DP Barcode : D198138
PC Code No : 819070,

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 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)		1
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

additional information is needed

P=Partial (Study partially fulfilled Guideline but

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

N=Unacceptable (Study was rejected)/Nonconcur

REREG CASE # 0350 DP BARCODE: D198138

CASE: 819070 DATA PACKAGE RECORD

DATE: 01/07/94 SUBMISSION: S456184 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

ACTION: 627 CORE DATA CASE TYPE: REREGISTRATION

CHEMICALS: 069105 Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 100.00 %

ID#: 069105 COMPANY:

703-308-8058 ROOM: CS1 3C3 PRODUCT MANAGER: 72 LARRY SCHNAUBELT 703-308-8053 ROOM: CS1 PM TEAM REVIEWER: BRIGID LOWERY 3G6

RECEIVED DATE: 10/25/93 DUE OUT DATE: 04/03/94

* * * DATA PACKAGE INFORMATION * * *

EXPEDITE: N DATE SENT: 01/07/94 DATE RET.: DP BARCODE: 198138 CHEMICAL: 069105 Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, DP TYPE: 001 Submission Related Data Package

CSF: N LABEL: N DATE IN ADMIN DUE DATE: 02/10/94 ASSIGNED TO DATE, OUT 61111194 NEGOT DATE: DIV : EFED PROJ DATE: BRAN: EEB 01 1/194 SECT: 01/12/94 REVR: Winnik 01/12/94 CONTR:

* 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 *

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



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 WCo

Ecological Effects Branch

Environmental Fate and Effects Division (7507C)

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 EPAs Pesticide Reregistration Rejection Rate Analysis¹ and on the further analysis of the data (see attached), EEB hereby ugrades the study from "Invalid" to "Supplemental." The 48-hr LC_{50} 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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	EPA,	1994, Pe	sticide R	eregistra	tion Reje	ction Rat	e Analysi	s, —	
	United St	ates Envi	<u>ronmental</u>	CONCURRENC	gn Agenc	y, EPA 73	8-R-94-03	5,	_
SYMBOL	75076	7567(_	7507-C	_					•••
SURNAME	NIMMIL	Creves	Cook for AM						••••
DATE	11-2-95 B	cycled/Recyclable	Printed with Wedetah	[100% Recycled Pap	er (40% Postconsum	·r)		
EDA For	m 1320-14 71/90)			Printed on Recycles	Paper		OFFICI	AL FILE CO	PY

٠.	SURVIVAL	total surviving	SD	mean	CV
ā	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

7	145 ppb	8 8 6	1.15	7.33	15.7
					ingger
	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

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

