

69105

DP Barcode : D167279, D167280,
D195152

PC Code No : 069105

EEB Out : NOV 30 1993

To: Larry Schnaubelt 72/Brigid Lowery
Product Manager
Special Review and Reregistration Division (H7508W)
Registration Division (H7505C)

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

Attached, please find the EEB review of...

Reg./File # : _____
Chemical Name : ADBAC
Type Product : _____
Product Name : ADBAC
Company Name : _____
Purpose : Data Review for Reregistration
Action Code : 627 Date Due : 11/03/91
Reviewer : Conchi Rodriguez Date In EEB: 8/8/91

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

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)	419472-03	Y	72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)	419472-01	Y	72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)	419472-02	Y	72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur

P=Partial (Study partially fulfilled Guideline but additional information is needed)

S=Supplemental (Study provided useful information but Guideline was not satisfied)

N=Unacceptable (Study was rejected)/Nonconcur



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

MEMORANDUM

To: Larry Schnaubelt 72/Brigid Lowery
Special Review and Reregistration Division
7508W

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

From: *for* Anthony F. Maciorowski, Chief
Ecological Effects Branch
7507C

Douglas J. Urban
11/30/93

Subject: Review of Studies for ADBAC

The following studies were submitted as part of the reregistration process for ADBAC (067105):

Pate, H.O. and D.O. McIntyre, 1991. Daily Static Renewal Acute 96-Hour Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Bluegill Sunfish. MRID No. 419472-01.

Pate, H.O. and D.O. McIntyre, 1991. Daily Static Renewal Acute 96-Hour Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Rainbow Trout. MRID No. 419472-02.

Pate, H.O. and D.O. McIntyre, 1991. Daily Static Renewal Acute 48-Hour Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Daphnia magna. MRID No. 419472-03.

Review Summary

Guide. Ref. No.	MRID No.	Test Type	Test Species	% ai	Test Results	Study Status
72-1 (a)	419472-01	Static Acute Toxicity	<u>Lepomis macrochirus</u>	30	LC50 = 515 µg ai/l	Core
72-1 (c)	419472-02	Static Acute Toxicity	<u>Oncorhynchus mykiss</u>	30	LC50 = 923.2 µg/l	Core
72-2 (a)	419472-03	Static Acute Toxicity	<u>Daphnia magna</u>	95-96	EC50 = 5.9 µg/l	Core



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The studies are scientifically sound and fulfill the guideline requirements. The attached Data Evaluation Records will provide the necessary information regarding the classification of the study. If you have any questions please contact Conchi Rodríguez (308-2805) or Harry Craven (305-5320).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MEMORANDUM

To: Larry Schnaubelt 72/Brigid Lowery
Special Review and Reregistration Division
7508W

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch
7507C

Subject: Review of Studies for ADBAC

The following studies were submitted as part of the reregistration process for ADBAC (067105):

Pate, H.O. and D.O. McIntyre, 1991. Daily Static Renewal Acute 96-Hour Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Bluegill Sunfish. MRID No. 419472-01.

Pate, H.O. and D.O. McIntyre, 1991. Daily Static Renewal Acute 96-Hour Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Rainbow Trout. MRID No. 419472-02.

Pate, H.O. and D.O. McIntyre, 1991. Daily Static Renewal Acute 48-Hour Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Daphnia magna. MRID No. 419472-03.

Review Summary

Guide. Ref. No.	MRID No.	Test Type	Test Species	% ai	Test Results	Study Status
72-1 (a)	419472-01	Static Acute Toxicity	<u>Lepomis macrochirus</u>	30	LC50 = 515 µg ai/l	Core
72-1 (c)	419472-02	Static Acute Toxicity	<u>Oncorhynchus mykiss</u>	30	LC50 = 923.2 µg/l	Core
72-2 (a)	419472-03	Static Acute Toxicity	<u>Daphnia magna</u>	95-96	EC50 = 5.9 µg/l	Core

CONCURRENCES

SYMBOL	7507C	7507C	7507C				
SURNAME	Maciorowski	Maciorowski	Maciorowski				
DATE	11/23/93	11/24/93	11/30/93				

The studies are scientifically sound and fulfill the guideline requirements. The attached Data Evaluation Records will provide the necessary information regarding the classification of the study. If you have any questions please contact Conchi Rodríguez (308-2805) or Harry Craven (305-5320).

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DATA EVALUATION RECORD

1. **CHEMICAL:** Alkyl Dimethyl Benzyl Ammonium Chloride.
Shaughnessey No. 069105.
2. **TEST MATERIAL:** 1) Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC); Lot No. 05-6K; 30% active ingredient; a clear yellowish liquid.
2) Radioactive (^{14}C) ADBAC; 95.5-96.5% radiochemical purity; a clear liquid.
3. **STUDY TYPE:** Freshwater Fish Static Acute Toxicity Test.
Species Tested: Bluegill Sunfish (*Lepomis macrochirus*).
4. **CITATION:** Pate, H.O. and D.O. McIntyre. 1991. Daily Static-Renewal Acute 96-Hour Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Bluegill Sunfish. Battelle Study No. SC890050. Prepared by Battelle Columbus Division, Columbus, OH. Submitted by ADBAC Quat Joint Venture/Chemical Specialties Manufacturers Association, Washington, D.C. EPA MRID No. 419472-01.
5. **REVIEWED BY:**

Conchi Rodríguez
Biologist
Ecological Effects Branch
Environmental Fate and Effects Division

Signature: *Conchi Rodríguez*
Date: 11/23/93
6. **APPROVED BY:**

Harry Craven
Supervisor
Ecological Effects Branch
Environmental Fate and Effects Division

Signature: *Harry T. Craven*
Date: 11/24/93
7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a static acute freshwater fish toxicity study. The 96-hour LC_{50} of 515 $\mu\text{g a.i./l}$ (based on mean measured concentrations) classifies ADBAC as highly toxic to bluegill. The NOEC was determined as 455.5 $\mu\text{g a.i./l}$ based on the lack of sublethal effects.
8. **RECOMMENDATIONS:** N/A.

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9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

- A. Test Animals: Juvenile bluegill sunfish (*Lepomis macrochirus*) were obtained from a commercial supplier in Elverson, PA. The fish were maintained in a mixture of reverse-osmosis and treated well water under flow-through conditions. The photoperiod was 16-hours light/8-hours dark and the temperature during the last 14 days of holding was $22 \pm 2.2^{\circ}\text{C}$. The fish were fed frozen brine shrimp, flake food, and a commercial trout chow 5-6 times per week. Feeding was discontinued 24 hours prior to test initiation.

Mean weight and length of the control fish measured at the end of the test were 0.76 (0.53-1.45) g and 39 (35-47) mm.

- B. Test System: The test chambers were 25-l glass aquaria filled with 22 l of test solution. The solution depth was approximately 21.7 cm. The test aquaria were positioned in a temperature-controlled water bath set to $22 \pm 1^{\circ}\text{C}$. The laboratory environment was maintained on a 16-hour daylight photoperiod with a light intensity was 74.2 to 81.3 ft-candles.

The dilution water was the same as that used in holding. Well water was carbon filtered. Some water was then deionized by passage through reverse-osmosis purifiers. The filtered water was mixed with the deionized water to obtain a dilution water with a final hardness of 50 mg/l as CaCO_3 . A chemical characterization of the dilution water was given in Appendix A (attached).

The test solutions were prepared individually using a single toxicant stock solution. The stock was a mixture of ^{14}C -ADBAC and ADBAC prepared in deionized water.

- C. Dosage: Ninety-six-hour static renewal test. Based on the results of a preliminary test, five nominal concentrations (180, 320, 490, 560, and 750 $\mu\text{g/l}$) and a dilution water control were used.

DATA EVALUATION RECORD

1. **CHEMICAL:** Alkyl Dimethyl Benzyl Ammonium Chloride.
Shaughnessey No. 069105.
2. **TEST MATERIAL:** 1) Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC); Lot No. 05-6K; 30% active ingredient; a clear yellowish liquid.
2) Radioactive (^{14}C) ADBAC; 95.5-96.5% radiochemical purity; a clear liquid.
3. **STUDY TYPE:** Freshwater Fish Static Acute Toxicity Test.
Species Tested: Bluegill Sunfish (*Lepomis macrochirus*).
4. **CITATION:** Pate, H.O. and D.O. McIntyre. 1991. Daily Static-Renewal Acute 96-Hour Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Bluegill Sunfish. Battelle Study No. SC890050. Prepared by Battelle Columbus Division, Columbus, OH. Submitted by ADBAC Quat Joint Venture/Chemical Specialties Manufacturers Association, Washington, D.C. EPA MRID No. 419472-01.
5. **REVIEWED BY:**

Louis M. Rifici, M.S. Associate Scientist KBN Engineering and Applied Sciences, Inc.	Signature: <i>Louis M Rifici</i> Date: 10/16/91
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6. **APPROVED BY:**

Pim Kosalwat, Ph.D. Senior Scientist KBN Engineering and Applied Sciences, Inc.	Signature: P. Kosalwat Date: 10/16/91
Henry T. Craven, M.S. Supervisor, EEB/EFED USEPA	Signature: <i>Henry T. Craven</i> Date: 11/23/93
	Signature: <i>Conch Rodriguez</i> Date: 5/18/93
7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a static acute freshwater fish toxicity study. The 96-hour LC_{50} of 154.5 μg a.i./l (based on mean measured concentrations) classifies ADBAC as highly toxic to bluegill. The NOEC was determined as 136.6 μg a.i./l based on the lack of sublethal effects.
8. **RECOMMENDATIONS:** N/A.

- D. **Design:** Bluegill were randomly distributed to each aquarium, two aquaria per concentration, for a total of 20 fish per concentration. Biomass loading rate was 0.35 g/l. Twenty liters of each test solution was renewed at 24, 48, and 72 hours. The fish were not fed during the test. Observations of mortality and sublethal responses were made every 24 hours.

The dissolved oxygen, temperature, and pH of the solutions were measured in each aquarium daily. The temperature of one aquarium was monitored continuously using a thermistor and chart recorder. Hardness, alkalinity, and specific conductance of the control and highest test concentration were measured daily.

The concentration of ADBAC in each test chamber was determined daily using liquid scintillation counting.

- E. **Statistics:** The 96-hour median lethal concentration (LC_{50}) and associated 95% confidence interval (C.I.) was calculated using the TOXDAT computer program cited in Peltier and Weber.

12. **REPORTED RESULTS:** The measured concentrations were 197.3, 317.1, 455.5, 515.0, and 638.4 $\mu\text{g/l}$. These values represent 85 to 110% of nominal concentrations (Table 1, attached).

The responses of the bluegill and LC_{50} values are given in Table 2 (attached). The 96-hour LC_{50} based on mean measured concentrations was 515 $\mu\text{g/l}$ (95% C.I. = 456-638 $\mu\text{g/l}$). Sublethal or lethal effects were observed at 515.0 and 638.4 $\mu\text{g/l}$. The no-observed-effect concentration (NOEC) was given as 456 $\mu\text{g/l}$.

Dissolved oxygen ranged from 6.9 to 8.8 mg/l or 83 to 106% of saturation at 22°C. The pH values ranged from 6.8 to 7.2 and the temperature was 21.5-22.0°C. Specific conductance, hardness, and alkalinity were 172-217 $\mu\text{mhos/cm}$, 48-84 mg/l as CaCO_3 , and 68-128 mg/l as CaCO_3 , respectively.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:**
The authors presented no conclusions.

Quality Assurance and good laboratory practice regulation statements were included in the report, indicating that the study was conducted in accordance with FIFRA Good Laboratory Practice Standards set forth in 40 CFR Part 160.

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

- A. **Test Procedure:** The test procedures were generally in accordance with protocols recommended by the guidelines, but deviated from the SEP as follows:

The period between test solution preparation and the initiation of the test was one hour. Tests should be initiated within 30 minutes of solution preparation.

A 15 to 30 minute transition between light and dark is recommended in the SEP. The transition periods were not used in this study.

- B. **Statistical Analysis:** The reviewer used EPA's Toxanal program to calculate the LC_{50} value and obtained the same results (see attached printout).

- C. **Discussion/Results:** The report did not state if the non-radioactive test material was technical grade or a formulation. However, additional information provided by the registrant identifies the non-radioactive material as "representative of a typical ADBAC MUP (manufacturing use product) with regard to actual composition of ADBAC and its impurities." See attached information.

This study is scientifically sound and meets the guideline requirements for a static acute freshwater fish toxicity study. The 96-hour LC_{50} of 515 $\mu\text{g a.i./l}$ or (based on mean measured concentrations) classifies ADBAC as highly toxic to bluegill. The NOEC was determined as 455.5 $\mu\text{g a.i./l}$ based on the lack of sublethal effects.

- D. **Adequacy of the Study:**

- (1) **Classification:** Core
- (2) **Rationale:** N/A.
- (3) **Repairability:** N/A.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 09-24-91.

Page ____ is not included in this copy.

Pages 11 through 13 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.

Rodriguez ADBAC LC50 Bluegill Sunfish

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
638.4	20	20	100	9.536742E-05
515	20	10	50	58.80985
455.5	20	0	0	9.536742E-05
317.1	20	0	0	9.536742E-05
197.3	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 455.5 AND 638.4 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 515

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

Page ____ is not included in this copy.

Pages 15 through 21 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.
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- ____ 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.

DATA EVALUATION RECORD

1. **CHEMICAL:** Alkyl Dimethyl Benzyl Ammonium Chloride.
Shaughnessey No. 069105.
2. **TEST MATERIAL:** 1) Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC); Lot No. 05-6K; 30% active ingredient; a clear yellowish liquid.
2) Radioactive (^{14}C) ADBAC; 95.5-96.5% radiochemical purity; a clear liquid.
3. **STUDY TYPE:** Freshwater Fish Static Acute Toxicity Test.
Species Tested: Rainbow Trout (*Oncorhynchus mykiss*).
4. **CITATION:** Pate, H.O. and D.O. McIntyre. 1991. Daily Static-Renewal Acute 96-Hour Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Rainbow Trout. Battelle Study No. SC890051. Prepared by Battelle Columbus Division, Columbus, OH. Submitted by ADBAC Quat Joint Venture/Chemical Specialties Manufacturers Association, Washington, D.C. EPA MRID No. 419472-02.
5. **REVIEWED BY:**
Conchi Rodriguez
Biologist
Ecological Effects Branch
Environmental Fate and Effects Division
Signature: *Conchi Rodriguez*
11/23/93
Date:
6. **APPROVED BY:**
Harry Craven
Supervisor
Ecological Effects Branch
Environmental Fate and Effects Division
Signature: *Harry F. Craven*
11/24/93
Date:
7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a static acute freshwater fish toxicity study. The 96-hour LC_{50} of 923.2 $\mu\text{g a.i./l}$ (based on mean measured concentrations) classifies ADBAC as highly toxic to rainbow trout. The NOEC was determined as 619.1 $\mu\text{g a.i./l}$ based on the lack of sublethal effects.
8. **RECOMMENDATIONS:** N/A.
9. **BACKGROUND:**

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

- A. Test Animals: Juvenile rainbow trout (*Oncorhynchus mykiss*) were obtained as eggs from a commercial supplier. The fish were maintained in a mixture of reverse-osmosis and treated well water under flow-through conditions. The photoperiod was 16-hours light/8-hours dark and the temperature during the last 14 days of holding was $12 \pm 2^\circ\text{C}$. The fish were fed flake food and a commercial trout chow 5-6 times per week. Feeding was discontinued 24 hours prior to test initiation.

Mean weight and length of the control fish measured at the end of the test were 1.54 (1.01-2.17) g and 57 (50-64) mm.

- B. Test System: The test chambers were 25-l glass aquaria filled with 22 l of test solution. The solution depth was approximately 21.7 cm. The test aquaria were positioned in a temperature-controlled water bath set to $22 \pm 1^\circ\text{C}$. The laboratory environment was maintained on a 16-hour daylight photoperiod with a light intensity was 74.6 to 92.9 ft-candles.

The dilution water was the same as that used in holding. Well water was carbon filtered. Some water was then deionized by passage through reverse-osmosis purifiers. The filtered water was mixed with the deionized water to obtain a dilution water with a final hardness of 50 mg/l as CaCO_3 . A chemical characterization of the dilution water was given in Appendix A (attached).

The test solutions were prepared individually using two toxicant stock solutions. The stocks were a mixture of ^{14}C -ADBAC and ADBAC prepared in deionized water.

- C. Dosage: Ninety-six-hour static renewal test. Based on the results of preliminary tests, five nominal concentrations (750, 1000, 1250, 1500, and 1750 $\mu\text{g/l}$) and a dilution water control were used.
- D. Design: Rainbow trout were randomly distributed to each aquarium, two aquaria per concentration, for a total of 20 fish per concentration. Biomass loading

DATA EVALUATION RECORD

1. **CHEMICAL:** Alkyl Dimethyl Benzyl Ammonium Chloride.
Shaughnessey No. 069105.
2. **TEST MATERIAL:** 1) Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC); Lot No. 05-6K; 30% active ingredient; a clear yellowish liquid.
2) Radioactive (^{14}C) ADBAC; 95.5-96.5% radiochemical purity; a clear liquid.
3. **STUDY TYPE:** Freshwater Fish Static Acute Toxicity Test.
Species Tested: Rainbow Trout (*Oncorhynchus mykiss*).
4. **CITATION:** Pate, H.O. and D.O. McIntyre. 1991. Daily Static-Renewal Acute 96-Hour Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Rainbow Trout. Battelle Study No. SC890051. Prepared by Battelle Columbus Division, Columbus, OH. Submitted by ADBAC Quat Joint Venture/Chemical Specialties Manufacturers Association, Washington, D.C. EPA MRID No. 419472-02.
5. **REVIEWED BY:**

Louis M. Rifici, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: *Louis M. Rifici*
Date: 10/16/91
6. **APPROVED BY:**

Pim Kosalwat, Ph.D.
Senior Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: *P. Kosalwat*
Date: 10/16/91

Henry T. Craven, M.S.
Supervisor, EEB/EFED
USEPA

Signature: *Henry T. Craven*
Date: 11/23/93

Conch Rodriguez 5/18/93
7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a static acute freshwater fish toxicity study. The 96-hour LC_{50} of 279 $\mu\text{g a.i./l}$ (based on mean measured concentrations) classifies ADBAC as highly toxic to rainbow trout. The NOEC was determined as 186 $\mu\text{g a.i./l}$ based on the lack of sublethal effects.
8. **RECOMMENDATIONS:** N/A.
9. **BACKGROUND:**

rate was 0.7 g/l. Twenty liters of each test solution was renewed at 24, 48, and 72 hours. The fish were not fed during the test. Observations of mortality and sublethal responses were made every 24 hours.

The dissolved oxygen, temperature, and pH of the solutions were measured in each aquarium daily. The temperature of one aquarium was monitored continuously using a thermistor and chart recorder. Hardness, alkalinity, and specific conductance of the control and highest test concentration were measured daily.

The concentration of ADBAC in each test chamber was determined daily using liquid scintillation counting.

- E. **Statistics:** The 96-hour median lethal concentration (LC_{50}) and associated 95% confidence interval (C.I.) was calculated using the TOXDAT computer program cited in Peltier and Weber.

12. **REPORTED RESULTS:** The measured concentrations were 619.1, 863.9, 1028.9, 1204.1, and 1353.7 $\mu\text{g/l}$. These values represent 77 to 86% of nominal concentrations (Table 1, attached).

The responses of the trout and LC_{50} values are given in Table 2 (attached). The 96-hour LC_{50} , based on mean measured concentrations, was 930 $\mu\text{g/l}$ (95% C.I. = 866-984 $\mu\text{g/l}$). Sublethal or lethal effects were observed at concentrations ≥ 863.9 $\mu\text{g/l}$. The no-observed-effect concentration (NOEC) was given as 619 $\mu\text{g/l}$.

Dissolved oxygen ranged from 6.9 to 10.8 mg/l or 64 to 100% of saturation at 12°C. The pH values ranged from 6.8 to 7.5 and the temperature was 11.5-12.8°C. Conductance, hardness, and alkalinity were 132-189 $\mu\text{mhos/cm}$, 52-124 mg/l as CaCO_3 , and 64-104 mg/l as CaCO_3 , respectively.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:**
The authors presented no conclusions.

Quality Assurance and good laboratory practice regulation statements were included in the report, indicating that the study was conducted in accordance with FIFRA Good Laboratory Practice Standards set forth in 40 CFR Part 160.

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

- A. **Test Procedure:** The test procedures were generally in accordance with protocols recommended by the guidelines, but deviated from the SEP as follows:

The period between test solution preparation and the initiation of the test was one hour. Tests should be initiated within 30 minutes of solution preparation.

A 15 to 30 minute transition between light and dark is recommended in the SEP. The transition periods were not used in this study.

- B. **Statistical Analysis:** The reviewer used EPA's Toxanal program to calculate the LC_{50} value and obtained the same results (see attached printout). The slope of the concentration-response curve was 15.3.
- C. **Discussion/Results:** The report did not state if the non-radioactive test material was technical grade or a formulation. However, additional information provided by the registrant identifies the non-radioactive material as "representative of a typical ADBAC MUP (manufacturing use product) with regard to actual composition of ADBAC and its impurities." See attached information.

This study is scientifically sound and meets the guideline requirements for a static acute freshwater fish toxicity study. The 96-hour LC_{50} of 923.2 μg a.i./l (based on mean measured concentrations) classifies ADBAC as highly toxic to rainbow trout. The NOEC was determined as 619.1 μg a.i./l based on the lack of sublethal effects.

D. **Adequacy of the Study:**

- (1) **Classification:** Core
- (2) **Rationale:** N/A.
- (3) **Repairability:** N/A.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 09-26-91.

Page ____ is not included in this copy.

Pages 27 through 29 are not included in this copy.

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- ☐ The document is a duplicate of page(s) _____.
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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.

RIFICI ADBAC ONCORHYNCHUS MYKISS 9-25-91

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
1353.7	20	20	100	9.536742E-05
1204.1	20	20	100	9.536742E-05
1028.9	20	12	60.00001	25.17223
863.9	20	8	40	25.17223
619.1	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 619.1 AND 1204.1 CAN BE
USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT
CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL
ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 942.7969

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	5.925257E-02		923.1577	870.661

974.9194

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
19	.1400631	1	.2449614

SLOPE = 15.26986

95 PERCENT CONFIDENCE LIMITS = 9.555116 AND 20.98461

LC50 = 930.3596

95 PERCENT CONFIDENCE LIMITS = 865.7638 AND 983.6384

LC10 = 768.211

95 PERCENT CONFIDENCE LIMITS = 654.4047 AND 833.5941

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Page ____ is not included in this copy.

Pages 31 through 37 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.

DATA EVALUATION RECORD

1. **CHEMICAL:** Alkyl Dimethyl Benzyl Ammonium Chloride.
Shaughnessey No. 069105.
2. **TEST MATERIAL:** Radioactive Alkyl Dimethyl Benzyl Ammonium Chloride (^{14}C ADBAC); 95.5-96.5% radiochemical purity (active ingredient); a clear liquid.
3. **STUDY TYPE:** Freshwater Invertebrate Static Acute Toxicity Test. Species Tested: *Daphnia magna*.
4. **CITATION:** Pate, H.O. and D.O. McIntyre. 1991. Daily Static-Renewal Acute 48-Hour Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to *Daphnia magna*. Battelle Study No. SC890052. Prepared by Battelle Columbus Operation, Columbus, OH. Submitted by ADBAC Quat Joint Venture/Chemical Specialties Manufacturers Association, Washington, D.C. EPA MRID No. 419472-03.
5. **REVIEWED BY:**

Conchi Rodríguez
Biologist
Ecological Effects Branch
Environmental Fate and Effects Division

Signature: *Conchi Rodríguez*
Date: 11/24/93
6. **APPROVED BY:**

Harry Craven
Supervisor
Ecological Effects Branch
Environmental Fate and Effects Division

Signature: *Harry T. Craven*
Date: 11/24/93
7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a static acute toxicity study using freshwater invertebrates. The 48-hour EC_{50} of $5.9 \mu\text{g ai/l}$ (based on mean measured concentrations) classifies ADBAC as very highly toxic to *Daphnia magna*. Lethal effects were observed at all test concentrations so a NOEC could not be determined ($< 6.02 \mu\text{g ai/l}$).
8. **RECOMMENDATIONS:** N/A.
9. **BACKGROUND:**

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10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

- A. Test Animals: *Daphnia magna* neonates (≤ 24 hours old) were obtained from 16-day old in-house cultures. The cultures were housed in 1-l glass beakers containing 800 ml of moderately hard reconstituted water. The cultures were maintained in an environmental chamber ($20 \pm 2^\circ\text{C}$) on a 16-hour light/8-hour dark photoperiod with a light intensity of 323-1076 lux. The daphnids were fed algae (*Selenastrum capricornutum*, 2.3×10^8 cells/l) and 5.0 ml of a suspension of yeast, trout chow, and Cerophyl® three times per week.
- B. Test System: The test chambers were 250-ml glass beakers filled with 200 ml of test solution. The solution depth was approximately 63 mm. The beakers were conditioned by placing solutions of the test material in them for 24 hours prior to the introduction of the actual test solutions. The test was conducted in an environmental chamber set to maintain $20 \pm 1^\circ\text{C}$. Light was provided for 16 hours each day at an intensity of 52 ft-candles.

The moderately hard dilution water was the same as that used in culturing. The water was prepared as described in Peltier and Weber (1985) using deionized reverse-osmosis treated well water. The water had a final hardness of 96 mg/l as CaCO_3 , an alkalinity of 60 mg/l as CaCO_3 , a pH of 7.5, and a conductivity of 264 $\mu\text{mhos/cm}$. A chemical characterization of the water used in the preparation of the dilution water was given in Appendix A (attached).

The test solutions were prepared using a stock solution of ^{14}C -ADBAC prepared in deionized water. The concentration of the stock was verified analytically on the day of the test.

- C. Dosage: Forty-eight-hour static renewal test. Based on the results of preliminary tests, five nominal concentrations (10, 18, 27, 32, and 57 $\mu\text{g/l}$) and a dilution water control were used.
- D. Design: *Daphnia magna* were randomly distributed to each beaker, four beakers per concentration, for a total of 20 daphnids per concentration. The test solutions were renewed at 24 hours and the daphnids

DATA EVALUATION RECORD

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5. **REVIEWED BY:**

Louis M. Rifici, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: *Louis M. Rifici*
Date: 10/16/91
6. **APPROVED BY:**

Pim Kosalwat, Ph.D.
Senior Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: *P. Kosalwat*
Date: 10/16/91

Henry T. Craven, M.S.
Supervisor, EEB/EFED
USEPA

Signature: *Henry T. Craven*
Date: 11/23/93
7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a static acute toxicity study using freshwater invertebrates. The 48-hour LC_{50} of 5.8 $\mu\text{g/l}$ (based on mean measured concentrations) classifies ADBAC as very highly toxic to *Daphnia magna*. Lethal effects were observed at all test concentrations so an NOEC could not be determined ($<6.02 \mu\text{g/l}$).
8. **RECOMMENDATIONS:** N/A.
9. **BACKGROUND:**

50

transferred to new solutions using a wide-bore pipette. The daphnids were not fed during the test. Observations of mortality (or immobilization) and sublethal responses were made every 24 hours.

The dissolved oxygen, temperature, and pH of the solutions were measured in each concentration daily. The temperature of one beaker containing control water only was monitored continuously using a thermistor and chart recorder. Hardness, alkalinity, and specific conductance of the control and highest test concentration were measured daily.

The concentration of ADBAC in each test chamber was determined daily using liquid scintillation counting.

- E. **Statistics:** The 48-hour median lethal concentration (LC₅₀) and associated 95% confidence interval (C.I.) was calculated using the TOXDAT computer program cited in Peltier and Weber.

12. **REPORTED RESULTS:** The mean measured concentrations were 6.02, 14.88, 22.71, 27.24, and 51.56 µg/l. These values represent 60 to 90% of nominal concentrations (Table 1, attached).

The responses of the daphnids and the LC₅₀ values are given in Table 2 (attached). There was 10% mortality in the dilution water control. The 48-hour LC₅₀, based on mean measured concentrations, was 5.8 µg/l (95% C.I. = 3.6-7.5 µg/l). The no-observed-effect concentration (NOEC) was given as <6.0 µg/l.

Dissolved oxygen ranged from 8.2 to 9.0 mg/l or 90 to 99% of saturation at 20°C. The pH values ranged from 7.9 to 8.1 and the temperature was 20.4-21.0°C. Conductance, hardness, and alkalinity were 260-275 µmhos/cm, 80-92 mg/l as CaCO₃, and 60-64 mg/l as CaCO₃, respectively.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:**
The authors presented no conclusions.

Quality Assurance and good laboratory practice regulation statements were included in the report, indicating that the study was conducted in accordance with FIFRA Good Laboratory Practice Standards set forth in 40 CFR Part 160.

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

- A. **Test Procedure:** The test procedures were generally in accordance with protocols recommended by the guidelines, but deviated from the SEP as follows:

The test material was not identified by a lot number.

A 15 to 30 minute transition between light and dark is recommended in the SEP. The transition periods were not used in this study.

- B. **Statistical Analysis:** The reviewer used EPA's Toxanal program to calculate the EC₅₀ value and obtained similar results (see attached printout). The slope of the concentration-response curve was 4.3.

- C. **Discussion/Results:** This study is scientifically sound and meets the guideline requirements for a static acute toxicity study using freshwater invertebrates. The 48-hour EC₅₀ of 5.9 µg ai/l (based on mean measured concentrations) classifies ADBAC as very highly toxic to *Daphnia magna*. Lethal effects were observed at all test concentrations so a NOEC could not be determined (< 6.02 µg ai/l).

- D. **Adequacy of the Study:**

(1) **Classification:** Core

(2) **Rationale:** N/A.

(3) **Repairability:** N/A.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 09-26-91.

Rodriguez ADBAC EC50 Daphnia

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
51.56	19	19	100	1.907348E-04
27.24	19	19	100	1.907348E-04
22.71	19	19	100	1.907348E-04
14.88	19	18	94.73685	3.814697E-03
6.02	19	10	52.63158	50

THE BINOMIAL TEST SHOWS THAT 0 AND 14.88 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 5.695182

THE MOVING AVERAGE METHOD CANNOT BE USED WITH THIS DATA SET BECAUSE NO SPAN WHICH PRODUCES MOVING AVERAGE ANGLES THAT BRACKET 45 DEGREES ALSO USES TWO PERCENT DEAD BETWEEN 0 AND 100 PERCENT.

RESULTS CALCULATED USING THE PROBIT METHOD
ITERATIONS G H
GOODNESS OF FIT PROBABILITY
5 .2814033 1
.9717712

SLOPE = 4.369745
95 PERCENT CONFIDENCE LIMITS = 2.051706 AND 6.687783

LC50 = 5.866772
95 PERCENT CONFIDENCE LIMITS = 3.557242 AND 7.561176

LC10 = 3.004446
95 PERCENT CONFIDENCE LIMITS = .9323669 AND 4.479406

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Page ____ is not included in this copy.

Pages 44 through 46 are not included in this copy.

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- ____ Identity of product inert ingredients.
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