



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 FIFRA 3(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 460087005*	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 FIFRA 3(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

* In Bibliographic Citation column indicates study may be upgradeable

1. Composition: TGA = 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

DP Barcode : D174193
 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 triadimefon aquatic plant growth study
 Action Code : 627 Date Due : 06/05/92
 Assigned Scientist : McLane, Dennis J. Date In EEB: 02/21/92

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	41616007	Supple.
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)	N/A		124-1	N/A	
72-1(A)	N/A		72-4(B)	N/A		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.

DP BARCODE: D174193

REREG CASE # 2700

CASE: 816353
SUBMISSION: S408729

DATA PACKAGE RECORD
BEAN SHEET

DATE: 02/06/92
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 627 GENERIC DATA SUBMISSION
CHEMICALS: 109901 1-(4-Chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triaz 100.00 %

Bayleton

ID#: 109901-003125

COMPANY: 003125 MOBAY CORPORATION

PRODUCT MANAGER: 53 BRUCE SIDWELL

703-308-8078 ROOM: CS1 3E3

PM TEAM REVIEWER: MARK WILHITE

703-308-8072 ROOM: CS1 3M1

RECEIVED DATE: 11/27/91 DUE OUT DATE: 03/26/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 174193 EXPEDITE: N DATE SENT: 02/06/92 DATE RET.: / /
CHEMICAL: 109901 1-(4-Chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-

DP TYPE: 999 Miscellaneous Data Package

ADMIN DUE DATE: 06/05/92

CSF: N

LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	12/12/91	/ /
BRAN: EEB	02/21/92	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

ATTN: Allen Vaughn

MRID# 416160-07

Copy of the aquatic plant growth study you requested.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
172492	EFGB	12/18/91	04/16/92	Y	N	N

D174193
DPBARCODE (RECORD)
109901
SHAUGHNESSY NO

REVIEW NO.

EEB REVIEW

DATE IN: 02-21-92 OUT: _____

CASE # : 816353 REREG CASE #: 2700
SUBMISSION # : S408729 LIST B
ID # : 109901-003125

DATE OF SUBMISSION _____ 11-27-91

DATE RECEIVED BY EFED _____ 02-12-92

SRRD/RD REQUESTED COMPLETION DATE _____ 03-26-92

EEB ESTIMATED COMPLETION DATE _____ 03-26-92

SRRD/RD ACTION CODE/TYPE OF REVIEW 627 - Generic Data

MRID #(S) 416160-07

DP TYPE 999 - Miscellaneous Data Package

PRODUCT MANAGER, NO. B. Sidwell (53)

PRODUCT NAME(S) Bayleton

TYPE PRODUCT F R I N H D Fungicide

COMPANY NAME Mobay Corp.

SUBMISSION PURPOSE Review aquatic plant growth study

INCLUDE USE(S) _____

COMMON CHEMICAL NAME Triadimefon

DATA EVALUATION RECORD

1. **CHEMICAL:** Triadimefon.
Shaughnessey No. 109901.
2. **TEST MATERIAL:** Bayleton 50% Wettable Powder; Batch No. 1030212; 50% active ingredient (Triadimefon); a tan powder.
3. **STUDY TYPE:** Growth and Reproduction of Aquatic Plants -- Tier 2. Species Tested: Selenastrum capricornutum.
4. **CITATION:** Forbis, A.D. 1986. Acute Toxicity of BAYLETON 50% W.P. to Algae (Selenastrum capricornutum Printz). Final Report No. 34215. Conducted by Analytical Bio-Chemistry Laboratories, Inc., Colombia MO. Submitted by Mobay Chemical Corporation, Stilwell, KS. EPA MRID No. 416160-07.
5. **REVIEWED BY:**

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

Signature: *Louis M. Rifici*
Date: *4/30/91*
Charles Terry
11/29/91
6. **APPROVED BY:**

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

Signature: *P. Kosalwat*
Date: *4/30/91*

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

Signature: *Henry T. Craven*
Date: *12/2/91*
7. **CONCLUSIONS:** This study is scientifically sound but does not fulfill the guideline requirements for a Tier 2 non-target aquatic plant toxicity test. The algae were exposed for 4 days instead of the required minimum of 5. The 96-hour EC₅₀ of Bayleton 50% W.P. for Selenastrum capricornutum was 0.91 mg a.i./L. The maximum application rate of Bayleton 50% W.P. is 5.44 lb/acre (4.0 mg/L). Therefore, Bayleton 50% W.P. would be detrimental to this species if applied at the maximum label rate. The NOEC could not be determined because significant growth inhibition was present at all test levels.
8. **RECOMMENDATIONS:** N/A

9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

A. Test Species: The alga used in the test, Selenastrum capricornutum, came from laboratory stock cultures originally obtained from the American Type Culture Collection, Rockville, MD. Stock cultures were maintained in synthetic algae nutrient medium (Miller et al., 1978). The culture used as inoculum had been transferred to fresh medium 5-7 days before test initiation.

B. Test System: The study was conducted in 250-mL Erlenmeyer flasks containing 100 mL of medium and stoppered with a foam plug. The test medium was the same as that used for culturing with the pH adjusted to 7.5 ± 0.1 .

The test vessels were incubated at $24 \pm 1^\circ\text{C}$ under continuous cool-white fluorescent light on a shaker set to 100 rpm. The light intensity was $400 \pm 10\%$ footcandles (1 footcandle = 10.764 lux).

The test concentrations were prepared by adding the appropriate amount of solid test material directly to medium.

C. Dosage: Ninety-six-hour static test. Based on the results of a preliminary test, five nominal concentrations (0.50, 1.0, 2.0, 4.0, and 8.0 mg/L) and a control were selected for the test.

D. Test Design: Three replicate 250-mL flasks were used per concentration and the control. An inoculum of Selenastrum capricornutum cells calculated to provide 1.0×10^4 cells/mL was aseptically introduced into each flask. The inoculum volume was 1.00 mL per flask.

Cell counts were performed using a hemacytometer and light microscope every 24 hours. One count per replicate was conducted on each counting day.

Temperature, pH, and light intensity were monitored daily.

One replicate of each level at 0 hour was sampled for

quantification of Bayleton 50% W.P. in solution; each replicate was sampled at 96 hours. The samples were analyzed by gas-liquid chromatography.

- E. Statistics: Cell counts for the exposure concentrations and the control were analyzed by analysis of variance (ANOVA) with subsequent means testing using Dunnett's test. The EC₅₀ value was determined using each exposure concentration's percent difference from the control. The best of two quadratic regression models was chosen by least squares and visual techniques.

12. REPORTED RESULTS: The mean measured concentrations are given in Table 4 (attached). Measured concentrations averaged 95 to 109% of nominal.

The growth of Selenastrum capricornutum was significantly inhibited by exposure to all concentrations of Bayleton 50% W.P. (Table 2, attached). The 96-hour EC₅₀ value, calculated based on the percent difference of the mean cell count of exposure concentrations compared to the mean cell count of the control, was calculated as 0.98 mg/L with a 95% confidence interval of 0.75-1.3 mg/L.

The pH of the test solutions increased with increasing toxicant concentration initially (7.6 in the lowest concentration to 8.2 in the highest concentration) but decreased with increasing concentration after 96 hours (7.5-7.0).

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:
No conclusions were made by the author.

Quality Assurance and Good Laboratory Practice Regulation Statements were included in the report, indicating that the study was conducted in accordance with FIFRA Good Laboratory Practice Standards set forth in 40 CFR Part 160.

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

- A. Test Procedure: The test procedure and the report were generally in accordance with the SEP and Subdivision J guidelines, except for the following deviations:

The test duration was four days. A minimum 5-day exposure period is required for tests of this type.

The formulation is 50% inert or carrier ingredients. A control containing the concentration of inert/carrier

ingredients equal to the concentration in the highest exposure level should have been included in the test design.

The number of cells used to inoculate the flasks was 10,000 cells/mL; 3000 cells/mL is recommended.

The dissolved oxygen and conductivity of the test solutions were not measured.

Light intensity during the test was 4.306 \pm 430 klux. The recommended light intensity is 4 klux.

B. Statistical Analysis: The reviewer used a computer program (Toxstat Version 3.0) to analyze the growth data and EPA's Toxanal program to determine the 96-hour EC₅₀ and obtained similar results (see attached printouts).

C. Discussion/Results: Bayleton 50% W.P. inhibited Selenastrum capricornutum growth at concentrations as low as 0.49 mg a.i./L. The maximum application rate for Bayleton 50% W.P. is 5.44 lb/acre or 4.0 mg/L if maximally applied to a 15-cm water column. Therefore the results indicate that Bayleton 50% W.P. would have a detrimental effect on Selenastrum capricornutum when applied at the maximum label application rate.

This study is scientifically sound but does not meet the guideline requirements for a Tier 2 aquatic plant growth and reproduction study. The study was not conducted to the required minimum of 5 days. The 96-hour EC₅₀ of Bayleton 50% W.P. for Selenastrum capricornutum was 0.91 mg a.i./L (95% C.I. = 0.72-1.11 mg a.i./L). The NOEC could not be determined because significant growth inhibition was present at all test levels.

D. Adequacy of the Study:

(1) Classification: Supplemental.

(2) Rationale: The algae were exposed to the test chemical for only 4 days. Five days of exposure are the minimum requirement.

(3) Repairability: No.

15. COMPLETION OF ONE-LINER: Yes, 03/07/91.

RIN 5710-93

TRIADMEFON EFB REVIEW

Page is not included in this copy.

Pages 12 through 13 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.

Printout 1

416160-07 SELENASTRUM GROWTH TRIADIMEFON
File: a:41616007.sel Transform: NO TRANSFORMATION

Chi-square test for normality: actual and expected frequencies

INTERVAL	<-1.5	-1.5 to <-0.5	-0.5 to 0.5	>0.5 to 1.5	>1.5
EXPECTED	1.206	4.356	6.876	4.356	1.206
OBSERVED	0	7	5	6	0

Calculated Chi-Square goodness of fit test statistic = 5.1491
Table Chi-Square value (alpha = 0.01) = 13.277

Data PASS normality test. Continue analysis.

Bartlett's test for homogeneity of variance

Calculated B statistic = 13.49
Table Chi-square value = 15.09 (alpha = 0.01)
Table Chi-square value = 11.07 (alpha = 0.05)

Average df used in calculation ==> df (avg n - 1) = 2.00
Used for Chi-square table value ==> df (#groups-1) = 5

Data PASS homogeneity test at 0.01 level. Continue analysis.

NOTE: If groups have unequal replicate sizes the average replicate size is used to calculate the B statistic (see above).

ANOVA TABLE

SOURCE	DF	SS	MS	F
Between	5	3842473611096.000	768494722219.000	34.874
Within (Error)	12	264434000016.000	22036166668.000	
Total	17	4106907611112.000		

Critical F value = 3.11 (0.05, 5, 12)
Since F > Critical F REJECT Ho: All groups equal

Printout 2

416160-07 SELENASTRUM GROWTH TRIADIMEFON
File: a:41616007.sel Transform: NO TRANSFORMATION

DUNNETTS TEST - TABLE 1 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	T STAT	SIG
1	control	1483000.000	1483000.000		
2	0.49 measured	924000.000	924000.000	4.612	*
3	0.96	768666.667	768666.667	5.894	*
4	1.9	542666.667	542666.667	7.758	*
5	4.0	290000.000	290000.000	9.843	*
6	8.7	49333.333	49333.333	11.828	*

Dunnett table value = 2.50 (1 Tailed Value, P=0.05, df=12,5)

DUNNETTS TEST - TABLE 2 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	NUM OF REPS	Minimum Sig Diff (IN ORIG. UNITS)	% of CONTROL	DIFFERENCE FROM CONTROL
1	control	3			
2	0.49 measured	3	303013.797	20.4	559000.000
3	0.96	3	303013.797	20.4	714333.333
4	1.9	3	303013.797	20.4	940333.333
5	4.0	3	303013.797	20.4	1193000.000
6	8.7	3	303013.797	20.4	1433666.667

Printout 3

LOUIS M. RIFICI TRIADIMEFON SELENASTRUM CAPRICORNUTUM 3-5-91

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
8.7	100	97	97	0
4	100	81	81	0
1.9	100	64	64	0
.96	100	49	49	0
.49	100	39	39	0

BECAUSE THE NUMBER OF ORGANISMS USED WAS SO LARGE, THE 95 PERCENT CONFIDENCE INTERVALS CALCULATED FROM THE BINOMIAL PROBABILITY ARE UNRELIABLE. USE THE INTERVALS CALCULATED BY THE OTHER TESTS.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 1.004144

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS
2	.3051687	.9483914	.6385731 1.390451

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
4	4.036838E-02	1	.1671956

SLOPE = 1.523631
95 PERCENT CONFIDENCE LIMITS = 1.217505 AND 1.829757

LC50 = .9129816
95 PERCENT CONFIDENCE LIMITS = .7159835 AND 1.112863

LC10 = .1339451
95 PERCENT CONFIDENCE LIMITS = 6.983807E-02 AND .2089556
