

US EPA ARCHIVE DOCUMENT

DP Barcode : D198138
 PC Code No : ~~819070~~ 069105
 EEB Out :

To: Bridgid Lowery
 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 : ADBAC
 Company Name : ADBAC Ouat Join Venture
 Purpose : review response submitted for consideration
 for upgrading of invalid eastern oyster embryo-larvae study
 (MRID 42479503)
 Action Code : 627 Date Due : 04/03/94
 Reviewer : Harry A. Winnik Date In EEB: 01/11/94

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)	42479503	S	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)			72-4(B)			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

DP BARCODE: D198138

REREG CASE # 0350

CASE: 819070
SUBMISSION: S456184

DATA PACKAGE RECORD
BEAN SHEET

DATE: 01/07/94
Page 1 of 1

*** CASE/SUBMISSION INFORMATION ***

CASE TYPE: REREGISTRATION ACTION: 627 CORE DATA
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: 10/25/93 DUE OUT DATE: 04/03/94

*** DATA PACKAGE INFORMATION ***

DP BARCODE: 198138 EXPEDITE: N DATE SENT: 01/07/94 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	ADMIN DUE DATE: 02/10/94
DIV : EFED	01/11/94	1/1	NEGOT DATE: / /
BRAN: EEB	01/11/94	1/1	PROJ DATE: / /
SECT:	01/12/94	1/1	
REVR :	Winnik 01/12/94	11/12/95	
CONTR:	1/1	1/1	

*** DATA REVIEW INSTRUCTIONS ***

EEB reviewed an ADBAC 48 hour mollusc toxicity test (mrid 42479503) on 8/19/93. The study was considered unacceptable/invalid because the control mortality was unacceptably high. Attached please find a seven page letter which serves as the response from the registrant. Please review this letter and determine whether their argument is convincing and the study can be acceptable.

*** 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

November 1, 1995

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of Information Submitted to Support the Upgrade of Previously Reviewed Eastern Oyster Embryo-Larvae Toxicity Study from Invalid to Core.

FROM: Anthony F. Maciorowski, Chief *AMC*
Ecological Effects Branch *for*
Environmental Fate and Effects Division (7507C) *11/02/95*

TO: Bridgid Lowery (PM 72)
Reregistration Branch
Special Review and Reregistration Division (7508W)

EEB has reviewed the information submitted to support the upgrade of the study; A 48-Hour Static Acute Toxicity Test with Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) in Embryo Larvae of the Eastern Oyster (*Crassostrea virginica*). Based on arguments presented in EPA's Pesticide Reregistration Rejection Rate Analysis¹ and on the further analysis of the data (see attached), EEB hereby upgrades the study from "Invalid" to "Supplemental." The 48-hr LC₅₀ was 55.0 ppb (95% confidence interval of 52.1-58.5 ppb) mean measured concentration. Although the study is scientifically sound, the high control mortality will not allow upgrade to "Core." The study will not need to be repeated.

¹EPA, 1994, Pesticide Reregistration Rejection Rate Analysis, United States Environmental Protection Agency, EPA 738-R-94-035, pp109-110.



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CONCURRENCES						
SYMBOL	7507C	7507C				
SURNAME	WINNIE	Craver	Cook for MM			
DATE	11-2-95	11/3/95	11/6/95			

SURVIVAL	total surviving	SD	mean	CV
Control	114 117 119 125	4.65	119	3.9
25 ppb	111 122 129	9.07	121	7.5
40.8 ppb	99 103 101	2.00	101	2
58.6 ppb	39 39 33	3.06	36.3	8.4
89.7 ppb	9 5 7	2	7	28.9
145 ppb	8 8 6	1.15	7.33	15.7

NORMALITY	total normal	SD	mean	CV
Control	114 117 119 125	4.65	119	3.9
25 ppb	111 122 129	9.07	121	7.5
40.8 ppb	94 93 89	2.65	92	2.9
58.6 ppb	24 18 10	7.02	17.3	40.5
89.7 ppb	5 4 6	1	5	20
145 ppb	6 7 5	1	6	16.7

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ABNORMALITY	total abnormal	SD	mean	CV
Control	0 0 0 0	0	0	undefined
25 ppb	0 0 0	0	0	undefined
40.8 ppb	5 10 12	3.6	9	40
58.6 ppb	15 19 23	4	19	21.1
89.7 ppb	4 1 1	1.73	2	57.7
145 ppb	2 1 1	0.58	1.33	43.3

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