109701

(15)

EEE BRANCH REVIEW

DATE: IN 9/8/77 OUT 1/4/78 IN _____ OUT _____ IN _____ OUT _____

FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. _____

PETITION OR EXP. PERMIT NO. 10182-EUP-3

DATE DIV. RECEIVED _____

DATE OF SUBMISSION _____

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCTS(S): (I) D, H, F, N, R, S COTTON

DATA ACCESSION NO(S). _____

PRODUCT MGR. NO. D. Stubbs

PRODUCT NAME(S) Ambush

COMPANY NAME ICI United States, Inc.

SUBMISSION PURPOSE EUP - Cotton

CHEMICAL & FORMULATION Permethrin

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Ambush™ Pyrethoid Insecticide

100.0 Pesticide Use

For the control of boll weevil, bollworm, tobacco budworm, pink bollworm, lygus bugs, whitefly, cotton aphid, cabbage looper, thrips, and cotton leafperforator in cotton.

100.1 Directions - Methods - Rates

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Apply AMBUSH as shown in the following chart, using sufficient water to obtain full coverage of foilage. Three to five gals./Ac. by aerial application is recommended. Apply every 5 to 7 days or as needed. Timing and frequency of applications should be based upon insect populations reaching locally determined economic thresholds.

COTTON SPRAY RECOMMENDATIONS

Target Pests	Dosage Per Acre	Minimum Spray Volume	Spray Interval
Boll weevil Bollworm Tobacco Budworm Pink Bollworm Lygus Bugs Whitefly Cotton Aphid Cabbage Looper Thrips Cotton Leafperforator	0.4 to 0.8 pint	1.5 gal/A aerial or 9 gal/A ground	5 to 7 days or as indicated by scouting

RATE CONVERSION CHART

Lb. Active/ Acre	Fluid Ozs./ Acre	Pints/ Acre	Acres Treated/ Gal.
0.10	6.4	0.4	20.0
0.125	8.0	0.5	16.0
0.15	9.6	0.6	13.3
0.175	11.2	0.7	11.4
0.20	12.8	0.8	10.0

Remarks
Do not graze livestock in treatec areas. Do not apply more than 1² pints per acre per season. The higher rates (0.6 to 0.8 pt/A) ma be required under conditions of heavy worm infestation or when weevils or late instars of worms are present.

For use in the following states only:
AL, AR, AZ, CA, GA, LA, MO, MS, NM, OK, SC, TN, TX.

100.3 Precautionary Labelling

Environmental Hazards: This product is toxic to fish. Do not contaminate water by cleaning of equipment or disposal of waste. Keep out of lakes, streams, ponds, tidal marshes or estuaries. This product is toxic to bees exposed to direct treatment. Protective information may be obtained from your Cooperative Agricultural Extension Service. Do not apply when weather conditions favor drift from target area. Apply this product only as specified on this label. Do not plant any crop except cotton within 120 days after last application. Any crop may be planted if it is not harvested or grazed.

In case of a significant spill, call 800/424-9300.

100.4 Proposed EUP

A. Objectives

Aerial and ground spraying tests will be conducted to determine the effectiveness of Ambush in controlling the boll weevil, bollworm, tobacco budworm, pink bollworm, lygus bugs, whitefly, cotton aphid, cabbage looper, thrips, and cotton leafperforator on cotton. Field trials will consider the following: methods of ground application, methods of aerial application, treatment interval as related to rate, cotton yield, cotton quality, current pest management concepts, and impact on non-target organisms.

The phytotoxicity of Ambush will be evaluated at rates up to 0.8 lb ai/A (4 times the maximum proposed use rate).

B. Duration

It is requested that the existing permit remain valid for an additional 12 months.

Dates: May 24, 1978 to May 24, 1979

C. Application Sites

State	Total Acres Required
Alabama	1625
Arkansas	1675
Arizona	985
California	1245
Georgia	1700
Louisiana	1650
Missouri	1000
Mississippi	3215
New Mexico	350
North Carolina	725
Oklahoma	795
South Carolina	915
Tennessee	875
Texas	3145
Total	19900

D. Quantity Requested

It has been determined that the least amount of active ingredient required for treating 20,000 acres is 15,000 lbs.

E. Method of Disposition of Unused Material

Unused material will be disposed of in compliance with EPA's Recommended Procedures for Disposal and Storage as described in 40 CFR, Part 165.

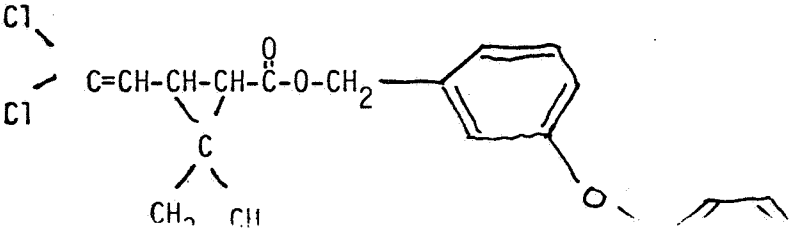
101.0 Chemical and Physical Properties

101.1 Chemical Name

(3-Phenoxyphenyl)methyl (±)-(1S, trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanencarboxylate

101.2 Common Name

Permethrin: PP557



101.4 Molecular Weight

391.28

101.5 Physical State

Liquid, colorless, odorless

101.6 Solubility

1 ppm in water, misible with or soluble in most organic solvents

102.0 Behavior in the Environment

See previous review by N. Cook (8-1-77)

103.0 Toxicological Properties

103.1 Acute Toxicity

103.1.1 Mammalian

See Review by Thomas O'Brian, 2/14/77

103.1.2 Bird Acute Toxicity LD_{50}

Mallard	> 10,327 mg/kg females	EA[1]
	> 9,868 mg/kg males	EA
Pheasant	> 13,740 mg/kg males	EA
	> 15,545 mg/kg females	EA
Starling	> 42,706 mg/kg	EA
Japanese Quail	> ~~15,500~~ 15,517 mg/kg Females	EA
	> ~~20,000~~ " " males.	

103.1.3 Fish Acute Toxicity LC_{50} 96-hr.

Channel Catfish	5.4	ppb	EA
Coho Salmon	17.0	ppb	EA
Atlantic Salmon	1.5	ppb	EA

103.1.4 Aquatic Invertebrate Toxicity LC_{50} (48-hr)

Daphnia Magna	1.8	ppb	(48 hr)	EA
Daphnia Magna	0.8	ppb	(48 hr)	FP[2]
Brown Shrimp	0.38	ppb	(48 hr)	EA
Fiddler Crab	2.2	ppb	(96 hr)	EA

103.2 Subacute

Ring-necked Pheasant	23,000 ppm	EA
Mallard Duck	23,000 ppm	EA
Japanese Quail	23,000 ppm	EA

103.4 Field Toxicity

See attached test (ID # ES-BB)

Footnotes

[1] EA = Technical material (each active)

[2] FP = Formulated product

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator: R. Balcomb			Date: Oct. 7, 1977				
Technical		Permethrin PP557	Test Type: Avian Acute Oral Mallard Duck							
			Test ID # ES-C-1							

CITATION: Ross, D.B., Cameron, D.M., and Roberts, N.L. "The Acute Oral Toxicity (LD_{50}) of PP557 (Permethrin) to the Mallard Duck According to EPA Guidelines." Huntingdon Research Center, Report No. ICI 68 WL/77205 (July, 1977).

VALIDATION CATEGORY: Core

RESULTS: Twenty male and 20 female Mallard ducks (Anas platyrhynchus p.) were evenly divided into test and control groups. Test ducks were dosed with 10 ml of technical material and controls received 10 ml of corn oil.

Group	Birds per Group	Sex	Dose level	Mortalities	(0-21 days) Body Weight Change
1	10	M	0	0	-1 g
2	10	M	9868 mg/kg	0	-27 g
3	10	F	0	0	+24 g
4	10	F	10,327 mg/kg	0	+10 g

All birds were subdued for 1-2 hours after dosing. Several birds in groups 2 and 4 made unsuccessful attempts to vomit but no other abnormal signs were observed. The birds appeared to remain in good health throughout the study and post-mortem examination revealed no abnormalities.

Male ducks showed slight body weight loss (3% controls, 4.8% test) during first 9 'days' after dosing but returned to near normal weight by day 21. Losses were not considered abnormal.

Due to the lack of mortalities, the LD_{50} values were estimated as > 10327 mg/kg for females and > 9869 mg/kg for males.

VALIDATION CATEGORY/RATIONALE: The study follows EPA guidelines. LD_{50} was not established as maximum practicable dose level was relatively non-toxic.

CATEGORY REPAIRABILITY/RATIONALE: NA

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator:			Date:				
Assumed to be Technical		Permethrin PP557	R. Balcomb x			Oct. 4, 1977				
			Test Type: Acute Oral Toxicity to the Ring-necked Pheasant							
			Test ID # ES-C-2							

CITATION: Ross, D.B., Cameron, D.M., and Roberts, N.L. "The Acute Oral Toxicity (LD_{50}) of PP557 (Permethrin) to the Pheasant" Huntingdon Research Center, Report No. ICI 68/WL/77154 (July 1977).

VALIDATION CATEGORY: Core

RESULTS: LD_{50} > 13,534 mg/kg.
Twenty male pheasants were equally divided into control and test groups. Test birds received 13,534 mg/kg of PP557 and control birds were dosed with 15 ml corn oil. All birds were subdued after dosing (1-2 hrs.) but soon recovered. Food consumption was normal during the 14 day post-dosage observation period. Control and test birds experienced weight loss:

Group Mean Body Weights (g/bird)

Group	# Birds	Dose (mg/kg) PP557	Days (wt) 0	7	14	% loss
1	10	0	1,320	1,260	1,265	4.1
2	10	13,534	1,330	1,280	1,260	5.2

The above weight losses were considered within normal limits.

VALIDATION CATEGORY/RATIONALE: The study was determined core as it generally adheres to guidelines. LD_{50} was not calculated as largest practicable dose was non-lethal.

CATEGORY REPAIRABILITY/RATIONALE: NA

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i. Assumed Technical	SC#	CHEMICAL NAME Permethrin PP-557	Validator: Richard Balcomb			Date: Oct. 6, 1977				
			Test Type: Acute Oral Toxicity (LD_{50}) Ring-necked Pheasant							
			Test ID # ES-C-3							

CITATION: Ross, D.B., Cameron, D.M., and Roberts, N.L. "The Acute Oral Toxicity (LD_{50}) of PP557 (Permethrin) to the Ring-necked Pheasant According to E.P.A. Guidelines" Huntingdon Research Center, Report No. ICI 68 WL/77206 (July, 1977).

VALIDATION CATEGORY: Core

RESULTS: Twenty male and female ring-necked pheasants were randomly divided into control and test groups of equal size. The test males received 13,740 mg/kg of Permethrin and females 15,345 mg/kg. Controls received a dose of corn oil.

Females did not experience marked weight loss, mortality or other observable toxic effects.

Males showed a slight tendency toward weight loss following PP-557 dosage and one died on day 5, however, this was judged not related to toxic effects.

A t-test comparing weight loss between day 0 and day 3 of the study showed the difference not to be significant (+ = 1.9, dF = 9).

Body Weight Change

Group	Sex	0-9	9-21	0-21	Dose mg/kg
1	Male	+ 5	- 2	+ 3	0
2	Male	-46*	+32	-14	13,740
3	Female	+ 2	+12	+14	0
4	Female	+ 4	- 4	0	15,345

*Included one mortality. Experimenter judged death not related to permethrin dosage.

LD_{50} is in excess of 13,740 mg/kg for males and 15,345 mg/kg for females.

VALIDATION CATEGORY/RATIONALE: Study generally adheres to guidelines. LD_{50} was not determined as permethrin is relatively non-toxic to birds.

CATEGORY REPAIRABILITY/RATIONALE: NA

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator: R. Balcomb			Date: Oct. 14, 1977				
Technical		Permethrin (PP557)	Test Type: Avian Acute Oral (LD_{50}): Japanese Quail							
			Test ID # ES-C-4							

CITATION: Ross, D.B., Cameron, D.M., and Roberts, N.L. "The Acute Oral Toxicity (LD_{50}) of PP557 (Permethrin) to Japanese Quail According to EPA Guidelines." Huntingdon Research Center, Report No. ICI 68 WL/77207 (July, 1977).

VALIDATION CATEGORY: Supplementary

RESULTS: Twenty male and 20 female Japanese Quail (Coturnix coturnix japonica) were allocated to treatement with technical grade PP557 as follows:

Group	Birds per Group	Sex	Dose Level	Mortality	Group Mean Body wt. Δ 0-21 days
1	10	M	0	1	- 1 g
2	10	M	20,000 mg/kg	0	- 2 g
3	10	F	0	1	+ 7 g
4	10	F	15,517 mg/kg	1	+13 g

The above controls received 3 ml of corn oil.

All birds were subdued for 1-2 hours after dosing. No other abnormal signs were observed and most birds appeared to remain in good health throughout the experimental period.

Mortalities: Two control birds died (one male, one female) and one female receiving PP557 died. The experimenters determined the deaths were not related to test treatments. All birds were examined post-mortem. No abnormalities were observed, even for the birds which died.

LD_{50} values were estimated as > 20,000 mg/kg for males and > 15,517 mg/kg for females.

VALIDATION CATEGORY/RATIONALE: Study follows EPA guidelines. LD_{50} was not established as maximum practicable dose level was non-lethal. Study is supplemental as species is not indigenous to N. America.

CATEGORY REPAIRABILITY/RATIONALE: NA

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator:			Date:				
Assumed Technical		Permethrin (PP-557)	R. Balcomb			Oct. 6, 1977				
			Test Type: Acute Oral Toxicity (LD_{50}) of PP557 to the Starling							
			Test ID # (ES)-C-5							

CITATION: Ross, D.B., Cameron, C.M., and Roberts, N.L. "The Acute Oral Toxicity (LD_{50}) of PP557 (Permethrin) to the Starling" Huntingdon Research Center, Report No. ICI 68 WL/76499 (July, 1977).

VALIDATION CATEGORY: Supplementary

RESULTS: LD > 42706 mg/kg for Starlings.

Group	Number Birds	Dose level mg/kg	Survival
1	10	0	100 %
2	10	14,070	100 %
3	10	42,706	100 %

Birds dosed with PP557 were seen to make unsuccessful attempts to vomit. All birds were subdued after dosing, but recovered within 24 hours and remained in good health throughout study.

VALIDATION CATEGORY/RATIONALE: Study generally adheres to guidelines. LD_{50} was not determined as maximum doses (42 g/kg) proved non-fatal.

CATEGORY REPAIRABILITY/RATIONALE: Species is not indigenous to North America. The study is therefore not repairable.

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FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator: R. Balcomb			Date: Oct. 4, 1977				
92		Permethrin PP557	Test Type: Avian Subacute Dietary LC_{50}: Ring-necked Pheasant							
			Test ID # ES-D							

CITATION: Ross, D.B., Cameron, D.M., and Roberts, N.L. "The Sub-acute Toxicity (LC_{50}) of PP557 (Permethrin) to Pheasants" Huntingdon Research Center, Report No. ICI 68/WL/75839 (Jan. 1976)

VALIDATION CATEGORY: Core

RESULTS: LC_{50} > 23,000 ppm permethrin.

Toxicant in diet	Treatment levels	Mortality
Control	0	0
Permethrin	2,300 to 23,000 ppm*	0
Dieldrin	25 to 125 ppm	100% at 100 and 125 ppm levels

*At the 23,000 ppm concentration, pheasants would ingest daily approximately 4,830 mg/kg.

VALIDATION CATEGORY/RATIONALE: The study generally adheres to EPA guidelines.

CATEGORY REPAIRABILITY/RATIONALE: NA

FORMULATION:	IA	IB	T	FW	EC	R		
% a.i. SC# CHEMICAL NAME FP Permethrin (24% Emulsifiable Concentrate PP557	Validator: R. Balcomb			Date: Nov. 15, 197				
	Test Type: Acute Toxicity of PP557 (FP) to Rainbow Trout							
	Test ID # ES-J							

CITATION: Hill, R.W. et al. "Determination of the Acute Toxicity of Formulation JFU5054 to Rainbow Trout (Salmo gairdnerii)." ICI No. BL/B/1798 (May, 1977)

VALIDATION CATEGORY: Supplemental

RESULTS: The acute toxicity to Rainbow Trout was determined at 13°C. Nominal concentrations ranging from .028 to 0.28 mg/L were used. The 96-hour LC_{50} (Geometric Mean Survival Period-Technique) was 0.052 mg/L. The registrant later (10-25-77) submitted a recalculation using a Log/probit technique. This method gave a 96-hour LC_{50} of 0.056 mg/l with 95% confidence limits of 0.049-0.064 mg/l. The 0.042 mg/L nominal concentration was found to be the no effect level.

VALIDATION CATEGORY RATIONALE: The study was determined supplemental for the following reasons: (1) The nominal concentrations were used in the calculation of LC_{50} values and these concentrations were not accurate indications of the amount of toxicant present. Measured levels ranged from 4% to 49% of nominal concentration levels. (2) Only one concentration level gave partial mortality results. (3) A linear regression (log/probit) using nominal concentrations indicated that a significant fit could not be obtained (r^2 = .980, + = 6.68, df = 1).

CATEGORY REPAIRABILITY/RATIONALE: The study is not repairable - see #1 above.

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator: R. Balcomb			Date: Nov. 29, 1977				
Technical PP557		Permethrin PP557	Test Type: Acute 96-hr. LC_{50}: Rainbow Trout							
			Test ID # ES-G-1							

CITATION: Hill, R.W. et al. "Determination of the Acute Toxicity of PP557 to Rainbow Trout (Salmo gairdnerii)." BL/B/1700, February, 1976.
Note: Additional data received October 25, 1977.

VALIDATION CATEGORY: Supplemental

RESULTS: LC_{50} = 0.0021 mg/L (96-hr)

The acute toxicity of PP557 to Rainbow Trout was studied at 9 concentrations ranging from 0.1 to 0.001 mg/L of technical PP557. Zero mortality was observed at the 0.001 mg/L level while the next highest level, 0.0022 mg/L, had 100% mortality (96-hr).

VALIDATION CATEGORY/RATIONALE: No partial mortalities were obtained at the concentrations tested (96-hours). LC_{50} values calculated without partial mortality data are unacceptable.

CATEGORY REPAIRABILITY/RATIONALE: The study is not repairable.

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator: R. Balcomb			Date: Nov. 15, 1977				
Technical		Permethrin PP557	Test Type: Acute 96-hr. LC_{50}: Brook trout							
			Test ID # ES-G-2							

CITATION: Hill, R.W. et al. "Determination of the Acute Toxicity of PP557 to Brook Trout." ICI Report No. BL/B/1712 (March, 1977).

VALIDATION CATEGORY: Supplemental

RESULTS: The acute toxicity of PP557 to Brook Trout was studied at 13°C. The 96-hour LC_{50} (Geometric Mean Survival Period-Technique) was determined to be 0.0047 mg/L. The registrant later (10-25-77) submitted a recalculation (log/probit-method) that showed the (96-hr) LC_{50} to be 0.0039 mg/L (.0031-.0048, 95% conf. limits).

VALIDATION CATEGORY RATIONALE: This study was determined Supplemental for the following reasons: (1) Only one concentration level obtained partial mortality results, (2) Nominal concentrations were used in the LC_{50} calculations instead of the measured levels of toxicant.

CATEGORY REPAIRABILITY/RATIONALE: The study is not repairable-see item #1 above.

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator: R. Balcomb			Date: Nov. 15, 1977				
Technical		Permethrin PP557	Test Type: Acute 96-hour LC_{50}: Fathead Minnow							
			Test ID # ES-F-1							

CITATION: Hill, R.W. et al. "Determination of the Acute Toxicity of PP557 to Fathead Minnows (Pimephales promelas)." ICI No. BL/B/1726 (July, 1976).

VALIDATION CATEGORY: Core

RESULTS: The acute toxicity of PP557 to the Fathead Minnow was investigated at nine concentration levels ranging from .0015 to .68 ppm. The LC_{50} was first calculated by a Geometric Mean Survival Period Technique obtaining: 96-hr. LC_{50} = .002 ppm PP557. The registrant submitted a supplement (10-25-77) with the LC_{50} calculated via log/probits. Using this method the 96-hr. LC_{50} was 0.0030 with 95% confidence limits of .0024-.0037 ppm. These values were based on nominal rather than measured concentrations of PP557. This reviewer calculated the LC_{50} via linear regression using the measured concentrations and obtained (96-hr) LC_{50} = 0.003 with 95% confidence limits 0.001-0.009.

The 0.0015 mg/L concentration was found to be the no effect level. At higher concentrations toxic symptoms included jaw spasms, loss of equilibrium and gill inflammation.

VALIDATION CATEGORY RATIONALE: The study generally adheres to guidelines. There is reasonable agreement between the methods used to calculate the LC_{50} values.

CATEGORY REPAIRABILITY/RATIONALE: NA

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator: R. Balcomb			Date: Oct. 11, 1977				
Technical		Permethrin PP557	Test Type: Acute 96-hr. LC_{50} for Mirror Carp							
			Test ID # ES-F-2							

CITATION: Hill, R.W., Maddock, B.G., Hart, B., and Gilbert, J.L. "Determination of the Acute Toxicity of PP557 to Mirror Carp (Cyprinus carpio)." ICI Brixham Laboratory Report No. BL/B/1715 (June, 1976).

VALIDATION CATEGORY: Invalid

RESULTS: A. Statistical Data

The 24, 48 and 96-hour LC_{50} values of PP557 were determined for Mirror Carp in freshwater at 23°C. A continuous flow-through bioassay system was used.

Toxic Levels Determined

24 hr. LC_{50} = 0.098 mg/l
49 hr. LC_{50} = 0.0385 mg/L
96 hr. LC_{50} = 0.015 mg/L

A no effect level was established at 0.0033 mg/L. The ET_{50} and LC_{50} values were determined as previously described (ID # ES-G, ES-F-1).

B. Toxic Symptoms

The toxic symptoms noted in this study were spasmodic movement of the jaw which were uncontrolled and prolonged. A major difference between this study and previous reports on other species of fish was that no spinal curvature was observed in mirror carp.

The first symptoms became apparent in the 0.47 and 0.22 mg/L concentration within 35 minutes and death occurred at these concentrations in 380 and 410 minutes respectively.

Symptoms in the lower concentrations 0.1 mg/L and 0.047 mg/L occurred after about 1 hour exposure but the first deaths did not occur until 1020 and 1590 minutes respectively.

The fish exposed to 0.0068 mg/L of PP557 exhibited toxic symptoms, while in the test vessel and, after transfer to fresh water, symptoms were still apparent.

No toxic symptoms were recorded in the 0.0033 mg/L concentration.

VALIDATION CATEGORY/RATIONALE: This study was determined invalid for the following reasons: (1) Statistically derived best estimate of LC_{50} is not provided, including 95% confidence limits. (2) The ET_{50} values were plotted against the nominal concentrations of PP557 and not the measured concentrations. (3) Concentrations of toxicant in each treatment level is not 60% of the next higher one. In two instances, using measured concentrations, levels are approximately 1/3 of next higher level ($\frac{.2200}{.80}$, $\frac{.0244}{.0078}$).

CATEGORY REPAIRABILITY/RATIONALE: Not repairable. See item #3 in Validation Category/Rationale.

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator: R. Balcomb			Date: Nov. 29, 1977				
? Technical		Permethrin PP557	Test Type: Acute 96-hr. LC_{50}: Bluegill Sunfish							
			Test ID # ES-F-3							

CITATION: Hill, R.W. et al. "Determination of the Acute Toxicity of PP557 to Bluegill Sunfish (Lepomis macrochirus) BL/B/1701, January, 1976.

VALIDATION CATEGORY: Supplemental

RESULTS: 96-hr. LC_{50} = 0.00079 mg/L

The toxicity of PP557 to Sunfish was studied at 13 concentrations ranging from 0.68 to 0.00068 mg/L of technical material. After 96 hours, 0% mortality was observed at the 0.00068 level and 100% mortality at the next higher level (0.001 mg/L).

VALIDATION CATEGORY RATIONALE: No partial mortalities were obtained at the concentrations tested (96 hours). LC_{50} values calculated without partial mortality data are unacceptable.

CATEGORY REPAIRABILITY/RATIONALE: The study is not repairable.

FORMULATION:	IA	IB	T	FW	EC	R		
% a.i. SC# CHEMICAL NAME JFU 5054 Permethrin (24% emulsifiable concentrate PP557 of PP557)	Validator: R. Balcomb			Date: Oct. 18, 1977				
	Test Type: Acute 96 hr. LC_{50} to Bluegill sunfish							
	Test ID # ES-I							

CITATION: Hill, R.W., Maddock, B.G., Hart, B., and Cornish, S.K. "Determination of the Acute Toxicity of Formulation JFU 5054 to Bluegill Sunfish." ICI Brixham Laboratory Report No. BL/B/1799, May, 1977.

VALIDATION CATEGORY: Supplemental

RESULTS: A. Statistical Data

The acute toxicity of formulation JFU 5054 to the Bluegill sunfish (Leponis macrochirus) was determined at 23°C in freshwater. The following levels were determined:

24 hr. LC_{50} = 0.021 mg/L as JFU 5054
48 hr. LC_{50} = 0.015 mg/L
96 hr. LC_{50} = 0.0108 mg/L

During the 96 hour test period there were no deaths in the four lowest concentrations tested: 0.01, 0.0068, 0.0047, 0.0033 mg/L. No toxic symptoms were observed at, or below, 0.0047 mg/L of JFU 5054 and this was designated the "no effect" level.

The LC_{50} values were determined by direct reading of the geometric mean survival period (GMSP)-toxicant concentration graph. The GMSP was calculated with the formula:

$$GMSP = \exp.\left\{ \sum_{i=1}^{N} N_i \sqrt{(\log_e t_1)^{N_1} \cdot (\log_e t_2)^{N_2} \ldots (\log_e t_N)^{N_N}} \right.$$

where Ni is the number of fish which died at time ti and $\sum_{i=1}^{N} N_i$ is total number of fish used.

The toxicant concentrations in the above analysis were nominal values and not measured concentrations. The measured concentrations were 50 to 82% of the nominal values with the exception of the 0.047 mg/L concentration where the measured level was 126% of the nominal (0.595 mg/L). The experimenters attribute discrepancies to difficulties of extracting an emulsion and to adsorption.

B. Toxic Symptoms

At the highest concentration level (.047 mg/L) hyperactivity began after five minutes with jaw spasms and hyperactivity becoming severe at 20 minutes elapse time. After 75 minutes the fish darkened in color and the first death was at 90 minutes. At the .033 mg/L and .022 mg/L levels similar observations were made, however, deaths were not recorded under 450 and 735 minutes respectively.

At the 0.0068 mg/L concentration of toxicant, symptoms were observed after 1,440 minutes but no deaths were recorded. No symptoms were observed at the two lowest levels: 0.0047 and 0.003 mg/L.

VALIDATION CATEGORY/RATIONALE: This study was determined supplemental for the following reasons: (1) LC_{50} values are not statistically derived test estimates with 95% confidence limits (also see review of this statistical procedure by N. Cook, 10182-EUP-7, ID # (es) (103.0) (E2) 8/1/77).

(2) Nominal values for the concentration of intoxicant were used in the presented statistical analysis in favor of the available measured values. The measured values would produce lower LC_{50} values. Furthermore, there is so much variability in the measured concentrations at the 0.0068 and 0.010 mg/L nominal concentration levels that it is statistically impossible to distinguish between the means of these values:

Nominal Concentrations	Number Measured Values	$\bar{x}$ conc.	SD	t-test Value
0.0068	5	0.0056	0.0021	+(.05)[8]=2.305
				0.459
0.0010	5	0.0062	0.0024	+(.5)[8]=0.706

Given this kind of experimental variability the accuracy of any derived LC_{50} values is questionable.

CATEGORY REPAIRABILITY/RATIONALE: Not repairable. See item #2 in Validation Category/Rationale.

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator: R. Balcomb			Date: Oct. 13, 1977				
Technical (89.11% a.i.)		Permethrin PP557	Test Type: 96 hr. Acute LC_{50}: Crayfish							
			Test ID # ES-H							

CITATION: Bentley, R.E. "Acute Toxicity of PP557 to Crayfish (Procambarus blandingi)." EG & G Bionomics Report (June, 1977).

VALIDATION CATEGORY: Supplemental

RESULTS: The acute 96-hour LC_{50} of PP557 to Crayfish was determined to be 0.21 mg/L (0.13-0.33). A flow-through method was used, at 22°C, with 20 crayfish in each test vessel.

It was noted by the experimenter that crayfish exposed to all concentrations of PP557 showed extremely aggressive behavior while control organisms were docile through the study.

This reviewer confirmed the above LC_{50} via probit analysis obtaining: LC_{50} = 0.22 mg/L (0.18-0.25).

VALIDATION CATEGORY/RATIONALE: This study was determined supplemental because the concentrations of toxicant were not measured during the testing. Such testing is required in flow-through tests.

CATEGORY REPAIRABILITY/RATIONALE: Not repairable unless toxicant measurements are available and LC_{50} values can be recalculated based on these known concentrations.

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator: R. Balcomb			Date: Oct. 21, 1977				
Technical 89% a.i.		Permethrin PP557	Test Type: Acute 96-hr. LC_{50} for Fiddler Crabs and Brown Shrimp (Static)							
			Test ID # ES-L, N							

CITATION: Heitmuller, T. "Acute Toxicity of PP557 to Brown Shrimp (Penaeus aztecus) and Fiddler Crabs (Uca pugilator)." E.G.&G. Bionomics Report (May, 1977).

VALIDATION CATEGORY: A. Brown Shrimp Data: Core
B. Fiddler Crab Data: Supplementary

RESULTS:

A. Brown Shrimp

The calculated 96-hour LC_{50} for brown shrimp exposed to static, unaerated seawater was 0.34 ppb with 95% confidence limits of 0.23-0.51 ppb.

Nominal Concentration:	Control*	.09 ppb	0.16 ppb	0.29 ppb	0.50 ppb	0.89 ppb
24 hr. % mortality	0	0	0	10	10	100
48 hr. % mortality	0	0	0	20	50	100
96 hr. % mortality	0	0	0	50	80	100

* 10 shrimp per treatment level

The 48-hour LC_{50} was 0.38 ppb (0.26-0.57) and the 24-hour LC_{50} was estimated only as $0.50 < x < 0.89$. These results were confirmed by this reviewer via probit analysis:

96 hr. LC_{50} = .34 ppb (.26-.48)

B. Fiddler Crabs (Uca pugilator)

The calculated 96-hour LC_{50} for Fiddler Crabs tested in static, unaerated seawater was 2.2 ppb with 95% confidence limits of 1.4 to 3.5 ppb.

(10 Crabs per treatment level)

Nominal Concentration: (ppb)	Control	0.5	0.89	1.6	2.9	5.0	8.9
24 hr. % mortality	0	0	0	10	40	50	60
48 hr. % mortality	0	0	0	20	50	50	100
96 hr. % mortality	0	0	10	40	50	60	100

The 24-hour LC_{50} was 5.3 (2.0-13.) and the 48-hour LC_{50} was 2.8 (1.9-4.4). The 96-hour LC_{50} was confirmed by this reviewer via probit analysis:

LC_{50} (96-hr.) = 2.65 ppb (1.68-4.16)

Reference

Stephan, Charles E. "Methods for Acute Toxicity Tests with Fish, Macroinvertebrates, and Amphibians," EPA-660/3-75-009, (1975).

VALIDATION CATEGORY/RATIONALE: The brown shrimp study is deemed core as methods adhere to guidelines and results were verified by probit analysis. The fiddler crab study is deemed supplementary as methods generally adhere to guidelines, results were verified by probit analysis, however, test species is not a recommended species (Stephan, 1975).

CATEGORY REPAIRABILITY/RATIONALE: A. Not applicable.
B. Not repairable.

VALIDATION SHEET CRF# _____ PAGE ___ OF ___

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator:			Date:				
Technical (98.7% a.i.) and 25% Emulsifiable Concentrate JF 5855		Permethrin PP557	R. Balcomb			Oct. 26, 1977				
			Test Type: Acute Toxicity and Reproduction Studies of Daphnia magna							
			Test ID # ES-K							

CITATION: Doma, S. and Evered, P. "PP557: Acute Toxicity and Reproduction Studies on First Instar and Ephippia of Daphnia magna." ICI Plan Protection Division Report No. TMJ1455B (Jan. 1977).

VALIDATION CATEGORY: I. Acute toxicity to first instar Daphnia magna: Core
II. Acute toxicity to Daphnia ephippia: Supplemental

RESULTS: Summary

I. The EC_{50} of Permethrin to first instar Daphnia magna was determined:

	Technical	25% Concentrate
24 hr. EC_{50}	2.1 ppb a.i.	~~1.8~~ ~~0.6~~ ppb a.i. } one of these pairs
48 hr. EC_{50}	~~1.8~~ 0.6 ppb a.i.	~~0.8~~ 0.8 ppb a.i. }

II. 48-hour EC_{50} of Permethrin to the ephippia of Daphnia magna

a. Ephippia dried prior to exposure to Permethrin: 0.034 mg/L
b. Ephippia dried after exposure to Permethrin: 0.108 mg/L

VALIDATION CATEGORY/RATIONALE:

I. The study of the acute toxicity of Permethrin to Daphnia magna was determined core as it generally adhered to guidelines and statistical methods were appropriate and accurate.

II. The study of the toxicity of Permethrin to Daphnia ephippia was deemed supplemental information as such testing is not required nor was it requested. In addition, this report cannot qualify as a reproduction or life-cycle study as there was not continuous exposure of the organisms to the pesticide.

CATEGORY REPAIRABILITY/RATIONALE:

Part I: NA

Part II: NA

Details and Discussion

I. Acute Toxicity of Permethrin to Daphnia magna

The acute toxicity of Permethrin (PP557) to first instar Daphnia magna was determined. The Daphnia were 12 hours old (± 12 hr.) and were tested at concentrations ranging from 100 mg/L a.i. down to 0.01 ug/L a.i. plus controls. The Daphnia were held at 18°C (± 1°), were not aerated or fed during the experiment and were allotted ten organisms per beaker. At each concentration level, three test groups were formed with each group containing six beakers of Daphnia (Ref. 1). Survival assessments were made after 24 and 48 hours. This determination was made by gently agitating each beaker and recording the number not free swimming after 5 seconds as affected.

The EC_{50} values and their 95% confidence limits were calculated statistically using linear regression on log concentration plotted against a logit transformation of the Daphnia reponse.

		EC_{50} ppb a.i.	95% Conf. Limits
Technical	24 hour	2.06	1.65-2.58
	48 hour	0.6	0.53-0.67
Formulated	24 hour	1.82	1.54-2.15
	48 hour	0.76	0.66-0.88

These data were recomputed by this reviewer and a 48 EC_{50} value of 0.58 ug/L was determined for the technical material and 0.65 ug/L for the formulated product. These values approximate those of the experimenters.

II. Acute Toxicity and Reproduction Studies on Ephippia

Ephippia are the resting eggs of Daphnia. The toxicity of PP557 to this life cycle stage of Daphnia was investigated by exposing the ephippia to concentrations of technical PP557 ranging from 0.001 mg/L to 100 mg/l plus controls for 48 hours. After exposure, the ephippia were rinsed and stored in dechlorinated tap water (20°C) until hatching 4-5 days later.

The ephippia were stimulated to an early hatch in the laboratory by drying them for 24 hours. This condition was incorporated into the experimental design by having two test series. In test series A the ephippia were exposed to PP557 after drying and in test series B ephippia were exposed to PP557 before drying.

In both tests the EC_{50} value was statistically calculated from the number of free swimming first instar Daphnia hatched in the treatment and control groups. The log/logit transformations were used as before.

	EC_{50} ppm	95% Confidence Limit
Test A:	0.034	0.022-0.047
Test B:	0.108	0.035-0.339

The experimenter did not supply a percent affected for each treatment level. When the reviewer calculated these data from the Table 6 and then computed an EC_{50} value, the result obtained was at slight variance with that presented in the paper (i.e., for test A: 0.034 ppm vs. 0.056 ppm (.045 - 0.069 ppm)).

In both cases, with the technical and formulated product, a marked reduction in survival of hatched ephippia occurred: for the technical at 0.1 ppm 85% of the hatched ephippia died, and for the formulated product at 1 ppm the % of hatched ephippia was reduced. The study on formulated product was conducted using ephippia that were exposed to FMC 33297 without being preconditioned by drying. This indicates that under most normal conditions, free swimming Daphnia could be killed before producing ephippia, and any ephippia produced may be killed.

A third portion of this study was conducted comparing toxicity of PP557 (FMC 33297) in a static bioassay and in a bioassay in the presence of soil. The soil type (pear tree soil) had a pH 7. (Chemical 25% a.i.)

Test Soil pH 7	EC_{50} = 1.1 ppb (.84-1.45 ppb) 95% C.L.
Test Standard Water	EC_{50} = .45 ppb (.35-.61 ppb) 95% C.L.

The researcher concludes from these studies that FMC 33297 will kill most free swimming Daphnia, but ephippia will be unharmed at normal application rates, will hatch and reproduce thus re-establishing the colony.

Reviewer Comment

This section takes exception to the researcher's second conclusion. This study has demonstrated that after exposure for 48 hrs., at normal application rates, Daphnia may re-establish their numbers from surviving ephippia. Under field conditions, however, we may well expect exposure to continue for weeks or months. It is impossible, we believe, to make such field predictions from short laboratory exposures. Secondly, the ephippia were hatching into untreated water, whereas under field conditions they may not have this advantage. It is our opinion, therefore, that parmethrin poses a strong threat to Daphnia in treated areas and that the ephippia stage does not offer sufficient protection to offset this threat.

Reference

Doma, S. and Evered, P., ICI Report No. TIJ 10454. Daphnia magna: Determination of Acute Toxicity of Pesticides. (1976)

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FORMULATION:			IA	IB	T	FW	EC	R		•
% a.i.	SC#	CHEMICAL NAME	Validator: R. Balcomb			Date: Oct. 19, 1977				
25% a.i. Formulation		Permethrin PP557	Test Type: 48 hr. LC_{50} to First Instar Daphnia (FP)							
			Test ID # ES-K							

CITATION: Everd, P. and Doma, S. "PP557 Acute Toxicity of Emulsifiable concentrate JFU5054 to First Instar Daphnia Magna" ICI Plant Protection Division Report No. TMJ 1504 B (June, 1977).

VALIDATION CATEGORY: Core

RESULTS: The EC_{50} values reported were: 24 hr. EC_{50} = 1.93 mg/L (1.76-2.12) and 48 hr. EC_{50} = 1.31 mg/L (1.17-1.48). These results were calculated using linear regression on log concentration plotted against a logit transformation of the Daphnia response.

The 24 hr. EC_{50} value was validated by this reviewer using probit analysis: 1.91 ~~u~~g/L (1.76-2.12). A 48 hr. EC_{50} value was estimated by the reviewer via probit analysis as 1.13 ~~u~~g/L but excess 0 and 100% effect values prevented accurate or complete analysis. Therefore, the 48 hr. data were also checked by regression analysis and an EC_{50} value of 1.000 ~~u~~g/L was obtained (Chi-square = 0.0015).

VALIDATION CATEGORY/RATIONALE: This study was determined core as guidelines were adhered to and statistical methods were appropriate and accurate.

CATEGORY REPAIRABILITY/RATIONALE: NA

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FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator: R. Balcomb			Date: Oct. 19, 1977				
NA		NA	Test Type: NA							
			Test ID # ES-GG							

CITATION: Doma, S. and Evered, P. "Daphnia Magna: Determination of Acute Toxicity of Pesticides" ICI Plant Protection Division Report No. TMJ 1405A (October, 1976).

VALIDATION CATEGORY: Supplementary

RESULTS: A methodology for acute toxicity tests to Daphnia is described. Protocol follows EPA suggested methods (Stephans, 1975, EPA-660/3-75-009) with some modifications.

VALIDATION CATEGORY/RATIONALE: NA

CATEGORY REPAIRABILITY/RATIONALE: NA

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator: R. Balcomb			Date: Oct. 17, 1977				
Technical		Ambush (TM) Permethrin (PP557)	Test Type: Acute (96-hr) LC_{50} for Pacific Oyster and Acute 48-hr. developmental bioassay with oyster larvae							
			Test ID # ES-GG							

CITATION: Thompson, R.S., Hill, R.W., and Cornish, S.K. Investigation of the Acute Toxicity of PP557 to the Pacific Oyster (Crassostrea gigas) ICI Brixham Laboratory Report No. BL/B/1796 (May, 1977).

VALIDATION CATEGORY: Supplemental

RESULTS:

A. 96-Hour LC_{50} for Juvenile Pacific Oysters

Technical grade permethrin (dissolved in dimethyl sulphoxide) was tested for its 96-hour LC_{50} to Pacific oysters. A continuous flow-through bioassay system was used with unfiltered seawater at 17°C. The test concentrations used in the study were:

Series I: (48 mg/L Solvent) Control, 0.1, 0.22, 0.48 mg/L PP557
Series II: (480 mg/L Solvent) Control, 1.0, 2.2, 4.8 mg/L PP557

After 24 and 48 hours each oyster was examined for its ability to perform active shell closure movements, if necessary by gently touching the shell with a glass rod. After 96 hours the oysters were removed from the test solutions and portions of gill tissue were excised and examined for presence or absence of gill ciliary activity which was used as the final criterion of acute lethal toxicity.

There were no mortalities of PP557 at any of the concentrations tested after 96 hours. The highest concentration tested, 4.8 mg/L PP557, was considered the no-effect level.

The LC_{50} was not calculated as the highest level tested was non-lethal.

B. Acute developmental bioassay with oyster larvae

Pacific oyster larvae were obtained and examined for normal 48-hour development following the procedure of Woelke (1967). The static test chambers maintained filtered seawater at 20°C. The test concentrations used were as follows: Control, solvent-control (480 mg/L), 0.48, 1.0, 2.2, 4.8 mg/L PP557. Duplicates were run on each test concentration.

There was no significant reduction in the percentage of normally developed larvae at any of the concentrations tested compared to the control or solvent-control groups:

Larvae Development

Concentration PP557 mg/L	Control	Solvent Control	0.48	1.0	2.2	4.8
Mean % Normal Development	97.5	97.9	97.1	98.0	97.1	97.5

The highest concentration of PP557 tested, 4.8 mg/L was considered the no-effect level.

1 C.E. Woelke, "Measurement of Water Quality with the Pacific Oyster Embryo Bioassay," Water Quality Criteria, ASTM STP 4/6, Am. Soc. Testing Mats, 1967, p. 112.

VALIDATION CATEGORY/RATIONALE: This study was determined supplemental as sufficient concentrations of PP557 were not used to adequately assess mortality. The level of toxicity should have been found (unless > 100 ppm) and a logarithmic series of concentrations determined for intensive testing.

CATEGORY REPAIRABILITY/RATIONALE: Not repairable. See above.

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator: R. Balcomb			Date: Oct. 8, 1977				
25% EC Formulation JF5855		Permethrin PP557	Test Type: Snail 48-hour acute toxicity and reproduction study							
			Test ID # ES-K							

CITATION: Doma, S. "Acute Toxicity and Reproduction Studies on the Large Pond Snail (Limnea Stagnalis)" ICI Plant Protection Division Report No. TMJ1395B, Oct., 1976.

VALIDATION CATEGORY: Supplementary

RESULTS:

A. Acute Toxicity

The 48-Hour acute toxicity of a 25% formulation of PP557 to the Large Pond Snail at 21°-22°C in reconstituted Freshwater was studied. Three replicates of ten snails each were run at nine toxicant levels from 200 mg/L to 0.001 mg/L PP557 plus controls. The highest concentrations (200 and 100 mg/L) produced 100% mortality in 48-hours. Dead snails were found floating on the surface of the test solutions with body pulled back into the shell. Prior to death intense mucor excretion was noticed floating around the animals.

None of the concentrations from 10 to 0.001 mg/L PP557 produced any appreciable harmful effects on the snails.

B. Reproductive Study

The test vessels for the concentration levels 10 to 0.001 mg/L, from the acute toxicity study, were decanted after 48-hours and refilled with de-chlorinated tap water. These snails were then kept for a week in a controlled environment room (21-22°C) and then transferred to a greenhouse for the 4 weeks of the reproductive study. The greenhouse temperature ranged from 22°-27°C and the snails were fed chinese cabbage every third day. The number and fertility of the egg clutches was measured at the end of the 4-week study, results were as follows:

Concentration PP557 mg/L	*Number snails alive after 36 days	*Number egg clutches	% egg clutches fertile	Average Number egg clutches per individual
200	0	-	-	-
100	0	-	-	-
10	17	64	53	4
3	25	93	77	4
1	21	69	59	3
0.3	14	75	57	5
0.1	21	87	51	4
0.01	11	40	52	4
0.001	20	79	77	4
Control	20	69	59	4

*Data are means of three replicates.

The 36 day survival rate for all groups (excluding 100 and 200 mg/L levels) receiving PP557 was judged the same as for controls.

C. Egg Toxicity (stock cultures)

A further egg toxicity study was conducted using 3 day old egg capsules from stock cultures. Eggs were examined microscopically for larval movement and only viable eggs were selected. In this study 10 egg clutches with fertilized eggs were exposed to PP557 as follows:

Concentration PP557 mg/L	200	100	10	3	1	0.1	0.01	0.001	Control
Numbers of egg clutches which developed normally	10	10	10	10	10	10	10	10	10

Assessment of above normality was done after the 16 days embryonal development span when the young snails left their egg capsules. The high survival rate indicates a lack of permeability of PP557 and/or formulation additives through the egg capsule.

D. Toxicity of Formulation Blank

The toxicity of a formulation blank (JF5855 containing no PP557) to large-pond snails was set up as follows:

Con. of Formulation Blank (mg/L)	Number of Snails Survived		
	Rep. 1	Rep. 2	Rep. 3
200	0	0	0
100	0	0	0
10	10	10	10
Control	10	10	10

The snails were exposed to toxicant for 48-hours and survival assessment was determined 4 days after the exposure. Formulation blank was 100% lethal at 100 and 200 mg/L levels. Experimenters state that 100 mg/L of formulation is equivalent to about 25 mg/L of PP557.

VALIDATION CATEGORY/RATIONALE: This study was determined supplementary due to the use of an unrecommended organism.

CATEGORY REPAIRABILITY/RATIONALE: Not repairable, see above.

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator:			Date:				
Technical 92.4%		Permethrin PP557	R. Balcomb			Nov. 16, 1977				
			Test Type: One generation Reproduction Study: Bobwhite Quail							
			Test ID # ES-V							

CITATION: Fink, R. "One generation Reproduction Study - Bobwhite Quail" Wildlife International Ltd. No. 123-112, Dec., 1976.

VALIDATION CATEGORY: ~~Supplemental~~ Core

RESULTS: PP557 was fed to mature Bobwhite Quail at dietary concentrations of 5 ppm and 25 ppm throughout a one generation study. No effect on the overall reproductive success of the birds was observed. Egg production, shell thickness, shell cracks, embryo viability, chick survival, body weight and food consumption were analyzed. No significant differences between control and test groups were found.

VALIDATION CATEGORY RATIONALE: The test procedure generally follows EPA guidelines. ~~However, insufficient data are presented to verify statistical tests.~~ RS

CATEGORY REPAIRABILITY/RATIONALE: ~~Study may be repaired by submission of more complete statistical data. For example, the following data should be supplied with ANOVA F-test: Σx, $\bar{x}$, SS, MS, Df, F, Standard Deviations within groups (Sx).~~ RS N.A.

Note: See review of this study by T. O'Brien on EMC product 33297 for more complete abstraction of data.

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator: R. Balcomb			Date: Nov. 16, 1977				
Technical 92.4%		Permethrin PP557	Test Type: One generation Reproduction Study - Mallard							
			Test ID # ES-W							

CITATION: Fink, R. "One Generation Reproduction Study - Mallard, PP557," Wildlife International Ltd., No. 123-113.

VALIDATION CATEGORY: ~~Supplemental~~ Core

RESULTS: PP557 was fed to mature Mallard ducks at dietary concentrations of 5 ppm and 25 ppm throughout a one generation study. Egg production, shell thickness, shell cracks, embryo viability, chick survival, body weight and food consumption were analyzed. No significant differences between control and test groups were reported.

VALIDATION CATEGORY RATIONALE: The test procedure generally follows EPA guidelines. ~~However, insufficient data are presented to verify statistical tests.~~ RB

CATEGORY REPAIRABILITY/RATIONALE: ~~Study may be repaired by submission of more complete statistical data. For example, the following data should be presented with an ANOVA F-test: Σx, $\bar{x}$, SS, MS, F, DF and Standard Deviation within groups.~~ N.A

Note: See review of FMC 33297 by T. O'Brien for more complete abstraction of these data.

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC#	CHEMICAL NAME	Validator: R. Balcomb			Date: Oct. 20, 1977				
.2 lb a.i./acre		Permethrin PP557	Test Type: Field Study: Aquatic Ecosystem Adjacent to a cotton field.							
			Test ID # ES-BB							

CITATION: Anon. "The Application of Two Permethrin Formulations on a Cotton Field Adjacent to an Aquatic Ecosystem." Union Carbide Environmental Services Report (Feb. 1977).

VALIDATION CATEGORY: Supplementary

RESULTS: Aquatic Ecosystem Study - Summary

1. There were no fish kills as a result of applications.

2. There were no mussel or crayfish mortalities due to applications.

3. Observed changes in zooplankton community were attributed to normal population fluctuations.

4. Extensive aquatic insect mortality attributed to was observed and attributed to permethrin applications.

VALIDATION CATEGORY/RATIONALE: This study is deemed supplementary for the following reasons: (1) Permethrin is intended as an aerial - and ground - applied spray, however, only ground application was used in this study.

(2) The introduction to the study indicates that fish, crayfish, mussels, water and sediment from the pond and soil from the cotton field were collected for residue analysis. Nowhere in the study are these data presented.

(3) The water level in the pond was maintained by pumped well water suggesting the possibility that runoff effects were reduced through dilution.

(4) Control pond data were not collected for zooplankton.

CATEGORY REPAIRABILITY/RATIONALE: Not repairable. See validation category/ rationale item #1.

Additional Data and Observations

The Application of Two Permethrin Formulations On A Cotton Field Adjacent To An Aquatic Ecosystem

A 5-acre cotton field adjacent to a 3-acre farm pond was treated with two formulations of permethrin: Pounce (TM) - FMC Corp. and Ambush (TM) - ICI United States, Inc. The two formulations were alternately applied, approximately every 5 days, for a total of 17 applications. Both formulations were applied at a rate of 0.2 lb a.i./acre. Application was made by tractor mounted sprayer covering 5 rows of cotton per pass.

Site

The five acre, approximately, rectangular cotton field is located 60 miles north of Beaumont, Texas. The field is separated from other crops by a drainage canal and an elevated dirt road. The test pond bordered one end of the cotton field, it was three acres in surface area and had a maximum depth of 3 feet. To facilitate drainage to the pond, the cotton rows were planted in rows perpendicular to the pond. The pond's water level was maintained during dry periods by well water.

Sampling

Fish, crayfish, mussels, zooplankton and macroinvertebrate populations were monitored prior to the initial treatment and bimonthly thereafter for 5 months. Samples of fish, crayfish, mussels, water and sediment from the pond and soil from the cotton field were collected for residue analysis.

Zooplankton

The zooplankton were sampled at ten stations in the pond. Fluctuations and blooms occurred among the rotifer, copepod and cladoceran populations but were determined to be that which would be expected in the summer-fall succession of a small pond.

REVIEWER COMMENT

Following an early October rainfall, contaminated runoff apparently caused considerable mortality among macroinvertebrates (see following section). Concurrently, the Oct. 7 zooplankton counts showed a 79% decrease in rotifers, a 36% decrease in copepods and a 24% increase in cladocerans. Given the known natural fluctuations in zooplankton numbers and the lack of control pond information, no definitive conclusions concerning zooplankton can be reached from this study.

Macroinvertebrates

Observational and quantitative data showed that the pesticide applications had detrimental effects on the macroinvertebrate populations. For the first two months of the study, many organisms living on or near the surface of the water were observed. These included the Gyrinidae (whirlygig beetles), Gerridae (water striders), and Vellidae (smaller water striders). On Oct. 7, approximately one week after 0.76 inches of rain fell on freshly treated cotton, none of these insects were to be found anywhere on the pond. It is significant that other ponds in the area that were not near permethrin treated fields did not show reductions in these insects. Approximately one month later these macroinvertebrates were still absent from the test pond. By the end of November small numbers of these insects were observed in the peripheral region of the test pond away from the cotton field. At the end of the study, Dec. 16, these organisms had not re-established their numbers.

Quantitative sampling revealed that other insect populations declined following the critical (≃ Oct. 1) rainfall. These included the Ephemeroptera (mayflies), Coenagrionidae (damsel flies), Libellulidae (dragon flies) and possibly the Palaemonidae and Belostomatidae. Inspection of other ponds in the region, not subject to permethrin contaminated runoff, did not show population declines among these organisms. The mayflies were the most severely affected group. At station 7 over 20 mayflies were collected on Aug. 26, Sept. 9 and Sept. 21. For the remaining eight samples, a total of only eight organisms were found at this station.

Fish, Mussels, and Crayfish

No mortalities attributable to the pesticide applications were reported.

Pesticide Residue Analysis

Data not presented.

104.0 Hazard Assessment

104.1 Dicsussion

This submission is a repeat application for an extension of an EUP. The original application for the extension was reviewed by R. Felthousen, 1/7/77. Due to the extreme toxicity of this compound to aquatic organisms and the probability of its eventual widespread use, the Environmental Safety Staff rejected the extension until the results of chronic fish and chronic avian studies were received. In addition, the registrant had failed to submit required quarterly reports of field observations noting adverse effects on non-target organisms.

In the present application, the appropriate chronic avian studies have been received; however, neither the field observations nor the chronic fish studies were included.

104.1.1 Adequacy of Toxicity Data

See attached validation sheets.

104.1.2 Additional Data Required

See conclusions

~~Before the EUP can be approved, a valid chronic fish study and field observations noting effects on non-target organisms must be received.~~ Note: these data have been received 2/16/78 K.B.

104.3 Likelihood of Exposure to Non-Target Organisms

Permethrin has been shown to be relatively non-toxic to birds and mammals and poses negligible hazard to these organisms at the proposed rates of application. Studies with aquatic animals, fish and invertebrates reveal that permethrin is extremely toxic to these organisms. Furthermore, given the anticipated widespread use of this product and the recommended multiple applications per season there exists a strong possibility of lethal exposure to aquatic organisms.

The field application study (ID # ES-BB) submitted in this report indicates that permethrin applications to cotton fields adjacent to ponds and streams are likely to cause extreme reductions in the numbers of macroinvertebrates such as waterstriders, mayflies, damselflies, and dragonflies. As these macroinvertebrates are important in the diets of many freshwater fish, the potential exists for permethrin applications to have a negative impact on fish populations by reducing food supply as well as through direct toxic exposure.

It was concluded in a submitted Daphnia toxicity test (PP557: Acute toxicity and reproduction studies on first instar and ephippia of Daphnia magna - Jan. 1977) that "contamination of water with normal application rates of PP557 (0.1-0.2 kg/ha) will kill most free swimming Daphnia. However, Daphnia ephippia will be unharmed and will hatch and reproduce normally, thus re-establishing the Daphnia colony." The Environmental Safety Section does not believe survival of ephippia can be predicted from the submitted tests as the ephippia were treated for only 48 hours whereas under field conditions toxicant exposure could last weeks or months. Furthermore, the ephippia were allowed to hatch into untreated water while natural populations may suffer toxicant exposure at this time also, thus much reducing their ability to re-establish the Daphnia colony.

104.1.4 Endangered Species

Given the high toxicity of this pesticide to fish and aqutic organisms, widespread use of this product may present a hazard to the following endangered fish:

1. Alabama: ~~(Birmingham area only)~~
   ~~Watercress Darter (Etheostoma nuchale)~~
   (a) Slackwater Darter (b) Alabama Cave Fish
2. Arizona:
   ~~Humpback Chub (Colinus virginianus ridgway)~~
   ~~Colorado River Squawfish (Ptychocheilus lucius~~)
   Gila Topminnow (Poeciliopsis occidentalis)
   ~~Arizona Trout (Salmo apache)~~
   ~~Woundfin (Plagoptorus argentissimus~~)

~~3. California:~~
   ~~Mohave Chub (Gila mohavensis)~~
   ~~Owens River Pupfish (Cyprinodon radiosus~~)
   ~~Tecopa Pupfish (Cyprinodon nevadensis calidae~~)
   ~~Unarmored threespine stickleFish (Gasterosterus aculeatus williamsoni)~~

~~4. New Mexico:~~
   ~~Gila Trout (Salmo Gilae)~~
   ~~Colorado River Squawfish (Ptchocheilus lucius~~)

~~5. Tennessee:~~
   ~~Snail Darter (Percina tanasi)~~

3. Nevada
   Pahrump Killifish
4. Oklahoma
   Leopard Darter
5. Georgia, South Carolina
   Shortnose Sturgeon

6. Mississippi
Bayou Darter

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7. Texas
~~Fountain Darter (Etheostoma fonticola)~~
Comanche Springs Pupfish (Cyprinodon elegans)
~~Clear Springs Gambusia (Gambusia heterochir)~~
Pecos Gambusia

105.0 Conclusions

The Environmental Safety Section ~~objects to~~ concurs with the extension of 10182-EUP-3, ~~until the information requested in section 104.2 has been received and reviewed.~~

~~Furthermore~~ However, due to the known toxicity of permethrin to aquatic organisms, the Environmental Safety Staff requires that the registrant contact the state agency responsible for fish and wildlife in each of the states included in the EUP to determine if endangered aquatic organisms are located in the immediate watershed of the application sites. Permethrin may not be applied in areas where runoff or drift may contaminate the habitat of endangered aquatic organisms.

Prior to consideration of registration of the proposed use, the following tests are required:

1. An aquatic microinvertebrate life-cycle study (Daphnia sp., preferably).

2. An acute and a life-cycle study using macroinvertebrates indigenous to the cotton growing region, e.g., mayflies, stoneflies, etc. This information is ncessary in view of the aquatic insect kills reported in the field application study (ID # ES-BB, 10.29/77).

The registrant should contact the Environmental Safety Section if any questions arise concerning the intent or scope of the research required.

The following observations were made of the data submitted to support the EUP:

1. The Japanese Quail LD_{50} study (No. ICI 68 WL/77207) is considered supplemental data and cannot be used to support registration. This organism is not indigenous to North America.

2. The Starling LD_{50} study (Report No. 68 WL/76499) is considered supplemental data and cannot be used to support registration. This organism is not indigenous to North America.

3. The Rainbow Trout acute toxicity study (BL/B/1798) is considered supplemental and cannot be used to support registration for the following reasons: (1) only one concentration level gave partial mortality results, (2) nominal rather than measured concentrations were used in LC_{50} calculations.

4. The Brooktrout acute toxicity study (BL/B/1712) is considered supplemental for the following reason: (1) nominal rather than measured concentrations were used in LC_{50} calculations, (2) only one concentration level gave partial mortality results.

5. The Bluegill Sunfish (BL/B/1799) and Mirror Carp (BL/L/1715) studies were considered unacceptable for the following reasons: (1) a novel method for the calculation of LC_{50} values was employed without supportive journal or textbook references documenting its validity, (2) LC_{50} values did not have 95% confidence limits, (3) nominal concentrations were used in the calculation of LC_{50} values.

6. The Mallard Duck and Bobwhite reproduction studies are acceptable and can be used to support registration.

7. The LC_{50} study for crayfish (E.C. & G Bionomics Report) is considered unacceptable and the data cannot be used to support registration. The levels of toxicant were not measured during the test.

8. The acute toxicity test for first instar Daphnia (No. TMJ1455B) is considered an acceptable study and can be used to support registration. The accompanying Daphnia ephippia toxicity test was judged suplemental information - such testing is not required nor was it requested. It should be noted that these tests together do not constitute a daphnia life-cycle study.

9. The acute toxicity data concerning the Large Pond Snail (No. TMJ1395B) is considered supplemental and cannot be used to support registration. The test species is not acceptable.

10. The acute toxicity tests for Rainbow Trout (BL/B/1700) and Bluegill Sunfish (BL/B/1701) were reevaluated after the receipt of additional information (Oct. 25, 1977). These data cannot be used to support registration as the 96-hour LC_{50} values were calcuated without partial mortalities at the concentrations tested.

The registrant is advised that the following basic requirements have been met:

(a) the avian acute oral LD_{50} for one species of waterfowl [redacted] or one species of upland game bird; [redacted]

(b) the dietary LC_{50} for one species of waterfowl [redacted] and one species of upland game bird; [redacted]

(c) the 96-hour LC_{50}'s for a coldwater species [redacted] and a warmwater species [redacted] of fish;

(d) the acute 48-hour LC_{50} for an aquatic invertebrate (Daphnia sp.).

Richard Balcomb HTC
Environmental Safety Section
EEEB WH 567

October 29, 1977

Memo to Files
10/20/77

Meeting with ICI to discuss remaining data requirements for permethrin in cotton.

ICI was informed that all basic data requirements had been satisfied by studies in hand. The chronic daphnia study had not been evaluated at the time of this meeting. ICI indicated the chronic fish study using fathead minnow would be submitted in December.

Attendees from ES:

H. Craven
R. Balcomb