H7507

Shaughnessy No.: 069149

Date Out of EFBWB: May 21 1990

TO: John Lee
Product Manager #31
Registration Division (H7505C)

FROM: Paul Mastradone, Ph.D., Section Chief
Chemistry Review Section #1
Environmental Fate & Ground Water Branch

THRU: Hank Jacoby, Chief
Environmental Fate & Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Attached, please find the EFGWB review of...

Reg./File # : 6836-53

Chemical Name: didecyl dimethyl ammonium chloride

Type Product : Microbiocide

Product Name : BARDAC 2280

Company Name : Lonza, Inc

Purpose : Review Hydrolysis and Photodegradation in Water studies.

Date Received: 9/14/89 Action Code: 300

Date Completed: 5/21/90 EFGBW#: 90775

Total Reviewing Time (decimal days) : 7.0

Deferrals to: _____ Ecological Effects Branch, EFED

_____ Science Integration & Policy Staff, EFED

_____ Non-Dietary Exposure Branch, HED

_____ Dietary Exposure Branch, HED

_____ Toxicology Branch, HED

Use this form for individual studies & to submit pesticide applications.

United States Environmental Protection Agency
Office of Pesticide Programs
Washington, DC 20460

Data Review Record

Confidential Business Information - Does not contain National Security Information (E.O. 12065)

Pack Number	Date Received
49690 EFED	9/20/89

1. Product Name: Bardac 2280 | Chemical Name: Quat

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
6x30-53	251449	300	411758-00	
			01	
			02	

7. Reference No.	8. Date Rec'd (EPA)	9. Prod/Review Mgr/DCI	10. PM/RM Team No.	11. Date to HED/ EFED/RD/BEAD	12. Proj Return Date	13. Date Returned to RD/SRRD
	7-24-89	Lee	31	9-14-89	10-21-89	

Instructions

Please review environmental chemistry studies on:

① Photolysis
② Hydrolysis

This Section Applies to Review of Studies Only

14. Check Applicable Box
- ☐ Adverse 6(a)(2) Data (405)
- ☐ Special Review Data (870)
- ☐ Generic Data (Reregistration) (660)
- ☐ Product Specific Data (Reregistration) (655)

15. No. of Individual Studies Submitted

16. Have any of the above studies *(in whole or in part)* been previously submitted for review?
- ☐ Yes *(Please identify the study(ies))*
- ☐ No

17. Related Actions

18.	To	Type of Review
HED	☐	Science Analysis & Coordination
	☐	Toxicology/HFA
	☐	Toxicology/IR
	☐	Dietary Exposure
	☐	Nondietary Exposure
EFED	☐	Ecological Effects
	☒	Environmental Fate & Groundwater
SRRD	☐	Special Review
	☐	Reregistration
	☐	Generic Chemical Support
RD	☐	Insecticide-Rodenticide
	☐	Fungicide-Herbicide
	☐	Antimicrobial
	☐	Product Chemistry
	☐	Precautionary Labeling
BEAD	☐	Economic Analysis
	☐	Analytical Chemistry
	☐	Biological Analysis

19. Reviews Also Sent to
- ☐ SAC
- ☐ TOX/HFA
- ☐ TOX/IR
- ☐ DEB
- ☐ NDE
- ☐ PC
- ☐ PL
- ☐ EA
- ☐ AC
- ☐ BA
- ☐ EEB
- ☐ EFGWB
- ☐ SR
- ☐ RER
- ☐ GSC
- ☐ IR
- ☐ FH
- ☐ AM

20. Data Review Criteria

A. Policy Note No. 31
- ☐ 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria
- ☐ 2 = data of particular concern from registration standard
- ☐ 3 = data necessary to determine tiered testing requirements

B. Section 18
- ☐ 1 = data in support of section 3 in lieu of section 18

C. Inert Ingredients
- ☐ 1 = data in support of continued use of List 1 inert

- ☐ Confidential Statement of Formula (EPA Form 8570-4) Attached *(Trade Secrets)*
- ☐ Label Attached

EPA Form 8570-17 (Rev. 11-88)
Previous editions are obsolete.

White - Data Coordinator
Yellow - Data Review Section
Pink - PM/RM/DCI
Green - Return with completed review

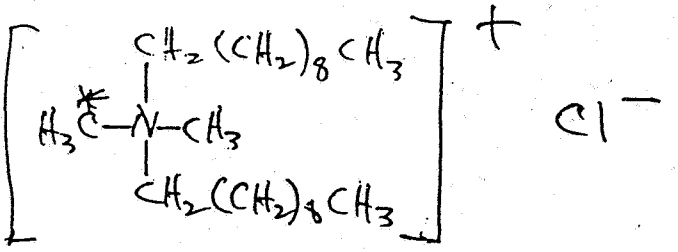
1.0 CHEMICAL:

Common Name- didecyl dimethylammonium chloride

Chemical Name- same as above

Trade Name- Bardac 2280 (formulating use product)

Chemical Structure-



* denotes position of ^{14}C label.

2.0 TEST MATERIAL: Both the Hydrolysis and the Photodegradation in Water studies used ^{14}C-didecyl dimethyl ammonium chloride (DDAC) (radiolabeled on a N-methyl carbon) at a nominal concentration of 10 ppm (ug/ml).

3.0 STUDY/ACTION TYPE: The registrant submitted studies on Hydrolysis and Photodegradation in Water for review to support reregistration.

4.0 STUDY IDENTIFICATION:

Study 1: Dykes, J. and M. Fennessey. 1989. Hydrolysis of didecyl dimethyl ammonium choride (DDAC) as a function of pH at 25 deg C, 21 April 1989, Analytical Bio-Chemistry Laboratories, Final Report #37004, MRID #41175801.

Study 2: Dykes, J. and M. Fennessey. 1989. Determination of photolysis rate of didecyl dimethyl ammonium chloride (DDAC) in pH 7 buffered solution at 25 deg C, 24 April 1989, ABC Laboratory Final Report #37005, MRID #41175802.

5.0 REVIEWED BY:

Herbert L. Manning, Ph.D.
Microbiologist, EFGWB/EFED

Signature: Herbert L. Manning
Date: MAY 21

6.0 APPROVED BY:

Paul J. Mastradone, Ph.D.
Chief, Section 1, EFGWB/EFED

Signature: Paul J Mastradone
Date: MAY 21 1990

7.0 CONCLUSION:

7.1 The EFGWB concludes that the hydrolysis study is acceptable and fulfills the data requirement.

7.2 ^{14}C-DDAC at a nominal concentration of 10 ppm, a radiopurity of 99.2%, and labeled on the N-methyl carbon was stable to hydrolysis in sterile, buffered solutions at pH 5, 7, and 9 after incubation at 25 +/-1C (in the dark) for 30 days. While linear regression analysis gave half-lives of 368 days at pH5, 175 days at pH 7, and 506 days at pH 9, they are based on very small amounts of degradation (at pH 7, 30 day samples had 93.4% DDAC) and, consequently, are rough estimates.

7.3 The EFGWB concludes that the photodegradation in water study is acceptable and fulfills the data requirement.

7.4 ^{14}C-DDAC at a nominal concentration of 10 ppm, a radiopurity of 98.5%, and labeled on a N-methyl carbon was stable to photolysis in a pH 7 buffered solution after continuous exposure to light from a xenon lamp for 30 days. Wavelengths below 290 nm were filtered from the xenon light.

7.5 The registrant's label (attached) indicates that Bardac 2280 will be used to formulate disinfectants, sanitizers, fungicides, and water treatment microbiocides. As such, these end-use products will probably have the following uses:

- Terrestrial nonfood
- Aquatic nonfood
- Greenhouse food
- Domestic outdoor
- Indoor use (no environmental fate data requirements.

Therefore, the following data are needed in order to support the reregistration of Bardac 2280:

- Aerobic Soil
- Aerobic Aquatic
- Anaerobic Aquatic
- Leaching- Adsorption/Desorption
- Laboratory Volatility
- Soil Field Dissipation
- Accumulation in Fish

- Accumulation in Irrigated Crops
- Accumulation in Aquatic Nontarget Organisms

8.0 RECOMMENDATIONS:

8.1 Inform the registrant that both the Hydrolysis and the Photodegradation in Water studies were acceptable and fulfill the data requirements.

8.2 Inform the registrant that the studies listed in Section 7.5 (above, under CONCLUSIONS) are required in order to support reregistration of Bardac 2280 if the uses are as those postulated (above).

9.0 BACKGROUND:

A. Introduction- See Section 3 of this review.

B. Directions for Use- Not applicable. This is a manufacturing use product. See the attached label.

10.0 DISCUSSION OF INDIVIDUAL STUDY:

See individual DER (DATA EVALUATION RECORD).

11.0 COMPLETION OF ONE-LINER: It will be updated.

12.0 CBI APPENDIX: There is no CBI in this review.

DATA EVALUATION RECORD

STUDY 1

STUDY IDENTIFICATION:

Dykes, J. and M. Fennessey. 1989. Hydrolysis of didecyl dimethyl ammonium choride (DDAC) as a function of pH at 25 deg C, 21 April 1989, Analytical Bio-Chemistry Laboratories, Final Report #37004, MRID #41175801.

REVIEWED BY:

Herbert L. Manning, Ph.D.
Microbiologist, EFGWB/EFED

Signature: Herbert L. Manning
Date: MAY 21 1990

APPROVED BY:

Paul J. Mastradone, Ph.D.
Chief, Section 1, EFGWB/EFED

Signature: Paul J. Mastradone
Date: MAY 21 1990

TYPE OF STUDY: Hydrolysis

CONCLUSION:

1. The study is acceptable and fulfills the data requirement.

2. ^{14}C-didecyl dimethyl ammonium chloride (DDAC) at nominal concentration of 10 ppm was shown to be stable to hydrolysis in sterile, buffered solutions at pH 5, 7, and 9 after incubation at 25 +/-1C (in the dark) for 30 days.

MATERIALS AND METHODS:

^{14}C-DDAC at a nominal concentration of 10 ppm, a radiopurity of 99.2%, and labeled on a N-methyl carbon was tested for hydrolysis in sterile, buffered solutions at pH 5, 7, and 9. Incubation was at 25 +/-1C in the dark for 30 days. Duplicate samples were taken at day 0, 4, 7, 14, 22, and 30. Analyses of samples was by LSC (liquid scintillation counting for total ^{14}C activity) and TLC (thin-layer chromatography for presence of degradates). In a preliminary experiment, samples were tested for storage stability at 4C and -20C for 14 days, and for adsorption to silanized and non-silanized glass.

REPORTED RESULTS:

Tables I-IV give the results of the preliminary study that tested adsorption of DDAC to treated (silanized) or untreated glass. Table VI gives the results of the preliminary storage stability study. Tables VIII-XV and Figures 4-7 sunmmarize the data. Figure 2 is a typical RTLC scan of the pH 7 Tris II, DDAC sample. Figure 3 is a typical chromatogram of day 30 DDAC samples.

The findings of the study are as follows:

1. ^{14}C-DDAC was shown to be stable to hydrolysis at pH 5, 7, and 9 in buffered solutions,

2. Although linear regression analyses gave a rough estimate of half-lives because of the very small amount of degradation, the values obtained were 368 days at pH 5, 175 days at pH 7 (HEPES buffer), and 506 days at pH 9,

3. Mass balance determinations averaged 98.5 +/-3.95% for the samples of each buffered solution,

4. The test for adsorption of DDAC to treated (silanized) and untreated glass tubes showed very little difference between the two, indicating that adsorption of DDAC to glass surface is not significant, and

5. The test for storage stability (4C vs -20C sampled on day 0, 1, 4, 7, and 14) showed no significant difference; however, the samples for the definitive study were analyzed within 24 hours of collection.

DISCUSSION:

1. The study is acceptable and fulfills the data requirement.

DATA EVALUATION RECORD

STUDY 2

STUDY IDENTIFICATION:

Dykes, J. and M. Fennessey. 1989. Determination of photolysis rate of didecyl dimethyl ammonium chloride (DDAC) in pH 7 buffered solution at 25 deg C, 24 April 1989, ABC Laboratory Final Report #37005, MRID #41175802.

REVIEWED BY:

Herbert L. Manning, Ph.D.
Microbiologist, EFGWB/EFED

Signature: Herbert L. Manning
Date: Mar 21 [illegible]

APPROVED BY:

Paul J. Mastradone, Ph.D.
Chief, Section 1, EFGWB/EFED

Signature: Paul J Mastradone
Date: Mar 21

TYPE OF STUDY: Photodegradation in Water

CONCLUSION:

1. The study is acceptable and fulfills the data requirement.

2. ^{14}C-DDAC at a nominal concentration of 10 ppm, a radiopurity of 98.5%, and labeled on a N-methyl carbon was stable to photolysis in a pH 7 buffered solution after continuous exposure to light from a xenon lamp for 30 days. Wavelengths below 290 nm were filtered from the xenon light.

MATERIALS AND METHODS:

^{14}C-DDAC at a nominal concentration of 10 ppm, a radiopurity of 98.5%, and labeled on a N-methyl carbon was stable to photolysis in a pH 7 sterile, buffered solution after continuous exposure to light from a xenon lamp for 30 days. Wavelengths below 290 nm were filtered from the xenon light. Incubation was at 25 +/-1C for both exposed samples and dark controls. Duplicate samples were taken on day 0, 1.03, 2.02, 7.03, 14.0, 21.0, and 29.9. Analyses of samples was by LSC (liquid scintillation counting for total radioactivity) and TLC (thin-layer chromatography for parent concentration and presence of degradates). A sterile, buffered solution of DDAC (nominal concentration of 10 ppm) at pH

7 was also tested with a photosensitizer (acetone at <1%). DDAC and possible degradates were tested (both sensitized and non-sensitized solutions) for volatility by passing water saturated, CO_2-free air over the surface of the solution and through five gas traps (in order as connected): D) ethylene glycol, E) 1N H_2SO_4, F) 1N KOH, F) 1N KOH, and G) a C_{18} Waters Associate Sep-Pak (see Figure 4 for the apparatus). The gas trap solutions were assayed (methanol extraction and LSC analysis) at zero time and at end of study. In a preliminary study, samples/solutions were tested for storage stability at 4C and -20C for 14 days, and for adsorption to silanized and untreated glass. In the definitive study, samples were analyzed within 24 hours of collection.

REPORTED RESULTS:

Tables I-IV show the results of the adsorption experiment. Table V shows the results of the storage stability experiment. Tables VIII-XI summarize the photodegradation of DDAC. Tables XII-XIII give the mass balance data. Table XIV gives the volatility data. Figure 2 shows the TLC scan of the 30 day, exposed sample. Figure 3 shows the results of the TLC analysis of the 30 day samples. Figures 5-8 are decline curves of the photolysis of DDAC. Figure 5 is the absorbance spectrum of non-sensitized DDAC.

The findings of the study are as follows:

1. ^{14}C-DDAC was stable to photodegradation in sensitized (acetone) and non-sensitized, buffered (pH 7) solutions. The absorbance spectrum of the DDAC-xenon light interaction indicated that DDAC did not absorb the xenon light,

2. Linear regression analyses gave a rough estimate (due to small amount of degradation) of the stabililty of DDAC to photolysis: the exposed, non-sensitized samples had a half-life of 367 days; exposed, sensitized samples had a half-life of 227 days,

3. Degradation (about 7%) on day 14 of the exposed, sensitized sample yielded one unidentifed degradate,

4. Recovery of ^{14}C-material ranged from 90.4% to 102%, with an average of 98.5%,

6. ^{14}C-DDAC was stable to storage for 14 days at 4C and -20C, and

7. ^{14}C-DDAC did not significantly absorb to the surface of glass tubes over a 96 hour period.

DISCUSSION:

1. The study is acceptable and fulfills the data requirement.