DP Barcode : D192155
PC Code No : 109701
EEB Out : SEP 15 1993

To: Jay Ellenberger
Product Manager 50
Special Review and Reregistration Division (H7508W)

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

Attached, please find the EEB review of...

Reg./File # : 109701
Chemical Name : Permethrin, mixed cis,trans
Type Product : Insecticide
Product Name : Permethrin products
Company Name : Zeneca Ag Products
Purpose : Submission of data for reregistration in support of 72-3(a) for List B, Case No. 2510.

Action Code : 627 Date Due : 10/02/93
Reviewer : C. Laird Date In : 06/16/93

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)	427951-01	N	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

DP BARCODE: D192155 REREG CASE # 2510

CASE: 819432 DATA PACKAGE RECORD DATE: 09/10/93
SUBMISSION: S442396 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 627 GENERIC DATA SUBMISSION
CHEMICALS: 109701 Permethrin, mixed cis,trans (ANSI) 100.00 %

ID#: 109701
COMPANY:
PRODUCT MANAGER: 50 JAY ELLENBERGER 703-308-8085 ROOM: CS1 4J1
PM TEAM REVIEWER: LINDA DELUISE 703-308-8065 ROOM: CS1 4N6
RECEIVED DATE: 06/03/93 DUE OUT DATE: 10/01/93

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 192155 EXPEDITE: N DATE SENT: 06/11/93 DATE RET.: / /
CHEMICAL: 109701 Permethrin, mixed cis,trans (ANSI)
DP TYPE: 999 Miscellaneous Data Package
CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT	
DIV : EFED	06/15/93	/ /	ADMIN DUE DATE: 10/02/96
BRAN: EEB	06/16/93	/ /	NEGOT DATE: / /
SECT: RS2	06/16/93	/ /	PROJ DATE: / /
REVR : CLAIRD	06/16/93	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

please review mrid 42795101 for 72-3(a)

* * * 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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100.0 Pesticide Name:

Permethrin

100.3 Submission Purpose:

Submission of a 96-hour LC_{50} for sheepshead minnow in support of registration

101.0 Chemical and Physical Properties:

101.1 Chemical Name:

(3-phenoxyphenyl) methyl 3-(2,2-dichloroethyl)-2,2-dimethyl cyclopropanecarboxylate

101.2 Common Name:

Permethrin

103.0 Toxicological Properties:

96-hour LC_{50} for sheepshead minnow

105.0 Conclusions:

EEB reviewed the submitted estuarine/marine study and has the following comments:

A. Sheepshead Minnow (LC_{50}; MRID No. 427951-01)

This study is not scientifically sound and does not meet the guideline requirements for a static acute toxicity test. Dissolved oxygen depletion affected the test results. In addition, while test solutions were cloudy and were aerated during the exposure period, test concentrations were not measured. Another study using TGAI is required if this study is intended to satisfy TGAI requirements. Otherwise, another study using the formulated product is required.

Curtis E. Laird 9-10-93

Curtis E. Laird, Fishery Biologist
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

Norman J. Cook 09.14.93

Norman J. Cook, Supervisory Biologist
Ecological Effects Branch
Environmental Fate and Effects Division (H7507)

Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

DATA EVALUATION RECORD

1. **CHEMICAL:** Permethrin.
Shaughnessey No. 109701.

2. **TEST MATERIAL:** Permethrin 2EC formulation; (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethyl cyclopropanecarboxylate; CAS No. 52645-53-1; 25.5% w/w purity; a clear, straw-colored liquid.

3. **STUDY TYPE:** 72-3. Saltwater Fish Acute Static Toxicity Test. Species Tested: Sheepshead Minnow (*Cyprinodon variegatus*).

4. **CITATION:** Sankey, S.A., S.J. Kent, M.M. Holland, and J.E. Caunter. 1993. Permethrin: Acute Toxicity to Sheepshead Minnow (*Cyprinodon variegatus*) of a 2EC Formulation. Laboratory Project ID No. BL4748/B. Conducted by Brixham Environmental Laboratory, Devon, UK. Submitted by Zeneca, Inc., Wilmington, DE. EPA MRID No. 427951-01.

5. **REVIEWED BY:**

Mark A. Mossler, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Mark A. Mossler
Date: 7/30/93

6. **APPROVED BY:**

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

Signature: P. Kosalwat
Date: 7/30/93

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

Signature: Curtis E. Laird 8-23-93
Henry T. Craven
Date:

7. **CONCLUSIONS:** This study is not scientifically sound and does not satisfy the guideline requirements for a static acute toxicity test. Dissolved oxygen depletion affected the test results. In addition, while test solutions were cloudy and were aerated during the exposure period, test concentrations were not measured. Under the conditions of the test, the 96-hour LC_{50} of 8.0 mg/l (nominal concentration of formulated product) or 2.0 mg ai/l classifies permethrin 2EC as moderately toxic to sheepshead

minnow. The NOEC could not be determined due to mortality at all treatment levels.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Sheepshead minnows (*Cyprinodon variegatus*) were obtained from a commercial supplier in Salem, MA. The fish were held in saltwater at 22 ±1°C and were fed a commercially available fish food during the 33 weeks prior to testing. The last mortality occurred 16 days prior to test initiation. The fish were not fed during the test or during the 48 hours preceding the test. The average length and weight of the control fish at test termination were 32 mm (range of 24-36 mm) and 0.93 g (range of 0.34-1.61 g), respectively.

B. **Test System:** Vessels used in the test were glass, 40-l aquaria (46 x 30 x 31 cm) which contained 30 l of test solution or control water. The test was performed in a temperature-controlled room maintained at 22 ±1°C. The dilution water was natural seawater from Tor Bay, Devon, which was filtered and UV sterilized prior to use. Salinity was 34.7 parts per thousand (ppt) and pH was 8.0 at test initiation. The photoperiod was 16 hours light/8 hours darkness with 10 minute transitions periods at dusk and dawn. The treatment solutions were prepared by adding appropriate amounts of the test material to the dilution water.

C. **Dosage:** Ninety-six-hour static test. Seven nominal concentrations (5.6, 10, 18, 32, 56, 100, and 180 mg of formulation/l) and a dilution water control were selected for the test.

D. **Design:** Ten minnows were randomly allocated to each treatment and control vessel. The loading rate was 0.31 g/l. The test solutions were aerated after the dissolved oxygen concentrations (DO) were measured on day 2 until test termination. All chambers were observed once every 24 hours for mortality and signs of toxicity.

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Temperature, DO, and pH measurements were made every 24 hours. Temperature was also monitored continuously in the dilution water control.

E. **Statistics:** The 96-hour median lethal concentration (LC_{50}) and associated 95% confidence interval (C.I.) were calculated using probit analysis.

12. **REPORTED RESULTS:** All treatment solutions were white and cloudy. The magnitude of this cloudiness increased with increasing concentration. "The lowest nominal concentration (5.6 mg/l) contained permethrin at 7 times its limit of solubility in freshwater and the top nominal concentration contained permethrin at 225 times it limit of solubility in freshwater. Due to the large amount of undissolved permethrin it was not possible to obtain reliable results from chemical analysis of the test solutions. Preliminary work, with chemical analysis, confirmed this to be the case. As analysis for permethrin would not have contributed to the assessment of the toxicity of the formulation to sheepshead minnow, chemical analysis was not conducted during the definitive run of the study. Therefore, all results are quoted on the basis of nominal concentrations."

Sublethal effects noted were surfacing, sounding, loss of balance, quiescence, and hyperactivity (Table 2, attached). The mortalities of the sheepshead minnows are given in Table 1 (attached). The 96-hour LC_{50}, based on nominal concentrations, was 8 mg/l (95% C.I.= 3.0-13 mg/l). The no-observed-effect concentration (NOEC) was <5.6 mg/l, based on nominal concentrations.

The pH of the test solutions ranged between 7.56 and 8.04. The DO was 6.6-7.0 mg/l (75-80% of saturation) at test initiation and 0.6-5.0 (7-57% of saturation) on day 2 before aeration was started. The DO remained above 66% of saturation for the remainder of the study. Temperature ranged between 21.1-22.0°C throughout the test.

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

Quality Assurance and Good Laboratory Practice compliance statements were included in the report, indicating that the study complied with EPA Good Laboratory Practice standards (40 CFR Part 160).

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

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A. **Test Procedure:** The test procedures were not in accordance with the SEP. The following are deviations:

Although the fish were held at the same temperature as in the test, it was not stated if the fish were acclimated for 48 hours to all the test conditions, as required by the guidelines.

The DO dropped below 60% of saturation in all solutions within the first 48 hours of the test (as low as 7%). For a static test, DO should be above 60% of saturation during the first 48 hours and above 40% of saturation thereafter.

While test solutions were aerated from day 2 until the end of the test, chemical analysis was not performed. If aeration is needed, test solutions must be analyzed for the test material to verify the test concentrations.

The test material was a formulated material rather than technical grade material.

The salinity of the test water was 35 ppt. Sheepshead minnows are euryhaline species and should be tested in water of lower salinity (i.e., 10-17 ppt).

The report did not state the time period between test solution preparation and fish addition.

B. **Statistical Analysis:** The reviewer did not perform any statistical analyses due to the factors mentioned in the following section.

C. **Discussion/Results:** There is no doubt that the reduced oxygen levels affected the outcome of this test (Table 3, attached). Although none of the control fish died, the control water contained the highest DO levels. Since Table 2 (attached) which presents sublethal effects does not include the control, it is not known whether the control fish showed any of the symptoms. In addition, the exposed fish might have died as a result of asphyxiation because of the test material precipitation on their gills.

Although, the test solutions were aerated from day 2 to test termination, the test concentrations were not measured. Chemical analysis is particularly important when test solutions are cloudy which is the case in this test. The authors indicated difficulties in

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performing chemical analysis due to the precipitates. The test solutions should have been filtered before the analysis.

If repeated, the test should be conducted using a flow-through test, or a static-renewal test if a flow-through system is not feasible because of the precipitates. Chemical measurements should then be conducted on filtered test solutions.

This study is not scientifically sound and does not satisfy the guideline requirements for a static acute toxicity test. Under the conditions of the test, the 96-hour LC_{50} of 8.0 mg/l (nominal concentration of formulated product) or 2.0 mg ai/l classifies permethrin 2EC as moderately toxic to sheepshead minnow. The NOEC could not be determined due to mortality at all treatment levels.

D. **Adequacy of the Study:**

(1) **Classification:** Invalid.

(2) **Rationale:** 1) Dissolved oxygen depletion affected the test results. 2) Test solutions were cloudy and were aerated during the exposure period, but test concentrations were not chemically measured.

(3) **Repairability:** No.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 7-16-93.

Page _____ is not included in this copy.

Pages 10 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 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.

X 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.

Ecological Effects Branch One-Liner Data Entry Form

Chemical Permethrin 2EC Shaughnessy No. 109701 Pesticide Use Insecticide

AQUATIC VERTEBRATE TOX.	% AI	LC_{50} (95%CL) SLOPE	HRS/ TYPE	NOEC	STUDY/REVIEW DATES	MRID/ CATEGORY	LAB	RC
1. Cyprinodon variegatus	25.5	8.0 mg/l (3-13 mg/l)	96 hr Static	CND*	1993/1993	427951-01 Invalid	BEL**	
2.								
3.								
4.								
5.								
6.								
7.								

CHRONIC TOX.	% AI	MATC LC_{50}	DAYS	AFFECTED PARA.	STUDY/REVIEW DATES	MRID/ CATEGORY	LAB	RC
1.								
2.								
3.								

COMMENTS: * CND = could not determine ** BEL = Brixham Environmental Laboratory

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