69105

DP Barcode : D179742
PC Code No : 069105
EEB Out : OCT 2 1992

To: Larry Schnaublet 72\Brigid Lowery
Product Manager
Special Review and Reregistration Division (H7508W)

From: Douglas J. Urban, Acting Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # :
Chemical Name : Alkylbenzyldimethylammonium chloride
Type Product : Microbiocide
Product Name : ADBAC
Company Name : ADBAC Quat Joint Venture/Chemical Specialities
Purpose : Data review to support reregistration

Action Code : 627 Date Due : 10/21/92
Reviewer : Conchi Rodriguez

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

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			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)	423021-02	S	124-1		
72-1(A)			72-4(B)	423021-01	S	124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

UPGRADED TO CORE
11/2/96
(CRR ATTACHED)

MEMORANDUM

OCT 2 1992

To: Larry Schnaubelt 72\Brigid Lowery
Special Review and Reregistration Division

From: Douglas Urban, Acting Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C) 10/1/93

Subject: Review of Studies for ADBAC

As part of the registration process the ADBAC Quat Joint Venture/Chemicals Specialties Manufacturers Association submitted the following studies:

McIntyre, D.O. and H.O. Pate, 1992. Daily Static-Renewal Chronic 21-Day Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Daphnia magna.

McIntyre, D.O. and H.O. Pate, 1992. Daily Static-Renewal Chronic 21-Day Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Fathead Minnow.

Summary of Studies

Guide. No.	Test Species	Test Type	% A.I.	Test Results	Study Status	MRID NO.
72-4(b)	Daphnia magna	Life Cycle	30%	NOEC 4.15 µg/L	Supplemental	423021-01
72-4(a)	Pimephales promelas	Early Life Stage	30%	MATC 32.2-75.9 µg/L	Supplemental	423021-02

The Daphnia life cycle study is classified as supplemental because and LOEC was not achieved. Even though a preliminary test was done, the range of concentrations chosen for the definitive test were not the most appropriate hence, the LOEC was not achieved.

The fish early life stage study is classified as supplemental because of apparent problems with the feeding regime. The registrant must submit a response concerning the feeding regime. Also additional information on the range finding study (dose mortality data) is also necessary. The attached Data Evaluation Record will provide the necessary information concerning the classification of the studies.

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The invertebrate life cycle study and the fish early life stage are not requirements for indoor food/nonfood and aquatic nonfood industrial patterns (Anne Barton Memo Aug., 6, 1992). However if the registrant wishes to add new use patterns then, the studies can be required.

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 (ADBAC). Shaughnessey No. 069105.

2. **TEST MATERIAL:** ^{14}C-Alkyl dimethyl benzyl ammonium chloride (ADBAC); 25 mCi/mmole; 98.4% radiopurity; a clear liquid.

3. **STUDY TYPE:** 72-4. Freshwater Invertebrate, Static-Renewal, Life-Cycle Test. Species Tested: *Daphnia magna*.

4. **CITATION:** McIntyre, D.O. and H.O. Pate. 1992. Daily Static-Renewal Chronic 21-Day Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to *Daphnia magna*. Battelle Study No. SC890056. Study conducted by Battelle Columbus Operations, Columbus, OH. Submitted by ADBAC Quat Joint Venture/Chemical Specialties Manufacturers Association, Washington, D.C. EPA MRID No. 423021-01.

5. **REVIEWED BY:**

Rosemary Graham Mora, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: P. Kosalwat for RGM
Date: 9/15/92

6. **APPROVED BY:**

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

Signature: P. Kosalwat
Date: 9/15/92

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

Signature: Henry T. Craven
Date: Concurred 9/30/92
9/30/92

7. **CONCLUSIONS:** This study is scientifically sound but does not fulfill the guideline requirements for a daphnid life-cycle toxicity test. An LOEC could not be determined since none of the concentrations tested significantly affected the daphids by test termination. The NOEC was 4.15 µg/l, the highest concentration tested. An MATC for *Daphnia magna* exposed to ADBAC could not be determined from this test.

8. **RECOMMENDATIONS:**

9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

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11. MATERIALS AND METHODS:

A. Test Animals: *Daphnia magna* were obtained from in-house cultures which were maintained in a temperature-controlled area at 20 ±2°C. The photoperiod was 16 hours of light per day at an intensity of 50-150 footcandles. The daphnids were fed a combination of *Selenastrum capricornutum* and a yeast/trout chow/Cerophyl® (YTC) suspension.

Less than 24-hour old daphnids were collected from 22-day old cultures. In the week prior to test initiation, the cultures demonstrated 100% survival and produced an average of 8.6 young per female per reproduction day.

B. Test System: The study was conducted in an environmental chamber under static renewal conditions. Test vessels were 250-ml glass beakers containing 200 ml of solution at a depth of 60 mm. Two sets of test vessels were assigned to each treatment and used at alternating daily renewal events.

Sixteen hours of light were provided daily. On the day prior to test initiation, the light intensity at the level of the test vessels was 103.9 footcandles. Test temperature was maintained at 20 ±2°C.

The dilution water (hard reconstituted well water) had a specific conductivity of 524 µmhos/cm and a pH of 8.1 at test initiation.

Three separate primary stock solutions of ^{14}C-ADBAC were prepared and used during the study period. The test solutions were prepared daily (immediately before solution renewals) by combining the appropriate amount of primary stock solution with dilution water to a total volume of 2 l (including food suspension).

C. Dosage: Twenty-one-day, static-renewal test. Based on results of preliminary testing, nominal test concentrations were 0.5, 0.9, 1.6, 2.8, and 5.0 µg/l. A dilution water control was also included.

D. Design: Daphnids (<24 hours old) were assigned to test vessels using a two stage randomization procedure. A total of ten test vessels were used per treatment. One daphnid was placed in each of seven vessels per treatment; five daphnids were placed in each of the three remaining test vessels per treatment. The

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daphnids were fed daily *Selenastrum capricornutum* (1 x 10^8 cells/l) and a YTC suspension (1.7 ml/l).

Observations of survival, behavior, and the number of young were recorded daily at each renewal and at test termination. At test termination, total body length (to the nearest 0.07 mm) of each surviving adult was recorded. Reproduction and growth data were collected from the 7 individually exposed replicates. Survival was determined for all replicates.

Dissolved oxygen concentration (DO), temperature, and pH were measured in each vessel on days 0 and 21 and at every renewal (old and new solutions). Hardness, alkalinity, and specific conductance were measured on days 0, 14 (old and new solutions), and 21 for the control and the highest exposure concentration with surviving daphnids.

Triplicate samples of fresh solutions and samples from three replicates of old solutions were collected daily. Determination of ^{14}C-ADBAC concentrations was performed using liquid scintillation counting method.

E. Statistics: Survival data of all 10 replicates in the test concentrations were compared to those of the control using Fisher's exact test. Reproduction and length data from the 7 replicates containing single daphnids were analyzed using one-way analysis of variance (ANOVA) coupled with Bonferroni's test ($p<0.05$).

The 21-day EC_{50} was calculated using a computer program (Toxstat, Version 1.61).

12. REPORTED RESULTS: Results of a 9-day range-finding study demonstrated a total reproduction of 42, 51, 58, 52, 0, and 0 young at mean measured concentrations of 0.06, 0.50, 0.96, 5.02, and 9.24 µg/l, respectively.

Based on analyses of new and old test solutions, mean measured concentrations for the definitive study were 0.41, 0.71, 1.33, 2.31, and 4.15 µg/l (Table 2, attached). Mean measured concentrations represent 79-83% of nominal concentrations.

"No significant signs of toxicity were noted in this study." Mortality, reproduction, and growth at the exposure levels were not significantly different from the control (Tables 3

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and 4, attached). Based on mortality, the 21-day $LC_{50}$was >4.15 µg/l.

During the test, the temperature and DO were 18.1-22.0°C and 5.6-9.6 mg/l, respectively. The pH ranged from 7.4 to 8.4 and conductivity from 464 to 695 µmhos/cm. The hardness and alkalinity ranges were 124-288 and 112-168 mg/l as $CaCO_3$, respectively.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES: "Therefore, while an effect level was not demonstrated in the definitive study, the principle objective of the definitive study was still accomplished since the no-effect levels for the parameters of reproduction and growth were clearly defined at levels just below concentrations which have been shown to produce effects on reproduction and survival."

"By supplementing the results of the 21-day definitive test with those from the 9-day range-finding test, the following conclusions can be drawn from this study:

1. The NOEC and LOEC for reproduction were 4.15 and 5.02 µg/l of ADBAC, respectively.

2. The MATC derived for the combined test results was 4.56 µg/l.

3. The NOEC and LOEC for survival and growth are ≥4.15 and >4.15 µg/l of ADBAC, respectively."

GLP compliance and Quality Assurance statements were included in the report indicating that this study was performed in accordance with FIFRA Good Laboratory Practice Standards (40 CFR 160).

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

A. Test Procedure: The test procedure generally followed the SEP, except for the following:

No LOEC was determined by the end of the definitive study.

Raw data for daphnid weight were not submitted with the study report.

Light intensity during the test was not reported; the SEP recommends a light intensity of 37-74 footcandles.

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B. Statistical Analysis: The reviewer used Toxstat (Version 3.1) computer program to compare the survival and reproduction (number of young/adult reproduction day) data of the test concentrations to the control. Since survival and reproduction data failed the assumptions of homogeneity of variance (Hartley or Bartletts test) or normality (Chi-Square or Shapiro Wilks test), a non-parametric test (Steels Many-One Rank test or Wilcoxon Rank Sum test) was used to analyze the data. These analyses demonstrated no significant differences between the control and exposure levels (printouts, attached).

Individual weight data were not included in the report.

C. Discussion/Results: This study is scientifically sound but does not meet the guideline requirements for a renewal life-cycle toxicity test using Daphnia magna. An LOEC could not be determined since none of the concentrations tested significantly affected the daphids by test termination. The authors's use of the LOEC value from the range-finding test is not acceptable because the experimental design, test conditions, and duration of the range-finding test are different from those of the definitive test. The NOEC was 4.15 µg/l, the highest concentration tested. Based the reviewer's verification of the length, survival and reproduction analyses, the MATC for Daphnia magna exposed to ADBAC could not be determined.

D. Adequacy of the Study:

(1) **Classification:** Supplemental.

(2) **Rationale:** None of the concentrations tested significantly affected the daphnids; therefore, an LOEC and MATC could not be determined.

(3) **Repairability:** No.

15. COMPLETION OF ONE-LINER: Yes, September 1, 1992.

Page ___ is not included in this copy.

Pages 9 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.

_____ 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.

ADBAC: Survival of Exposed Daphnia magna
File: 423021.sur Transform: ARC SINE(SQUARE ROOT(Y))

Chi-square test for normality: actual and expected frequencies

INTERVAL	<-1.5	-1.5 to <-0.5	-0.5 to 0.5	>0.5 to 1.5	>1.5
EXPECTED	1.206	4.356	6.876	4.356	1.206
OBSERVED	0	5	6	7	0

Calculated Chi-Square goodness of fit test statistic = 4.2237
Table Chi-Square value (alpha = 0.01) = 13.277

Data PASS normality test. Continue analysis.

ADBAC: Survival of Exposed Daphnia magna
File: 423021.sur Transform: ARC SINE(SQUARE ROOT(Y))

Shapiro Wilks test for normality

D = 0.151

W = 0.890

Critical W (P = 0.05) (n = 18) = 0.897
Critical W (P = 0.01) (n = 18) = 0.858

Data PASS normality test at P=0.01 level. Continue analysis.

ADBAC: Survival of Exposed Daphnia magna
File: 423021.sur Transform: ARC SINE(SQUARE ROOT(Y))

Hartley test for homogeneity of variance
Bartletts test for homogeneity of variance

These two tests can not be performed because at least one group has zero variance.

Data FAIL to meet homogeneity of variance assumption.
Additional transformations are useless.

TITLE: ADBAC: Survival of Exposed Daphnia magna
FILE: 423021.sur
TRANSFORM: ARC SINE(SQUARE ROOT(Y)) NUMBER OF GROUPS: 6

GRP	IDENTIFICATION	REP	VALUE	TRANS VALUE
1	control	1	1.0000	1.3453
1	control	2	1.0000	1.3453
1	control	3	1.0000	1.3453
2	0.41 ug/l mmc	1	0.8000	1.1071
2	0.41 ug/l mmc	2	1.0000	1.3453
2	0.41 ug/l mmc	3	1.0000	1.3453
3	0.71	1	1.0000	1.3453
3	0.71	2	1.0000	1.3453
3	0.71	3	1.0000	1.3453
4	1.33	1	1.0000	1.3453
4	1.33	2	0.8000	1.1071
4	1.33	3	1.0000	1.3453
5	2.31	1	1.0000	1.3453
5	2.31	2	1.0000	1.3453
5	2.31	3	0.8000	1.1071
6	4.15	1	0.8000	1.1071
6	4.15	2	1.0000	1.3453
6	4.15	3	0.8000	1.1071

ADBAC: Survival of Exposed Daphnia magna
File: 423021.sur Transform: ARC SINE(SQUARE ROOT(Y))

WILCOXON RANK SUM TEST W/ BONFERRONI ADJUSTMENT - Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	RANK SUM	CRIT. VALUE	REPS	SIG
1	control	1.345				
2	0.41 ug/l mmc	1.266	9.00	None	3	
3	0.71	1.345	10.50	None	3	
4	1.33	1.266	9.00	None	3	
5	2.31	1.266	9.00	None	3	
6	4.15	1.187	7.50	None	3	

Critical values use k = 5, are 1 tailed, and alpha = 0.05

ADBAC: Reproduction of Exposed Daphnia magna
File: 42302101.rep Transform: NO TRANSFORMATION

Chi-square test for normality: actual and expected frequencies

INTERVAL	<-1.5	-1.5 to <-0.5	-0.5 to 0.5	>0.5 to 1.5	>1.5
EXPECTED	2.814	10.164	16.044	10.164	2.814
OBSERVED	6	3	19	14	0

Calculated Chi-Square goodness of fit test statistic = 13.4630
Table Chi-Square value (alpha = 0.01) = 13.277

Data FAIL normality test. Try another transformation.

Warning - The two homogeneity tests are sensitive to non-normal data and should not be performed.

ADBAC: Reproduction of Exposed Daphnia magna
File: 42302101.rep Transform: NO TRANSFORMATION

Shapiro Wilks test for normality

D = 376.969

W = 0.865

Critical W (P = 0.05) (n = 42) = 0.942
Critical W (P = 0.01) (n = 42) = 0.922

Data FAIL normality test. Try another transformation.

Warning - The two homogeneity tests are sensitive to non-normal data and should not be performed.

ADBAC: Reproduction of Exposed Daphnia magna
File: 42302101.rep Transform: NO TRANSFORMATION

Bartletts test for homogeneity of variance

Calculated B statistic = 14.21
Table Chi-square value = 15.09 (alpha = 0.01)
Table Chi-square value = 11.07 (alpha = 0.05)

Average df used in calculation ==> df (avg n - 1) = 6.00
Used for Chi-square table value ==> df (#groups-1) = 5

Data PASS homogeneity test at 0.01 level. Continue analysis.

TITLE: ADBAC: Reproduction of Exposed Daphnia magna
FILE: 42302101.rep
TRANSFORM: NO TRANSFORMATION NUMBER OF GROUPS: 6

GRP	IDENTIFICATION	REP	VALUE	TRANS VALUE
1	control	1	17.1000	17.1000
1	control	2	6.9000	6.9000
1	control	3	10.9000	10.9000
1	control	4	11.5000	11.5000
1	control	5	13.6000	13.6000
1	control	6	15.3000	15.3000
1	control	7	13.8000	13.8000
2	0.41	1	7.2000	7.2000
2	0.41	2	17.2000	17.2000
2	0.41	3	15.1000	15.1000
2	0.41	4	12.7000	12.7000
2	0.41	5	16.3000	16.3000
2	0.41	6	15.4000	15.4000
2	0.41	7	16.5000	16.5000
3	0.71	1	16.1000	16.1000
3	0.71	2	15.2000	15.2000
3	0.71	3	16.0000	16.0000
3	0.71	4	15.6000	15.6000
3	0.71	5	13.0000	13.0000
3	0.71	6	15.6000	15.6000
3	0.71	7	14.7000	14.7000
4	1.33	1	16.1000	16.1000
4	1.33	2	18.0000	18.0000
4	1.33	3	14.3000	14.3000
4	1.33	4	13.5000	13.5000
4	1.33	5	12.0000	12.0000
4	1.33	6	16.2000	16.2000
4	1.33	7	17.9000	17.9000
5	2.31	1	15.3000	15.3000
5	2.31	2	13.6000	13.6000
5	2.31	3	12.4000	12.4000
5	2.31	4	16.0000	16.0000
5	2.31	5	1.5000	1.5000
5	2.31	6	16.3000	16.3000
5	2.31	7	16.8000	16.8000
6	4.15	1	12.8000	12.8000
6	4.15	2	8.3000	8.3000
6	4.15	3	12.2000	12.2000
6	4.15	4	15.1000	15.1000
6	4.15	5	13.5000	13.5000
6	4.15	6	12.5000	12.5000
6	4.15	7	10.5000	10.5000

ADBAC: Reproduction of Exposed Daphnia magna
File: 42302101.rep Transform: NO TRANSFORMATION

STEELS MANY-ONE RANK TEST - Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	RANK SUM	CRIT. VALUE	df	SIG
1	control	12.729				
2	0.41	14.343	62.00	35.00	7.00	
3	0.71	15.171	65.00	35.00	7.00	
4	1.33	15.429	65.00	35.00	7.00	
5	2.31	13.129	58.00	35.00	7.00	
6	4.15	12.129	47.00	35.00	7.00	

Critical values use k = 5, are 1 tailed, and alpha = 0.05

ADBAC: Survival of Exposed Daphnia magna
File: 42302101.sur Transform: ARC SINE(SQUARE ROOT(Y))

Chi-square test for normality: actual and expected frequencies

INTERVAL	<-1.5	-1.5 to <-0.5	-0.5 to 0.5	>0.5 to 1.5	>1.5
EXPECTED	2.814	10.164	16.044	10.164	2.814
OBSERVED	3	0	39	0	0

Calculated Chi-Square goodness of fit test statistic = 56.0001
Table Chi-Square value (alpha = 0.01) = 13.277

Data FAIL normality test. Try another transformation.

Warning - The two homogeneity tests are sensitive to non-normal data and should not be performed.

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ADBAC: Survival of Exposed Daphnia magna
File: 42302101.sur Transform: ARC SINE(SQUARE ROOT(Y))

Shapiro Wilks test for normality

D = 0.705

W = 0.495

Critical W (P = 0.05) (n = 42) = 0.942
Critical W (P = 0.01) (n = 42) = 0.922

Data FAIL normality test. Try another transformation.

Warning - The two homogeneity tests are sensitive to non-normal data and should not be performed.

ADBAC: Survival of Exposed Daphnia magna
File: 42302101.sur Transform: ARC SINE(SQUARE ROOT(Y))

Hartley test for homogeneity of variance
Bartletts test for homogeneity of variance

These two tests can not be performed because at least one group has zero variance.

Data FAIL to meet homogeneity of variance assumption.
Additional transformations are useless.

TITLE: ADBAC: Survival of Exposed Daphnia magna
FILE: 42302101.sur
TRANSFORM: ARC SINE(SQUARE ROOT(Y)) NUMBER OF GROUPS: 6

GRP	IDENTIFICATION	REP	VALUE	TRANS VALUE
1	control	1	1.0000	1.0472
1	control	2	0.0000	0.5236
1	control	3	1.0000	1.0472
1	control	4	1.0000	1.0472
1	control	5	1.0000	1.0472
1	control	6	1.0000	1.0472
1	control	7	1.0000	1.0472
2	0.41 ug/l mmc	1	1.0000	1.0472
2	0.41 ug/l mmc	2	1.0000	1.0472
2	0.41 ug/l mmc	3	1.0000	1.0472
2	0.41 ug/l mmc	4	1.0000	1.0472
2	0.41 ug/l mmc	5	1.0000	1.0472
2	0.41 ug/l mmc	6	1.0000	1.0472
2	0.41 ug/l mmc	7	1.0000	1.0472
3	0.71	1	1.0000	1.0472
3	0.71	2	1.0000	1.0472
3	0.71	3	1.0000	1.0472
3	0.71	4	1.0000	1.0472
3	0.71	5	1.0000	1.0472
3	0.71	6	1.0000	1.0472
3	0.71	7	1.0000	1.0472
4	1.33	1	1.0000	1.0472
4	1.33	2	1.0000	1.0472
4	1.33	3	1.0000	1.0472
4	1.33	4	1.0000	1.0472
4	1.33	5	1.0000	1.0472
4	1.33	6	1.0000	1.0472
4	1.33	7	1.0000	1.0472
5	2.31	1	1.0000	1.0472
5	2.31	2	1.0000	1.0472
5	2.31	3	1.0000	1.0472
5	2.31	4	1.0000	1.0472
5	2.31	5	0.0000	0.5236
5	2.31	6	1.0000	1.0472
5	2.31	7	1.0000	1.0472
6	4.15	1	1.0000	1.0472
6	4.15	2	0.0000	0.5236
6	4.15	3	1.0000	1.0472
6	4.15	4	1.0000	1.0472
6	4.15	5	1.0000	1.0472
6	4.15	6	1.0000	1.0472
6	4.15	7	1.0000	1.0472

ADBAC: Survival of Exposed Daphnia magna
File: 42302101.sur Transform: ARC SINE(SQUARE ROOT(Y))

STEELS MANY-ONE RANK TEST - Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	RANK SUM	CRIT. VALUE	df	SIG
1	control	0.972				
2	0.41 ug/l mmc	1.047	56.00	35.00	7.00	
3	0.71	1.047	56.00	35.00	7.00	
4	1.33	1.047	56.00	35.00	7.00	
5	2.31	0.972	52.50	35.00	7.00	
6	4.15	0.972	52.50	35.00	7.00	

Critical values use k = 5, are 1 tailed, and alpha = 0.05

TITLE: ADBAC Daphnia Length
FILE: a:\length
TRANSFORM: NO TRANSFORMATION NUMBER OF GROUPS: 6

GRP	IDENTIFICATION	REP	VALUE	TRANS VALUE
1	Control	1	4.9000	4.9000
1	Control	2	4.7000	4.7000
1	Control	3	4.8000	4.8000
1	Control	4	4.9000	4.9000
1	Control	5	4.8000	4.8000
2	0.5 ppb	1	4.6000	4.6000
2	0.5 ppb	2	5.0400	5.0400
2	0.5 ppb	3	5.1000	5.1000
2	0.5 ppb	4	4.9000	4.9000
2	0.5 ppb	5	4.8000	4.8000
3	0.9 ppb	1	4.9000	4.9000
3	0.9 ppb	2	5.1000	5.1000
3	0.9 ppb	3	4.9000	4.9000
3	0.9 ppb	4	4.6000	4.6000
3	0.9 ppb	5	4.9000	4.9000
4	1.6 ppb	1	4.8000	4.8000
4	1.6 ppb	2	4.9000	4.9000
4	1.6 ppb	3	5.0400	5.0400
4	1.6 ppb	4	5.1000	5.1000
4	1.6 ppb	5	4.6000	4.6000
5	2.8 ppb	1	4.8000	4.8000
5	2.8 ppb	2	4.9000	4.9000
5	2.8 ppb	3	5.0400	5.0400
5	2.8 ppb	4	5.1000	5.1000
5	2.8 ppb	5	4.6000	4.6000
6	5.0 ppb	1	4.6000	4.6000
6	5.0 ppb	2	4.6000	4.6000
6	5.0 ppb	3	4.8000	4.8000
6	5.0 ppb	4	4.9000	4.9000
6	5.0 ppb	5	4.8000	4.8000

ADBAC Daphnia Length
File: a:\length Transform: NO TRANSFORMATION

SUMMARY STATISTICS ON TRANSFORMED DATA TABLE 1 of 2

GRP	IDENTIFICATION	N	MIN	MAX	MEAN
1	Control	5	4.700	4.900	4.820
2	0.5 ppb	5	4.600	5.100	4.888
3	0.9 ppb	5	4.600	5.100	4.880
4	1.6 ppb	5	4.600	5.100	4.888
5	2.8 ppb	5	4.600	5.100	4.888
6	5.0 ppb	5	4.600	4.900	4.740

ADBAC Daphnia Length
File: a:\length Transform: NO TRANSFORMATION

SUMMARY STATISTICS ON TRANSFORMED DATA TABLE 2 of 2

GRP	IDENTIFICATION	VARIANCE	SD	SEM
1	Control	0.007	0.084	0.037
2	0.5 ppb	0.040	0.199	0.089
3	0.9 ppb	0.032	0.179	0.080
4	1.6 ppb	0.040	0.199	0.089
5	2.8 ppb	0.040	0.199	0.089
6	5.0 ppb	0.018	0.134	0.060

ADBAC Daphnia Length
File: a:\length Transform: NO TRANSFORMATION

ANOVA TABLE

SOURCE	DF	SS	MS	F
Between	5	0.091	0.018	0.621
Within (Error)	24	0.705	0.029	
Total	29	0.796		

Critical F value = 2.62 (0.05,5,24)
Since F < Critical F FAIL TO REJECT Ho:All groups equal

ADBAC Daphnia Length
File: a:\length Transform: NO TRANSFORMATION

DUNNETTS TEST - TABLE 1 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	T STAT	SIG
1	Control	4.820	4.820		
2	0.5 ppb	4.888	4.888	-0.631	
3	0.9 ppb	4.880	4.880	-0.557	
4	1.6 ppb	4.888	4.888	-0.631	
5	2.8 ppb	4.888	4.888	-0.631	
6	5.0 ppb	4.740	4.740	0.743	

Dunnett table value = 2.36 (1 Tailed Value, P=0.05, df=24,5)

ADBAC Daphnia Length
File: a:\length Transform: NO TRANSFORMATION

DUNNETTS TEST - TABLE 2 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	NUM OF REPS	Minimum Sig Diff (IN ORIG. UNITS)	% of CONTROL	DIFFERENCE FROM CONTROL
1	Control	5			
2	0.5 ppb	5	0.254	5.3	-0.068
3	0.9 ppb	5	0.254	5.3	-0.060
4	1.6 ppb	5	0.254	5.3	-0.068
5	2.8 ppb	5	0.254	5.3	-0.068
6	5.0 ppb	5	0.254	5.3	0.080

Shaughnessey # 069105 Chemical Name C-12-16-alkylbenzyldimethyl ammoniumchloride Chemical Class _____ Page 1 of 1

Study/Species/Lab/ MRID #	Chemical % a.i.	Results	Reviewer/ Date	Validatic Status
Chronic Fish		Concentrations Tested (pp b) - _____		
	_____	_____		
Species:		MATC - >_____<_____ pp___.	_____	_____
		Effected Parameters - _____		
Lab:		_____		
		Control Mortality (%) - Solvent Control Mortality (%) -		
MRID #		Comments:		
Chronic Invertebrate	98.4%	Concentrations Tested (pp b *) - 0.41, 0.71, 1.33, 2.31, 4.15	LCM 9/1/92	Supplem
		_____		
Species: Daphnia magna		MATC - >_____<_____ pp b.		
		Effected Parameters - no effected parameters		
Lab: Battelle Columbus Operations		_____		
		Control Mortality (%) - 4.5 Solvent Control Mortality (%) - NA		
MRID # 423021-01		Comments: * Mean measured concentrations.		
		NOEC = 4.15 µg/l.		

DATA EVALUATION RECORD

1. **CHEMICAL:** Alkyl dimethyl benzyl ammonium chloride (ADBAC). Shaughnessey No. 069105.

2. **TEST MATERIAL:** 1) ^{14}C-alkyl dimethyl benzyl ammonium chloride (ADBAC); 25 mCi/mmole; 98.4% radiopurity; a clear liquid. 2) Non-radiolabelled ADBAC; ADBAC Quat/Lot No. 05-6K, BTC 835; 30% active ingredient; a clear yellowish liquid.

3. **STUDY TYPE:** 72-4. Freshwater Fish Early Life-Stage Test. Species Tested: Fathead Minnow (*Pimephales promelas*).

4. **CITATION:** McIntyre, D.O. and H.O. Pate. 1992. Daily Static-Renewal Early Life Stage Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Fathead Minnows. Battelle Study No. SC890057. Conducted by Battelle Columbus Operations, Columbus, OH. Submitted by ADBAC Quat Joint Venture/Chemical Specialties Manufacturers Association, Washington, D.C. EPA MRID No. 423021-02.

5. **REVIEWED BY:**

Rosemary Graham Mora, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: P. Kosalwat for RGM
Date: 9/15/92

6. **APPROVED BY:**

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

Signature: P. Kosalwat
Date: 9/15/92

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

Signature: Henry T Craven
Date: Concurrence Only 9/30/92

7. **CONCLUSIONS:** This study is scientifically sound but does not fulfill the guideline requirements for a fish early life-stage toxicity test. It appears that the fish were not fed at the same rate (g food/fish) in all chambers; consequently, the food appears to be a limiting factor in this test. Based on mean measured concentrations, the MATC for *Pimephales promelas* was >32.2 and <75.9 µg/l ADBAC (geometric mean MATC = 49.4 µg/l).

8. **RECOMMENDATIONS:**

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9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

A. Test Animals: *Pimephales promelas* were obtained from in-house cultures under conditions favorable for the production of healthy eggs. The cultures were checked daily for eggs. Eggs were removed from the spawning tiles and rinsed in a common beaker with 0.2% NaCl solution. This solution was replaced with RO/well water before being transferred to the test vessels.

B. Test System: The study was conducted in an environmental chamber under static renewal conditions. Test vessels were 1-l glass beakers containing 500 ml of solution at a depth of 65 cm. At each daily renewal, approximately 450 ml of test solution was siphoned from each test vessel. New solution was gently added to the appropriate vessel.

Sixteen hours of light were provided daily. On the day prior to test initiation, the light intensity range at the level of the test vessels was 76.4-80.5 footcandles. Test temperature was maintained at 25 $\pm$1°C.

The dilution water was a mixture of carbon-filtered well water and treated (carbon-filtered, reverse osmosis [RO]) well water combined to obtain a hardness of 75 mg/l as $CaCO_3$. At test initiation, the pH of the dilution water control was 6.8.

A primary stock solution (3.93 mg/ml ^{14}C-ADBAC/ADBAC) was prepared by combining appropriate amounts of ^{14}C-ADBAC and non-radiolabelled ADBAC in deionized water. Immediately prior to each daily renewal, the test solutions were prepared by combining the appropriate amount of primary stock solution with dilution water.

C. Dosage: Thirty-four-day, static-renewal test. Based on results of preliminary testing, nominal test concentrations were 27, 74, 135, 180, 270, and 490 µg/l. A dilution water control was also included.

D. Design: Twenty fathead minnow embryos (<24 hours old) were assigned, in groups of 2-7, to each of four test vessels per treatment (i.e., 80 embryos per treatment). After 7 days of exposure, surviving larvae from two

replicates were thinned to 10 larvae per replicate for each treatment (i.e., 20 fish per treatment).

Observations of mortality and behavior were recorded daily. At test termination, dry weights were recorded.

Dissolved oxygen concentration (DO) and pH were measured daily in one replicate of new solutions (all treatments) and old solutions (control and high test concentration). Temperature of old test solution was measured daily in a control and high concentration replicate. In addition, temperature was measured continuously in a surrogate control replicate containing no test animals. Hardness, alkalinity, and specific conductance were measured on days 0, 7, 14, 21, 28, and 34 in the new and old solutions of the control and the high exposure concentration.

Triplicate samples of fresh solutions and samples from three replicates of old solutions were collected for each treatment daily. Determination of ^{14}C-ADBAC concentrations was performed using the method of liquid scintillation counting.

E. Statistics: Survival data for the test concentrations were compared to those of the control using Fisher's exact test. Hatchability data were analyzed using analysis of variance (ANOVA) coupled with Dunnett's test ($p<0.05$). The LC_{50} values were calculated using a computer program (Toxstat).

12. REPORTED RESULTS: Based on analyses of new and old test solutions, mean measured concentrations were 32.2, 75.9, 134.2, 186.8, 273.2, and 488.7 µg/l (Table 2, attached). Mean measured concentrations represent 99-119% of nominal concentrations.

Hatchability was significantly affected at 488.7 µg/l when compared to the control (Table 3, attached). Survival was significantly reduced at concentrations ≥75.9 µg/l (Table 4, attached). Based on mortality, the 28-day (post-hatch) LC_{50} was 94 µg/l. Average dry weight increased with increasing concentrations of ADBAC and in each case was higher than the control (Table 5, attached). "The trend of increased growth also correlated with decreased numbers of fish present in each test concentration suggesting food and space may have been the reason for the increased weights in the higher concentrations which were lethal to the less tolerant or weaker fish."

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During the test, the temperature and DO were 24.2 to 26.3°C and 5.0-9.2 mg/l (61-111% of saturation), respectively. The pH ranged from 6.7 to 7.6 and conductivity from 174 to 249 µmhos/cm. The hardness and alkalinity ranges were 60-92 and 76-100 mg/l as $CaCO_3$, respectively.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES: No conclusions were presented by the authors.

GLP compliance and Quality Assurance statements were included in the report indicating that this study was performed in accordance with FIFRA Good Laboratory Practice Standards (40 CFR 160).

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

A. Test Procedure: Due to the problems associated with the test material (see pages 4 and 5, attached), the reviewer accepts the static-renewal procedures used in this test. Since there is no SEP for a static-renewal chronic fish test, the SEP for a flow-through system was used as a general guidance to evaluate this study. Weaknesses of this study are noted as follows:

The non-radiolabelled test material appeared to be a formulated product (30% a.i.) and no inert ingredient or carrier control was included in the test design.

After 7 days of exposure, fish were thinned to 20 per treatment; at least 30 fish remaining after thinning are recommended. In addition, four replicates were reduced to two after thinning which weakened the statistical analyses.

The authors did not report whether test organisms were randomly assigned to the test vessels as required.

Food and feeding frequency were not reported.

During the study, the DO range was 61-111% of saturation; a DO of >75% of saturation should have been maintained.

During the test, the pH in the dilution water control ranged from 6.7-7.5; a pH range of 7.2-7.6 is recommended.

Light intensity during the test was not reported.

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Raw data for weight were not submitted with the study report. However, the average growth in Table 5 (attached) shows increasing weight with increasing concentrations and, therefore, raw data submission may be waived.

B. **Statistical Analysis:** The reviewer used Toxstat (Version 3.1) computer program to compare the hatchability and survival data of the test concentrations to the control. Since hatchability and survival data failed the assumptions of homogeneity of variance (Hartley or Bartletts test) or normality (Chi-Square or Shapiro Wilks test), Steels Many-One Rank test or Williams test was used to analyze the data (printouts, attached). The results were the same as those presented by the authors.

Raw weight data were not included in the report, therefore, the reviewer could not verify the authors' result. However, the analysis may not be needed since Table 5 shows increasing average weight with increasing test concentrations.

C. **Discussion/Results:** This study is scientifically sound but does not meet the guideline requirements for an early life-stage test using *Pimephales promelas*. Since the amount and frequency of feeding are not reported, it cannot be determined whether the feeding regime used in this test is appropriate. Food appears to be a limiting factor in this test. The authors stated that "the trend of increased growth also correlated with decreased numbers of fish present in each test concentration suggesting food and space may have been the reason for the increased weights in the higher concentrations which were lethal to the less tolerant or weaker fish.". Growth cannot be used as a meaningful parameter if the amount of food is not adjusted according to the number of surviving fish in each test chamber.

Based on mean measured concentrations, the MATC for fathead minnows was >32.2 and <75.9 µg/l ADBAC (geometric mean MATC = 49.4 µg/l).

D. **Adequacy of the Study:**

(1) **Classification:** Supplemental.

(2) **Rationale:** It appears that surviving fish were not fed at the same rate (g food/fish);

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consequently, food appears to be a limiting factor in this test.

(3) **Repairability:** Pending a satisfactory response from the laboratory concerning feeding.

15. COMPLETION OF ONE-LINER: Yes, September 2, 1992.

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Page ___ is not included in this copy.

Pages 31 through 44 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.

ADBAC: Hatchability of Exposed FHM Embryos
File: 42302102.hat Transform: NO TRANSFORM

STEELS MANY-ONE RANK TEST - Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	RANK SUM	CRIT. VALUE	df	SIG
1	Control	0.887				
2	27 ug/l	0.780	15.00	10.00	4.00	
3	74 ug/l	0.810	16.00	10.00	4.00	
4	135 ug/l	0.850	16.00	10.00	4.00	
5	180 ug/l	0.795	14.00	10.00	4.00	
6	270 ug/l	0.863	17.00	10.00	4.00	
7	490 ug/l	0.000	10.00	10.00	4.00	*

Critical values use k = 6, are 1 tailed, and alpha = 0.05

TITLE: ADBAC: Hatchability of Exposed FHM Embryos
FILE: 42302102.hat
TRANSFORM: NO TRANSFORM NUMBER OF GROUPS: 7

GRP	IDENTIFICATION	REP	VALUE	TRANS VALUE
1	Control	1	0.9500	0.9500
1	Control	2	0.8000	0.8000
1	Control	3	0.8000	0.8000
1	Control	4	1.0000	1.0000
2	27 ug/l	1	0.8500	0.8500
2	27 ug/l	2	0.8400	0.8400
2	27 ug/l	3	0.8000	0.8000
2	27 ug/l	4	0.6300	0.6300
3	74 ug/l	1	0.8500	0.8500
3	74 ug/l	2	0.8400	0.8400
3	74 ug/l	3	0.7000	0.7000
3	74 ug/l	4	0.8500	0.8500
4	135 ug/l	1	0.8000	0.8000
4	135 ug/l	2	0.9000	0.9000
4	135 ug/l	3	0.9000	0.9000
4	135 ug/l	4	0.8000	0.8000
5	180 ug/l	1	0.9000	0.9000
5	180 ug/l	2	0.8000	0.8000
5	180 ug/l	3	0.8000	0.8000
5	180 ug/l	4	0.6800	0.6800
6	270 ug/l	1	0.8000	0.8000
6	270 ug/l	2	0.9000	0.9000
6	270 ug/l	3	0.8500	0.8500
6	270 ug/l	4	0.9000	0.9000
7	490 ug/l	1	0.0000	0.0000
7	490 ug/l	2	0.0000	0.0000
7	490 ug/l	3	0.0000	0.0000
7	490 ug/l	4	0.0000	0.0000

ADBAC: Hatchability of Exposed FHM Embryos
File: 42302102.hat Transform: ARC SINE(SQUARE ROOT(Y))

Chi-square test for normality: actual and expected frequencies

INTERVAL	<-1.5	-1.5 to <-0.5	-0.5 to 0.5	>0.5 to 1.5	>1.5
EXPECTED	1.876	6.776	10.696	6.776	1.876
OBSERVED	0	8	9	11	0

Calculated Chi-Square goodness of fit test statistic = 6.8752
Table Chi-Square value (alpha = 0.01) = 13.277

Data PASS normality test. Continue analysis.

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ADBAC: Hatchability of Exposed FHM Embryos
File: 42302102.hat Transform: ARC SINE(SQUARE ROOT(Y))

Shapiro Wilks test for normality

D = 0.232

W = 0.951

Critical W (P = 0.05) (n = 28) = 0.924
Critical W (P = 0.01) (n = 28) = 0.896

Data PASS normality test at P=0.01 level. Continue analysis.

ADBAC: Hatchability of Exposed FHM Embryos
File: 42302102.hat Transform: ARC SINE(SQUARE ROOT(Y))

Hartley test for homogeneity of variance
Bartletts test for homogeneity of variance

These two tests can not be performed because at least one group has zero variance.

Data FAIL to meet homogeneity of variance assumption.
Additional transformations are useless.

ADBAC: Survival of Exposed FHM Larvae
File: 42302102.sur Transform: ARC SINE(SQUARE ROOT(Y))

Chi-square test for normality: actual and expected frequencies

INTERVAL	<-1.5	-1.5 to <-0.5	-0.5 to 0.5	>0.5 to 1.5	>1.5
EXPECTED	0.804	2.904	4.584	2.904	0.804
OBSERVED	0	4	4	4	0

Calculated Chi-Square goodness of fit test statistic = 2.5097
Table Chi-Square value (alpha = 0.01) = 13.277

Data PASS normality test. Continue analysis.

ADBAC: Survival of Exposed FHM Larvae
File: 42302102.sur Transform: ARC SINE(SQUARE ROOT(Y))

Shapiro Wilks test for normality

D = 0.187

W = 0.942

Critical W (P = 0.05) (n = 12) = 0.859
Critical W (P = 0.01) (n = 12) = 0.805

Data PASS normality test at P=0.01 level. Continue analysis.

TITLE: ADBAC: Survival of Exposed FHM Larvae
FILE: 42302102.sur
TRANSFORM: ARC SINE(SQUARE ROOT(Y)) NUMBER OF GROUPS: 6

GRP	IDENTIFICATION	REP	VALUE	TRANS VALUE
1	Control	1	0.9000	1.2490
1	Control	2	0.9000	1.2490
2	27 ug/l	1	0.5600	0.8455
2	27 ug/l	2	0.9000	1.2490
3	74 ug/l	1	0.4000	0.6847
3	74 ug/l	2	0.4000	0.6847
4	135 ug/l	1	0.6000	0.8861
4	135 ug/l	2	0.3300	0.6119
5	180 ug/l	1	0.3000	0.5796
5	180 ug/l	2	0.5000	0.7854
6	270 ug/l	1	0.2000	0.4636
6	270 ug/l	2	0.0000	0.1588

ADBAC: Survival of Exposed FHM Larvae
File: 42302102.sur Transform: ARC SINE(SQUARE ROOT(Y))

WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	Control	2	0.900	1.249	1.249
2	27 ug/l	2	0.730	1.047	1.047
3	74 ug/l	2	0.400	0.685	0.717
4	135 ug/l	2	0.465	0.749	0.717
5	180 ug/l	2	0.400	0.683	0.683
6	270 ug/l	2	0.100	0.311	0.311

ADBAC: Survival of Exposed FHM Larvae
File: 42302102.sur Transform: ARC SINE(SQUARE ROOT(Y))

WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
Control	1.249				
27 ug/l	1.047	1.144		1.94	k= 1, v= 6
74 ug/l	0.717	3.018	*	2.06	k= 2, v= 6
135 ug/l	0.717	3.018	*	2.10	k= 3, v= 6
180 ug/l	0.683	3.212	*	2.12	k= 4, v= 6
270 ug/l	0.311	5.318	*	2.13	k= 5, v= 6

s = 0.176
Note: df used for table values are approximate when v > 20.

Shaughnessey # 069105 Chemical Name C-12-16-alkylbenzyl*dimethylammonium chloride Chemical Class _____ Page 1 of 1

Study/Species/Lab/ MRID #	Chemical % a.i.	Results	Reviewer/ Date	Validatic Status
Chronic Fish Species: Pimephales promelas Lab: Battelle Columbus Operations MRID # 423021-02	98.4 and 30%	Concentrations Tested (ppb*) - 32.2, 75.9, 134.2, 186.8, 273.2, 488.7 MATC - >32.2 <75.9 ppb*. Effected Parameters - survival (most sensitive parameter), hatchability. Control Mortality (%) - 10 Solvent Control Mortality (%) - NA Comments: * Mean measured concentrations.	[illegible] 9/2/92	Supplem
Chronic Invertebrate Species: Lab: MRID #	_____	Concentrations Tested (pp___) - _____ MATC - >_____<_____ pp___. Effected Parameters - _____ Control Mortality (%) - Solvent Control Mortality (%) - Comments:	_____	_____

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(Duplicate)

DP. Barcode : D194368
PC Code No : 069105
EEB Out : 4/2/96

To: Larry Schnaubelt
Product Manager
Special Review and Reregistration Division (7508W)

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

Attached, please find the EEB review of...

Reg./File # : 069105
Chemical Name : Alkyl Dimethyl Benzyl Ammonium Chloride
Type Product : Biocide
Product Name : Various
Company Name : Chemical Specialties Manufacturers Association
Purpose : Review of information submitted to support upgrading of previously reviewed studies

Action Code : 627 Date Due :
Reviewer : Harry A. Winnik Date In EEB: 08/25/93

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

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			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)	423021-02	Y	124-1		
72-1(A)			72-4(B)	423021-01	S	124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed.
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

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DP BARCODE: D194368 REREG CASE # 0350

CASE: 819070 DATA PACKAGE RECORD DATE: 08/23/93
SUBMISSION: S446617 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 627 GENERIC DATA SUBMISSION
CHEMICALS: 069105 Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 100.00 %

ID#: 069105
COMPANY:
PRODUCT MANAGER: 72 LARRY SCHNAUBELT 703-308-8058 ROOM: CS1 3C3
PM TEAM REVIEWER: BRIGID LOWERY 703-308-8053 ROOM: CS1 3G6
RECEIVED DATE: 07/13/93 DUE OUT DATE: 03/10/94

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 194368 EXPEDITE: N DATE SENT: 08/23/93 DATE RET.: / /
CHEMICAL: 069105 Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12,
DP TYPE: 001 Submission Related Data Package
CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	08/24/93	/ /
BRAN: EEB	08/25/93	4/2/96
SECT: IV	4/2/96	4/2/96
REVR : wmds	4/2/96	4/2/96
CONTR:	/ /	/ /

ADMIN DUE DATE: 11/21/93
NEGOT DATE: 11/21/93
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

On 10/2/92, EEB reviewed an early life stage fish study and a life cycle invertebrate study. (72-4a = 42302102; 72-4b = 42302101) Both studies were graded supplemental. The life cycle study could be upgraded pending a response concerning the feeding regime and add'l info. from the range finding study. The invertebrate study was graded supplemental because a LOEC was not achieved. Attached please find a 7/12/93 ltr. which contains the registrant's response to the 10/92 review. (CSMA submits the info. on behalf of the ADBAC registrants.) I requested that this information be resubmitted and formatted correctly to receive a mrid while I sent it into review. Any questions please give me a call on 308-8053. Thanks Brigid Lowery

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

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

March 20, 1996

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of Information Submitted to Support the Upgrade of Previously Reviewed *Daphnia magna* Life Cycle and Fish Early Life Stage Studies.

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

TO: Larry Schnaubelt (PM 72)
Reregistration Branch
Special Review and Reregistration Division (7508W)

EEB has reviewed the information submitted to support the upgrade of the previously Reviewed *Daphnia magna* Life Cycle and Fish Early Life Stage Studies and has come to the following conclusions.

Daphnia magna Life Cycle Study[1]

EEB agrees with the registrant that both the 9-day dose range-finding study and the definitive 21-day life cycle study were scientifically sound. In fact, when the 21-day study was originally reviewed (DP barcode D179742, Oct. 2, 1992) it was considered scientifically sound and was classified as supplemental. A supplemental classification does not mean that the study was invalid. What it means is that although the study was scientifically sound it lacks the information that would allow classification as core. In this case, an MATC could not be determined from the definitive study. We cannot use information from a separate study to upgrade the original definitive study. As such, the study will not be upgraded and retains the supplemental classification. The information from the definitive study can be used in a risk assessment and based on the current use ~~information~~ patterns for ADBAC (SHA# 069105), the study will not have to be repeated at this time.

Fish Early Life Stage Study[2]

EEB accepts the arguments presented by the registrant regarding the feeding regime used in the Fish Early Life Stage study. Based on the information submitted EEB hereby upgrades the classification of the Freshwater Fish Early Life-Stage Test (MRID 423021-02) to CORE. Based on mean measured concentrations, the NOEC and LOEL for *Pimephales promelas* were 32.2 and 75.9 µg/l. The MATC was calculated to be 49.4 µg/l.

1. McIntyre, D.O. and H.O. Pate, 1992, Daily Static-Renewal Chronic 21-Day Toxicity Test of Alkyl dimethyl Benzyl Ammonium Chloride (ADBAC) to *Daphnia magna*, Batelle Study No. SC890056, conducted by Batelle Columbus Operations, Columbus, OH, submitted by ADBAC Quat Joint Venture/Chemical Specialties Manufacturers Association, Washington, D.C., EPA MRID No. 423021-01.

2. McIntyre, D.O. and H.O. Pate, 1992, Daily Static-Renewal Early Life Stage Toxicity Test of Alkyl dimethyl Benzyl Ammonium Chloride (ADBAC) to Fathead Minnows, Batelle Study No. SC890057, conducted by Batelle Columbus Operations, Columbus, OH, submitted by ADBAC Quat Joint Venture/Chemical Specialties Manufacturers Association, Washington, D.C., EPA MRID No. 423021-02.

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CONCURRENCES								
SYMBOL	7507C	7507C	7507C					
SURNAME	WINNIK	Crave	Cook for AM					
DATE	4/2/96	4/2/96	04/02/96					

1. McIntyre, D.O. and H.O. Pate, 1992, Daily Static-Renewal Chronic 21-Day Toxicity Test of Alkyl dimethyl Benzyl Ammonium Chloride (ADBAC) to *Daphnia magna*, Batelle Study No. SC890056, conducted by Batelle Columbus Operations, Columbus, OH, submitted by ADBAC Quat Joint Venture/Chemical Specialties Manufacturers Association, Washington, D.C., EPA MRID No. 423021-01.

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