188255
RECORD NO.

010501
SHAUGHNESSY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 02/03/87 OUT JUN 1 1987

FILE OR REG. NO. 707-ENG

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 12/30/86

DATE RECEIVED BY HED 01/28/87

RD REQUESTED COMPLETION DATE 02/17/87

EEB ESTIMATED COMPLETION DATE 02/17/87

RD ACTION CODE/TYPE OF REVIEW 161

TYPE PRODUCT(S): I, D, H, F, N, R, S Miticide

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. D. Edwards (12)

PRODUCT NAME(S) Kelthane Technical Miticide

COMPANY NAME Rohm & Haas Company

SUBMISSION PURPOSE Submission of Avian Reproduction and Aquatic Data in Response to Registration Standard

SHAUGHNESSY NO.	CHEMICAL & FORMULATION	% A.I.
010501	Dicofol Technical	95-96%

52
56
60

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of Dicofol Studies Submitted in Response to DCI

FROM: Larry Turner, Biologist
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

THRU: Norman J. Cook, Head-Section II
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

THRU: Michael W. Slimak, Chief
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

TO: Dennis Edwards, Acting PM 12
Insecticide/Rodenticide Branch
Registration Division (TS-767C)

The Ecological Effects Branch (EEB) has reviewed seven studies on technical dicofol that were submitted in response to requirements outlined in the Registration Standard for dicofol. The studies and EEB's summary findings are presented below; DER's are attached and contain additional details of the reviews.

1. Bobwhite reproduction study (Accession No. 400420-55). This study was considered supplemental because the percentage of DDT-related compounds was not reported. The study may be upgraded by reporting the level of DDT-r contaminants.

2. Oyster shell growth study (Accession No. 400420-61). This study is invalid due to flow-through testing without measured concentrations. An additional serious difficulty was the pump delivery malfunction. No upgrading is possible.

3. Fiddler crab acute toxicity study (Accession No. 400420-59). This study is not valid because a surface film/precipitate was observed and test concentrations were not measured. In addition, fiddler crab is not an acceptable species for fulfilling Guidelines requirements. No upgrading is possible.

4. Sheepshead minnow acute toxicity study (Accession No. 400420-58). This study is not valid because of the very poor fit of the dose-response line, which may have been due to using very small fish and fasting them 48 hours before the test began. No upgrading is possible.

5. Daphnia acute toxicity study (Accession No. 400420-57). As an LC50 study, this test is invalid due to the poor fit of the dose-response line. However, EEB recalculated the results based on immobilization and derived an EC50 of 0.14 ppm. If the registrant accepts the use of this EC50 in place of the reported LC50, the test is considered core and fulfills the requirement.

6. Rainbow trout acute toxicity study (Accession No. 400420-56). This study is not valid because the test material was not fully soluble and the test concentrations were not measured. No upgrading is possible.

7. Mysid shrimp acute toxicity study (Accession No. 40042060). This study is scientifically sound and shows an LC50 of 0.06 ppm, but does not fulfill requirements because of inadequate reporting. The study may be upgraded if additional information on the test organisms and system is submitted, as outlined in the attached DER.

Additional data requirements were outlined in DCIs of April 16, and September 12, 1986, some of which were modifications of data required in the Registration Standard. These additional requirements are not considered in this review. It should be noted that the data reviewed herein satisfy the requirement for timely submission in response to the Registration Standard, except as modified by the subsequent DCIs.

However, as noted above, several of the studies are not acceptable at all, and others require additional information. As a result of this review, the following data requirements, in addition to those required in the subsequent DCIs, are considered outstanding. The time fram for submission should be nine months. In view of the current status of past and present registrants for dicofol products, it is unclear to EEB which registrant(s) should be responsible for these data.

A. The following data requirements may be satisfied by submission of additional information:

1. Avian reproduction study on bobwhite.
2. Mysid shrimp acute toxicity.

B. The following data requirements must be fulfilled by new studies.

1. Estuarine shrimp acute toxicity.
2. Estuarine fish acute toxicity.
3. Oyster embryolarvae acute toxicity or oyster shell growth study.
4. Coldwater fish acute toxicity.

C. The freshwater invertebrate (daphnid) acute toxicity test may be satisfied by the Registrant's acceptance of EEB's calculated EC50 of 0.14 ppm. Alternatively, the test may be repeated.

D. No additional data are required on fiddler crab because it is not an acceptable species. The three estuarine tests listed above (B-1, 2, and 3) are sufficient to address estuarine acute toxicity.

The registrant is encouraged strongly to ensure that the test material is fully solubilized in static aquatic tests. If this cannot be achieved, then the test concentrations must be measured in either static or flow-through tests. More statistically reliable results are likely to result from narrowing the concentration intervals in order to obtain more partial mortality concentrations.

EEB is not able to complete a risk assessment at this time because of the poor quality of these studies and because exposure and fate data are not yet available.

DATA EVALUATION REPORT

1. Chemical: Dicofol (Kelthane), Shaughnessy No. 010501

2. Test Material: Technical Dicofol, 93.3% ai

3. Study Type: Avian Reproduction Study

   Species Tested: Northern Bobwhite (Colinus virginianus)

4. Study ID: Frank, P.; Beavers, J.; Jaber, M. (1986) Dicofol (Kelthane® Technical Miticide): A One-Generation Reproduction Study with the Bobwhite (Colinus virginianus). Study conducted by Wildlife International, Ltd. (Project No. 129-126), Easton, MD; Submitted by Rohm and Haas Company (Report No. 86RC-47), Spring House, PA. Accession No. 400420-55.

5. Reviewed By:

   Larry Turner, Biologist
   Ecological Effects Branch
   Hazard Evaluation Division

   Signature: Larry Turner
   Date: June 1, 1987

6. Approved By:

   Norman J. Cook, Head-Section II
   Ecological Effects Branch
   Hazard Evaluation Division

   Signature: Norman J. Cook
   Date: 6.1.87

7. Conclusions:

   The study shows that technical dicofol does not significantly affect reproductive parameters of bobwhite quail at dietary concentrations up to 120 ppm.

   The study is scientifically valid, but cannot fulfill Guidelines requirements because the percentage of DDT-related compounds was not reported.

8. Recommendations:

   The study can be upgraded from supplemental to core by reporting the percentage of DDT-related compounds in the technical test material.

9. Background:

   This study was conducted in response to requirements in the Registration Standard for dicofol. The requirement for a reproductive study with bobwhite was subsequently deleted and replaced with a study on another species.

However, the bobwhite study apparently was already underway, and the registrant elected to submit the study, even though it no longer satisfies the requirements outlined in the Registration Standard.

10. Discussion of Individual Test: N/A.

11. Materials and Methods:

a. Test Animals - Test birds were Northern Bobwhite (Colinus virginianus) obtained from Fritts' Quail Farm, Phillipsburg, NJ. Birds were young adults, 22 weeks of age at initiation. All birds were from the same hatch and were approaching their first breeding season. At initiation, mean body weights were 198 g for males and 195 g for females. Test birds underwent a 3-week acclimation and quarantine period prior to the start of the study.

b. Test System - Housing and Diet - Test birds were housed, one pair per pen, in galvanized wire mesh/sheeting pens with approximately 1530 cm^2 (1.6 ft^2) floor area and 21 to 26 cm high. Pens had sloping floors. Each adult was identified individually be a leg band. Feed and water were available ad libitum.

Average temperature for adult birds was 23 $\pm$ 3 °C (73 $\pm$ 5 °F); average relative humidity was 67 percent; ventilation rate was 5 to 8 room air volumes per hour. Photoperiod was 8L/16D for the first eight weeks and then was increased to 17L/7D. Illumination was approximately 320 lux, with the spectrum approximating noon-day sunlight.

Basal diet for adult birds was a formulation prepared by Agway, Inc. to Wildlife International specifications for breeding birds. No medication was added. Ground lime-stone (5% by weight) was added to the diets of breeding birds. Dicofol was added to basal diet to form a premix; the premix was prepared into test diets weekly and was presented to the appropriate test group on Fridays. Control diets were prepared fresh weekly also. Dietary concentrations were adjusted for the purity of dicofol. Nominal concentrations were 30 and 120 ppm.

c. Test System - Procedures - Test birds were randomly distributed into groups as controls (0 ppm), 30 ppm, or 120 ppm. Following acclimation, the initiation of treatment was on 24 January 1986. Termination of treatment was on 6 June 1986, resulting a 19-week exposure period for adults. Egg laying was induced by lengthening the photoperiod beginning week 9. The first eggs were set for incubation during week 13.

Adult birds were observed for signs of toxicity or abnormal behavior at least daily. All birds that died were necropsied, as were 5 males and 5 females from each of the control and 120 ppm groups. Adult body weights were measured at initiation, weeks 2, 4, 6, 8, and at terminal sacrifice. Feed consumption was measured each week for the whole week.

Eggs were collected daily from all pens, marked, and stored in a cold room. Each week, eggs were removed from the cold room, candled, and (except cracked eggs and those use for shell thickness) fumigated and incubated. Eggs were candled again on day 11 for viability and on day 21 for survival. Eggs were placed in hatchers on day 21 and removed on day 25 or 26, whether hatched or not. Incubation temperature was 99.25 $\pm$ 0.25 °F; relative humidity was 56%. Hatcher temperature and humidity were 99 $\pm$ 0.25 °F and 76% respectively.

Test diets were sampled for analysis immediately after mixing (pretest and homogeneity check) and every week at the end of the 7-day feeding period. Samples were shipped on dry ice to Tegeris Laboratories, Temple Hills, MD for analysis. Analysis was for p,p'dicofol, with the results multipled by 1.15 to correct to all dicofol. It appears that analysis was conducted five times, with each analysis being for samples from several weeks. All analyzed concentrations were corrected for mean percent recovery of 3 or 6 spiked samples in each of the five analyses. Mean recovery was 89.2 to 101.8 percent. Detection limits were not reported.

Analysis of pretest samples taken immediately after mixing showed test concentrations of 28.5 and 113.9 ppm. Weekly samples taken at the end of the 7-day feeding period had mean (and range) concentrations of 26.2 (23.6 to 31.4) and 109.8 (104.4 to 119.6) ppm of dicofol. No detectable dicofol was found in control diets.

Hatchlings were housed in Beacon battery brooders, model B735Q, constructed of galvanized sheeting and wire mesh. Floor area of pens was 6480 cm^2 (7 ft^2); height was 23 cm (9 in). Temperature in the brooding compartment of the pen was 38 °C from hatching until termination at 14 days. Photoperiod was 17L/7D.

Hacthlings were identified to pen of origin, then housed for 14 days. They were fed an untreated diet. Average body weights were determined at hatching and at 14 days.

For shell thickness determination, one egg was collected weekly from (1) odd-numbered pens in odd-numbered weeks and (2) even-numbered pens in even-numbered weeks.

7

Shells were opened at the waist, washed, and allowed to air dry for at least one week. Average thickness was determined by measuring the shell plus membrane at five points around the waist.

Records were maintained on eggs laid, eggs set, eggs cracked, viable embryos, live three-week embryos, hatchlings, body weight of hatchlings, 14-day-old survivors, body weight of 14-day old survivors, and egg shell thickness.

d. Dose - Nominal dietary concentrations were 0 (control), 30 ppm, and 120 ppm, as adjusted for percent ai. Mean analyzed concentrations, after 7 days, were 26.2 and 109.8 ppm in the two treated groups. Recovery averaged 89.2 to 101.8 percent for the various spiked samples. Treatment level were based upon "known toxicity data and a consideration of expected environmental residue levels".

e. Design - Each of the two treatment groups and the control consisted of 16 males and 16 females, housed as pairs.

f. Statistics - Statistical analysis was by Dunnett's multiple comparison method, eliminating from analysis any pen in which a mortality occurred. Each of the following parameters was analyzed statistically:

1) Adult body weight.
2) Adult feed consumption.
3) Eggs laid per hen (based upon maximum laid).
4) Eggs cracked (of eggs laid).
5) Viable embryos (of eggs set).
6) Live three-week embryos (of viable embryos).
7) Hatchlings (of live three-week embryos).
8) 14-Day-old survivors (of hatchlings).
9) 14-Day-old survivors (of eggs set).
10) Hatchlings per hen (based on maximum number of eggs set/hen).
11) 14-Day-old survivors per hen (based on maximum number of eggs set/hen).
12) Hatchling and 14-day-old body weights.
13) Egg shell thickness.

12. Reported Results:

One mortality occurred in the 30 ppm group; it was considered to be incidental to treatment. The report states that no overt signs of toxicity were observed during the study, but then the report goes on to state that one female exhibited reduced reation to external stimuli during week 14, but this female responded normally by week 16, although preferring to stay in the rear of the pen.

Necropsy findings were considered all to be incidental to treatment. Some birds exhibited external lesions, conjunctivitis, or egg yolk peritonitis.

No treatment-related effects were observed on adult body weights or feed consumption. Statistically significant increases in feed consumption were reported for 4/19 weeks at 30 ppm and 3/19 weeks for 120 ppm, relative to controls.

No statistically significant effects, relative to controls, were found for any reproductive parameter or for egg-shell thickness. No differences were found in body weights of offspring.

The following summary data on reproductive parameters were reported:

Parameter	Treatment Level (ppm)		
	0	30	120
Eggs laid (n)	495	514	636
Eggs laid ($\bar{x}$)	31	34	40
Eggs laid/hen/day (56 days)	0.55	0.61	0.71
Eggs cracked (n)	19	6	21
Eggs cracked (% of laid)	3	1	3
Egg shell thickness (mm) ($\bar{x}$)	0.216	0.224	0.222
Eggs set (n)	414	453	551
Viable embryos (n)	362	399	473
Viable embryos (% of set)	86	91	84
Live 3-week embryos (n)	362	396	466
Live 3-week embryos (% of viable)	100	99	99
Hatchlings (n)	346	375	431
Hatchlings (% of 3-week embryos)	97	96	90
14-Day Survivors (n)	322	341	375
14-Day Survivors (% of hatched)	91	91	84
14-Day Survivors (% of set)	76	78	65
14-Day Survivors/hen ($\bar{x}$)	20	23	23

13. Study Authors' Conclusions/QA Measures:

"Dietary concentrations of dicofol technical at 30 or 120 ppm did not result in mortality or overt signs of toxicity during the 19-week exposure study. There were no apparent treatment related effects upon body weight or feed consumption among adults at either of the concentrations tested. Dietary concentrations of dicofol technical at 30 or 120 ppm active ingredient did not result in treatment related effects upon any reproductive parameter measured.

The no-observed-effect concentration for dicofol technical in this study was 120 ppm, the highest concentration tested."

QA Measures:

1. The study was reported to be conducted in conformance to OPP GLPs.

2. The QA unit determined that the final report was an accurate reflection of the results obtained.

3. Audits were performed by the QA unit on various procedures, including diet preparation, body weights, candling, necropsies, and shell measurements.

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

a. Test Procedures - Test procedures were scientifically sound and in general accordance with acceptable protocols. Allowing test diets for dicofol analysis to be placed on top of cages for one week may not be appropriate because, with labile chemicals, disturbance of the feed by birds may enhance loss of active ingredient. However, with a vapor pressure of 3.9×10^{-7} for p,p'-dicofol (S. Hummel, RCB. pers. comm.), the test compound is unlikely to be volatilized in disturbed feed to a much greater extent than in undisturbed feed.

As dicofol is a compound with a demonstrated fish bioconcentration factor of 10,000 or greater, this test would have been enhanced by the use of extra test birds for residue analysis in tissues and eggs. No specific request was made for residue analysis, and no data gap exists as long as the other avian studies (e.g., mallard, kestrel) include such analysis.

Finally, the test compound is inadequately described even though the testing facility reported the percent active ingredient and the lot number. Because of the nature of the concerns for dicofol, it is imperative that the percentage of DDT-related contaminants in the test substance be reported.

b. Statistical Analysis - A review of the results tabulated in section 12 of this review shows that cracked eggs, percentage of viable embryos, percentage of hatchlings, and percentage of 14-day survivors were the only parameters that were at all affected adversely at the 120 ppm level, relative to controls. Of these, differences in cracked eggs or viable embryos were too small to warrant analysis. Statistical analyses were conducted on 14-day-old survivors (percent of eggs set) and on hatchlings (percent of eggs set). Analysis was by EEB's program for ANOVA (arc sine transformation) and Duncan's Multiple range test (analyses attached). No significant difference was found between

treated and control groups for either parameters. However, the difference in 14-day survivors was significant ($p < .05$) between the 30 ppm and 120 ppm groups. Therefore, EEB concurs that no statistically significant differences occurred between either treatment group and the control.

The reduction in 14-day survivors as a percent of eggs set suggests a possible effect, even if not significant. For this parameter, the control coefficient of variation was 19%, which yields a power of 0.68 for detecting a 25% difference, according to ASTM method E 1062-86 (Appendix). Although this power is satisfactory ($P = 0.8$ is desirable), it is low enough to consider that a treatment-related effect may have occurred without being statistically significant.

c. Discussion/Results: This reviewer concurs with the study authors that the statistically significant NOEL is greater than 120 ppm for the Northern Bobwhite. It would have been desirable to test three dietary concentrations, one of which should have been high enough to produce effects even at environmentally unrealistic levels, so that a dose-response relationship could be obtained. The use of two dietary concentrations based upon expected environmental concentrations satisfies the letter of the regulations, but has largely been replaced in most modern tests by use of three concentrations intended to define the dose-response line. In other respects, the test was generally well done.

d. Adequacy of Study

1) Classification - Supplemental.

2) Rationale - The study is valid. However, even though the percent active ingredient was reported, the test material was inadequately described as to the content of DDT-related compounds.

3) Repairability - The study may be upgraded to core if the percentage of DDT-related compounds in the test material is reported.

15. Completion of One-Liner:

One-liner form completed April 29, 1987.

16. CBI Appendix: N/A.

DATA EVALUATION REPORT

1. Chemical: Dicofol (Kelthane), Shaughnessy No. 010501

2. Test Material: Kelthane Technical, 95.6% ai

3. Study Type: Saltwater Invertebrate Acute Toxicity

   Species Tested: Fiddler Crab (Uca pugilator)

4. Study ID: Nicholson, R.B.; Surprenant, D.C. (1985) Dicofol (Kelthane® Technical Miticide): Acute Toxicity of Kelthane Technical to the Fiddler Crab, Uca pugilator. Study Conducted by Springborn Bionomics, Inc., Wareham, MA (Report No. BW85-8-1836). Study Submitted by Rohm & Haas Co., Spring House, PA (Report No. 85RC-60). Accession No. 400420-59.

5. Reviewed By:

   Larry Turner
   Biologist
   EEB/HED

   Signature: Larry Turner

   Date: June 1, 1987

6. Approved By:

   Norman Cook
   Head-Section II
   EEB/HED

   Signature: Norman J. Cook

   Date: 6.1.87

7. Conclusions:

   The study is not scientifically sound and can not fulfill Guidelines requirements because of insolubility and a lack of measured concentrations.

8. Recommendations: No repair is possible.

9. Background:

   This study was submitted in response to the data requirements listed in the Registration Standard for dicofol.

10. Discussion of Individual Test: N/A.

11. Materials and Methods:

    a. Test Animals - The test animals were fiddler crabs, Uca pugilator, collected locally and held for 7 days in 300 L fiberglass tanks at 21 °C. Mean wet weight was 1.2 grams. Mean carapace width was 13 mm. Crabs were fed brine shrimp until test initiation.

b. Test System - The test was conducted in 250 ml glass beakers containing 200 ml of ABC aged well water. Test temperature was 20 ± 2 °C; photoperiod was 16 L/8D with a 30-minute transition at dusk and dawn. Lighting intensity was 50-70 foot candles. Dissolved oxygen was 7.8-8.3 mg/l; pH was 8.5-8.6. Dilution water had a hardness of 225-275 ppm (hard to very hard).

c. Dose - Nominal concentrations were 0 (control and acetone control), 0.10, 0.18, 0.32, 0.56, and 1.0 mg/l. There was no report of any precipitate, film, or other solubility problems.

d. Design - Each of the control and treatment groups consisted of two replicate beakers, each containing 10 daphnids.

e. Statistics - Analysis was done according to the Stephan program, with the moving average method selected for these data.

12. Reported Results:

The 48-hour LC_{50} for Daphnia magna is 0.32 ppm with 95% confidence limits of 0.27-0.38 ppm. The NOEL for mortality and abnormal effects was 0.10 mg/l. Mortality and water quality data are presented on the following page.

Nominal Concentration (mg/l)	Percent Mortality Hours		Water Quality					
			0 hours			48 hours		
	24-hr.	48-hr.	Temp. °C	D.O. mg/l	pH	Temp. °C	D.O. mg/l	pH
Control	0	0	19	8.4	8.4	20	8.3	8.5
Solvent	0	0						
0.10	0	0				20	8.2	8.6
0.18	5	40						
0.32	20	60				20	7.9	8.6
0.56	10	50						
1.0	20	100				20	7.8	8.6

13. Study Authors' Conclusions/QA Measures:

None beyond reported results.

QA Measures:

Data were audited by the QA unit to assure compliance with GLPs, SOPs, and the protocol. The report was stated to reflect accurately the raw data.

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

a. Test Procedures - Test procedures generally followed acceptable protocols. However, two items preclude much utility for the results. First, a surface film occurred in all concentrations containing dicofol, and a bottom precipitate occurred at the two highest concentrations. When insolubility occurs, test concentrations must be measured for the test to be valid. Second, fiddler crabs are not an acceptable species for fulfilling guidelines requirements.

b. Statistical Analysis - EEB's analysis was identical to the reported value when the test concentrations were not adjusted for solvent control mortality.

c. Discussion/Results: With a surface film and precipitate, the results are not useful because actual test concentrations were not measured.

d. Adequacy of Study

1) Classification - Invalid

2) Rationale - Jars containing the test substance had a surface film, precipitate, or both, and test concentrations were not measured. The test could not fulfill guidelines requirements even with measured concentrations because fiddler crab is not an acceptable species.

3) Repairability - No repair is possible.

15. Completion of One-Liner:

One-liner form completed May 4, 1987.

16. CBI Appendix: N/A.

DATA EVALUATION REPORT

1. Chemical: Dicofol (Kelthane), Shaughnessy No. 010501

2. Test Material: Kelthane Technical, 95.6% ai, (<0.1% DDTr)

3. Study Type: Estuarine Fish Acute Toxicity

   Species Tested: Sheepshead Minnow, (Cyprinodon variegatus)

4. Study ID: McAllister, W.A.; Cole P.; Bowman, J. (1985) Dicofol (Kelthane® Technical Miticide): Acute Toxicity of Kelthane Technical to Sheepshead Minnows (Cyprinodon variegatus). Study Conducted by Analytical Biochemistry Laboratories, Inc., Columbia, MO (Study No. 32808). Submitted by Rohm & Haas Co., Spring House, PA (Report No. 85RC-0047). Accession No. 400420-58.

5. Reviewed By:

   Larry Turner
   Biologist
   EEB/HED

   Signature: Larry Turner
   Date: June 1, 1987

6. Approved By:

   Norman Cook
   Head-Section II
   EEB/HED

   Signature: Norman J. Cook
   Date: 6.1.87

7. Conclusions:

   The study is not scientifically sound and does not fulfill Guidelines requirements because the goodness of fit of the dose-response line was extremely poor.

8. Recommendations: No repair is possible.

9. Background:

   This study was submitted in response to the data requirements listed in the Registration Standard for dicofol.

10. Discussion of Individual Test: N/A.

11. Materials and Methods:

    a. Test Animals - The test animals were sheepshead minnows, Cyprinodon variegatus, obtained from SP Engineering, Salem, MA, and acclimated for seven days prior to testing. Mean weight of test fish was 0.22 ± 0.04 g, and mean standard length was 20 ± 0.85 mm. Fish were acclimated for 48-96 hours prior to testing.

b. Test System - The static test was conducted in 5 gallon glass vessels containing 15 L of "reconstituted saltwater composed of hw-Marinemix® & Bio-Elements (Table 1) and deionized water." Since Table 1 is a list of 13 major and 56 minor constituents without any quantification, it cannot be ascertained whether or not the saltwater is typical. Water quality parameters were reported to be 22 ppt salinity, 22°C temperature, 7.4-8.0 pH, and 5.8 - 7.9 mg/l (corrected for salinity) of dissolved oxygen (82-111% of saturation). Dimethylformamide was used as a solvent. Loading was 0.15 mg/l.

c. Dose - Nominal test concentrations were 0 (control and solvent control), 0.18, 0.32, 0.56, 1.0, 1.8, 3.2, and 5.6 ppm.

d. Design - Ten fish, all in one test vessel, were used for each of the controls and test concentrations.

e. Statistics - Analysis was done according to the Stephan program, with the moving average method selected as the most appropriate.

12. Reported Results:

The 96-hour LC_{50} value was reported as 1.1 mg/l, with confidence limits of 0.81-1.6 mg/l. Since effects, but no mortality, were observed at all test concentrations, the NOEL was considered to be < 0.18 mg/l. The 24- and 48-hour LC_{50} values were 2.8 and 2.4 mg/l, respectively, as determined by binomial probability. Responses by concentration are presented in EEB's statistical analysis (attached).

13. Study Authors' Conclusions/QA Measures:

None beyond reported results.

QA Measures:

The study was conducted in accordance with the intent of GLP regulations. A QA statement indicated that the study report accurately reflects the data generated by the facility.

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

a. Test Procedures - The test procedures generally followed acceptable protocols. However, there were several deviations, one or more of which may have contributed to the aberrant dose-response pattern:

1) Acceptable protocols recommend the use of fish weighing 0.5-5.0 g, whereas the test fish were 0.22 g. When using recommended size fish, they should not be fed

16

for 48-96 hours prior to test initiation; but when smaller fish are used, they should be fed up to the time of the test. In this study, the small fish were not fed for 48-96 hours before the test. It is possible that starvation of smaller fish, perhaps in conjunction with exposure to the toxicant, was a reason for the unusual mortality pattern.

2) A list of the unquantified components of reconstituted seawater is insufficient for evaluating water quality. Since water quality cannot be assessed, it must be considered a possible contribution to the mortality pattern.

3) Dissolved oxygen and pH were measured in the high and low concentrations rather than in the high, medium, and low concentrations. Variation in pH over the 96-hour test period 0.4-0.5 units, which is over half the ASTM recommended maximum monthly pH range of 0.8 units. These discrepancies are not likely to have been a major contribution to the mortality pattern.

b. Statistical Analysis - EEB's analysis via the Stephan computer program produced a moving average LC_{50} value of 1.1 mg/l with 95% confidence limits of 0.81-1.6 mg/l, which are all the same as reported. However, the reason for using moving average results is because the dose-response line by probit analysis has a goodness of fit probability less than 0.001. Below the top two concentrations, the mortality pattern is nearly inverse of what would be expected. The very poor fit of the dose-response line renders the study unacceptable.

c. Discussion/Results - In some cases, a slightly poor fit of the dose-response line may produce acceptable results. For this study, the goodness of fit has such a very low probability that the study is not useful.

d. Adequacy of Study

1) Classification - Invalid

2) Rationale - Extremely poor goodness of fit of dose-response line.

3) Repairability - No repair is possible.

15. Completion of One-Liner:

One-liner form completed May, 4, 1987.

16. CBI Appendix: N/A.

17

DATA EVALUATION REPORT

1. Chemical: Dicofol (Kelthane), Shaughnessy No. 010501

2. Test Material: Kelthane Technical, 95.6% ai, (<0.1% DDTr)

3. Study Type: Aquatic Invertebrate Acute Toxicity

   Species Tested: Daphnia magna

4. Study ID: Forbis, A.D.; L. Georgie, and D. Burgess (1985) Dicofol (Kelthane® Technical Miticide): Acute Toxicity of Kelthane Technical to Daphnia magna. Study Conducted by Analytical Bio-chemistry Laboratories, Inc., Columbia, MO (Study No. 32807). Submitted by Rohm & Haas Co., Spring House, PA (Report No. 85RC-0014). Accession No. 400420-57.

5. Reviewed By:

   Larry Turner
   Biologist
   EEB/HED

   Signature: Larry Turner
   Date: June 1, 1987

6. Approved By:

   Norman Cook
   Head-Section II
   EEB/HED

   Signature: Norman J. Cook
   Date: 6.1.87

7. Conclusions:

   As an LC_{50} study, this test is invalid due to the poor fit of the dose-response line. However, if the registrant accepts the use of the EC_{50} value of 0.14 ppm, the test is valid and acceptable for fulfilling requirements. With an EC_{50} of 0.14 ppm, technical kelthane is considered highly toxic to fresh-water invertebrates.

8. Recommendations: N/A.

9. Background:

   This study was submitted in response to the data requirements listed in the Registration Standard for dicofol.

10. Discussion of Individual Test: N/A.

11. Materials and Methods:

    a. Test Animals - The test animals were first instar Daphnia magna obtained from in-house laboratory cultures. At test initiation, daphnids were less than 24 hours old.

b. Test System - The test was conducted in 5 gallon glass vessels containing 15 L of reconstituted soft water with an initial pH of 7.6 and dissolved oxygen of 9.4 mg/L. At test termination, pH had dropped to 7.1 and dissolved oxygen was 8.3-8.5 mg/l. Temperature was 11 ± 1.0 °C throughout the test. Photoperiod was 16L/8D. Loading was 0.52 g/L. Acetone was used as a solvent for stock solutions, however, a light surface film was noted in the 0.1 to 1.0 mg/l chambers. Maximum acetone concentration in the test vessels was 0.1 ml acetone per liter of solution.

c. Dose - Nominal test concentrations were 0 (control and solvent control), 0.056, 0.1, 0.18, 0.32, 0.56, and 1.0 mg/l.

d. Design - There were ten fish in one test vessel for each of the two control and six treatment groups.

e. Statistics - Data were analyzed according to the Stephan computer program, with the binomial method being selected for the 96-hour LC_{50}.

12. Reported Results:

The authors reported a 96-hour LC_{50} of 0.21 mg/L for rainbow trout, with 95% confidence limits of 0.10-0.32 mg/L. The NOEL concentration was reported to be < 0.056 mg/L in the text, but in Table 2 (footnote) it was reported (apparently erroneously) as 0.056 mg/L. The responses by concentration were:

Conc (mg/L)	Percent Mortality		
	24 hr	48 hr	96 hr
control	0	0	0
solvent control	0	0	0
0.056	0	0	0
0.10	0	0	0
0.18	0	10	30
0.32	50	90	100
0.56	70	90	100
1.0	100	100	100

Signs of toxicity included surfacing, loss of equilibrium, flared gills, dark discoloration, quiescence, and fish on the bottom. One or more signs were observed at all test concentrations.

13. Study Authors' Conclusions/QA Measures:

None beyond reported results.

QA Measures:

The study was reported to have been conducted in compliance with OPP GLPs. The QA Officer stated that the report is an accurate reflection of the study as it was conducted.

13. Study Authors' Conclusions/QA Measures:

None beyond reported results.

QA Measures:

A QA statement indicated that the study was conducted in conformance with GLPs and that the report is an accurate reflection of the study.

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

a. Test Procedures - The test followed acceptable protocols, although dilution water was considerably harder than recommended.

b. Statistical Analysis - EEB's analysis (attached) is identical to the reported values. However, when calculated by probit analysis, the dose-response line had a goodness of fit probability of 0.0012. Such a poor fit is normally considered unacceptable. However, a review of the raw data on observations indicates that, where the mortality pattern deviates, most surviving daphnids were "quiescent" and on the bottom of the test chamber. This appears to be the same as "immobilization" which is defined by ASTM (Standard E-729-80) "as the lack of movement except for minor activity of the appendages." Since death may be difficult to determine in daphnids, ASTM states that an EC_{50} is usuall y determined instead of an LC50.

Because of the somewhat aberrant mortality pattern and the general difficulty in determining death versus immobilization, this reviewer has re-evaluated the results using immobilization as the endpoint. On this basis, the response pattern at the various test concentrations is:

Conc. (ppm)	Number Affected/Number Exposed
0.1	0/20
0.18	18/20
0.32	20/20
0.56	20/20
1.0	20/20

EEB's analysis (attached) of these data show an EC_{50} of 0.14 ppm, based upon the binomial approach. The "statistically sound conservative" binomial confidence limits were 0.1-0.18 ppm.

c. Discussion/Results - Based upon the EC_{50} of 0.14 ppm, technical kelthane is considered highly toxic to freshwater invertebrates. The same category would apply to the LC_{50} of 0.32 ppm, however, the LC_{50} value could not be considered valid due to the lack of homogeneity.

d. Adequacy of Study

1) Classification - Core, if registrant accepts an EC_{50} of 0.14 ppm rather than the reported LC_{50} of 0.32 ppm.

2) Rationale - Because the LC_{50} had poor "fitness", the EC_{50} value is the only statistically valid result.

3) Repairability - None for LC_{50}; not applicable for EC_{50}.

15. Completion of One-Liner:

One-liner form completed May 6, 1987.

16. CBI Appendix: N/A.

DATA EVALUATION REPORT

1. Chemical: Dicofol (Kelthane), Shaughnessy No. 010501

2. Test Material: Technical Dicofol, 95.6% ai, (<0.1% DDTr)

3. Study Type: Fish Acute Toxicity

   Species Tested: Rainbow Trout (Salmo gairdneri)

4. Study ID: McAllister, W.A.; Cohle, P.; Bowman, J. (1985) Dicofol (Kelthane® Technical Miticide): Acute Toxicity of Kelthane Technical to Rainbow Trout (Salmo gairdneri). Study Conducted by Analytical Bio-chemistry Laboratories, Inc., Columbia, MO (Study No. 32806). Submitted by Rohm & Haas Co., Spring House, PA (Report No. 85RC-0016). Accession No. 400420-56.

5. Reviewed By:

   Larry Turner
   Biologist
   EEB/HED

   Signature: Larry Turner
   Date: June 1, 1987

6. Approved By:

   Norman Cook
   Head-Section II
   EEB/HED

   Signature: Norman J. Cook
   Date: 6.1.87

7. Conclusions:

   The study is not scientifically sound because the test material was not fully soluble and concentrations were not measured. The study does not satisfy guidelines requirements.

8. Recommendations: No repair is possible.

9. Background:

   This study was submitted in response to the data requirements listed in the Registration Standard for dicofol.

10. Discussion of Individual Test: N/A.

11. Materials and Methods:

    a. Test Animals - The test animals were rainbow trout (Salmo gairdneri) obtained from Spring Creek Trout Hatchery, Lewistown, MT. Test fish had a mean weight of 0.78 ± 0.11 g and a mean standard length of 46 ± 1.9 mm, based on a control sample at test termination. Test fish were acclimated for 14 days in culture tanks in dilution water at the test temperature. They were not fed for 48 hours prior to testing.

b. Test System - The test was conducted in 19.6 L glass jars containing 15 L of test solution at a depth of 27.5 cm. Dilution water was filtered natural seawater with a salinity of 31 ppt, pH of 8.1, and specific conductance of 36,000 umhos/cm. Photoperiod was 16L/8D. Temperature was 20 °C.

Crabs were distributed impartially to the test jars within 15 minutes of test solution preparation. Leading was 0.33 g/L. Crabs were not fed during exposure. Dissolved oxygen, temperature, and pH were measured at regular intervals in one or more of the test chambers.

c. Dose - Test concentrations (nominal) were 0 (control and solvent control), 27, 43, 72, 120, and 200 ppb (a bottom precipitate was observed at 120 and 200 ppb) and a surface film was present in all test concentrations).

d. Design - At each of the seven control or treatment concentrations, there were four replicates of four crabs each (16 crabs per test concentration).

e. Statistics - Analysis was conducted by the Stephan program, with moving average angle analysis being the selected method.

12. Reported Results:

The authors reported the 96-hour LC_{50} to be 64 mg/l, with 95% confidence limits of 50-89 mg/l. Complete mortality data are presented on the following page.

Nominal concentration (mg/l)	Cumulative mortality (%)			
	24-hour	48-hour	72-hour	96-hour
200	31	50	75	81
120	19	38	44	100
72	0	0	0	25
43	0	0	12	25
27	0	0	0	38
solvent control	0	0	6	6
control	0	0	0	0

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

a. Test Procedures - With one major exception, the test procedures were basically sound. The authors reported a surface film in all but the lowest concentration after the working stock was added to the test chambers. This appears to have been observed prior to the addition of fish, which should have led to termination of the test unless actual test concentrations could be measured. Alternatively, use of additional solvent (up to 0.5 m/L is acceptable) might have eliminated the surface film.

b. Statistical Analysis - Statistics were checked according to the EEB computer program. The results were evaluated by the binomial method and yielded an LC_{50} of 0.21 ppm, the same as reported.

c. Discussion/Results - In this otherwise well run test, the lack of measured concentrations when a surface film (or precipitate) occurs means that the results are not reliable.

d. Adequacy of Study

1) Classification - Invalid

2) Rationale - Test material was not completely dissolved and actual concentrations were not measured to compensate for the insolubility.

3) Repairability - No repair is possible.

15. Completion of One-Liner:

One-liner form completed May 18, 1987.

16. CBI Appendix: N/A.

DATA EVALUATION REPORT

1. Chemical: Dicofol, Shaughnessy No. 010501

2. Test Material: Technical Dicofol, 95.6% ai, (<0.1% DDTr)

3. Study Type: Estuarine Invertebrate Acute Toxicity

   Species Tested: Mysid Shrimp (Mysidopsis bahia)

4. Study ID: Forbis, A.D.; D. Burgess, and L. Georgie (1985) Dicofol (Kelthane® Technical Miticide): Acute Toxicity of Kelthane Technical to Mysid Shrimp (Mysidopsis bahia). Study Conducted by Analytical Bio-chemistry Laboratories, Inc., Columbia, MO (Study No. 32809). Submitted by Rohm & Haas Co., Spring House, PA (Report No. 85RC-0046). Accession No. 400420-60.

5. Reviewed By:

   Larry Turner
   Biologist
   EEB/HED

   Signature: Larry Turner
   Date: June 1, 1987

6. Approved By:

   Norman Cook
   Head-Section II
   EEB/HED

   Signature: Norman J. Cook
   Date: 6.1.87

7. Conclusions:

   The study is scientifically sound. With a 96-hour LC_{50} of 0.06 ppm, technical dicofol is considered very highly toxic to mysid shrimp.

   The study does not meet guideline requirements because of inadequate reporting on the test system.

8. Recommendations:

   The study may be upgraded to core if additional information on the test animals and water quality is reported (see 14 D 3).

9. Background:

   This study was submitted in response to the data requirements listed in the Registration Standard for Dicofol.

10. Discussion of Individual Test: N/A.

11. Materials and Methods:

a. Test Animals - The test animals were mysid shrimp, Mysidopsis bahia, obtained from Multi-Aqua Culture Systems, Inc., Amagansett, NY. Neither size nor age of mysids was reported. Mysids were fed brine shrimp nauplii daily during an unspecific holding period. Acclimation was mentioned, but no duration reported. The raw data indicates that the culture was on hand for four days prior to the test. Shrimp were fed approximately 2 ml of brine shrimp per vessel during the test. The report is unclear about feeding during the unspecified acclimation period.

b. Test System - The static test was conducted in 400 ml glass vessels containing 300 ml of aged artificial saltwater. The constituents, but not their quantities, of the artificial seawater were reported. Measured water quality parameters in control water at the beginning of the test were 21‰ salinity, 9.0 mg/l dissolved oxygen, and 7.7 pH. Test temperature was 22 ± 2 °C. Loading could not be calculated.

c. Dose - Nominal test concentrations were 0 (control and solvent control), 0.032, 0.056, 0.10, 0.32, 0.56, and 1.0 ppm.

d. Design - Ten mysids, all in one test vessel, were tested for each control or treatment group.

e. Statistics - Statistical analysis was done according to the Stephan program, with the binomial approach selected as the particular method.

12. Reported Results:

The authors reported the nominal LC_{50} as 0.060 ppm with 95% confidence limits of 0.032-0.100 ppm according to the binomial method. The NOEL was reported as 0.032 ppm, with no mortality or abnormal behavior at this concentration.

The responses by concentration were:

Conc (mg/l)	Percent Mortality		
	24 hr	48 hr	96 hr
Control	0	0	0
Solvent control	0	0	0
0.032	0	0	0
0.056	0	0	40
0.10	50	100	100
0.18	100	100	100
0.32	100	100	100
0.56	100	100	100
1.0	100	100	100

13. Study Authors' Conclusions/QA Measures:

None beyond reported results.

QA Measures:

The study was reported to have been conducted following the intent of GLPs. The QA statement indicated that the final report is an accurate reflection of the study as it was conducted.

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

a. Test Procedures - In general, the study followed an acceptable protocol, however, several items were not reported.

1) Size and age of mysids was not reported.

2) No loading was reported.

3) The duration of acclimation was not reported, nor was the feeding regimen entirely clear during acclimation.

4) The saltwater preparation was not adequately described as to the quantification of major constituents.

5) Photoperiod was not reported.

6) Water quality parameters were not reported at 48 hours.

b. Statistical Analysis - EEB's analysis according to the Stephan program yielded an LC_{50} of 0.060 ppm, the same as reported.

c. Discussion/Results - Although the study appears to have been done properly, too many items were unreported to provide much confidence. Based upon the reported LC_{50} value of 0.06 ppm, technical dicofol is considered very highly toxic to marine/estuarine invertebrates.

d. Adequacy of Study

1) Classification - Supplemental

2) Rationale - Inadequate reporting, particularly with respect to test animals.

3) Repairability - Possibly to core if the following information is reported and found to be acceptable:

1) Size and age of mysids.

2) Loading.

3) Duration of acclimation; feeding during acclimation.

4) Photoperiod.

5) Quantity of major constituents in the saltwater mixture.

15. Completion of One-Liner:

One-liner form completed May 18, 1987.

16. CBI Appendix: N/A.

DATA EVALUATION REPORT

1. Chemical: Dicofol (Kelthane), Shaughnessy No. 010501

2. Test Material: Technical Dicofol, 95.6% ai (< 0.1% DDT-r)

3. Study Type: Oyster Shell Growth

   Species Tested: Eastern Oyster (Crassostrea virginica)

4. Study ID: Ward, G.S. (1986) Dicofol (Kelthane® Technical Miticide): Acute Toxicity of Kelthane Technical on the Shell Growth of the Eastern Oyster (Crassostrea virginica). Study conducted by Environmental Science and Engineering, Inc., Gainesville, FL (Report No. 85-351-0100-2130). Submitted by Rohm and Haas Company (Report No. 86RC-010), Spring House, PA. Accession No. 400420-61.

5. Reviewed By:

   Larry Turner — Signature: Larry Turner
   Biologist
   EEB/HED — Date: June 1, 1987

6. Approved By:

   Norman Cook — Signature: Norman J. Cook
   Head-Section II
   EEB/HED — Date: 6.1.87

7. Conclusions:

   The test is not scientifically sound and does not fulfill Guidelines requirements because the test was a flow-through test without measured concentrations.

8. Recommendations: No repair is possible.

9. Background:

   This study was submitted in response to the Registration Standard requirements for Dicofol.

10. Discussion of Individual Test: N/A.

11. Materials and Methods:

    a. Test Animals - Test animals were eastern oysters (Crassostrea virginica). Oysters were obtained from Cosper Environmental Services, Inc. (location unknown) and were maintained in a submerged cage at Marineland, FL for 7 days and then transferred to ESE where they were acclimated for an additional 3 days in unfiltered seawater at 20 °C. Shell length (umbo to distal value edge) was approximately 20 to 30 cm.

b. Test System - Test water was natural, unfiltered seawater collected from Marineland, FL. Water was not adjusted for salinity, but was adjusted to 20 °C. The test was conducted in 16.3 L glass aquaria, each containing 8.8 L of water to a depth of 8.2 cm. Test was flow-through with a rate of 20.4 L/hour. Temperature during the test was 20 to 23 °C; photoperiod was 14L/10D. Just prior to test initiation, 2 to 5 mm of shell was ground by hand to provide a smooth, flattened edge. A range-finding test indicated that the EC_{50} was between 10 and 100 ppb.

Test concentrations were prepared by metering stock solutions into mixing chambers with dilution water. Stock solutions were prepared by dissolving the dicofol in acetone. Delivery of stock solutions was intended to be 1.146 mL/hours, but averaged only 0.86 mL/hour apparently because of "tackiness" due to acetone evaporation. Oysters were removed after 96 hours and new shell growth was measured to the nearest 0.1 mm and compared with the solvent control.

During the test, water quality parameters included temperature of 21 ± 2 °C, salinity of 23 to 26 ppt, dissolved oxygen greater than 7.2 mg/L, and pH range of 7.3 to 7.9.

c. Dose - Intended test concentrations were 0 (control), 10, 17, 29, 48, and 80 ppb. Because of the reduction in pump delivery rate, test concentrations were calculated as 0 (control), 7.5, 12.8, 21.8, 36, and 60 ppb. Although stated as "actual test concentrations, based upon average delivery rate", it appears that the actual concentrations were calculated rather than measured.

d. Design - Twenty oysters were tested at each concentration and in the control and solvent controls. There is no information as to the number of replicates for each concentrations.

e. Statistics -

1) A comparison of solvent control and seawater control was done by "Student's" t-test.

2) Differences of treated concentrations versus controls was determined by ANOVA followed by Williams multiple comparison test.

3) The response variable was transformed by probit and then regressed, using least square regression, against log-concentration. An F test for linearity was conducted to determine if regression adequately described the data.

12. Reported Results:

The 96-hour EC_{50} for shell growth is 22.3 ppb with 95% confidence limits of 16.7 to 29.8 ppb. Tabular results for the various concentrations are presented below.

Table 3-1. Effect of Kelthane Technical on Shell Deposition of Eastern Oysters (Crassostrea virginica) Exposed Continuously for 96 Hours in Flowing, Natural Seawater

Nominal Concentration (ug/L; ppb)	Mean Shell Deposition (mm)	Percentage[a] Change
Seawater Control	3.28 ± 1.22	+11
Solvent Control	2.96 ± 1.21	---
7.5	2.79 ± 1.39	-6
12.8	2.54 ± 1.37	-14
21.8	1.64 ± 0.77	-44[b]
36	0.62 ± 0.78	-79[b]
60	0.14 ± 0.22	-95[b]

a/Percentage change = $\frac{\text{Shell deposition of exposed oysters minus Shell deposition of solvent control oysters}}{\text{Shell deposition of solvent control oyters}} \times 100$

b/Statistically different from solvent control at $p \geq 0.95$.

13. Study Author's Conclusions/QA Measures:

None beyond reported results.

QA Measures:

The study was conducted in conformance with GLPs except the "test article/carrier mixture was not assayed for homogeneity, stability, or test article concentration." The QA statement indicates that the protocol and SOPs were followed and that the report is an accurate reflection of the raw data.

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

a. Test Procedures - The study more or less followed acceptable protocols. The report identified five deviations from the investigator's protocol and claimed that these deviations had no apparent effect. These deviations were:

1) Initial control pH in the control was lower than allowed in the protocol (7.3 vs. 8.0 ± 0.5), although the reliability of the measurement was considered doubtful.

2) Initial size of oysters was 19.4 to 28.4 mm rather than 30 to 50 mm.

3) Acclimation procedures were altered from the protocol, but were reasonable.

4) Test temperature deviation was more than 1 °C on day 1, but was corrected.

5) EC_{50} was calculated by least squares regression rather than the Stephan program.

EEB is not particularly concerned with the above deviations. However, if the reliability of the initial pH measurement is considered doubtful, then, since no description of correction was provided, it is possible that other pH measurements are also unreliable. In addition, the temperature variation was 3 °C between day 1 and day 2 and was 2 °C between day 2 and day 3. Although oysters of this size may not be very sensitive to such changes in temperature, it is important to ensure consistency among the treatment levels. No temperature measurement was reported for the solvent control or the test concentrations. The variation was corrected in the saltwater control, but (1) similar or greater variation could have occurred undetected, and therefore uncorrected, in other test chambers, and (2) other chambers may not have been tested at the same temperature.

However, the above deviations are minor in comparison with the test concentrations. First, in a flow-through test, actual concentrations must be measured. Second, if the metering system delivers 0.86 mL/hr of stock solution of dicofol in acetone and the flow rate of dilution water is 20.4 L/hr, then stock solution concentration in dilution water is 0.042 mL/L (0.86 mL/hr ⊛ 20.4 L/hr). No information was reported on dicofol concentrations in the stock solution; if the stock solution was 100% w/v, then the maximum concentration could be only 42 ppb. Yet the highest concentration was reported as 60 ppb. Finally, the pump delivery rate was inconsistent, which means that

concentrations were not constant. The variation might have been accommodated if concentrations had been measured, but such a problem should have been dealt with by reinitiating the test and cleaning the syringes more frequently.

It also should be noted that the text of the report states that salinity was 23 to 26 ppt. However, the submitted water quality data showed only a single salinity measurement in one chamber for the entire test. Single measurements do not result in ranges.

b. Statistical Analysis - An analysis by ANOVA/Duncan's multiple range test showed 21.8 ppb to be the lowest level significantly different from the solvent control, but that 12.8 ppb was also significantly different from the seawater control. EEB's EC_{50} analysis (22.8 ppb) was comparable to that reported (22.3 ppb).

c. Discussion/Results - The test is not scientifically sound because of equipment malfunctions and a lack of measured concentrations.

d. Adequacy of Study

1) Classification - Invalid.

2) Rationale - Test concentrations were not measured, as they should be in flow-through tests. Problems with pump delivery compounded the lack of measured concentrations.

3) Repairability - No repair is possible.

15. Completion of One-Liner Form:

One-liner completed May 18, 1987.

16. CBI Appendix: N/A.

33