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

010477

AUG 1 0 1993

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Registrant's Response to a Deficiency Identified in an 8/16/89 Review of a Light Sensitization Study of ADBAC in Guinea Pigs (MRID # 409585-01)

Tox Chem No.	16E
Submission No.	S425942
DP Barcode No.	D182927
ID No.	069105
Case No.	819070
MRID Nos.	419475-01
	408356-02
	408356-03

FROM: Brian Dementi, Ph.D., D.A.B.T. Brian Dementi 1/15/93
Review Section III
Toxicology Branch-I
Health Effects Division (H7509C)

TO: Brigid Lowery, PM Team 72
Reregistration Branch
Special Review and Reregistration Division (H7508W)

THRU: Karen Hamernik, Ph.D., Acting Section Head
Review Section III
Toxicology Branch-I
Health Effects Division (H7509C)
K. Hamernik 10/29/93 KB 8/2/93

In August, 1985 Toxicology Branch reviewed a light sensitization study of ADBAC in guinea pigs (MRID # 409585-01). A copy of that review is appended. The reviewer concluded the study to be core minimum, but noted a deficiency described as a lack of information showing that the test material was homogeneous and stable during the course of the study.

In attempting to address these deficiencies, the registrant has submitted information from three sources. These include a chronic/oncogenicity study of ADBAC in rats (MRID # 419475-01); a study on the hydrolysis of ADBAC as a function of pH at 25°C (MRID # 408356-02); and a study of the photolysis of ADBAC at pH 7 and 25°C (MRID # 408356-03).

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The registrant advises that when the light sensitization study was being conducted, the same lot of ADBAC was being used in the rat chronic/oncogenicity study identified above. In that long term study, according to the registrant, periodic analyses showed that technical ADBAC was stable over the two year study period. An independent Tox Branch inspection of information provided from the chronic/oncogenicity study is sufficient to establish the correctness of the registrant's claim as to the stability of the test material. Repeated analyses over the period March 30, 1988 through November 8, 1989 showed the percent active ingredient to range from 79.6-81.5%. (See appended excerpt from DER of MRID (419475-01).

The registrant also claims that the additional two studies submitted on ADBAC establish that test solutions of ADBAC are hydrolytically and photolytically stable for 30 days. An independent inspection of these two studies is convincing that solutions of ADBAC prepared for use in the photosensitization study would have been stable. In the hydrolysis study, there was no evidence of significant degradation in the pH range 5-9 for the 30-day study period. In the photolysis study ADBAC did not degrade in sterile aqueous pH 7 buffered solutions continuously irradiated using a Xenon arc lamp. The duration of the photolysis study was not indicated. (See appended review from E. Regelman, 8/2/89).

As to the question of homogeneity, the registrant advises that ADBAC is a cationic compound with high water solubility. Since aqueous solutions used in the light sensitization study employed concentrations of the test material well below the limit of solubility in water, there is no reason to believe the test solutions were not homogenous. This line of thinking is considered acceptable.

Conclusion:

Toxicology Branch considers the information provided by the registrant to be adequate to address the deficiencies identified in the light sensitization study. The study is considered to be Acceptable.

According to SRRD (personal communication from B. Lowery), the light sensitization study had been required in the last Registration Standard. Now that the deficiency has been addressed, the submitted study provides acceptable support for that requirement.

In original review of the study (HED document #7437), the study was categorized as Minimum (with a deficiency). Since, there is no Toxicology Guideline for this type of study, the study cannot be upgraded to Guideline. Categorization of the study as Acceptable is considered to be more appropriate in this case.

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81-6 Guinea Pig - Photoallergy Study

Reviewed by: John H.S. Chen, D.V.M. John H.S. Chen 8/8/89
Section I, Toxicology Branch - HFAS (H7509C)
Secondary-reviewer: Yiannakis M. Ioannou, Ph.D. Stephen C Dapson for 8/8/89
Section I, Toxicology Branch - HFAS (H7509C)

DATA EVALUATION REPORT

Study Type: Photoallergy Study in Guinea Pigs

Tox. Chem. No.: 16E (not 16I)

MRID NUmber: 409585-01

Accession No.:

EPA File Symbol: 069105

Test Material: Alkyl dimethyl benzyl ammonium chloride (ADBAC)
(80% Purity: Lot No. 7293K)

Synonyms/CAS No.:

Study Number(s): 88-3226-21

Sponsor: Chemical Specialties Manufacturers Association
Washington, DC 20036

Testing Facility: Hill Top Biolabs, Inc.
Miamville, OH 45147

Title of Report: Photoallergy Study in Guinea Pigs

Author(s): James J. Kreuzmann, B.A.

Report Issued: January 5, 1989

Conclusions:

ADBAC is not a photoallergen at the dose levels tested.

Level tested: 0.5% (induction 1 through 4) and 0.25% (induction 5 through nine) - A total of 9 applications for 3 consecutive weeks.

Classification of Data: Core Minimum

(Deficiency: lack of the information of chemical analysis showing that the test material was homogeneous and stable during the course of this study)

Procedures:

1. The test material, alkyl dimethyl benzyl ammonium Chloride (Lot No. 7293K) containing 80% of ADBAC, was used in this study.

2. The study was performed on 52 Hartley guinea pigs (weighed 309-351 grams) of both sexes in three phases (primary irritation, induction of sensitization, and primary challenge) as indicated below:

Group	No. of Animals Male	Female	Primary Irritation	Induction of Sensitization	Primary Challenge
1. Primary Irritation with Irradiation	4	4	X	-	-
Primary Irritation without Irradiation	2	2	X	-	-
2. Test Material (ADBAC)	5	5	-	X	X
3. Vehicle Control	5	5	-	X	X
4. Naive Test Control	5	5	-	-	X
5. Positive Control	5	5	-	X	X

3. The test procedure used was based on that of Buehler (Fd. Chem. Toxic 23: 689-694, 1985). The day prior to treatment, the hair was clipped from the area (back of animal)and around treatment site. The test material, positive control or vehicle (0.3 ml), was applied to the pad of a 25mm Hill Top Chamber from which the adehesive backing had been removed. For contact primary irritation screening the adhesive backing was left intact. The chamber was applied to the appropriately prepared skin site and occluded with rubber dental dam pulled taut across the animal and fastened to the bottom of a restrainer using biner clips. Approximately 4 hours later, the chambers were removed. Animals not scheduled for irradiation were removed from their restrainers and returned to their cages. Animals to be irradiated were removed from their restrainers and placed on the irradiation table. Irradiation commenced within approximately 30 minutes. Irradiation method and grading method described in the protocol of this photoallergy study in guinea pigs is attached.

4. For contact primary irritation screening, preselected test concentrations of 100%, 50%, 25%, 10%, 5%, 2.5%, 1%, and 0.5% ADBAC in distilled water were tested in two groups of 4 animals. Animal preparation, test material administration, and grading methods were carried out as previously described in the

respective section. Because two of the four animals which received 100%, 50%, 25%, and 10% concentrations died prior to their 48-hour scoring, the two remaining two animals were sacrificed prior to their 48-hour scoring. Two concentrations (0.5% and 0.25% ADBAC in distilled water) were chosen from contact primary irritation screening for further investigation using irridation. These concentrations were screened using a group of two animals per concentration.

5. For definitive study, animals were assigned to one of four groups listed below:

Group	No. of Animals		Induction Treatment	Challenge Treatment
	Male	Female		
1	5	5	0.5% ADBAC + UV	0.5% ADBAC + UV
2	5	5	Vehicle + UV	0.5% ADBAC + UV
3	5	5	Untreated + UV	0.5% ADBAC + UV
4	5	5	Musk Ambrette + UV	Musk Ambrette + UV

During the induction phase, animals in all appropriate groups were treated on Monday, Wednesday and Friday for three consecutive weeks (total of 9 applications). A concentration of 0.5% ADBAC in distilled water was chosen for induction and primary challenge. Due to excessive irritation at induction sites following repeated applications, the concentration was lowered to 0.25% ADBAC for induction five through nine. Animal preparation, test material administration and irradiation were carried out as previously described. No grading of skin sites was done during the induction phase. Twelve days following the last induction exposure, all animals underwent a single primary challenge treatment consistent with that indicated above. Animal preparation, test material administration, irradiation and grading were carried out as previously described. Scores of 1 or greater in the test group were considered to be indicative of sensitization since grades of less than 1 were present in the naive and vehicle control groups.

Reported Results:

1. The results of the contact primary irritation screening and the contact primary irritation screening with irradiation were summarized in Tables 1, 2, and 3 (attached). Because of the severity of responses in animals which received 100%, 50%, 25%, and 10% concentrations, two concentrations (0.5% and 0.25% ADBAC in distilled water) were chosen for the contact primary screening with irradiation.

2. The incidence and severity of responses at primary challenge with irradiation for the test material, vehicle control, naive control, and positive control animals were summarized in the Tables 4. 5, 6, and 7 (attached).

In the test material animal group, following primary challenge there was a 0 of 10 incidence of grade 1 responses and a 6 of 10 incidence of grade ± responses. The 24 and 48 hour severity indices were 0.3 and 0.1, respectively.

In the vehicle control animal group, following primary challenge there was a 0 of 10 incidence of grade 1 responses and a 4 of 10 incidence of grade ± responses. The 24 and 48 hour severity indices were 0.2 and 0.1. respectively.

In the naive test animal group, following primary challenge there was a 0 of 10 incidence of grade 1 responses and a 5 of 10 incidence grade ± responses. The 24 and 48 hour severity indices were 0.3 and 0.3, respectively.

In the positive control animal group (Musk Ambrette, 25% in acetone), following primary challenge there was a 2 of 10 incidence of grade 1 response and a 8 of 10 incidence of grade ± responses. The 24 and 48 hour severity indices were 0.6 and 0.6, respectively.

3. The individual body weight data in guinea pigs for the test material, vehicle control, naive control, and positive control animals was shown in Table 8 (attached). There was no significant difference in the mean body weight value (grams) between the test material animal group and the vehicle control or naive control animal group during the course of this study.

4. Signed and dated GLP and QAU statement were included.

Conclusion:

1. The positive control compound (Musk Ambrette) adequately demonstrate the sensitivity of the test guinea pigs to detect a photoallergic effect.

2. The test material (ADBAC) was not a photoallergen at the concentrations tested in this study.

3. Classification of Data: Core Minimum

The study can be upgraded if the study author can provide the information of chemical analysis showing that the test material was homogeneous and stable during the course of this study.

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ADBAC Quat Steering Committee Response to Agency Data Evaluation Report (DER)

Data Requirement: Photoallergy in Guinea Pigs
Active Ingredient: Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC)
MRID No.: 409585-01
Laboratory: Hill Top Biolabs, Inc., Miamiville OH
Lab Project No.: 88-3226-21
Title: Photoallergy Study in Guinea Pigs

Agency Conclusion:

Classification: Core minimum

The Agency states that "the study can be up-graded if the study author can provide their information of chemical analysis showing that the test material was homogeneous and stable during the course of this study."

Response to Agency DER:

It is unclear if the Agency conclusion regarding chemical analysis showing that the test material was homogeneous and stable during the course of this study refers to the ADBAC 80% MUP (Lot No. 7293K) test substance or to the aqueous solutions prepared in this study.

The stability of the ADBAC test substance has been demonstrated in the course of the ADBAC data development program. During the period of time that this photoallergy study was being conducted, stability analyses were conducted on the same lot of this test substance which was being used in a chronic toxicity/oncogenicity study in rats at another

laboratory. Periodic analyses showed that ADBAC was stable under storage during the course of this two-year study (MRID No. 419475-01). A copy of the summary results from these analyses is attached.

If the Agency reviewer's concern is with the stability of the test substance in the prepared test solution, ADBAC has been shown to be hydrolytically and photolytically stable in 30-day hydrolysis and aqueous photolysis studies (MRID Nos. 408356-02 and 408356-03).

With regard to homogeneity, ADBAC is a cationic compound with high water solubility. Since the aqueous solutions in this test were well below the water solubility limit for ADBAC, there is no reason to believe that these test solutions were not homogeneous.

Page ___ is not included in this copy.

Pages 10 through 11 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product inert 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.

EPA Reviewer: Brian Dementi, Ph.D.
Review Section III, Toxicology Branch I
Health Effects Division

Signature: Brian Dementi
Date: 8/20/92

EPA Acting Section Head:
Karen Hamernik, Ph.D., Review Section III
Toxicology Branch I, Health Effects Division

Signature: Karen Hamernik
Date: 8/28/93

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DATA EVALUATION REPORT

STUDY TYPE: Combined chronic toxicity/oncogenicity in rats

TEST MATERIAL: Alkyl dimethyl benzyl ammonium chloride (ADBAC)

TOX. CHEM. NUMBER: 016E

P.C. NUMBER: 069105

SYNONYMS: Benzalkonium chloride

CAS Number: 68391-01-5

STUDY NUMBER: 53-543

MRID NUMBER: 419475-01

SPONSOR: ADBAC QUAT Joint Venture/
Chemical Specialties Manufacturers Association
1913 Eye Street, N.W.
Washington, D.C. 20006

TESTING FACILITY: Bushy Run Research Center
6702 Mellon Road
Export, PA 15632

TITLE OF REPORT: Chronic Dietary Toxicity/Oncogenicity Study with Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) in Rats

AUTHORS: M.W. Gill, S.J. Hermansky, and C.L. Wagner

REPORT ISSUED: Completion date, July 8, 1991

CONCLUSIONS: ADBAC was administered via the diet to Sprague-Dawley rats for 104 weeks at doses of 0, 300, 1,000, and 2,000 ppm. The average daily intake values of ADBAC at these dietary levels were 13, 44, and 88 mg/kg/day for males and 17, 57, and 116 mg/kg/day for females. ADBAC was not oncogenic under the conditions of this study. Systemic toxicity, as indicated by decreased body weight, body weight gain, and food consumption, occurred with a LOEL of 2,000 ppm and a NOEL of 1,000 ppm. The following treatment related effects were observed:

300 ppm -- Equivalent to 13 mg/kg/day in males and 17 mg/kg/day in females. No treatment-related effects were observed.

1,000 ppm -- Equivalent to 44 mg/kg/day in males and 57 mg/kg/day in females. No treatment-related toxicity was observed.

2,000 ppm -- Equivalent to 88 mg/kg/day in males and 116 mg/kg/day in females. Male and female body weights were decreased by approximately 5% and 6%, respectively. Male and female body weight gains were decreased by approximately 11% and 14%, respectively. Food consumption was significantly decreased in both males and females. In general, the effects on body weight and body weight gain paralleled the effects on food consumption. No treatment-related toxicity was observed based on clinical pathology parameters, and gross and microscopic pathology did not reveal any evidence of toxicity in the treated animals.

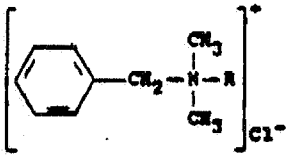
CORE CLASSIFICATION: This study is classified as Core Minimum for combined chronic toxicity/oncogenicity studies because although adequate toxicity as shown by at least a 10% decrease in body weight gain was demonstrated in both males and females, a palatability problem may have contributed to the effects observed on body weight and body weight gain.

A. MATERIALS, METHODS, AND RESULTS

1. Test Article Description

Name: Alkyl dimethyl benzyl ammonium chloride (ADBAC)

Formula: A mixture of alkyl dimethyl benzyl ammonium chlorides of the general formula in which R represents a mixture of the alkyls from $C_{12}H_{25}$ to $C_{16}H_{33}$. The distribution analogs with alkyl chain lengths of 12, 14, and 16 were 40%, 50%, and 10%, respectively.



Lot number: 7293K

Purity: 81.09% active ingredient; the sponsor indicated that the substance also contained ethanol (10-15%)

Physical property: Pale-yellow, viscous liquid

Stability: Stable for at least 14 days when stored at room temperature

2. Rationale for Dose Selection

Dietary levels of ADBAC for the current study were selected based upon the results of 14-day and 90-day dietary range-finding studies (BRRC report numbers 51-513 and 51-503, respectively). The doses selected for the current study were intended to produce toxicity at the high dose and no toxicity at the low dose. The specific toxic end points used to set the doses for the current study were not

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Pages 17 through 12 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product inert 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.

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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.

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Shaughnessy No.: 069105
Date Out of EFGWB: AUG 2 1989

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

From: Emil Regelman, Supervisory Chemist AUG 2 1989
Environmental Chemistry Review Section #2
Environmental Fate & Ground Water Branch/EFED (H7507C)

Thru: Henry Jacoby, Acting Chief
Environmental Fate & Ground Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of...

Reg./File # : 069105

Chemical Name: ADBAC

Type Product : biocide

Product Name : n.a.

Company Name : ADBAC Quat Joint Venture

Purpose : Review studies submitted in response to the 1985 Registration Standard.

Action Code: 400 EFGWB #(s): 90363

Date Received: 10/3/88 Total Reviewing Time: 8 days

Date Completed: 8/2/89

Deferrals to: ___ Ecological Effects Branch

___ Dietary Exposure Branch

___ Non-Dietary Exposure Branch

___ Toxicology Branch I

___ Toxicology Branch II

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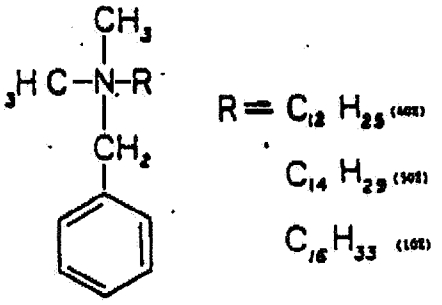
1. **CHEMICAL:** **Common name:**

ADBAC.

Chemical name:

Alkyl dimethyl benzyl ammonium chloride.

Structure:



2. **TEST MATERIAL**

Ring-labeled [^{14}C]alkyl dimethyl benzyl ammonium chloride.

3. **STUDY/ACTION TYPE:**

Review studies submitted in response to the September 1985 Registration Standard.

4. **STUDY IDENTIFICATION:**

Carpenter, M. and M. Fennemey. 1988a. Determination of the photolysis rate of ADBAC in pH 7 buffered solution at 25°C. ABC Final Report #35713. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by Chemical Specialties Manufacturing Association, Washington, DC. (40835603)

Carpenter, M. and M. Fennemey. 1988b. Hydrolysis of ADBAC as a function of pH at 25°. ABC Amended Final Report #35712. Unpublished study performed by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by Chemical Specialties Manufacturers Association, Washington, DC. (40835602)

Daly, D. and W. Cranor. 1988. Soil/sediment adsorption-desorption of alkyl dimethyl benzyl ammonium chloride. ABC Final Report 35716. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by Chemical Specialties Manufacturers Association, Washington, DC.

Daly, D. and W. Cranor. 1988. Aerobic aquatic metabolism of alkyl dimethyl benzyl ammonium chloride. ABC Final Report #35715. Unpublished study performed by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by Chemical Specialties Manufacturers Association, Washington, DC. (40835604)

Fackler, P. 1989. Bioconcentration and elimination of ^{14}C-residues by bluegill (Lepomis macrochirus) exposed to alkyl dimethyl benzyl ammonium chloride (ADBAC). Study No. 11572-0287-6103-140B, Report No. 89-1-2921. Unpublished study performed by Springborn Life Sciences, Inc., Wareham, MA, and submitted by ADBAC Quat Joint Venture/Chemical Specialties Manufacturers Assoc., Washington, DC. (41926801)

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5. **REVIEWED BY:**

Dana Spatz
Chemist, ECRS #2
EFGWB/EFED/OPP

Date: AUG 2 1989

6. **APPROVED BY:**

Emil Regelman
Supervisory Chemist, ECRS #2
EFGWB/EFED/OPP

Date: AUG 2 1989

7. **CONCLUSIONS:**

A. HYDROLYSIS

This study is acceptable and fulfills EPA Data Requirements for Registering Pesticides by providing information on the hydrolysis of ring-labeled [^{14}C]ADBAC at pH 5, 7, and 9. ADBAC did not hydrolyze in pH 9 sterile aqueous buffer solutions incubated at 25 ± 1°C; ADBAC was relatively stable to hydrolysis in pH 5 and 7 solutions, decreasing by ≤2.3% of the recovered during 30 days.

B. PHOTODEGRADATION IN WATER

This study is scientifically sound, but does not meet Subdivision N guidelines for the following reason:

the intensity and wavelength distribution of the light source were not reported, nor were they compared to natural sunlight.

ADBAC did not degrade in sterile aqueous pH 7 buffered solutions that were continuously irradiated using a xenon arc lamp; ADBAC degraded with a half-life of 7.1 days in similar solutions that were sensitized with 1% acetone. ADBAC did not degrade in the respective dark controls.

One [^{14}C]compound, isolated 30 days posttreatment from the sensitized irradiated solution at 74.5% (6.97 ppm) of the applied, was not identified. Because there are many organic photosensitizers present in the environment, it is important to identify the major photoproduct that was detected in the photosensitized system. Therefore, the identification of this photoproduct is also required in order to satisfy the Photodegradation in Water data requirement.

C. LEACHING-ADSORPTION/DESORPTION

This study is unacceptable because the soils were autoclaved prior to testing. Autoclaving of soils prior to the initiation of an adsorption/desorption study renders the validity of the study as questionable, because autoclaving may affect the physical and chemical properties of the soils. Soil CEC, crystalline structure, and hydrophobicity may be affected by autoclaving.

D. AEROBIC AQUATIC METABOLISM

This study is scientifically sound, but does not meet Subdivision N guidelines for the following reason:

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several [^{14}C]residues present at ≥0.01 ppm were not identified (one degradate, present at up to 0.12 ug/g was isolated but not identified; and "remainder", defined as a composite of all the scraped TLC material exclusive of the origin, the parent, and the unidentified degradate, accounted for up to 0.97 ug/g).

Alkyl dimethyl benzyl ammonium chloride (ADBAC) was fairly stable during 30 days of incubation in flooded sandy loam soil maintained at 24–27°C in the dark.

E. ACCUMULATION IN FISH

This study is scientifically sound, but does not meet Subdivision N guidelines for the following reason:

[^{14}C]residues in the water and fish were not characterized.

Total [^{14}C]ADBAC residues accumulated in bluegill sunfish with maximum bioconcentration factors of 33x in edible tissues, 160x in nonedible tissues, and 79x in whole fish during 35 days of exposure to [^{14}C]ADBAC residues at 0.036–0.13 ppm in a flow–through system. Maximum concentrations of residues (uncharacterized) occurred after 35 days of exposure and were 3.4, 13, and 6.6 ppm in edible tissues, nonedible tissues, and whole fish, respectively. After 21 days of depuration, [^{14}C]residues in edible tissues, nonedible tissues, and whole fish were 2.4, 5.3, and 3.7 ppm, respectively; [^{14}C]residues in the edible tissues did not decline significantly from the concentrations detected during the exposure period.

8. RECOMMENDATIONS:

HYDROLYSIS

The Hydrolyis data requirement has been fulfilled by this submission.

PHOTODEGRADATION IN WATER

The Photodegradation In Water data requirement remains a data gap. In order for this study to fulfill the photodegradation data requirement, the ADBAC degradate isolated at 30 days posttreatment must be identified, and the artificial light source must be characterized and compared to natural sunlight.

LEACHING–ADSORPTION/DESORPTION

The Leaching–Adsorption/Desorption data requirement remains a data gap.

AEROBIC AQUATIC METABOLISM

The Aerobic Aquatic Metabolism data requirement remains a data gap. In order for this study to fulfill the aerobic aquatic metabolism data requirement, [^{14}C]residues isolated at ≥0.01 ppm must be identified.

ACCUMULATION IN FISH

The Accumulation in Fish data requirement remains a data gap. In order for this study to fulfill the accumulation in fish data requirement, the registrant must characterize [^{14}C]residues in the treated water and fish tissues present at concentrations ≥0.05 ppm.

Status of Data Requirements as per the 1985 Registration Standard

Satisfied

Hydrolysis 161-1

Not Satisfied

Photodegradation in Water 161-2
Anaerobic Aquatic Metabolism 162-3
Aerobic Aquatic Metabolism 162-4
Leaching-Adsorption/Desorption 163-1
Aquatic (sediment) Field Dissipation 164-2
Accumulation in Fish 165-4
Accumulation in Aquatic Non-Target Organisms 165-5

9. **BACKGROUND:**

ADBAC is effective against a broad spectrum of microorganisms. It is registered as a bactericidal, fungicidal, and algaecidal agent in a variety of indoor and aquatic sites such as cooling towers, oil field recovery systems, swimming pools, animal quarters, household premises, commercial and industrial premises, hospital premises, food processing equipment, etc.

10. **DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:**

See individual DER's attached.

11. **COMPLETION OF ONE-LINER:**

One-liner is attached.

12. **CBI APPENDIX:**

Not applicable.