DATA EVALUATION RECORD

1. Chemical: PP321 Lambda cyhalothrin

2. Test Material: ^{14}C-Cyclopropane-labeled PP321, 94% a.i.

3. Study Type: Freshwater Invertebrate 96-Hour Acute Toxicity Testing - Flowthrough

   Test Species: Gammarus pulex

4. Study ID: Hamer, M.J.; Farrelly, E.; and I.R. Hill. 1985. PP321-Toxicity to Gammarus pulex. Submitted by ICI Americas, Inc., prepared by ICI Plant Protection Division, Jealotts Hill Research Station, Bracknell, Berkshire. EPA Accession No. 073989.

5. Reviewed By: Candy Brassard
   Environmental Protection Specialist
   EEB/HED
   Signature: Candy Brassard
   Date: 8-26-87

6. Approved By: Douglas J. Urban
   Head, Section III
   EEB/HED
   Signature: Douglas J. Urban
   Date: 8/31/87

7. Conclusions:

These studies appear to be scientifically sound; however, there are major discrepancies that detracted from the studies, consequently, the studies were classified as "Supplemental."

entered in data base → Test I reported an LC_{50} (95% Confidence Limits) value of 6.68 (4.9-9.2) ng/L (pptr).

Test II reported an LC_{50} (95% Confidence Limits) value of 9.13 (7.13-11.98) ng/L (pptr).

These values indicate that PP321 is very highly toxic to the freshwater invertebrate, Gammarus pulex.

These studies do not fulfill Guideline Requirements Reference No. 72-2, for acute freshwater invertebrate toxicity testing.

8. Recommendations:

This study should be conducted again with the recommended modifications identified in section 14.a.

1

9. Background:

These data were submitted prior to registration of PP321 for use on cotton.

10. Discussion of Individual Test: N/A

11. Materials and Methods:

a. Test Animals - Gammarus pulex, approximately 5 mm in length, originally collected from River Wye, High Wycombe, England, were acclimatized to test water temperature and lighting for over 3 weeks. These test organisms were fed vegetation that was collected with the organisms. Over the 2 days prior to testing, mortality was < 1%.

b. Test System - Test vessels consisted of 3 liter glass beakers fitted with overflow to contain 2 liters of solution. Water was pumped through saturation column at 0.2 mL min^{-1}. The output flowed into mixing chamber, and thereafter the water was pumped to the eight test chambers at flow rates ranging from 0.008 to 0.84 mL min^{-1}.

Each test chamber had a further 6 mL min^{-1} water added. Another chamber, the control, had 6 mL min^{-1} diluent water only. Dechlorinated tap water was used as the dilution water. Flows to the test chambers were initiated 2 days before the organisms were introduced to allow time for equilibration of test concentrations.

Two studies were conducted consecutively using the same saturation column. In between tests I and II, the test chambers were emptied and cleaned. The test vessels were randomly placed in a water bath at 15 °C and 700 Lux for 16 hours a day.

The temperature was measured at assessment times. The pH and dissolved oxygen (DO) were measured at 0 and 96 hours in each test. The DO levels remained > 9.3 mg/L (> 91% saturation), pH ranged from 8.1 to 8.4. The temperature remained at 15.0 $\pm$ 0.5 °C for the duration of the study.

c. Dose - A control and the following eight treatment levels were included in the study: 65.5, 38.0, 20.5, 11.3, 5.3, 3.5, 1.8, and 0.7 ng/L PP321 (Theoretical Concentration).

d. Study Design - Twenty test organisms were placed into each chamber. The Gammarus pulex were exposed in a flowthrough system for 96 hours.

e. Statistics - (excerpted from submission)

"The EC_{50} and LC_{50} values and their 95% confidence limits were calculated using the weighted linear regression log concentration plotted against logit transformation of the Gammarus response. For the statistical analysis at each assessment time the concentrations used were mean of the measured concentration in PP321 equivalents of each test chamber between 0 hours and assessment time."

12. Reported Results:

Test II showed a slightly lower toxicity than Test I. The study author was not surprised since the concentrations were based on total radioactivity and throughout the study there was an increase in the ester hydrolysis product Compound Ia, and also the isomerization product, enantiomer pair A (see Table 2). Compound Ia (ester hydrolysis of PP321 results in formation of cis-'cyclopropane acid') and is likely to be three orders of magnitude less toxic than the parent PP321.

13. Study Author's Conclusions/QA Measures:

The mean EC_{50} values and LC_{50} values from the two tests were 10.2, 8.0, 6.4, and 5.9 ng/L. PP321 at 24, 48, 72, and 96 hours, respectively, and the corresponding LC_{50}s were 665, 71, 31, and 13 ng/L.

"During the conduct of this study the Quality Assurance Unit carried out the following audits in accordance with ICI Policy of Good Laboratory Practice..."

14. Reviewer's Discussion and Interpretation of the Study:

a. Test Procedures - The following major discrepancies were noted in the study:

- o The raw data were not submitted.
- o Gammarus pulex is not a recommended test species.
- o The age of the test species was not reported. Amphipods should be in the second instar.
- o Dechlorinated tap water was used for the dilution water. EEB recommends soft reconstituted water (well, spring, or surface water source). Dechlorinated water should not be used because removal of chlorine is rarely complete and residual chlorine can be quite toxic to aquatic organisms. If dechlorinated water is used, then it must be shown that first instar daphnids can survive in it for 48 hours without food or the residual chlorine must be measured.
- o The mean water hardness was reported to be 237 mg/L. The $CaCO_3$ level should be 40 to 48 mg/L. Alkalinity should be 30 to 35 mg/L. The study author reported a mean of 260 mg/L.
- o Amphipods should be tested at 17 °C.
- o The loading factor should be reported.
- o The temperature should have been recorded every 6 hours and the DO should have been measured at 0, 48, and 96 hours, not just 0 and 96 hours.
- o To extrapolate measured concentrations for the two lowest levels is not scientifically sound.

b. Statistics - The Stephans program was run for both Test I and Test II using mean measured concentrations of each test. See Attachment A. Based on available information the The LC_{50} values and 95% confidence limit appear to be as follows:

Test I LC_{50} = 6.68 (4.9 - 9.2)
Test II LC_{50} = 9.13 (7.13 - 11.98)

c. Discussion of Results - Gammarus pulex is not a recommended test species for acute freshwater invertebrate toxicity testing. There were several other discrepancies that were also noted in section 14.b.

d. Adequacy of Study

1) Classification - Supplemental 94% ai

2) Rationale - Due to the concerns identified in section 14.a.

3) Repairability - Since a recommended test species was not used, the studies cannot be repaired.

Attachment

Test I

Candy Brassard PP321 Gammarus pulex 08-20-87

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
54	20	17	85	.1288414
29.3	20	18	90	2.012253E-02
14.6	20	17	85	.1288414
6.8	20	13	65	13.1588
3.9	20	5	25	2.069473
2.1	20	2	10	2.012253E-02
1.4	20	3	15	.1288414
.5	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 3.9 AND 14.6 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 5.540247

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
7	.069073	6.662199	4.744637	9.658575

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
4	6.676436E-02	1	.1322558

SLOPE = 1.822397
95 PERCENT CONFIDENCE LIMITS = 1.351511 AND 2.293282

LC50 = 6.684083
95 PERCENT CONFIDENCE LIMITS = 4.906415 AND 9.20891

LC10 = 1.343251
95 PERCENT CONFIDENCE LIMITS = .7114045 AND 2.038804

Trial II

Candy Brassard PP321 Gammarus pulex 08-20-87

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
39.4	20	18	90	2.012253E-02
21.3	20	15	75	2.069473
10	20	15	75	2.069473
5.5	20	7	35	13.1588
3.4	20	2	10	2.012253E-02
2.1	20	0	0	9.536742E-05
1	20	0	0	9.536742E-05
.4	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 3.4 AND 10 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS. BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 6.855627

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
5	5.729854E-02	9.154304	7.272779	11.77913

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
4	.0738314	1	.3137629

SLOPE = 2.542797
95 PERCENT CONFIDENCE LIMITS = 1.85187 AND 3.233724

LC50 = 9.130429
95 PERCENT CONFIDENCE LIMITS = 7.125043 AND 11.97525

LC10 = 2.890954
95 PERCENT CONFIDENCE LIMITS = 1.80608 AND 3.942808

Page 8 is not included in this copy.

Pages _____ through _____ 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 confi by product registrants. If you have any questions, please the individual who prepared the response to your request.