	3. ACTION CODE <i>160</i>	4. ACCESSION NUMBER <i>265 838</i>	TO BE COMPLETED BY PM
			5. RECORD NUMBER <i>184447</i>
			6. REFERENCE NUMBER

19530 HEL  
11-24-86

**REGISTRATION DIVISION DATA REVIEW RECORD**  
Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME <i>Glutaraldehyde</i>			
2. IDENTIFYING NUMBER <i>662-TU</i>	3. ACTION CODE <i>160</i>	4. ACCESSION NUMBER <i>265 838</i>	TO BE COMPLETED BY PM
			5. RECORD NUMBER <i>184448</i>
			6. REFERENCE NUMBER

19530 HEL  
11-21-86

**REGISTRATION DIVISION DATA REVIEW RECORD**  
Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME <i>Glutaraldehyde</i>			
2. IDENTIFYING NUMBER <i>662-TL</i>	3. ACTION CODE <i>160</i>	4. ACCESSION NUMBER <i>265 838</i>	TO BE COMPLETED BY PM
			5. RECORD NUMBER <i>184449</i>
			6. REFERENCE NUMBER <i>1</i>
			7. DATE RECEIVED (EPA) <i>11-24-86</i>
			8. STATUTORY DUE DATE
			9. PRODUCT MANAGER (PM) <i>Lee</i>
			10. PM TEAM NUMBER <i>31</i>
			TO BE COMPLETED BY PCB
			11. DATE SENT TO HED/TSS <i>11-24-86</i>
			12. PRIORITY NUMBER <i>34</i> (2)
			13. PROJECTED RETURN DATE <i>12-24-86</i>
14. CHECK IF APPLICABLE			
<input type="checkbox"/> Public Health/Quarantine		<input type="checkbox"/> Minor Use	
<input type="checkbox"/> Substitute Chemical		<input type="checkbox"/> Part of IPM	
<input type="checkbox"/> Seasonal Concern		<input type="checkbox"/> Review Requires Less Than 4 Hours	
15. INSTRUCTIONS TO REVIEWER		F. INSTRUCTIONS	
A. HED <input type="checkbox"/> Total Assessment (2/1/85)		AH	

1. CHEMICAL: Common name:

Glutaraldehyde

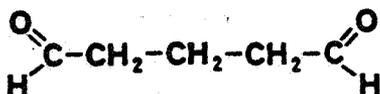
Chemical name:

1,5-Pentanediol

Trade name(s):

GDA-25, GDA-50, Sepacide-25, Sepacide-50

Structure:



Formulations:

1.99-26% SC/L, 2-50% RTU

Physical/Chemical properties:

Molecular formula: C<sub>5</sub>H<sub>8</sub>O<sub>2</sub>.  
Molecular weight: 100.13

2. TEST MATERIAL:

Uniformly-labeled [<sup>14</sup>C]glutaraldehyde (radiochemical purity 99%).

3. STUDY/ACTION TYPE:

Review of environmental fate studies for registration.

4. STUDY IDENTIFICATION:

Cranor, W. 1986a. Aerobic soil metabolism of <sup>14</sup>C-glutaraldehyde. Report No. 32734. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by BASF Corporation, Wyandotte, MI. Acc. No. 265840.

Cranor, W. 1986b. Aerobic aquatic metabolism of glutaraldehyde. Report No. 32736. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by BASF Corporation, Wyandotte, MI. Acc. No. 265842.

Cranor, W. 1986c. Anaerobic aquatic metabolism of glutaraldehyde. Report No. 32735. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by BASF Corporation, Wyandotte, MI. Acc. No. 265841.

Warren, J. and C. Carlton. 1985. Determination of adsorption/desorption constants of  $^{14}\text{C}$ -glutaraldehyde. Report No. 32737. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by BASF Corporation, Wyandotte, MI. Acc No. 265843.

Warren, J. and W. Cranor. 1986a. Determination of the hydrolysis rate of  $^{14}\text{C}$ -glutaraldehyde. Report No. 32738. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by BASF Corporation, Wyandotte, MI. Acc. No. 256838.

Warren, J. and W. Cranor. 1986b. Determination of the photolysis rate constants and degradation products of glutaraldehyde. Report No. 32739. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by BASF Corporation, Wyandotte, MI. Acc. No. 265839.

5. REVIEWED BY:

Herbert L. Manning, Ph.D.  
Microbiologist  
EAB/HED/OPP

Signature: Herbert L. Manning  
Date: 4/14/87

6. APPROVED BY:

Dr. Akiva D. Abramovitch  
Acting Chief  
Review Section #1, EAB/HED/OPP

Signature: Akiva Abramovitch  
Date: ~~APR 14 1987~~

7. CONCLUSIONS:

The studies submitted for review (hydrolysis, photolysis in water, aerobic soil metabolism, aerobic aquatic metabolism, anaerobic aquatic metabolism, and adsorption/desorption) were all judged to be deficient in some respect (with regard to our guidelines, subdivision N) and are presently unacceptable. See Dynamac reviews for specifics.

8. RECOMMENDATIONS:

BASF, at this time, is only going for a manufacturing use registration, which may have various end uses. Studies in this submission are the only ones EAB have reviewed. Since we do not know the out-door uses for the formulating product, we cannot determine the data required.

9. BACKGROUND:

A. Introduction

As stated in the attached letter from BASF Corp, they have withdrawn the previous application for registration of glutaraldehyde and any

new submissions will be considered as new applications. Their main use applications will be in oilfields, with no direct discharge. Two of the attached labels (Sepacide-25 and -50) apply to oilfields; two other labels apply to formulating use (their other primary aim) for indoor-use microbicides or other use pesticides.

B. Directions for Use

Glutaraldehyde is a microbicide/microbistat registered for use on aquatic nonfood and indoor (agricultural premises and equipment, and commercial and industrial uses) sites to control bacteria, fungi, algae, and viruses. Single active ingredient formulations consist of 1.99, 2, 6, 10, 12, 12.8, 20, 20.5, and 26% SC/L; and 2, 15, 25, 45, and 50% RTU. Application rates range from 0.8 to 100 ppm on aquatic sites and from 964-24,000 ppm on indoor sites. Glutaraldehyde may be applied to aquatic sites by slug feed, intermittent feed, and continuous feed treatment. Glutaraldehyde is applied to indoor sites by cloth, swab, sponge, brush, spray, or immersion.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

See attached reviews of individual studies.

11. COMPLETION OF ONE-LINER:

Not applicable.

12. CBI APPENDIX:

All data reviewed here are considered CBI by the registrant and must be treated as such.

EF

September 23, 1986

Dr. Samuel Creeger  
Environmental Chemistry Review Section  
Exposure Assessment Branch  
Hazard Evaluation Division (TS-769)  
EPA-OPTS-OPP-RD  
401 M Street SW  
Washington, D.C. 20460

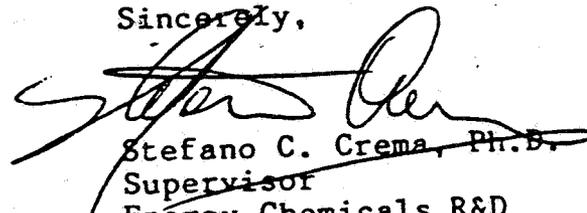
Dear Dr. Creeger:

It was a pleasure meeting you on Thursday, September 18, to discuss the requirements for glutaraldehyde registration. We were all very appreciative of you taking time off your busy schedule to sit in on our meeting. Thanks to your comments, we now have a much better understanding of where we stand with regard to the data needed for the registration application.

In order to ensure we have a common understanding of the points discussed at the meeting, I have taken the liberty to send you the attached memorandum which I would ask you to review. If you feel that our interpretation of any of your comments is not correct, please let us know so that we can clarify the misunderstanding.

I would like to thank you again for your support and understanding of our efforts.

Sincerely,



Stefano C. Crema, Ph.D.  
Supervisor  
Energy Chemicals R&D

/bk  
Enclosure  
cc: Dr. H. Manning

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MEMORANDUM OF MEETING

1:30 p.m.  
September 19, 1986  
CM Building 2, Room 711  
Arlington, VA

EPA - Registration Division  
Disinfectants Branch  
Product Manager Team 31

PERSONS ATTENDING

Mr. John Lee, Product Manager 31  
Mr. Valdis Goncarvos, PM Team 31  
Dr. Samuel Creeger, Environmental Chemistry Review Section,  
Exposure Assessment Branch, Hazard Evaluation Division  
Dr. Stefano C. Crema, Chemicals Group R&D, BASF Corporation  
Dr. Kurt A. Reimann, Research Manager, GC and Environmental  
Research, BASF Corporation  
Mr. Fred Tollefson, Business Manager, Oilfield Chemicals,  
BASF Corporation  
Ms. Mary A. Klosowski, Manager, Government Regulations,  
BASF Chemicals Division  
Dr. W. A. Olson, CFR Services

SUBJECT

Environmental Fate Studies - Glutaraldehyde Registration

DISCUSSION

Mr. Lee clarified the record by indicating that the previous application for registration for glutaraldehyde as made by BASF had been withdrawn, and any new applications would be considered as original new applications.

Dr. Crema acknowledged that BASF was aware that the application as previously submitted had been administratively withdrawn. Dr. Crema said there was a data gap regarding environmental fate studies, and BASF had submitted to EPA protocols for a series of six environmental fate studies, and EPA had responded with concurrence/comments. The studies were conducted at ABC Laboratories, and Dr. Reimann was prepared to discuss the results of the studies and determine if the EPA had any further suggestions.

The principal reviewer of the environmental fate studies, Dr. Herbert Manning, could not attend this meeting, and Dr. Creeger, the head of the Environmental Chemistry Review Section sat in for him.

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Dr. Creeger was not directly familiar with the previous communications, but did have access to the existing files. Dr. Creeger inquired specifically as to the EPA's letter requiring the six studies. Dr. Crema said the EPA had simply referred BASF to the guidelines for environmental fate studies rather than making a specific request. Dr. Creeger was interested in knowing the applications. It was mentioned that the specific application of interest had to do with oilfield application, but not to be used in discharge water. BASF will be going for manufacturing use only registration, which might have various end uses.

Dr. Reimann informally outlined the studies, primarily showing the summary results to Dr. Creeger. This included the half-life determination from the various studies, and a general discussion of the individual studies. For the oilfield applications, Dr. Creeger was not especially concerned about the studies of soil decomposition. He was interested in the aqueous hydrolysis studies and the adsorption/desorption studies.

With respect to the photolysis studies, Dr. Creeger mentioned that the requirements would probably be waived for the applications as discussed. He mentioned, however, that the EPA requires the use of a xenon lamp instead of a mercury one for these types of studies.

With respect to the adsorption/desorption studies, Dr. Creeger is interested in the zero time adsorption/desorption determinations, and inquired as to why report only evaluated 30 days incubated soils.

There was a good deal of discussion regarding the identification of metabolites by TLC, GC/MS and other chromatographic methods. Dr. Creeger believed that the presumptive identification of molecular weights and structures of decomposition products for which there are no analytical standards would satisfy the EPA requirements. In those cases where there was evidence of ring closure, this could probably be an artifact caused by the chromatographic conditions. Dr. Creeger also inquired as to whether there was a possibility of formation of dimers and trimers at the use concentrations, and Dr. Reimann indicated that these products were determined from higher concentrations than would be found in normal use.

Following his inquiry, Dr. Creeger was told that the pH of the oilfield applications was expected to be in the neutral or alkaline range.

It was pointed out that glutaraldehyde does react with many compounds, thus making it unavailable and difficult to extract from soil, and in the soil decomposition studies from 25 to 40% of the labeled carbon comes off as carbon dioxide. Also

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most of the identified and theoretical intermediate products are those that would be expected intermediates in the formation of CO<sub>2</sub> from glutaraldehyde.

Dr. Creeger believes that the attempts to identify decomposition products was satisfactory, and he had no reason to believe that if the studies were appropriately prepared and submitted, that they would not be satisfactory.

**GLUTARALDEHYDE**

Final Report

**Task 1: Review and Evaluation of  
Individual Studies**

**Contract No. 68-02-4250**

**MARCH 27, 1987**

**Submitted to:**  
Environmental Protection Agency  
Arlington, VA 22202

**Submitted by:**  
Dynamac Corporation  
The Dynamac Building  
11140 Rockville Pike  
Rockville, MD 20852

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GLUTARALDEHYDE

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## INTRODUCTION

Glutaraldehyde is a microbicide/microbistat registered for use on aquatic nonfood and indoor (agricultural premises and equipment, and commercial and industrial uses) sites to control bacteria, fungi, algae, and viruses. Single active ingredient formulations consist of 1.99, 2, 6, 10, 12, 12.8, 20, 20.5, and 26% SC/L; and 2, 15, 25, 45, and 50% RTU. Application rates range from 0.8 to 100 ppm on aquatic sites and from 964-24,000 ppm on indoor sites. Glutaraldehyde may be applied to aquatic sites by slug feed, intermittent feed, and continuous feed treatment. Glutaraldehyde is applied to indoor sites by cloth, swab, sponge, brush, spray, or immersion.

CASE GS --                      GLUTARALDEHYDE                      STUDY 1                      PM --

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CHEM 043901                      Glutaraldehyde

BRANCH EAR                      DISC --

FORMULATION 00 - ACTIVE INGREDIENT

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FICHE/MASTER ID No MRID                      CONTENT CAT 01

Warren, J. and W. Cranor. 1986a. Determination of the hydrolysis rate of <sup>14</sup>C-glutaraldehyde. Report No. 32738. Prepared by Analytical Bio-Chemistry Laboratories, Inc.; Columbia, MO, and submitted by BASF Corporation, Wyandotte, MI. Acc. No. 256838.

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SUBST. CLASS = S.

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DIRECT RVW TIME = 12                      (MH) STAPT-DATE                      END DATE

-----  
REVIEWED BY: T. Colvin-Snyder  
TITLE: Staff Scientist  
ORG: Dynamac Corp., Rockville, MD  
TEL: 468-2500

-----  
APPROVED BY: H. Manning *HJM*  
TITLE: Microbiologist  
ORG: EAB/HED/OPP  
TEL: 557-2243

SIGNATURE:

DATE:

CONCLUSIONS:

Degradation - Hydrolysis

1. This study is scientifically valid.
2. [<sup>14</sup>C]Glutaraldehyde (radiochemical purity 99%), at 250 ppm, degraded with half-lives of 7-14 days (EPA calculated half-life 19 days) at pH 9 and >30 days (EPA calculated half-life 72 days) at pH 7 in aqueous buffered solutions. In pH 5 solutions, glutaraldehyde ranged from 221-284 ppm throughout the study with no discernible pattern; degradation did not appear to occur. At least nine degradates were isolated but not identified in the solutions; each was <16.4% of the recovered.
3. This study does not fulfill EPA Data Requirements for Registering Pesticides because degradates >10% of the applied were not identified.

MATERIALS AND METHODS:

[<sup>14</sup>C]Glutaraldehyde (uniformly labeled, radiochemical purity 99%, specific activity 3.4 mCi/mM, Midwest Research Institute) was added at ~250 ppm

to sterile aqueous buffered solutions adjusted to pH 5, 7, and 9. The flasks containing the treated solutions were purged with argon, sealed, and incubated in the dark at  $25 \pm 1^\circ\text{C}$ . The solutions were sampled at intervals up to 32 days posttreatment.

Samples were analyzed without extraction by LSC and by GC equipped with flame ionization detection. Samples from days 7, 14, and 30 posttreatment were also analyzed by TLC on silica gel plates developed in hexane:ethyl acetate:methanol (55:25:20, v:v:v). Radioactive areas were located by autoradiography, scraped from the TLC plates, and quantified by LSC.

#### REPORTED RESULTS:

[ $^{14}\text{C}$ ]Glutaraldehyde degraded with half-lives of 7-14 days (EPA calculated half-life 19 days) at pH 9 and >30 days (EPA calculated half-life 72 days) at pH 7 in aqueous buffered solutions (Tables 1 and 2). In pH 5 solutions, glutaraldehyde ranged from 221-284 ppm throughout the study with no discernible pattern; degradation did not appear to occur. At least nine degradates were isolated but not identified in the solutions; each was <16.4% of the recovered.

#### DISCUSSION:

1. Degradates comprising >10% of the applied were not identified.
2. Data on degradates were reported as percent of recovered from the TLC plate rather than percent of applied.

Table 1. Total radioactivity (ppm) in aqueous buffered solutions treated with [<sup>14</sup>C]glutaraldehyde (radiochemical purity 99%) at ~250 ppm and incubated in the dark at 25 ± 1°C.<sup>a</sup>

Sampling interval (days)	pH		
	5	7	9
0	261	275	266
7	278	271	269
14	288	265	279
24	289	274	264
30	284	269	274

<sup>a</sup> Values average of three samples.

Table 2. [<sup>14</sup>C]Glutaraldehyde (ppm) in aqueous buffered solutions treated with [<sup>14</sup>C]glutaraldehyde (radiochemical purity >99%) at ~250 ppm and incubated in the dark at 25 ± 1°C.<sup>a</sup>

Sampling interval (days)	pH		
	5	7	9
0	274	263	270
3	231	283	242
4	250	269	200
7	254	256	173
14	221	201	127
21	284 <sup>b</sup>	217	115
32	268	217	86

<sup>a</sup> Values average of three samples based on GC analysis.

<sup>b</sup> Sample taken at 22 days.

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Table 3. Distribution of radioactivity (% of recovered from the TLC plates) in aqueous buffered solutions treated with [<sup>14</sup>C]glutaraldehyde (radiochemical purity >99%) at ~250 ppm and incubated in the dark at 25 ± 1°C.

Sampling interval (days)	Glutaraldehyde	Unknowns									Origin
		II	III	IV	V	VI	VII	IX	X	XI	
<u>pH 5</u>											
7	78.6	3.2	1.7	ND <sup>a</sup>	7.0	ND	ND	ND	ND	ND	4.7
14	73.1	16.4	ND	ND	5.9	ND	ND	ND	ND	ND	2.7
30	69.2	6.9	1.5	2.1	5.3	0.9	4.2	ND	0.8	ND	6.3
<u>pH 7</u>											
7	75.1	5.2	1.6	ND	ND	ND	ND	ND	4.9	ND	7.0
14	80.8	6.9	ND	ND	4.4	ND	ND	ND	ND	ND	5.0
30	62.8	10.5	2.0	4.7	2.9	1.6	3.2	0.9	3.2	ND	8.3
<u>pH 9</u>											
7	57.6	6.9	3.8	ND	12.7	ND	ND	ND	ND	ND	12.7
14	48.3	7.7	5.4	ND	ND	ND	ND	14.5	7.1	ND	16.0
30	26.4	5.9	4.0	15.9	ND	1.6	2.1	3.0	ND	12.9	22.5

<sup>a</sup> Not detected.

CASE GS -- GLUTARALDEHYDE STUDY 2 PM --

CHEM 043901 Glutaraldehyde

BRANCH EAB DISC --

FORMULATION 00 - ACTIVE INGREDIENT

FICHE/MASTER ID No MRID CONTENT CAT 01  
Warren, J. and W. Cranor. 1986b. Determination of the photolysis rate constants and degradation products of glutaraldehyde. Report No. 32739. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by BASF Corporation, Wyandotte, MI. Acc. No. 265839.

SUBST. CLASS = S.

DIRECT RVW TIME = 14 (MH) START-DATE END DATE

REVIEWED BY: T. Colvin-Snyder  
TITLE: Staff Scientist  
ORG: Dynamac Corp., Rockville, MD  
TEL: 468-2500

APPROVED BY: H. Manning *HSM*  
TITLE: Microbiologist  
ORG: EAB/HED/OPP  
TEL: 557-2243

SIGNATURE:

DATE:

CONCLUSIONS:Degradation - Photodegradation in Water

This study is scientifically invalid because data were too variable to accurately assess the decline of glutaraldehyde. In addition, this study would not fulfill EPA Data Requirements for Registering Pesticides because the study was terminated prior to establishing the half-life, degradates were not identified, the artificial light was inadequately characterized and was not compared to natural sunlight, and the temperature fluctuated between 19 and 28°C.

MATERIALS AND METHODS:

[<sup>14</sup>C]Glutaraldehyde (uniformly labeled, radiochemical purity 99%, specific activity 3.40 mCi/mM, Midwest Research Institute) was added at 250 ppm to sterile buffered (pH 5) solutions of either deionized water, deionized water containing 1% acetone, or deionized water containing 1% acetonitrile. Aliquots of the solutions were transferred to screw-capped culture tubes and placed on an Ace photochemical turntable reactor. The solutions were irradiated with a 450-W Ace-Hanovia mercury-vapor lamp

contained within a borosilicate immersion cell; the lamp emitted wavelengths of 366-578 nm with an intensity of 10975-25097  $\mu\text{W}/\text{cm}^2$  (light source not further characterized). Additional samples were incubated in the dark in a box wrapped in aluminum foil. Both the irradiated and dark control samples were kept in a fume hood; air temperatures in the hood ranged from 19 to 28°C throughout the study. Irradiated and dark control solutions were sampled at intervals up to 18 days posttreatment.

Samples were analyzed by LSC and by GC equipped with flame ionization detection. Samples were also analyzed by TLC on silica gel plates developed in hexane:ethyl acetate:methanol (55:25:20). Radioactive areas were located by autoradiography, scraped from the TLC plates, and quantified by LSC.

#### REPORTED RESULTS:

The half-life of glutaraldehyde in deionized water could not be determined because data were too variable. [ $^{14}\text{C}$ ]glutaraldehyde degraded with half-lives of 14-18 days in irradiated aqueous 1% acetone solutions and >18 days in its dark control; [ $^{14}\text{C}$ ]glutaraldehyde degraded with a half-life of >18 days in the irradiated and dark control aqueous 1% acetonitrile solutions (Tables 1 and 2). Several unidentified degradates were present in all six solutions at <35.1% of the recovered (Tables 3-5).

#### DISCUSSION:

1. Data were too variable to assess the decline of glutaraldehyde.
2. The study was conducted for 18 days rather than for either 30 days or one half-life.
3. Degradates comprising >10% of the applied were not identified.
4. The wavelength distribution of the artificial light was not provided. The intensity of light was calculated from manufacturer's data and was not measured. It was not compared to natural sunlight. Since natural or simulated sunlight were not used, the adsorption spectrum of glutaraldehyde is needed.
5. The incubation temperature was not maintained at  $25 \pm 1^\circ\text{C}$ .

Table 1. Total radioactivity (ppm) in aqueous pH 5 solutions treated with [<sup>14</sup>C]glutaraldehyde (radiochemical purity 99%) at ~250 ppm.

Sampling interval (days)	Deionized water	1% Acetone in deionized water	1% Acetonitrile in deionized water
		<u>Irradiated</u>	
0	245	245	240
2	--	239	--
3	244	247	245
6	241	245	--
7	--	--	249
10	234	243	167
14	241	240	242
17	261	--	251
		<u>Dark control</u>	
0	246	245	240
2	--	248	253
3	247	250	253
6	--	254	249
7	255	--	--
10	253	255	253
14	252	238	242
17	260	--	--

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Table 2. [<sup>14</sup>C]Glutaraldehyde (ppm) in aqueous pH 5 solutions treated with [<sup>14</sup>C]glutaraldehyde (radiochemical purity 99%) at ~250 ppm.

Sampling interval (days)	Deionized water	1% Acetone in deionized water	1% Acetonitrile in deionized water
		<u>Irradiated</u>	
0	244a	221	307
1	227	196	225
2	216	--	238
3	163	166	197
7	173	--	184
10	158 <sup>b</sup>	123	202
14	226	113	199
17	211	--	208
18	--	109	--
		<u>Dark control</u>	
0	259 <sup>b</sup>	238	253
1	224	202	250
2	269	--	179
3	176	222	264
7	213	--	--
10	242 <sup>b</sup>	236	268
14	230	246	247
17	243	--	--
18	--	223	230

a Values average of three samples.

b Values average of two samples.

Table 3. Distribution of radioactivity (% of the recovered) in deionized water treated with [<sup>14</sup>C]glutaraldehyde (radiochemical purity 99%) at ~250 ppm.

Sampling interval (days)	Glutaraldehyde	Unknowns								Origin
		II	III	IV	V	VI	VII	VIII		
<u>Irradiated</u>										
3	72.9	ND <sup>a</sup>	2.1	3.7	ND	ND	ND	ND	ND	9.4
7	63.5	ND	ND	ND	9.5	ND	ND	ND	ND	11.5
10	71.2	4.6	1.1	5.4	7.5	1.3	ND	ND	ND	5.6
14	81.0	2.9	0.9	ND	0.2	ND	12.1	ND	ND	1.2
17	62.2	4.9	2.6	6.4	9.8	ND	1.5	0.4	ND	11.3
<u>Dark control</u>										
3	76.7	ND	1.7	2.9	ND	ND	ND	ND	ND	8.3
7	71.6	4.4	2.1	3.3	5.5	ND	ND	ND	ND	10.1
10	79.8	4.3	1.6	2.6	4.0	ND	ND	ND	ND	5.6
14	88.3	ND	1.2	ND	0.2	ND	7.0	ND	ND	0.9
17	73.5	4.0	1.7	3.2	7.5	ND	2.7	0.4	ND	6.4

<sup>a</sup> Not detected.

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Table 4. Distribution of radioactivity (% of the recovered) in deionized water containing 1% acetone treated with [<sup>14</sup>C]glutaraldehyde (radiochemical purity 99%) at ~250 ppm.

Sampling interval (days)	Glutaraldehyde	Unknowns					Origin
		II	III	IV	V	VII	
<u>Irradiated</u>							
2	51.1	15.3	ND <sup>a</sup>	ND	ND	ND	14.0
3	60.8	2.2	2.8	6.4	9.8	ND	15.5
6	46.2	4.2	4.2	9.1	13.2	ND	19.4
10	44.1	4.7	4.6	10.8	13.0	ND	21.5
14	53.7	ND	1.7	0.9	0.9	35.1	3.5
<u>Dark controls</u>							
2	78.1	ND	ND	5.1	ND	ND	6.8
3	85.4	1.6	1.2	2.0	3.1	ND	5.2
6	71.8	4.1	2.5	3.7	5.2	ND	10.3
10	79.0	3.1	1.7	3.2	4.1	ND	6.7
14	85.0	ND	1.7	0.9	0.8	6.8	2.2

<sup>a</sup> Not detected.

Table 5. Distribution of radioactivity (% of the recovered) in deionized water containing 1% acetone treated with [<sup>14</sup>C]glutaraldehyde (radiochemical purity 99%) at ~250 ppm.

Sampling interval (days)	Glutaraldehyde	Unknowns					Origin
		II	III	IV	V	VII	
<u>Irradiated</u>							
3	67.9	ND <sup>a</sup>	2.4	2.9	ND	ND	9.9
7	66.7	4.2	2.3	4.9	6.8	ND	11.9
10	63.8	9.8	4.1	4.9	7.6	ND	7.2
14	80.8	2.7	0.9	ND	0.2	11.5	1.1
17	58.3	7.1	3.1	7.8	10.2	ND	9.5
<u>Dark controls</u>							
2	78.2	ND	2.2	3.9	ND	ND	7.4
3	82.2	1.7	1.1	2.5	3.2	ND	5.3
6	71.5	4.0	1.7	3.3	5.5	ND	9.6
10	78.0	3.2	1.8	3.4	4.2	ND	7.1
14	83.7	ND	1.6	1.1	0.9	6.8	2.9

<sup>a</sup> Not detected.

CASE GS --                      GLUTARALDEHYDE                      STUDY 3                      PM --

-----  
CHEM 043901                      Glutaraldehyde

BRANCH EAB                      DISC --

FORMULATION 00 - ACTIVE INGREDIENT  
-----FICHE/MASTER ID No MRID                      CONTENT CAT 01  
Cranor, W. 1986. Aerobic soil metabolism of <sup>14</sup>C-glutaraldehyde. Report  
No. 32734. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia,  
MO, and submitted by BASF Corporation, Wyandotte, MI. Acc. No. 265840.  
-----SUBST. CLASS = S.  
-----DIRECT RVW TIME = 16                      (MH) START-DATE                      END DATE  
-----REVIEWED BY: T. Colvin-Snyder  
TITLE: Staff Scientist  
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-----APPROVED BY: H. Manning *HJM*  
TITLE: Microbiologist  
ORG: EAB/HED/OPP  
TEL: 557-2243  
-----

SIGNATURE:

DATE:

CONCLUSIONS:Metabolism - Aerobic Soil

This study is scientifically invalid because the concentration of glutaraldehyde throughout the study was <3.42% of the applied and the material balance was incomplete. In addition, this study would not fulfill EPA Data Requirements for Registering Pesticides because the analytical methodology (extraction of soil samples and the TLC analysis) was inadequate, degradates were not identified, and the moisture content of the soil was not reported.

MATERIALS AND METHODS:

[<sup>14</sup>C]Glutaraldehyde (uniformly labeled, radiochemical purity >98%, specific activity 3.4 mCi/mM, Midwest Research Institute) was applied at ~10 ppm to loamy sand soil (83.6% sand, 9.2% silt, 7.2% clay, 0.3% organic matter, pH 7.8, CEC 5.9 meq/100 g). The treated soil was incubated in a glass vessel (3000 mL) attached sequentially to silica gel sep-packs, and tubes containing ethylene glycol, sulfuric acid, and potassium hydroxide volatile trapping solutions (Figure 1). The system was maintained under positive pressure in the dark at 25 ± 1°C.

Soil, sep-packs, and trapping solutions were sampled at intervals up to 120 days posttreatment.

Portions of each soil sample were analyzed for total radioactivity by LSC following combustion. Soil samples were extracted (vortex shaking for 1 minute) three times with methanol and the extracts were combined. Aliquots of the extracts were analyzed for total extractable radioactivity by LSC; the remainder was analyzed by TLC on silica gel plates developed with hexane:ethyl acetate:methanol (55:25:20). Radioactive zones were located by autoradiography, scraped from the plates, and quantitated by LSC. Extracted soils were analyzed for unextractable radioactivity by LSC following combustion. Silica gel sep-packs were extracted five times with methanol and the combined extracts were analyzed by LSC. Trapping solutions were analyzed by LSC.

#### REPORTED RESULTS:

Total [ $^{14}\text{C}$ ]residues in the system (soil plus volatiles) ranged from 64.0 to 100.0% during the study (Table 1). At all sampling intervals, >50% of the residues remained unextracted from the soil. A total of 38.01% of the residues were volatilized during 120 days of incubation.

[ $^{14}\text{C}$ ]Glutaraldehyde was 3.42% of the total residues in the system immediately after treatment, and was <0.16% at days 1, 3, 7, and 14 post-treatment (Table 2). Two degradates, comprising 26.6-30.1% of the residues recovered from the TLC plate, were isolated but not identified.

#### DISCUSSION:

1. Glutaraldehyde comprised <3.42% of the total [ $^{14}\text{C}$ ]residues recovered at day 0 throughout the study.
2. The material balance was incomplete; total [ $^{14}\text{C}$ ]residues in the system were as low as 64% of the recovered on day 0.
3. The extraction of soil samples was inadequate. At day 0, unextractable residues were 79.2% of total [ $^{14}\text{C}$ ]residues recovered. Throughout the study, unextractable residues comprised 50.5-79.2% of total [ $^{14}\text{C}$ ]residues recovered at day 0 (Table 1).
4. The TLC methods were inadequate; a reference standard for glutaraldehyde chromatographed as only 41.8% glutaraldehyde while 33.2% remained at the origin. Residues were lost during TLC analysis. Recoveries ranged from 36-81% of the radioactivity applied to TLC plates (Table 2).
5. Degradates were not identified.
6. The moisture content of the soil was not reported.

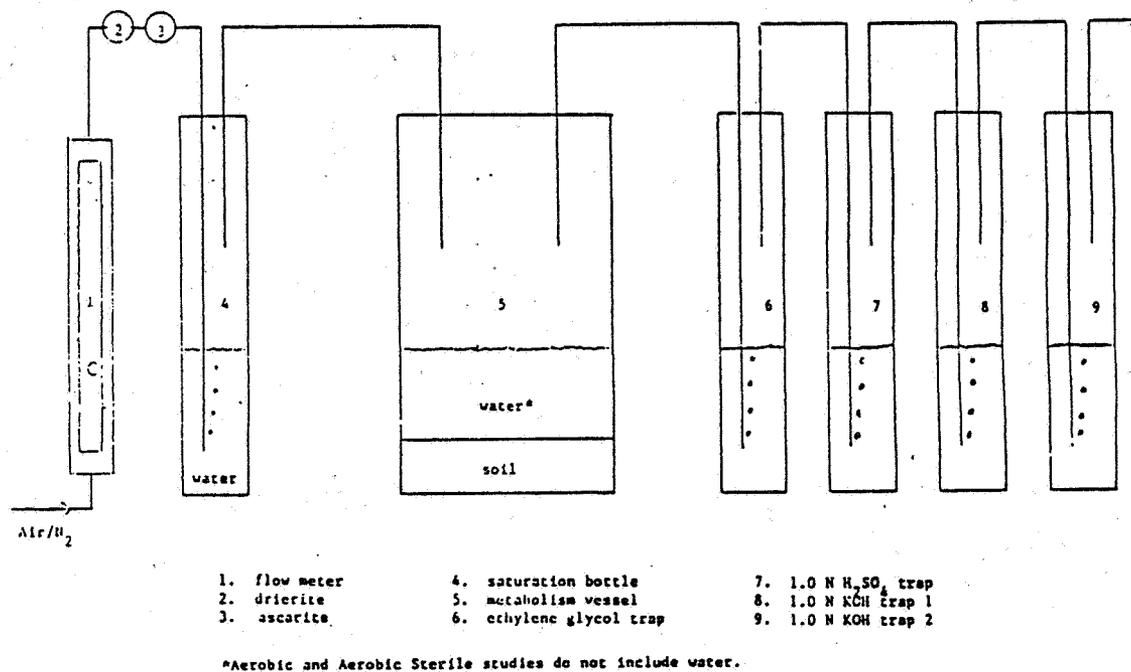


Figure 1. Soil metabolism apparatus.

Table 1. Distribution of radioactivity (ppm) in loamy sand soil treated with [<sup>14</sup>C]glutaraldehyde at ~10 ppm and incubated aerobically at 25 ± 1°C.

Sampling interval (days)	Total residues in soil <sup>a</sup>	Extractable	Unextractable	Cumulative volatiles	Total in system (% of day 0)
0	7.48	1.92	5.93	--	100.0
1	4.72	0.76	5.74	0.22	66.0
3	5.36	0.11	4.56	0.32	75.9
7	4.42	0.10	4.76	0.42	64.7
14	4.06	0.04	4.02	0.73	64.0
21	4.15	0.07	4.90	0.78	65.9
30	4.41	0.07	4.41	0.89	70.8
60	4.47	0.05	4.28	1.02	73.4
91	4.32	0.05	3.78	1.07	72.0
120	4.06	0.05	3.89	1.10	69.0

<sup>a</sup> Total [<sup>14</sup>C]residues in the soil prior to extraction.

Table 2. Distribution of radioactivity in methanol extracts of loamy sand soil treated with [<sup>14</sup>C]glutaraldehyde at ~10 ppm and incubated aerobically at 25 ± 1°C.

Sampling interval (days)	Total recovery (% of applied)	Glutaraldehyde <sup>a</sup> % of recovered	Unknowns		Origin	Remainder <sup>b</sup>
			R <sub>f</sub> 0.07	R <sub>f</sub> 0.082		
0	66.3	20.1	30.1	NDC <sup>c</sup>	25.6	24.3
1	81.0	ND	ND	ND	76.5	23.5
3	38.9	ND	ND	ND	85.7	14.3
7	58.8	20.2	ND	26.6	29.8	23.4
14	36.7	ND	ND	ND	69.3	30.7
Reference	41.8	41.8	12.3	ND	33.2	18.8

<sup>a</sup> At day 0, 3.42% of the total residues in the system were identified as glutaraldehyde (20.1% of the recovered was glutaraldehyde x 66.3% of the applied were recovered on the TLC plates x 25.7% of the total residues were applied contained in the methanol extract of the soil). On day 7, only 0.16% of the total residues applied to the system were glutaraldehyde.

<sup>b</sup> Remainder was not defined by the registrant.

<sup>c</sup> Not detected; the detection limit was not specified.

CASE GS --                      GLUTARALDEHYDE                      STUDY 4                      PM --

-----  
CHEM 043901                      Glutaraldehyde

BRANCH EAB                      DISC --

FORMULATION 00 - ACTIVE INGREDIENT  
-----FICHE/MASTER ID No MRID                      CONTENT CAT 01  
Cranor, W. 1986. Anaerobic aquatic metabolism of glutaraldehyde. Report  
No. 32735. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia,  
MO, and submitted by BASF Corporation, Wyandotte, MI. Acc. No. 265841.  
-----SUBST. CLASS = S.  
-----DIRECT RVW TIME = 20                      (MH) START-DATE                      END DATE  
-----REVIEWED BY: T. Colvin-Snyder  
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ORG: Dynamac Corp., Rockville, MD  
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-----APPROVED BY: H. Manning *HJM*  
TITLE: Microbiologist  
ORG: EAB/HED/OPP  
TEL: 557-2243  
-----

SIGNATURE:

DATE:

CONCLUSIONS:Metabolism - Anaerobic Aquatic

This study is scientifically invalid because glutaraldehyde was not detected at any interval during the study and the material balance was incomplete. In addition, this study would not fulfill EPA Data Requirements for Registering Pesticides because the analytical methodology (extraction of soil samples and TLC analysis) was inadequate, degradates were not identified, and the soil may not have been anaerobic prior to the addition of the pesticide.

MATERIALS AND METHODS:

[<sup>14</sup>C]Glutaraldehyde (uniformly labeled, radiochemical purity >98%, specific activity 3.4 mCi/mM, Midwest Research Institute) was applied at 10.5 ppm to silty clay loam soil (17.2% sand, 49.2% silt, 33.6% clay, 1.4% organic matter, pH 6.5, CEC 23.3 meq/100 g) that had been flooded (1:2, w:v) with water (pH 7.95) prior to the application of the pesticide (specific interval not reported). The treated soil:water system was incubated in a glass vessel (3000 mL) attached sequentially to silica gel sep-packs, and tubes containing ethylene glycol, sulfuric acid,

and potassium hydroxide volatile trapping solutions (Figure 1). The system was maintained under positive pressure (100 mL/minute) using N<sub>2</sub> gas in the dark at 25 ± 1°C. Soil, water, sep-packs, and trapping solutions were sampled at intervals up to 90 days posttreatment.

Portions of each soil samples were analyzed for total radioactivity by LSC following combustion. Soil samples were extracted (vortex shaking for 1 minute) three times with methanol and the extracts were combined. Aliquots of the extracts were analyzed for total extractable radioactivity by LSC. Extracted soils were analyzed for unextractable radioactivity by LSC following combustion. Aliquots of each water sample were analyzed by LSC. Water samples were extracted three times with hexane and the extracts were combined. Aliquots of the hexane extracts and the unextracted water were analyzed by TLC on silica gel plates developed with hexane:ethyl acetate:methanol (55:25:20). Radioactive zones were located by autoradiography, scraped from the plates, and quantitated by LSC. Extracted soils were analyzed for unextractable radioactivity by LSC following combustion. Silica gel sep-packs were extracted five times with methanol and the combined extracts were analyzed by LSC. Trapping solutions were analyzed by LSC.

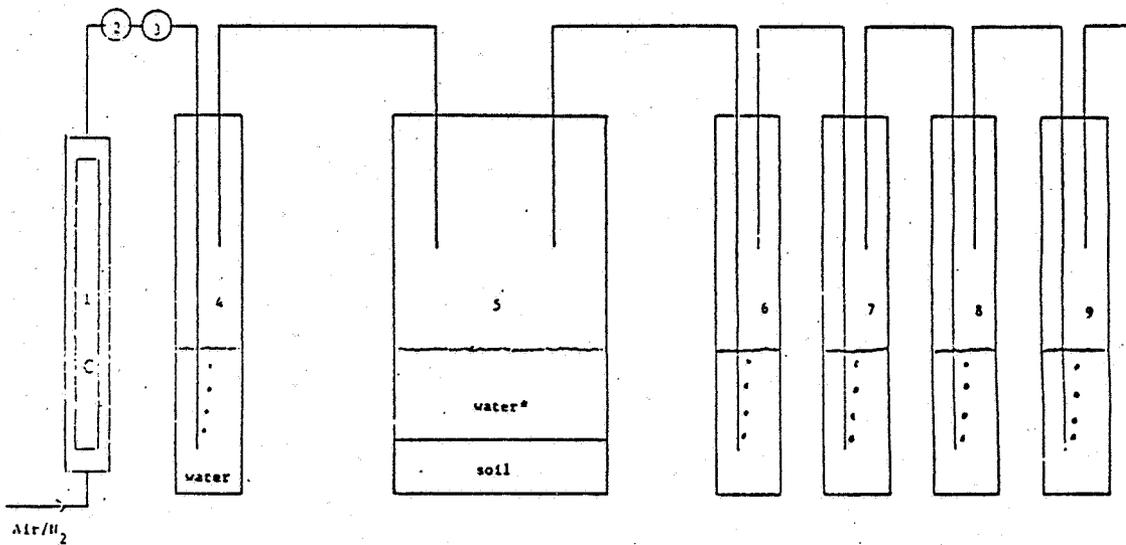
#### REPORTED RESULTS:

Total [<sup>14</sup>C]residues in the system (soil, water, and volatiles) ranged from 33 to 100% during the study (Table 1). At all sampling intervals, >50% of the residues remained unextracted from the soil and water. A total of 13.17% of the residues were volatilized during 90 days of incubation.

[<sup>14</sup>C]Glutaraldehyde was not detected (detection limit not reported) in the system at any sampling interval (Table 2). Two degradates, comprising 16-64% of the recovered from the TLC plate, were isolated but not identified.

#### DISCUSSION:

1. Glutaraldehyde was not detected in the soil at any sampling interval.
2. The material balance is incomplete; total [<sup>14</sup>C]residues in the system were as low as 33% of the recovered on day 0.
3. The extraction of soil and water samples was inadequate. At day 0, unextractable residues were 83% of total [<sup>14</sup>C]residues recovered. Throughout the study, unextractable residues comprised >50% of total [<sup>14</sup>C]residues recovered at day 0 (Table 1).
4. The TLC methods were inadequate; a reference standard for glutaraldehyde chromatographed as only 41.8% glutaraldehyde while 33.2% remained at the origin.
5. Degradates were not identified.
6. Although this was described as an anaerobic aquatic study by the registrants, there was no indication the soil:water system was anaerobic before the pesticide was added to the system. Anaerobic conditions should be established over a 30-day period.



- |               |                         |  |
|---------------|-------------------------|--|
| 1. flow meter | 4. saturation bottle    | 7. 1.0 N H <sub>2</sub> SO <sub>4</sub> trap |
| 2. drierite   | 5. metabolism vessel    | 8. 1.0 N KOH trap 1                          |
| 3. ascarite   | 6. ethylene glycol trap | 9. 1.0 N KOH trap 2                          |

\*Aerobic and Aerobic Sterile studies do not include water.

Figure 1: Anaerobic aquatic metabolism apparatus.

Table 1. Distribution of radioactivity (% of total [<sup>14</sup>C]residues recovered at day 0) in silty clay loam sediment and water (1:2, w:v) treated with [<sup>14</sup>C]glutaraldehyde at 10.5 ppm and incubated at 25 ± 1°C.

Sampling interval (days)	Total by LSC <sup>a</sup>	Sediment		Water		Cumulative volatiles	Total in system
		Extractable	Unextractable	Extractable	Unextractable		
0	100	0.02	9.21	0.06	72.8	--	82.1
1	91.6	0.20	7.33	0.05	58.2	ND <sup>b</sup>	65.8
3	96.4	0.29	17.88	0.03	31.9	0.13	50.2
7	49.7	0.15	7.10	0.02	1.6	3.65	12.5
14	41.57	0.21	9.37	0.01	1.4	6.77	17.8
30	43.50	0.19	7.03	0.01	1.2	11.50	19.9
61	37.62	0.18	6.54	0.002	0.67	12.94	20.3
90	32.85	0.12	3.61	0.001	0.21	13.17	17.1

<sup>a</sup> Total radioactivity in sediment and water prior to extraction and volatiles.

<sup>b</sup> Not detected; the detection limit was not reported.

Table 2. [<sup>14</sup>C]Glutaraldehyde and its degradates in pond water.

Sampling interval (days)	Total recovery (% of applied)	Glutaraldehyde	Unknowns		Origin	Remainder <sup>a</sup>
			% of recovered	R <sub>f</sub> 0.30		
0	36.7	ND <sup>b</sup>	16.0	64.8	13.6	5.5
1	73.7	ND	ND	13.1	82.4	4.5
3	92.4	ND	ND	24.2	73.4	2.4
Standard	65.9	44.9	3.2	8.9	32.2	10.9

<sup>a</sup> Remainder was not defined by the registrant.

<sup>b</sup> Not detected; the detection limit was not specified.

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CASE GS --                      GLUTARALDEHYDE                      STUDY 5                      PM --

-----  
CHEM 043901                      Glutaraldehyde

BRANCH EAB                      DISC --

FORMULATION 00 - ACTIVE INGREDIENT

-----  
FICHE/MASTER ID No MRID                      CONTENT CAT 01  
Cranor, W. 1986. Aerobic aquatic metabolism of glutaraldehyde. Report No. 32736. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by BASF Corporation, Wyandotte, MI. Acc. No. 265842.-----  
SUBST. CLASS = S.-----  
DIRECT PVW TIME = 10                      (MH) START-DATE                      END DATE-----  
REVIEWED BY: T. Colvin-Snyder  
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APPROVED BY: H. Manning *HJM*  
TITLE: Microbiologist  
ORG: EAB/HED/OPP  
TEL: 557-2243

SIGNATURE:

DATE:

CONCLUSIONS:Metabolism - Aerobic Aquatic

This study is scientifically invalid because the concentration of glutaraldehyde throughout the study was <1.9% of the recovered and the the material balance was incomplete. In addition, this study would not fulfill EPA Data Requirements for Registering Pesticides because the analytical methodology (TLC analysis) was inadequate and degradates were not identified.

MATERIALS AND METHODS:

[<sup>14</sup>C]Glutaraldehyde (uniformly labeled, radiochemical purity >98%, specific activity 3.4 mCi/mM, Midwest Research Institute) was applied at ~10 ppm to silty clay loam soil (17.2% sand, 49.2% silt, 33.6% clay, 1.4% organic matter, pH 6.5, CEC 23.3 meq/100 g) that had been flooded (1:2, w:v) with water (pH 7.95, dissolved oxygen 8.55) prior to the application of the pesticide. The treated soil:water system was incubated in a glass vessel (3000 mL) attached sequentially to silica gel sep-packs, and tubes containing ethylene glycol, sulfuric acid, and potassium hydroxide volatile trapping solutions (Figure 1). The

system was maintained under positive pressure using N<sub>2</sub> gas in the dark at 25 ± 1°C. Soil, water, sep-packs, and trapping solutions were sampled at intervals up to 30 days posttreatment.

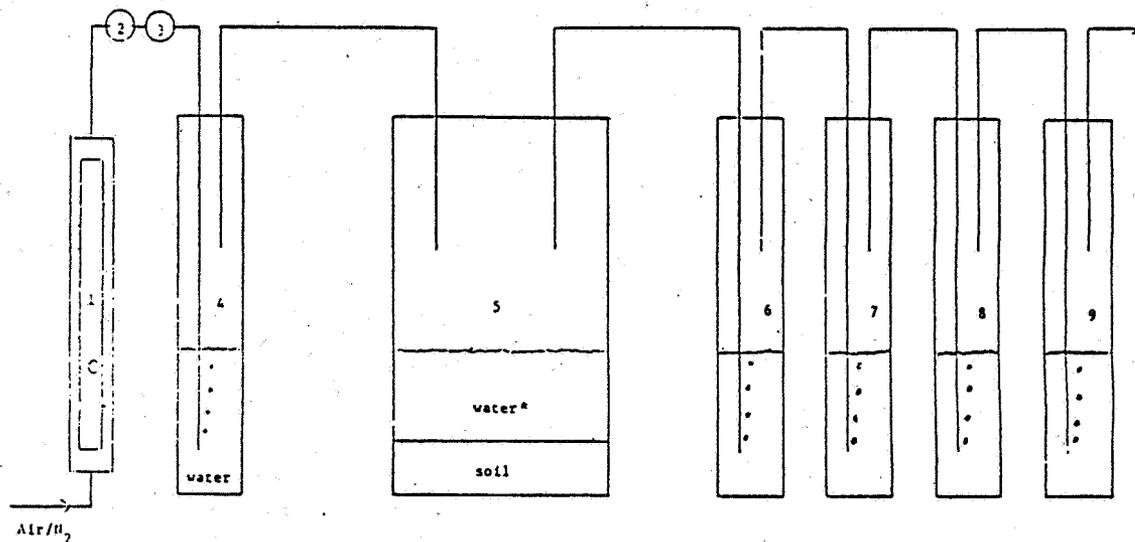
Portions of each soil samples were analyzed for total radioactivity by LSC following combustion. Soil samples were extracted (vortex shaking for 1 minute) three times with methanol and the extracts were combined. Aliquots of the extracts were analyzed for total extractable radioactivity by LSC. Extracted soils were analyzed for unextractable radioactivity by LSC following combustion. Aliquots of each water sample were analyzed by LSC. Water samples were extracted three times with hexane and the extracts were combined. Aliquots of the hexane extracts and the unextracted water were analyzed by TLC on silica gel plates developed with hexane:ethyl acetate:methanol (55:25:20). Radioactive zones were located by autoradiography, scraped from the plates, and quantitated by LSC. Extracted soils were analyzed for unextractable radioactivity by LSC following combustion. Silica gel sep-packs were extracted five times with methanol and the combined extracts were analyzed by LSC. Trapping solutions were analyzed by LSC.

#### REPORTED RESULTS:

Total [<sup>14</sup>C]residues in the system (soil, water, and volatiles) ranged from 60 to 126% of the applied during the study (Table 1). At all sampling intervals, >90% of the residues remained unextracted from the soil. A total of 12.92% of the residues were volatilized during 90 days of incubation. In the water, [<sup>14</sup>C]glutaraldehyde was 1.9% of the recovered immediately posttreatment and was not detected (detection limit not reported) at any other sampling interval (Table 2). Three degradates, comprising 2-28% of the recovered from the TLC plate, were isolated but not identified.

#### DISCUSSION:

1. The amount of glutaraldehyde (1.6% of total [<sup>14</sup>C]residues recovered) at day zero was insufficient to establish the decline of glutaraldehyde in pond water.
2. The material balance is incomplete. Recoveries ranged from 52-122% of the applied throughout the study (Table 1).
3. The TLC methods were inadequate; a reference standard for glutaraldehyde chromatographed as only 48% glutaraldehyde while 24% remained at the origin. Residues were lost during TLC analysis. Recoveries ranged from 30-84% of the radioactivity applied to TLC plates.
4. Degradates were not identified.



- |               |                         |  |
|---------------|-------------------------|--|
| 1. flow meter | 4. saturation bottle    | 7. 1.0 N H <sub>2</sub> SO <sub>4</sub> trap |
| 2. drierite   | 5. metabolism vessel    | 8. 1.0 N KOH trap 1                          |
| 3. ascarite   | 6. ethylene glycol trap | 9. 1.0 N KOH trap 2                          |

\*Aerobic and Aerobic Sterile studies do not include water.

Figure 1: Aerobic aquatic metabolism apparatus.

Table 1. Distribution of radioactivity (% of the applied) in silty clay loam sediment and water (1:2, w:v) treated with [<sup>14</sup>C]glutaraldehyde at 10 ppm and incubated at 25 ± 1°C.

Sampling interval (days)	Total by LSC <sup>a</sup>	Sediment		Water	Cumulative volatiles	Total in system
		Extractable	Nonextractable			
0	126	0.85	18.0	103	--	122
1	115	0.67	29.3	78	ND <sup>b</sup>	108
2	94	0.65	25.1	59	0.13	85
7	79	0.68	26.7	37	3.65	68
16	67	0.57	34.3	15	6.77	60
23	65	0.47	32.6	11	11.50	55
30	60	0.40	30.0	9	12.94	52

<sup>a</sup> Total radioactivity in sediment, water, and volatiles.

<sup>b</sup> Not detected; the detection limit was not reported.

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Table 2. Distribution of radioactivity in the water fraction of a soil:water system treated with [<sup>14</sup>C]glutaraldehyde at 10 ppm.

Sampling interval (days)	Recovery from TLC plates (% of applied)	Glutaraldehyde	Unknowns			Origin	Remainder <sup>a</sup>
			R <sub>f</sub> 0.30 % of recovered	R <sub>f</sub> 0.09	R <sub>f</sub> 0.59		
0	83.5	1.9	2.4	21	ND <sup>b</sup>	71	3.1
1	78.6	ND	ND	33	6.9	53	6.9
2	46.6	ND	23	28	ND	42	6.8
7	30.2	ND	ND	ND	ND	85	15.0
16	62.3	ND	ND	ND	ND	91	9.4
23	71.8	ND	ND	ND	ND	88	12.0
Standard	77.7	48	6.7	8.8	3.2	24	9.0

<sup>a</sup> Remainder was not defined by the registrant.

<sup>b</sup> Not detected; the detection limit was not specified.

CASE GS --                      GLUTARALDEHYDE                      STUDY 6                      PM --

CHEM 043901                      Glutaraldehyde

BRANCH EAP                      DISC --

FORMULATION 00 - ACTIVE INGREDIENT

FICHE/MASTER ID No MRID                      CONTENT CAT 01  
 Warren, J. and C. Carlton. 1985. Determination of adsorption/desorption constants of <sup>14</sup>C-glutaraldehyde. Report No. 32737. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by BASF Corporation, Wyandotte, MI. Acc No. 265843.

SUBST. CLASS = S.

DIRECT RVW TIME = 8	(MH) START-DATE	END DATE

REVIEWED BY: T. Colvin-Snyder  
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 TITLE: Microbiologist  
 ORG: EAB/HED/OPP  
 TEL: 557-2243

SIGNATURE:

DATE:

CONCLUSIONS:Mobility - Leaching and Adsorption/Desorption

1. This study is scientifically valid.
2. Aged (30 days) [<sup>14</sup>C]glutaraldehyde residues were mobile to very mobile in loam, silt loam, clay loam and loamy sand soils, with Freundlich  $K_{ads}$  values of 0.183-6.3.  $K_{des}$  values were 0.278-1.55.
3. This study does not fulfill EPA Data Requirements for Registering Pesticides because  $K_{ads}$  and  $K_{des}$  values for degradation were not determined.

MATERIALS AND METHODS:

Based on a preliminary adsorption study, a soil:solution ratio of 1:2 was selected. It was stated that there was no change in solution concentration after 48 hours.

Loamy sand, loam, silt loam, and clay loam soils (Table 1) were treated with [<sup>14</sup>C]glutaraldehyde (uniformly-labeled, radiochemical purity 99% *40*)

specific activity 3.40 mCi/mM, Midwest Research Institute) at 10 ppm and incubated aerobically for 30 days at  $25 \pm 1^\circ\text{C}$ . Following incubation, the soils were extracted with methanol:deionized water (80:20). Aqueous 0.01 N calcium chloride solutions at three concentrations of [ $^{14}\text{C}$ ]glutaraldehyde residues ranging from 0.012-0.054 ppm were prepared from extracts of each soil. The solutions were mixed with autoclaved soil samples (2:1; v:w) and shaken for a minimum of 24 hours at  $25 \pm 1^\circ\text{C}$ , centrifuged, and the supernatants analyzed for radioactivity by LSC.

Desorption of [ $^{14}\text{C}$ ]glutaraldehyde residues was studied using the soil solutions from the adsorption study. After a known volume of supernatant was discarded, pesticide-free 0.01 N calcium chloride solution was added to reestablish the 2:1 solution:soil ratio. The samples were shaken for a minimum of 48 hours at  $25 \pm 1^\circ\text{C}$  and then centrifuged. The supernatant from each solution was analyzed by LSC. Soil samples were then analyzed for adsorbed radioactivity by LSC following combustion.

#### REPORTED RESULTS:

Aged [ $^{14}\text{C}$ ]glutaraldehyde residues were very mobile in loam, silt loam, and clay loam soils and were mobile in loamy sand soil (Tables 2 and 3). Freundlich  $K_{ads}$  values ranged from 0.183 to 6.3;  $K_{des}$  values were 0.278-1.55.

#### DISCUSSION:

1.  $K_{ads}$  and  $K_{des}$  values were not determined for degradates.
2. The percent of [ $^{14}\text{C}$ ]glutaraldehyde residues extracted from the soils prior to the adsorption study was not reported.
3. The registrants states that there was no change in the solution concentration after 48 hours in the preliminary study. The actual adsorption study was conducted for a minimum of 24 hours; it was not clear if equilibrium was reached in 24 hours. Also, the preliminary study was conducted using soil:solution ratios of 1:5 and 1:10. The equilibration time for a 1:2 soil:solution slurry may differ from those of 1:5 and 1:10 soil:solution slurries.

Table 1. Soil characteristics.

Soil type	Sand	Silt	Clay	Organic matter	pH	CEC (meq/100 g)
	%					
Loamy sand	82.0	14.0	4.0	0.7	8.0	7.7
Loam	50.8	36.0	13.2	1.9	5.4	11.2
Silt loam	12.8	70.0	17.2	4.1	5.3	25.7
Clay loam	20.8	40.0	39.2	8.4	6.2	54.2

Table 2. Freundlich K and 1/n values for the adsorption and desorption of  $[^{14}\text{C}]$ glutaraldehyde residues on four soils.

Soil type	Adsorption			Desorption		
	$K_{ads}$	$K_{oc}$	n	$K_{des}$	$K_{oc}$	n
Loamy sand	6.3	2070	0.653	0.867	285	1.22
Loam	0.183	22.2	1.33	0.278	33.7	1.68
Silt loam	0.336	18.9	1.26	1.41	79.2	1.1
Clay loam	0.186	5.1	1.36	1.55	42.5	1.03

Table 3. Distribution of radioactivity, as determined by LSC, in four types of soil equilibrated with 0.01 N calcium chloride solutions containing aged (30 days) [<sup>14</sup>C]glutaraldehyde residues.

Initial concentration in solution (µg/mL)	Replicate	Adsorption		Desorption		In soil <sup>b</sup>
		Total at initiation	In solution after adsorption µg	Total at initiation <sup>a</sup>	In solution after adsorption	
<u>Loamy sand</u>						
0.0121	1	0.0726	0.0566	0.0368	0.0150	0.0098
	2	0.0726	0.0587	0.0325	0.0154	0.0076
0.0184	1	0.11	0.0792	0.0493	0.0323	0.0153
	2	0.11	0.0864	0.0639	0.0308	0.0101
0.0366	1	0.22	0.157	0.1232	0.0600	0.0420
	2	0.22	0.147	0.1000	0.0311	0.0274
<u>Loam</u>						
0.0147	1	0.104	0.0792	0.0512	0.0210	0.0083
	2	0.104	0.0828	0.0488	0.0173	0.0135
0.0258	1	0.155	0.128	0.0590	0.0322	0.0240
	2	0.155	0.128	0.0825	0.0425	0.0196
0.0521	1	0.313	0.260	0.157	0.0864	0.0360
	2	0.313	0.258	0.154	0.0810	0.0348
<u>Silt loam</u>						
0.0131	1	0.0786	0.0549	0.0420	0.0207	0.0125
	2	0.0786	0.0518	0.0415	0.0181	0.0120
0.0191	1	0.115	0.0834	0.0566	0.0272	0.0158
	2	0.115	0.0840	0.0604	0.0280	0.0192
0.0389	1	0.233	0.172	0.107	0.0503	0.0339
	2	0.233	0.169	0.126	0.0624	0.0315
<u>Clay loam</u>						
0.0176	1	0.106	0.0810	0.0614	0.0312	0.0182
	2	0.106	0.0882	0.0531	0.0299	0.0136
0.0266	1	0.160	0.115	0.0891	0.0402	0.0309
	2	0.160	0.129	0.0826	0.0440	0.0218
0.0537	1	0.322	0.268	0.166	0.096	0.0756
	2	0.322	0.267	0.180	0.090	0.0876

<sup>a</sup> Initial concentrations for desorption were obtained by subtracting the concentration removed following desorption from the total in the system.

<sup>b</sup> Concentration adsorbed to the soil following desorption was determined by LSC following combustion.

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The following studies are new submittals reviewed in this report.

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