

10-3-94

DP Barcode : D199281  
PC Code No : 129086  
EEB Out : / /

To: Robert Forrest  
Product Manager 14  
Registration Division (7505C)

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

430 48201

Attached, please find the EEB review of...

Reg./File # : 003125-URR  
Chemical Name : Phostebupirim  
Type Product : insecticide  
Product Name : MAT 7484  
Company Name : Miles  
Purpose : Review freshwater mussel study.

Action Code: 101

Date Due: 6/10/94

Reviewer: ~~Regina Hirsch~~  
R. FEINHOUSEN

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)			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

ECOLOGICAL EFFECTS BRANCH

Chemical: Phostebupirim, Cyfluthrin  
AZTEC 2.1 G

100.0 Purpose of Submission

The Registrant (Miles, Inc.) has submitted a freshwater mussel acute toxicity study (MRID# 43048201) conducted in response to EEB's endangered species concern for the proposed use of AZTEC 2.1% granular insecticide.

101.0 Data Adequacy

The study was scientifically sound and conducted in accordance with good laboratory practice (See attached statistical analysis).

102.0 Results

The 96-hour LC50 was 2.12 mg/L with 95% confidence limits of 1.65 to 2.92 mg/L. The slope of the 96-hour LC50 toxicity curve was 1.91 as determined by the probit method. The no-observed-effect-concentration (NOEC) was 0.53 mg/L (measured). The lowest-observed-effect-concentration (LOEC) was 1.08 mg/L (measured).

103.0 Discussion

Based on toxicity data for the D. magna and EECs, it was expected that there was a presumption of unacceptable risk to endangered aquatic invertebrates from the proposed use pattern. Because there are numerous endangered freshwater mussels and snails, that are likely to be exposed from the use of AZTEC, and because such exposure may result in a "may affect" situation to numerous endangered pelecypods and gastropods, the Registrant felt it necessary to conduct a 96-hour static acute toxicity study for freshwater mussels.

104.0 Summary

The EEB has completed a Data Evaluation Report (DER) for a static acute 96-hour toxicity study for phostobupirim to the freshwater mussel. The study was scientifically sound and done in accordance with good laboratory practice. It is noted, however, that this study may not represent the most sensitive life stage and/or end point to demonstrate safety for freshwater mussels.

The 96-hour LC50 was 2.12 mg/L with 95% confidence limits of 1.65 to 2.92 mg/L. The slope of the 96-hour LC50 toxicity curve was 1.91 as determined by the probit method. The no-observed-effect-concentration (NOEC) was

0.53 mg/L (measured). The lowest-observed-effect-  
concentration (LOEC) was 1.08 mg/L (measured).

*Richard W. Felthousen* 9/15/94  
Richard W. Felthousen, Wildlife Biologist  
EFED/EEB

*Les Touart* 9/27/94  
Les Touart, Head Section -1  
EFED/EEB

*Anthony F. Maciorowski* 10/3/94  
Anthony F. Maciorowski, Chief  
EFED/EEB

*A. Maciorowski*

DATA EVALUATION RECORD

- 1. CHEMICAL: Phostebupirim, Cyfluthrin, AZTEC
- 2. TEST MATERIAL: MAT 7484 Technical, and C-MAT 7484
- 3. STUDY TYPE: 96-Hour LC50 static acute test to the Freshwater Mussel (Anodonta imbecilis)
- 4. CITATION AND MRID NO:


"Acute Toxicity of MAT 7484 Technical to the Freshwater Mussel (Anodonta imbecilis) Under Static Renewal Conditions  
MRID NO. 43048201)

- 5. AUTHORS, STUDY DATE, TEST LABORATORY :

G. G. Gagliano and L. M. Bowers  
November 12, 1993  
Miles Incorporated Agriculture Division

- 6. REVIEWED BY:


Richard W. Felthousen  
Wildlife Biologist  
EEB/EFED

Signature: 

Date: 9/15/94

- 7. APPROVED BY:

Les Touart  
Supervisory Biologist  
EEB/EFED

Signature: 

Date: 9/29/94

- 8. CONCLUSIONS:

The study was scientifically sound and conducted in accordance with good laboratory practice. The 96-hour LC50 was 2.12 mg/L with 95% confidence limits of 1.65 to 2.92 mg/L. The no-observed-effect-concentration (NOEC) was 0.53 mg/L (measured). The lowest-observed-effect-concentration (LOEC) was 1.08 mg/L (measured).

- 9. RECOMMENDATIONS: N/A

- 10. BACKGROUND:

The study was conducted to obtain toxicity data for freshwater mussels in order to better address endangered species concerns.

- 11. DISCUSSION OF INDIVIDUAL TESTS:

- 12. MATERIALS AND METHODS:

A. Test Animals: Freshwater mussel (Anodonta imbecilis)

B. Dosage:

Nominal Conc.= 0.312, 0.624, 1.25, 2.5 and 5.0 mg/L  
Measured Conc.= 0.288, 0.507, 1.18 2.08 4.2 mg/L

C. Test System:

The test was performed under static unaerated conditions with five concentrations of test material, a solvent control and a dilution water control at the temperature of 20.1 to 21.5° C. The dissolved oxygen concentration ranged from 8.6 to 9.3 mg/L representing 97 to 102 percent concentration. pH values ranged from 7.8 to 8.2. The mean hardness was 183 mg/L as CaCO<sub>3</sub>, alkalinity was 134 mg/L, and conductivity was 426 umhos/cm. There was a single protocol deviation noted in the conduct of this study. The protocol specified a dilution water (blended spring water) 180 mg/L as CaCO<sub>3</sub>. The mean hardness during the study was 183 mg/L. It did not appear that this deviation adversely affected the results of the study. Test methods and procedures are based on those developed and used by Dr. Robert Hudson, Professor of Biology at Presbyterian College and Dr. Donald Wade of the Tennessee Valley Authority.

D. Test Species:

The test species used in the study were obtained from Dr. Robert G. Hudson. Dr. Hudson collected gravid Anodonta imbecilis from the region and brought them into the laboratory. The glochidia were then transformed into juveniles using an artificial medium developed by Isom and Hudson (1982). They were fed mixed phytoplankton and cultured in natural water containing silt (Hudson, 192). The culture, consisting of 7-day old juveniles, was received at Miles Aquatic Toxicology Lab on 9/21/93. The mussels were cultured in hard blended water with gentle aeration. The mussels were fed algae (Selenastrum capricornutum and Ankistrodesmus falcatus) ad libitum. The holding area was maintained on a 16-hour daylight photoperiod and 20 ± 2° C temperature range.

E. Statistics:

The probit method was used to calculate the 96-hour LC50.

13. REPORTED RESULTS:

The 96-hour LC50 was 2.12 mg/L with 95% confidence limits of 1.65 to 2.92 mg/L. The slope of the 96-hour LC50 toxicity curve was 1.91 as determined by the probit method. The no-observed-effect-concentration (NOEC) was

0.53 mg/L (measured). The lowest-observed-effect-concentration (LOEC) was 1.08 mg/L (measured). There is no guideline requirement for this study.

14. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:

15. REVIEWER'S DISCUSSION:

A. Test Procedure:

The test procedure was designed and conducted in such a manner that the study was scientifically sound and done in accordance with GLP.

B: Statistical analyses:

The 96-hour EC50 was determined using the probit method. All calculations were performed using the mean measured concentrations with the percent mortality being used in the statistical analysis. (See attached sheet).

C. Discussion/Results:

Although scientifically sound, the life stage (juvenile) and endpoint (mortality) may not be the most sensitive life stage and/or endpoint to demonstrate safety for freshwater mussels. It does provide useful supplementary information.

D. Adequacy of the Study:

The study is adequate for use in a risk assessment.

(1) Classification: Supplemental

(2) Rationale: The study is scientifically sound and done in accordance with GLP, but does not address any specific Guideline requirement.

(3) Repairability: N/A

NOTE: BECAUSE THERE WAS CONTROL MORTALITY, AND NONE OF THE LOWER CONCENTRATIONS PRODUCED ZERO MORTALITY, THE DATA HAS BEEN SUBJECTED TO ABBOTT'S CORRECTION.

felthousen phostobupirim 96-hour LC50

\*\*\*\*\*

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
4.22	38	31	81.5789	0
2.04	38	12	31.5789	0
1.08	38	8	21.0526	0
.54	38	4.000001	10.5263	0
.29	38	1	2.6316	0

BECAUSE THE NUMBER OF ORGANISMS USED WAS SO LARGE, THE 95 PERCENT CONFIDENCE INTERVALS CALCULATED FROM THE BINOMIAL PROBABILITY ARE UNRELIABLE. USE THE INTERVALS CALCULATED BY THE OTHER TESTS.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 2.643271

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
2	.1251124	2.50102	2.029368	3.246078

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H
3	7.720391E-02	1
GOODNESS OF FIT PROBABILITY		
	.1692438	

SLOPE = 2.29974  
 95 PERCENT CONFIDENCE LIMITS = 1.660744 AND 2.938737

LC50 = 2.315896  
 95 PERCENT CONFIDENCE LIMITS = 1.852057 AND 3.083755

LC10 = .6493559  
 95 PERCENT CONFIDENCE LIMITS = .4230583 AND .8579421

\*\*\*\*\*

NOTE: BECAUSE THERE WAS CONTROL MORTALITY, AND NONE OF THE LOWER CONCENTRATIONS PRODUCED ZERO MORTALITY, THE DATA HAS BEEN SUBJECTED TO ABBOTT'S CORRECTION.

felthousen phostobupirim 96-hour LC50

\*\*\*\*\*

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
4.22	36	29	80.5556	0
2.04	36	10	27.7778	0
1.08	36	6	16.6667	0
.54	36	2	5.5556	0
.29	40	3	7.500001	0

THE BINOMIAL TEST SHOWS THAT 2.04 AND 4.22 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT

7

CASE TYPE: REGISTRATION ACTION: 101 RESB NC-FOOD/FEED USE  
RANKING : 35 POINTS (KO)  
CHEMICALS: 129086 Phostebupirim

92.0000%

ID#: 003125-URR mat 7484 technical  
COMPANY: 003125 MILES INC  
PRODUCT MANAGER: 14 ROBERT FORREST 703-305-6600 ROOM: CM2 219  
PM TEAM REVIEWER: MARILYN MAUTZ 703-305-6785 ROOM: CM2 221  
RECEIVED DATE: 12/14/93 DUE OUT DATE: 06/22/94

*Sy 55845*

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 199281 EXPEDITE: N DATE SENT: 02/10/94 DATE RET.: / /  
CHEMICAL: 129086 Phostebupirim  
DP TYPE: 001 Submission Related Data Package

CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 06/10/94
DIV : EFED	02/14/94	/ /	NEGOT DATE: / /
BRAN: EEB	02/15/94	/ /	PROJ DATE: / /
SECT: RS1	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Review attached freshwater mussel acute toxicity study (MRID# 43048201) conducted in response to EEB's endangered species concern with the proposed use of this chemical. Refer to the attached bean sheet for 3125-URE(S455843) which transmits the applicant's endangered species risk assessment for the proposed end use product.

Refer also to the other data packages (D194492, D191767 & D191130) submitted to support sec. 3 registration of this pesticide which are currently in EEB, Sect. 1.

\* \* \* 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
-------	----------------	----------	----------	-----	-----	-------

*2/32 WMAAL*

*8*