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

APR 19 1993

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Subject: Triadimefon Data Requirements Update

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

To: Mark Wilhite, PM Team 53 Reviewer
Special Review and Reregistration Division (H7508C)

Attached are 5 actions (D167380, D174193, D166958, D179333, and D162709, Case No. 816353, S# 109901) which resulted in 14 EEB Data Evaluation Record of studies plus 2 addendums for previously submitted studies.

The enclosed table, "Data Requirements for Ecological Effects Branch", summarizes the data requirements for triadimefon.

Please contact Dennis J. McLane (305-5096) if you have any further questions.

Date:4-9-93
Case No:816353
Chemical No:109901

TRIADIMEFON
DATA REQUIREMENTS FOR
ECOLOGICAL EFFECTS BRANCH

Data Requirements	Composition[1]	Use Group[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA3(c)(2)(B)?
6 Basic Studies in Bold					
71-1(a) Acute Avian Oral, Quail/Duck	(TGAI)	A,C,I,K	YES	41895901*	NO
71-1(b) Acute Avian Oral, Quail/Duck	(TEP)	-------	NO	------	NO
71-2(a) Acute Avian Diet, Quail	(TGAI)	A,C,I,K	YES	00050066	NO
71-2(b) Acute Avian Diet, Duck	(TGAI)	A,C,K	NO	00050067	YES
71-3 Wild Mammal Toxicity	(TGAI)	-------	NO	-------	NO
71-4(a) Avian Reproduction Quail	(TGAI)	A,C	YES	248177, 42342301	NO
71-4(b) Avian Reproduction Duck	(TGAI)	A,C	YES	42342302	NO
71-5(a) Simulated Terrestrial Field Study	-------	-------	NO	-------	NO
71-5(b) Actual Terrestrial Field Study	-------	-------	NO	-------	NO
72-1(a) Acute Fish Toxicity Bluegill	(TGAI)	A,C,K	NO	00070704	YES
72-1(b) Acute Fish Toxicity Bluegill	(TEP)	A,C	NO	147863 or 460087004*	NO
72-1(c) Acute Fish Toxicity Rainbow Trout	(TGAI)	A,C,I,K	NO	00070704	YES
72-1(d) Acute Fish Toxicity Rainbow Trout	(TEP)	A,C	NO	147864 or 4600087005*	NO
72-2(a) Acute Aquatic Invertebrate Toxicity	(TGAI)	A,C,I,K	YES	231311, 147862 or 460089003	NO
72-2(b) Acute Aquatic Invertebrate Toxicity	(TEP)	A,C	NO	147865 or 460087006	NO
72-3(a) Acute Estu/Mari Tox Fish	(TGAI)	-------	NO	NO	RESERVED
72-3(b) Acute Estu/Mari Tox Mollusk	(TGAI)	-------	NO	NO	RESERVED
72-3(c) Acute Estu.Mari Tox Shrimp	(TGAI)	-------	NO	NO	RESERVED

* In Bibliographic Citation column indicates study may be upgradeable

Date:4-9-93
Case No:816353
Chemical No:109901

TRIADIMEFON
DATA REQUIREMENTS FOR
ECOLOGICAL EFFECTS BRANCH

Data Requirements	Composition[1]	Use Group[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA3(c)(2)(B)?
72-3(d) Acute Estu/Mari Tox Fish	(TEP)	-------	NO	-------	RESERVED
72-3(e) Acute Estu/Mari Tox Mollusk	(TEP)	-------	NO	-------	RESERVED
72-3(f) Acute Estu/Mari Tox Shrimp	(TEP)	-------	NO	-------	RESERVED
72-4(a) Early Life-Stage Fish	(TGAI)	A,C	NO	248177 41922103* 251243	YES
72-4(b) Life-Cycle Aquatic Invertebrate	(TGAI)	A,C	YES	246736 41922102	NO
72-5 Life-Cycle Fish	(TGAI)	A,C	NO	-------	RESERVED
72-6 Aquatic Org. Accumulation	(TGAI)	A,C	NO	-------	NO
72-7(a) Simulated Aquatic Field Study	(TEP)	A,C	NO	-------	NO
72-7(b) Actual Aquatic Field Study	(TEP)	A,C	NO	-------	NO
122-1(a) Seed Germ./Seedling Emerg.	(TGAI)	A,C	NO	-------	NO
122-1(b) Vegetative Vigor	(TGAI)	A,C	NO	-------	NO
122-2 Aquatic Plant Growth	(TGAI)	A,C	NO	-------	NO
123-1(a) Seed Germ./Seedling Emerg.	(TGAI)	A,C	NO	-------	NO
123-1(b) Vegetative Vigor	(TGAI)	A,C	NO	-------	NO
123-2 Aquatic Plant Growth	(TGAI)	A,C	NO	159558 41616007	YES
124-1 Terrestrial Field Study	(TGAI)	A,C	NO	-------	NO
124-2 Aquatic Field Study	(TGAI)	A,C	NO	-------	RESERVED
141-1 Honey Bee Acute Contact	(TGAI)	A,C	YES	42307804	NO
141-2 Honey Bee Residue on Foliage	(TGAI)	A,C	NO	-------	NO
141-5 Field Test for Pollinators	(TGAI)	A,C	NO	-------	NO

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* In Bibliographic Citation column indicates study may be upgradeable

1.Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product

2. Use Group: A = Terrestrial/Food; B = Terrestrial/Feed; C = Terrestrial Non-Food; D = Aquatic Food; E = Aquatic Non-Food (Outdoor); F = Aquatic Non-Food (Industrial); G = Aquatic Non-Food (Residential); H = Greenhouse Food; I = Greenhouse Non-Food; J = Forestry; K = Residential Outdoor; L = Indoor Food; M = Indoor Non-Food; N = Indoor Medical; O = Indoor Residential; Z = Use Group for Site 0000

FEB Files

DP Barcode : D167380
PC Code No : 109901
EEB Out :

To: Mark Wilhite
PM Team Reviewer 53
Special Review & Reregistration Division (H7508C)

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

Attached, please find the EEB review of...
Reg./File # : 003125
Chemical Name : 1-(4-Chlorophenoxy)-3,3-dimethyl-1-(1H1,2,4 - triazol-1-yl)-2-butanone
Type Product : Fungicide
Product Name :
Company Name : Mobay Corporation
Purpose : Review 72-4(a) MRID 41922102 & 72-4(b) 41922103
Action Code : 627 , Date Due : 11/06/91
Assigned Scientist : McLane, Dennis J. Date In EEB: 08/12/91

_____EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)	N/A		72-2(A)	N/A		72-7(A)	N/A	
71-1(B)	N/A		72-2(B)	N/A		72-7(B)	N/A	
71-2(A)	N/A		72-3(A)	N/A		122-1(A)	N/A	
71-2(B)	N/A		72-3(B)	N/A		122-1(B)	N/A	
71-3	N/A		72-3(C)	N/A		122-2	N/A	
71-3	N/A		72-3(C)	N/A		122-2	N/A	
71-4(A)	N/A		72-3(D)	N/A		123-1(A)	N/A	
71-4(B)	N/A		72-3(E)	N/A		123-1(B)	N/A	
71-5(A)	N/A		72-3(F)	N/A		123-2	N/A	
71-5(B)	N/A		72-4(A)	41922103	Invalid	124-1	N/A	
72-1(A)	N/A		72-4(B)	41922102	Supple.	124-2	N/A	
72-1(B)	N/A		72-5	N/A		141-1	N/A	
72-1(C)	N/A		72-6	N/A		141-2	N/A	
72-1(D)	N/A					141-5	N/A	

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur
N/A=No studies submitted for EEB.

EEB files

MRID No. 419221-02

DATA EVALUATION RECORD

1. **CHEMICAL:** Bayleton.
Shaughnessey No. 109901.

2. **TEST MATERIAL:** Bayleton technical; 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1*H*-1,2,4-triazol-1-yl)-2-butanone; CAS No. 43121-43-3; Batch No. 9-00-6001; 94.2% active ingredient; a tan powder.

3. **STUDY TYPE:** *Daphnia magna* Life-Cycle (21-day Renewal) Chronic Toxicity Test. Species Tested: Water Flea (*Daphnia magna*).

4. **CITATION:** Gagliano, G.G. 1991. Chronic Toxicity of Bayleton® Technical to the Water Flea (*Daphnia magna*) Under Static Renewal Conditions. Mobay Report No. 101298. Prepared by Biochemistry and Ecological Effects Section, Mobay Corporation, Stilwell, KS. Submitted by Mobay Corporation, Kansas City, MO. EPA MRID No. 419221-02.

5. **REVIEWED BY:**

Louis M. Rifici, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Louis M Rifici
Date: 1/2/92
Doris Peter 3/15/93

6. **APPROVED BY:**

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

Signature: P. Kosalwat
Date: 1/6/92

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

Signature: Henry T. Craven
Date: 4/13/93

7. **CONCLUSIONS:** This study is scientifically sound but does not meet the guideline requirements for a chronic toxicity study using *Daphnia magna*. The individual daphnid length data were not included in the report. The MATC, based on the most sensitive biological parameter, adult daphnid length, was >52.1 µg/l and <119 µg/l mean measured concentration. The geometric mean MATC was 78.7 µg/l mean measured concentration.

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8. **RECOMMENDATIONS:** The registrant should submit the raw length data.

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** First instar *Daphnia magna* (<24 hours old) used in this test were obtained from in-house cultures. The adults used as the source of the test daphnids were maintained under test conditions. They were fed algae (*Selenastrum capricornutum*, *Ankistrodesmus falcatus*, and/or *Nitzchia* sp.) and a trout chow, yeast, and cereal leaves suspension three times per week.

B. **Test System:** The test chambers were 1-l glass beakers containing approximately 900 ml of test solution. The beakers were randomly positioned in a water bath (20 ±1°C) under a 16-hour light/8-hour dark photoperiod. The intensity of the cool white and Agro-lite fluorescent tubes was 40-65 ft-candles. Thirty-minute transition periods between light and dark were used.

The dilution water was soft-blended water produced by mixing spring water with treated city water for a final hardness of 160-180 mg/l. The water was screened weekly for residual chlorine and was aerated and UV sterilized prior to use. A chemical characterization of the water is presented in Table 1 (attached).

The test substance was dissolved in acetone. Aliquots of this solution or a secondary stock solution were diluted in dilution water to make the test solutions.

C. **Dosage:** Twenty-one-day, static-renewal, life-cycle chronic toxicity test. Based on a preliminary test, six nominal concentrations (7.5, 15, 30, 60, 120, and 240 µg a.i./l), a dilution water control, and a solvent control (0.020 mL acetone/l) were selected for the test.

D. **Design:** Ten first instar daphnids were impartially selected and distributed to each of 4 test beakers per concentration. The loading rate was approximately 1 daphnid per 100 ml of test solution. The test

solutions were renewed every Monday, Wednesday, and Friday (study days 3, 5, 8, 10, 12, 15, 17, and 19). The adult daphnids were transferred to corresponding beakers containing freshly prepared test solutions within 4 hours of preparation. Survival of the parent daphnids was determined daily until the release of the first broods, after which observations for mortality, sublethal effects, and reproduction were made on solution renewal days. On day 21, the body lengths of the adult daphnids were measured using a dissecting microscope and stage micrometer.

The daphnids were fed algae (1.0×10^7 to 5.7×10^7 cells/l) and supplemented with 0.5 to 1 ml/l of a yeast, trout chow, and cereal leaves suspension.

Temperature, dissolved oxygen concentration (DO), conductivity, total alkalinity, total hardness, and pH were measured in alternating replicates of the controls and the low, middle, and high test levels on days 1, 8, 15 and 21. Hourly temperatures of a centrally-located test chamber were documented using a data logger.

Samples of the fresh test solutions were taken on days 1, 5, 8, 15, and 19 to measure the actual concentration of Bayleton using gas chromatography. The old test solutions on day 8 were also sampled to determine the stability of the test material.

E. Statistics: Tests for normality and homogeneity of variance were performed using chi-square and Bartletts's tests on the data sets prior to analysis. Survival data were analyzed using Fisher's Exact test. The number of young per adult reproductive day was calculated for each replicate and analyzed using one-way analysis of variance (ANOVA) and Dunnett's test. The time (days) to first brood release and adult length were analyzed using the same methods as the reproduction data. The responses of the exposed daphnids were compared to those of the pooled control data in all tests. Conclusions of statistical significance were based on a 95% confidence level.

12. REPORTED RESULTS: The results of analyses of the freshly-prepared test solutions are presented in Table 2 (attached). The mean measured concentrations calculated from this data were 14.0, 15.7, 29.6, 52.1, 119, and 283 µg/l. These values represented 187, 105, 99, 87, 99, and 118% of nominal concentrations. "Bayleton technical was shown to be stable

A. **Test Procedure:** The test procedures were generally in accordance with protocols recommended by the SEP and ASTM (1986) guidelines, but deviated as follows:

The design of the test (i.e., four chambers per concentration, ten daphnids per chamber) deviated from SEP and ASTM (1986) guidelines. The SEP recommends seven chambers containing a single daphnid and three chambers containing five daphnids. The ASTM guidelines recommend ten chambers, each containing a single daphnid. The loading rate in the chambers met the guideline requirements.

The report stated that the temperature, hardness, alkalinity, and conductivity were measured in the controls and several test levels at least weekly. The hardness, alkalinity, and conductivity results were not presented in the report. The individual temperature measurements were not presented, however, the results of continuous temperature monitoring were. These data indicate that the temperature remained within the recommended range of 19-21°C throughout the study period.

The daphnids were measured to the nearest 0.1 mm at the end of the test. The SEP states that the daphnids should be measured to the nearest 0.01 mm.

The raw adult length data were not included in the report. Raw data must be included to allow independent statistical analysis.

B. **Statistical Analysis:** To validate the author's statistical analysis, the reviewer used non-parametric (Steel's Many-One rank test) or one-way ANOVA to analyze the survival and number of young produced per female reproductive day (see attached printouts 1-4). The survival data were arcsine square root transformed before the analysis. The results were the same as the author's. The raw adult length data were not included in the report so the author's statistical analysis could not be validated. A two-way ANOVA using the individual length data would be appropriate.

C. **Discussion/Results:** The author reported the reduction in the concentration of the test compound ranged from 2.4% at 29.6 µg/l to 6.7% at 283 µg/l mean measured concentration. It appears that the author used the day 5-8 interval (Table 2, attached) to determine the

stability of the test material. The reviewer used the same interval and found that the concentration of the test material decreased by as much as 8.9% (119 µg/l) and increased by as much as 22.1% (15.7 µg/l). It is unclear how the author calculated the percent reduction in the compound.

The concentration of Bayleton in the 7.5 µg/l (nominal) test solutions was highly variable. The author chose to exclude the biological data from statistical analysis due to this variability citing that "omission of this test level does not influence the validity of the study." Since there were no biological effects at this level and significant effects occurred only at much higher levels, the study need not be classified "invalid" based on the anomalous results at this concentration.

This study is scientifically sound but does not meet the guideline requirements for a chronic toxicity study using *Daphnia magna*. The individual daphnid length data were not included in the report. The MATC, based on the most sensitive biological parameter, adult daphnid length, was >52.1 µg/l and <119 µg/l mean measured concentration. The geometric mean MATC was 78.7 µg/l mean measured concentration.

D. Adequacy of the Study:

(1) **Classification:** Supplemental.

(2) **Rationale:** The individual daphnid length data were not included in the report. Raw data must be included to allow independent statistical analysis.

(3) **Repairability:** The registrant should submit the raw length data. The study may be upgraded to "core" upon satisfactory review of the submitted data.

15. COMPLETION OF ONE-LINER FOR STUDY: Yes, 12-17-91.

REFERENCES: ASTM. 1986. New Standard Guide for Conducting Renewal Life-Cycle Toxicity Tests with Daphnia magna. Draft No. 8.

RIN 5710-93

TRIADIMEFON EFB REVIEW

Page_____ is not included in this copy.

Pages 11 through 15 are not included.

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.

✓ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

TITLE: 419221-02, bayleton, daphnid survival, 21 days
FILE: a:41922102.dt1
TRANSFORM: ARC SINE(SQUARE ROOT(Y)) NUMBER OF GROUPS: 7

GRP	IDENTIFICATION	REP	VALUE	TRANS VALUE
1	solvent control	1	0.9000	1.2490
1	solvent control	2	1.0000	1.4120
1	solvent control	3	1.0000	1.4120
1	solvent control	4	1.0000	1.4120
2	dilut. control	1	0.9000	1.2490
2	dilut. control	2	0.9000	1.2490
2	dilut. control	3	1.0000	1.4120
2	dilut. control	4	1.0000	1.4120
3	15.7	1	1.0000	1.4120
3	15.7	2	1.0000	1.4120
3	15.7	3	1.0000	1.4120
3	15.7	4	1.0000	1.4120
4	29.6	1	0.8000	1.1071
4	29.6	2	1.0000	1.4120
4	29.6	3	0.8000	1.1071
4	29.6	4	1.0000	1.4120
5	52.1	1	0.9000	1.2490
5	52.1	2	1.0000	1.4120
5	52.1	3	0.9000	1.2490
5	52.1	4	1.0000	1.4120
6	119	1	1.0000	1.4120
6	119	2	1.0000	1.4120
6	119	3	1.0000	1.4120
6	119	4	1.0000	1.4120
7	283	1	0.9000	1.2490
7	283	2	1.0000	1.4120
7	283	3	1.0000	1.4120
7	283	4	1.0000	1.4120

Shapiro Wilks test for normality
Data PASS normality test at P=0.01 level. Continue analysis.

Hartley test for homogeneity of variance
Bartletts test for homogeneity of variance
These two tests can not be performed because at least one group has zero variance.
Data FAIL to meet homogeneity of variance assumption.
Additional transformations are useless.

DATA EVALUATION RECORD

1. **CHEMICAL:** Bayleton (triadimefon).
Shaughnessey No. 109901.

2. **TEST MATERIAL:** Bayleton Technical; Batch No. 9-00-6005; 94.2% active ingredient; an off-white powder.

3. **STUDY TYPE:** Freshwater Fish Early Life-Stage Test.
Species Tested: Fathead Minnow (*Pimephales promelas*).

4. **CITATION:** Cohle, P. and K.C. Friesen. 1991. Early Life Stage Toxicity of BAYLETON® to Fathead Minnows (*Pimephales promelas*) in a Flow-Through System. Report No. 101301. Study conducted by Analytical Bio-Chemistry Laboratories, Inc., Columbia, Missouri. Submitted by Mobay Corporation, Agricultural Chemicals Division, Kansas City, Missouri. EPA MRID No. 419221-03.

5. **REVIEWED BY:**

Rosemary Graham Mora, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Rosemary Graham Mora
Date: 1/3/92
Dan Peterson 3-15-93

6. **APPROVED BY:**

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

Signature: P. Kosalwat
Date: 1/6/92

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

Signature:
Date:

7. **CONCLUSIONS:** This study is not scientifically sound and does not meet the guideline requirements for a fish early life-stage test. The dilution water control group had high mortality (i.e., 35% mortality in one of the control chambers) and the %RSD of weight data in three control replicates and two solvent control replicates was >40%. In addition, individual growth data were not presented in the report, therefore the authors' results could not be verified. According to the authors' report, the MATC of Bayleton for *Pimephales promelas* was >0.17 and <0.27 mg a.i./l mean measured concentrations (geometric mean MATC = 0.21 mg a.i./l).

INVALID

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8. **RECOMMENDATIONS:**

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Fertilized eggs of fathead minnow (*Pimephales promelas*) were obtained from an in-house spawning culture. The eggs were spawned onto stainless steel tiles which had been placed into broodstock spawning aquaria. The tiles were placed into a pan of water and the eggs were harvested from the tiles. Usable intact eggs were sorted into a dish until they were distributed to the incubation cups.

B. **Test System:** The test system was a 2-l intermittent proportional diluter. The diluter delivered (via flow-splitting chambers) selected nominal concentrations of test material and controls to four replicate test chambers. The diluter was allowed to equilibrate for 44 hours prior to test initiation. The diluter delivered approximately 94 l of test solution per day to each replicate which resulted in 8.0 volume replacements per day. At test termination, a biomass loading rate of 0.05 g/l/day was established at this flow rate.

Each glass test aquarium was divided into two duplicate chambers (2 aquaria/concentration). Each chamber measured 15.7 x 30.5 cm with a water depth of 24.4 cm yielding an approximate 11.7-l chamber volume and was equipped with a stainless steel screen-covered drain to prevent fry escape. Embryo incubation cups were constructed from glass jars (9.0 cm diameter) with 40-mesh Nytex screen bottoms and were suspended in each replicate chamber.

Embryos and newly hatched fry were shielded from excess light exposure until one week post-hatch. At this time a photoperiod of 16 hours of light with a light intensity of 64 ±4.3 footcandles at the water surface was initiated. Thirty-minute simulated dawn and dusk transition periods were provided. Test aquaria were arranged in one row on one tier, using a random number table, in a heated water bath set at 25 ±2°C.

Treated (reverse osmosis) deep well water was combined with untreated well water to obtain a mean pH of

approximately 7.8 and a total hardness range of approximately 160-180 mg/l as $CaCO_3$. The dilution water had an alkalinity of 178-194 mg/l as $CaCO_3$ and a specific conductivity of 374-426 μmhos/cm.

Diluter stock solutions were prepared by dissolving 10,293 mg of Bayleton total product in a total volume of 100 ml of dimethylformamide (DMF) resulting in a concentration of 97,000 mg a.i./l. Solutions were delivered by the diluter system in aliquots of 10-100 ml.

C. Dosage: Thirty-five-day embryo-larval, flow-through test. Nominal test concentrations selected, based on results of preliminary testing, were 0.075, 0.15, 0.3, 0.6, and 1.2 mg a.i./l. A dilution water control and a solvent control were also included. The solvent control contained 0.012 ml of DMF/l which is equal to the highest concentration of solvent at the highest test level.

D. Design: Twenty embryos (<24 hours post-spawn) were impartially distributed in groups of two to each incubation cup in each replicate chamber (i.e., 80 embryos/concentration). A rocker arm apparatus vertically oscillated the cups in the test solutions. Egg mortality in each cup was recorded and dead eggs removed daily.

Once hatching was complete (test day 7), the fry were released into the test chambers. From day 4, fish were fed rotifers, brine shrimp nauplii, and salmon starter mash. Fish were fed generally 3 times daily, except on day 4 (1 feeding) and ≥24 hours prior to test termination (no feeding). The aquaria were siphoned as needed to remove excess food, fecal matter, and any biological growth.

Test chambers were inspected daily and observations of abnormal physical changes, abnormal behavior, and mortality were recorded. Dead fry were discarded. At test termination (test day 35), surviving fish were sacrificed and blotted wet weight for individual fish was measured using direct computer capture. Standard length was measured using a digitizing tablet and data were directly entered into a data worksheet. Hatchability and total survival data were collected along with growth measurements.

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Dissolved oxygen (DO) concentration and temperature were measured in one replicate of each control and test concentration with surviving fish. Hardness, alkalinity, conductivity, and pH were measured in one replicate of the control, low and highest test concentration with surviving fish. These water quality parameters were measured on days 0, 1, 7, 14, 21, and 35. Temperature was also monitored continuously in a centrally located test chamber using a data logger and checked twice daily with a mercury thermometer.

Test solutions were analyzed for on days 0, 1, 7, 14, 21, 28, and 35 for Bayleton concentrations using gas-liquid chromatography.

E. Statistics: The random arrangement of duplicate test aquaria (2 replicate chambers/aquaria) provided a nested experimental design.

The dilution water control and solvent control responses were pooled when no significant difference was detected by the chi-square statistic and Fisher's exact test. The treatments were then compared to the pooled control.

Hatchability and survival data were analyzed using frequency analysis (coupled with the chi-square statistic and Fisher's exact test) comparing each test concentration to the control. The experimental unit for these analyses was the replicated chamber. Test concentrations demonstrating a significant reduction in survival were not assessed in growth analysis.

Growth data were analyzed using one-way analysis of variance (ANOVA), appropriate for a nested experimental design. The experimental unit for these analyses was the individual fish. A Dunnett's one-tailed comparison procedure was used when necessary. "A Shapiro-Wilk normality test statistic was computed within each test concentration to assess departures from normality. Should the normality test indicate a deviation from strict normality, the data for each concentration would be examined for indications of central tendency. In cases where the assumptions for an analysis of variance hold entirely or even approximately, the ANOVA is generally the more efficient statistical test for detecting departures from the null hypothesis. If the variability between replicates within aquaria was not statistically significant, or there was no strong and consistent evidence of biological significance, then

the aquaria within concentrations and replicate within aquaria error sources were combined." All conclusions of statistical significance were based on a $p \leq 0.05$.

12. **REPORTED RESULTS:** The mean measured concentrations of test substance established in the test solutions were 0.077, 0.17, 0.27, 0.57, and 1.1 mg a.i./l. These values represent 90-113% of the nominal exposure concentrations (Table 3, attached).

Egg hatch began on day 3 and was complete by day 7 (Table 7, attached). Egg hatch did not appear to be delayed by dose related effects. Egg hatchability in the control, solvent control, and the five test concentrations was 98, 95, 96, 96, 95, 95, and 99%, respectively (Table 8, attached). No significant reduction in hatch at any test level was indicated when compared to the pooled control.

At test termination, survival ranged from 65 to 95% in the control and 80 to 95% in the solvent control (Table 8, attached). No significant difference was detected between the two controls. "Survival was slightly low in the control D replicate at 65%." The authors attributed this low survival to biological variability and did not considered it to have a negative impact on the results of the study. Survival at the two highest test concentrations (0.57 and 1.1 mg a.i./l) were significantly reduced when compared to that of the pooled control.

At test termination, mean standard length and mean wet weight were significantly reduced only at the 0.27 mg a.i./l test level when compared to those of the pooled control (Table 9, attached). Growth data for the two highest test concentrations (0.57 and 1.1 mg a.i./l) were excluded from the statistical growth analysis since survival was significantly reduced at these concentrations and no data were collected from the highest test concentration since mortality was 100%.

"In general, morphological and behavioral abnormalities were sporadically observed in the control, vehicle blank and the three lowest test levels and involved only a few fish...Abnormalities in the two highest test levels were noted primarily during the first week following the completion of hatch and were considered dose related. This week was also a period of heavy fry mortality for these two levels."

During the study, the pH and specific conductance were 8.0-8.4 and 374-426 μmhos/cm, respectively. The temperature

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ranged from 23.9 to 25.8°C and the DO concentration ranged from 6.2 to 8.6 mg/l (79-110% of saturation). Hardness and alkalinity ranges were 164-174 and 178-194 mg/l as $CaCO_3$, respectively.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES: "Based on these results for hatch, survival and growth, the no observed effect concentration (NOEC) was determined to be the 0.17 mg/l test concentration. The lowest observed effect concentration (LOEC) was the 0.27 mg/l test concentration. The NOEC and LOEC represent the MATC limits for an early life stage toxicity study. The point estimate MATC value, defined as the geometric mean of the NOEC and LOEC, was determined to be 0.21 mg/l."

A Study Compliance Statement (signed by the study director) and a Good Laboratory Practice Certification statement (signed by the study director and representatives of the sponsor) were included in the report indicating that this study was conducted in compliance with the U.S. EPA Good Laboratory Practice Standards; Pesticide Programs (40 CFR 160). The report also included a Quality Assurance Statement which was signed by an officer of the laboratory's quality assurance unit.

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

A. Test Procedure: The test procedure is generally in accordance with the SEP and ASTM guidelines, except for the following deviations:

The percent relative standard deviation (%RSD) of weight data was greater than 40% in the A, C, and D replicates of the dilution water control and in the A and D replicates of the solvent control (Table 9, attached). According to the guidelines, the %RSD for weight data in any control replicate must not be >40%.

By test termination, 35% mortality occurred in the D replicate of the dilution water control. A test is considered unacceptable if mortality in any control chamber exceeds 30%.

Individual growth data were not submitted by the registrant. All raw data for each biological endpoint and for physical and chemical parameters measured during the test must be submitted.

The author did not report the number of males and females involved in producing the embryos used in this

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study; the SEP recommends at least 3 males and 3 females.

The report does not indicate whether the dilution water was intensely aerated prior to addition of the test material. However, the DO range in the test solutions during the study is acceptable.

Total hardness of the dilution water (160-180 mg/l as $CaCO_3$) used in the test was higher than the recommended hardness of 40-48 mg/l as $CaCO_3$.

Fish weight was measured as blotted wet weight; ASTM prefers dry weight.

B. Statistical Analysis: The survival and hatchability data (arcsine square-root transformed) were analyzed using a one-way ANOVA. The survival at each treatment level was compared with that of the solvent control using a multiple comparison test (i.e., Dunnett's). Analysis of hatchability data demonstrated no significant difference between the solvent control and any test concentration (printout, attached). Analysis of the survival data demonstrated a significant difference between the solvent control and the two highest test concentrations (0.57 and 1.1 mg a.i./l) (printout, attached). These results are the same as those of the authors'.

Individual growth data were not included in the report; therefore, the results presented by the authors could not be verified.

C. Discussion/Results: This study is not scientifically sound and does not meet the guideline requirements for a fish early life-stage test. There was high mortality (35%) in one replicate of the dilution water control and the %RSD for the weight data of three control replicates and two solvent control replicates was >40%. According to the guidelines, a test is unacceptable if >30% mortality is observed in any control chamber and if the %RSD in any control chamber is greater than 40%. In addition, individual growth data were not included in the report, therefore the authors' analyses could not be verified.

The author excluded from statistical growth analysis the highest level from which growth data were available (0.57 mg a.i./l) since this level showed effects on survival. Growth data from this treatment level should

have been included in the analysis since it is part of the experiment and could have contributed to the experimental error in the ANOVA. Furthermore, excluding these growth data from statistical analysis would make it appear as if only survival was affected at this treatment level.

Based on the results presented by the authors, the MATC of Bayleton for the fathead minnow was >0.17 and <0.27 mg a.i./l mean measured concentrations (geometric mean MATC = 0.21 mg a.i./l).

D. **Adequacy of the Study:**

(1) **Classification:** Invalid.

(2) **Rationale:** 1) There was high mortality (35%) in one replicate of the dilution water control. 2) The %RSD for weight data in three control replicates and two solvent control replicates was >40%. 3) Individual growth data were not submitted with the report. 4) Statistical analyses could not be verified due to the lack of raw data.

(3) **Repairability:** No.

15. **COMPLETION OF ONE-LINER:** Yes, December 18, 1991.

RIN 5710-93

TRIADIMEFON EFB REVIEW

Page____ is not included in this copy.

Pages 25 through 27 are not included.

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.

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TITLE: Bayleton: Pecentage Survival of Exposed P.p. Larvae
FILE: 41922103.sur
TRANSFORM: ARC SINE(SQUARE ROOT(Y)) NUMBER OF GROUPS: 7

GRP	IDENTIFICATION	REP	VALUE	TRANS VALUE
1	Solvent Control	1	0.9000	1.2490
1	Solvent Control	2	0.9500	1.3453
1	Solvent Control	3	0.8000	1.1071
1	Solvent Control	4	0.9000	1.2490
2	Control	1	0.9000	1.2490
2	Control	2	0.9500	1.3453
2	Control	3	0.9000	1.2490
2	Control	4	0.6500	0.9377
3	0.077 mg/l	1	1.0000	1.4588
3	0.077 mg/l	2	0.7000	0.9912
3	0.077 mg/l	3	0.9000	1.2490
3	0.077 mg/l	4	1.0000	1.4588
4	0.17 mg/l	1	0.7500	1.0472
4	0.17 mg/l	2	1.0000	1.4588
4	0.17 mg/l	3	0.9000	1.2490
4	0.17 mg/l	4	0.9000	1.2490
5	0.27 mg/l	1	0.9000	1.2490
5	0.27 mg/l	2	0.8500	1.1731
5	0.27 mg/l	3	0.9500	1.3453
5	0.27 mg/l	4	0.6500	0.9377
6	0.57 mg/l	1	0.4500	0.7353
6	0.57 mg/l	2	0.4000	0.6847
6	0.57 mg/l	3	0.5000	0.7854
6	0.57 mg/l	4	0.5500	0.8355
7	1.1 mg/l	1	0.0000	0.1120
7	1.1 mg/l	2	0.0000	0.1150
7	1.1 mg/l	3	0.0000	0.1120
7	1.1 mg/l	4	0.0000	0.1120

BAYLETON: Percentage Survival of Exposed P. promelas Larvae
Analysis of Variance
File: bayleton
Date: 12-17-1991

N's, means and standard deviations based on dependent variable: SURVIVAL

* Indicates statistics are collapsed over this factor

	LEVEL	CONCENTRATION	N	Mean	S.D.
Factors:	C				
	*		28	1.0032	0.4272
	1	SOLVENT CONTROL	4	1.2376	0.0981
	2	CONTROL	4	1.1952	0.1776
	3	0.077 mg a.i./l	4	1.2894	0.2221
	4	0.17 mg a.i./l	4	1.2510	0.1681
	5	0.27 mg a.i./l	4	1.1763	0.1740
	6	0.57 mg a.i./l	4	0.7602	0.0649
	7	1.1 mg a.i./l	4	0.1127	0.0015

Fmax for testing homogeneity of between subjects variances:21918.36
Number of variances= 7 df per variance= 3.

Source	df	SS (H)	MSS	F	P
Between Subjects	27	4.9279			
C (CONC)	6	4.4683	0.7447	34.027	0.0000
Subj w Groups	21	0.4596	0.0219		

Post-hoc tests for factor C (CONC)

Level	Mean	Level	Mean
1	1.238	6	0.760
2	1.195	7	0.113
3	1.289		
4	1.251		
5	1.176		

Comparison	Dunnett
1 > 2	
1 < 3	
1 < 4	
1 > 5	
1 > 6	0.0100
1 > 7	0.0100
2 < 3	N.A.
2 < 4	N.A.
2 > 5	N.A.
2 > 6	N.A.
2 > 7	N.A.
3 > 4	N.A.
3 > 5	N.A.
3 > 6	N.A.
3 > 7	N.A.
4 > 5	N.A.
4 > 6	N.A.
4 > 7	N.A.
5 > 6	N.A.
5 > 7	N.A.
6 > 7	N.A.

For Dunnett's test only the P-values .05 and .01 are possible and only for comparisons with the control mean (level 1).

TITLE: Bayleton: Pecentage Hatched of Exposed P.p. Embryos
FILE: 41922103.hat
TRANSFORM: ARC SINE(SQUARE ROOT(Y)) NUMBER OF GROUPS: 7

GRP	IDENTIFICATION	REP	VALUE	TRANS VALUE
1	Solvent Control	1	0.9500	1.3453
1	Solvent Control	2	1.0000	1.4588
1	Solvent Control	3	0.9000	1.2490
1	Solvent Control	4	0.9500	1.3453
2	Control	1	0.9500	1.3453
2	Control	2	0.9500	1.3453
2	Control	3	1.0000	1.4588
2	Control	4	1.0000	1.4588
3	0.077 mg/l	1	1.0000	1.4588
3	0.077 mg/l	2	0.9000	1.2490
3	0.077 mg/l	3	0.9500	1.3453
3	0.077 mg/l	4	1.0000	1.4588
4	0.17 mg/l	1	0.9000	1.2490
4	0.17 mg/l	2	1.0000	1.4588
4	0.17 mg/l	3	0.9500	1.3453
4	0.17 mg/l	4	1.0000	1.4588
5	0.27 mg/l	1	1.0000	1.4588
5	0.27 mg/l	2	0.9500	1.3453
5	0.27 mg/l	3	0.9500	1.3453
5	0.27 mg/l	4	0.9000	1.2490
6	0.57 mg/l	1	1.0000	1.4588
6	0.57 mg/l	2	0.9500	1.3453
6	0.57 mg/l	3	0.9000	1.2490
6	0.57 mg/l	4	0.9500	1.3453
7	1.1 mg/l	1	1.0000	1.4588
7	1.1 mg/l	2	1.0000	1.4588
7	1.1 mg/l	3	1.0000	1.4588
7	1.1 mg/l	4	0.9500	1.3453

BAYLETON: Percentage Hatch of Exposed P. promelas Embryos
Analysis of Variance
File: bayleton
Date: 12-17-1991

N's, means and standard deviations based on dependent variable: HATCH

* Indicates statistics are collapsed over this factor

	LEVEL	CONCENTRATION	N	Mean	S.D.
Factors:	C		28	1.3767	0.0801
	*		4	1.3496	0.0858
	1	SOLVENT CONTROL	4	1.4020	0.0655
	2	CONTROL	4	1.3780	0.1013
	3	0.077 mg a.i./l	4	1.3780	0.1013
	4	0.17 mg a.i./l	4	1.3496	0.0858
	5	0.27 mg a.i./l	4	1.3496	0.0858
	6	0.57 mg a.i./l	4	1.4304	0.0567
	7	1.1 mg a.i./l			

Fmax for testing homogeneity of between subjects variances: 3.18
Number of variances= 7 df per variance= 3.

Source	df	SS (H)	MSS	F	P
Between Subjects	27	0.1733			
C (CONC)	6	0.0229	0.0038	0.534	0.7784
Subj w Groups	21	0.1503	0.0072		

Post-hoc tests for factor C (CONC)

Level	Mean	Level	Mean
1	1.350	6	1.350
2	1.402	7	1.430
3	1.378		
4	1.378		
5	1.350		

Comparison	Dunnett
1 < 2	
1 < 3	
1 < 4	
1 > 5	
1 = 6	
1 < 7	
2 > 3	N.A.
2 > 4	N.A.
2 > 5	N.A.
2 > 6	N.A.
2 < 7	N.A.
3 = 4	N.A.
3 > 5	N.A.
3 > 6	N.A.
3 < 7	N.A.
4 > 5	N.A.
4 > 6	N.A.
4 < 7	N.A.
5 < 6	N.A.
5 < 7	N.A.
6 < 7	N.A.

For Dunnett's test only the P-values .05 and .01 are possible and only for comparisons with the control mean (level 1).

Shaughnessey # 109901 Chemical Name Bayleton (triadimefon) Chemical Class _____ Page 1 of 1

Study/Species/Lab/ MRID #	Chemical % a.i.	Results	Reviewer/ Date	Validation Status
Chronic Fish	94.2	Concentrations Tested (ppm)* - 0.077, 0.17, 0.27, 0.57, 1.1	RCM 12/18/91	Invalid
Species: Pimephales promelas		MATC - > 0.17 < 0.27 ppm*.		
Lab: Analytical Bio-Chemistry Laboratory		Effected Parameters - survival, growth		
MRID # 419221-03		Control Mortality (%) - 15% Solvent Control Mortality (%) - 11%.		
		Comments: *Based on mean measured concentrations of active ingredient. % RSD of 3 dilution water control reps. and 2 solvent reps was >40%. Mortality in rep. D of dilution water control was 35%. Individual growth data were not presented.		
Chronic Invertebrate	_____	Concentrations Tested (pp___) - _____	_____	_____
Species:		MATC - >_____<_____ pp___.		
Lab:		Effected Parameters - _____		
MRID #		Control Mortality (%) - Solvent Control Mortality (%) -		
		Comments:		

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