Shaughnessy No.: 109901

Date Out of EFGWB: 11/8/90

TO: Lewis/Stone
Product Manager # 21
Registration Division (H7505C)

FROM: Michael R. Barrett, Acting Head
Ground-Water Technology Section
Environmental Fate & Ground-Water Branch/EFED (H7505C)

THRU: Henry Jacoby, Chief
Environmental Fate & Ground-Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of:

Reg./File #: 3125-320

Chemical Name: triadimefon

Type Product: fungicide

Product Name: Bayleton

Company Name: Mobay

Purpose: Evaluation of Ground-Water Contamination Potential Prior to Consideration of Tomato Use Inclusion on the Label.

Date Received : 4/9/90 (by EFED)

Action Code: 330

Date Completed: _____

EFGWB # (s): 90-0497

Monitoring study requested: _____

Total Review Time: _____

Monitoring study voluntarily: ____

Deferrals To: ____ Ecological Effects Branch

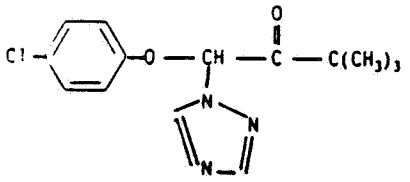
X Health Effects Division

1. Chemical: Common names: triadimefon

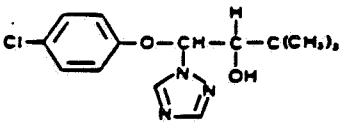
Chemical name: 1-(4-chlorophenoxy-3,3-dimethyl-1(1H-1,2,4-trizol-1-yl)-2-butanone

Trade name: Bayleton®

Structure:



(Baytan)



2. TEST MATERIAL: N/A

3. STUDY/ACTION TYPE: Review/evaluate potential for ground-water contamination prior to consideration of tomatoe use on the label.

4. STUDY IDENTIFICATION: The proposed label was provided but no other information regarding the proposed use of 50% WP on tomatoes was received.

5. REVIEWED BY:

John H. Jordan, Microbiologist
OPP/EFED/EFGWB/Ground-Water Section
Signature: John H. Jordan Date: 10/23/90

6. APPROVED BY:

Michael R. Barrett, Acting Head
OPP/EFED/EFGWB/Ground-Water Section
Signature: Eliz. Behl for MRB Date: 11/8/90

7. CONCLUSIONS:

Triademenol (Baytan®) the major degradate of triadimefon, has a high potential to leach into ground water through vulnerable (sandy) soils and to persist in aquifers that may be used for drinking water.

Dr. George Ghali (Science Analysis and Coordination Branch, HED)†provided the following conclusions concerning the toxicological concerns of parent and degradates:

> Animal data indicate that triadimefon (parent) and baytan, the major degradate, have the potential for developmental toxicity (teratogenicity), maternal toxicity and low level carcinogenicity. There is more immediate concern for the potential developmental (teratogenic) effects than for the potential chronic carcinogenic effects.

†Ghali, George Z. 1990. Evaluation of the Carcinogenic Potential of Triadimefon (Bayleton)®. A Weight of the Evidence Determination. Science Analysis and Coordination Branch, Health Effects Division. June 8, 1990.

8. RECOMMENDATIONS:

Triadimefon (Bayleton®) data indicate that the major degradate triademenol (Baytan®) is persistent and moderately mobile. The registrant's proposed use of Bayleton® on tomatoes, grown on sandy soils, may result in leaching of the major degradate, triademenol (Baytan®) into ground water.

The proposed label application rate of Bayleton® on tomatoes is 20 ounces of 50% W.P. (10 oz. ai). If all of the applied Bayleton® gets into the soil, the soil residue concentration would be 0.625 pound triadimefon per acre; we are assuming that all of the triadimefon is degraded to triademenol. When the pesticide is mixed with the top soil, approximately 6.7 inches deep, the concentration of triademenol in a silt or clay loam will be approximately 0.312 ppm (312 ppb). The concentration in a sand soil would be approximately 0.250 ppm (250 ppb) because a sand soil weights 2,500,000 instead of 2,000,000 lbs./Ac and a conversion factor of 2.5 is used instead of 2.0.

We assumed that all of the Bayleton® applied to the tomatoes reaches the soil but some will remain on the foliage, part will run-off in the surface water, and some will be taken up by the plant and will degrade enzymatically. If we assume that all of the above environmental factors remove approximately one order of magnitude equal to 10, the residue would be reduced to 0.0312 ppm or 31 ppb.

Acceptable concentrations of triadimefon and baytan in drinking water are based on the reference dose (RfD).

$$\text{The reference dose (RfD)} = \frac{\text{daily dose NOEL}(2.5\ \text{mg/kg/day})}{100\ \text{(safety factor)}}$$

$$= 0.025\ \text{mg/kg/day}$$

$$0.025 \times 70\ \text{Kg person} = 1.75\ \text{mg/person/day}$$

$$\frac{1.75\ \text{mg/person/day}}{2\ \text{L/day}(2 \times 10^6\ \text{mg/L})} = 0.875\ \text{ppm (875 ppb)}$$

The maximum acceptable drinking water concentration for a 70 Kg person, assuming two liters/day, is 875 ppb (0.875 ppm)

When the field dissipation study (data gap) is conducted it should be planned and carried out in a manner similar to the plan below:

Conduct a field dissipation study reproducing the highest use application regime of triadimefon to be allowed under the proposed new label. Soil samples must be analyzed at a minimum of intervals, e.g., at 0, 7, 14, 30, 60, and 120 days after the final (total) as well as immediately after each treatment. The registrant must document how much pesticide reaches the soil and the amount retained by the foliage.

Tomatoes are frequently grown on sandy soils and at least one of the test soils must be a sand or loamy sand soil. If residues leach to a depth of 2 to 3 feet, a small-scale prospective ground-water monitoring study will be required to support the new use registration on tomatoes.

In order to avoid mis-communication, a field dissipation study protocol should be submitted to the Environmental Fate and Ground-Water Branch for discussion prior to initiation of the study.

9. BACKGROUND:

Bayleton is a systemic fungicide used against powdery mildew affecting deciduous fruit, cereals and vegetables, azalea petal blight, rust diseases of cereals and coffee, seed grasses and pine, and pineapple disease on sugarcane and pineapple. Formulations include: wettable powder, emulsifiable concentrate, suspension concentrate and paste. Up to 64 oz. (4 lbs.) of Bayleton 50% WP per acre per season are applied to some crops, e.g., to almonds, by label directions.

10. DISCUSSION:

Field dissipation data reviewed in 1978 do not meet the current, 1982, guidelines but the registrant is committed to conducting a new study. The data gaps and commitment of the registrant to submit new data over a period of years was documented in EFGWB# 900658 on 7/24/90.

Tomatoes as well as some other vegetables and truck crops are grown on sandy soils in various regions of the USA. Although triadimefon is applied to foliage and not to soil, some of the a.i. may reach the soil and leach to ground water because the pesticide and major degradate do not degrade by photolysis or hydrolysis.

The vapor pressure of triadimefon (Bayleton®) is $<10^{-5}$ mbar at 20° C and therefore no significant volitalization is expected. Up to 20 ounces of 50% W.P. per Ac./season may be applied according to the proposed label. Specific proposed use information, including soils and areas of proposed use, is needed from the registrant in order to properly assess the potential ground-water hazard for tomatoes.

Triadimefon, the parent compound, is moderately mobile but relatively non-persistent in the environment. The parent's aerobic soil half-life is 6-18 days, and the anaerobic half-life is 15 days. However; baytan, the major degradate and a registered pesticide, has an aerobic half-life of 8-9 months and an anaerobic half-life of >9-12 months. Triadimenol (Baytan®) is the principal compound of concern because of persistence under aerobic and anaerobic conditions and mobility in sandy soils.

Leaching Assessment For Triadimefon

Property	Bayleton[1]	Baytan[2]	Guidelines[3]
Adsorption Partion Coefficient	3.5 - 9.3 1.9 - 6.9 - Rev'd 1/91	0.5 - 3.7	<5.0; usually <1.0 or 2.0
Solubility (ppm)	70 @ 20°C	95 @ 20° C	>30 ppm
Hydrolysis half-life	stable	stable	>25 weeks
Photolysis half-life	stable soil 1-day aqueous	stable soil 36 hr aqueous	>1 week
Aerobic soil half-life	6-18 days	8-9 months	>2-3 weeks
Anaerobic soil half-life	15 days	>9-12 months	>2-3 weeks

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[1]EFGWB Pesticide Environmental Fate One line Summary, 6/22/89

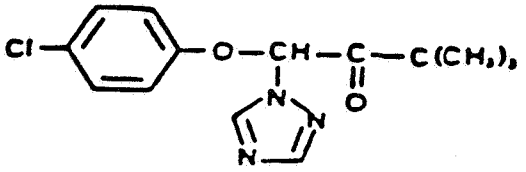
[2]EFGWB Pesticide Environmental Fate One LIne Summary, 1/27/84

[3]Cohen, S.Z., S.M. Creeger, R.F. Carsel, and C.G. Enfield, "Potential Pesticide Contamination of Groundwater from Agricultural Uses, in Treatment and Disposal of Pesticide Wastes", ACS Symposium Series #259, R.F. Krueger and J.N. Seiber, ed., American Chemical Society, Washington, D.C., 1984.

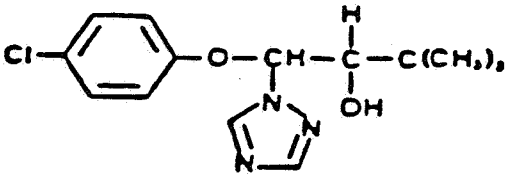
11. ONE-LINER:

No new environmental fate data were submitted for the one-liner; the new toxicology data will be entered on the toxicology one-liner.

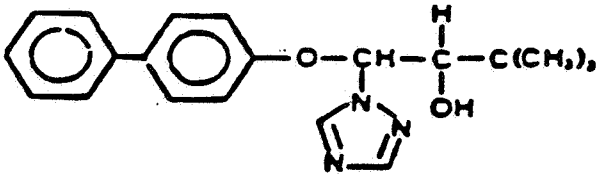
12. CBI:
The new toxicology data are CBI at present and were confirmed by the Health Effects Division's Peer Review Comittee on June 6, 1990.



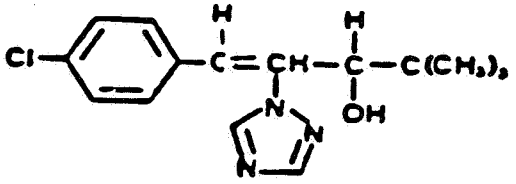
Triadimefon
(Bayleton)



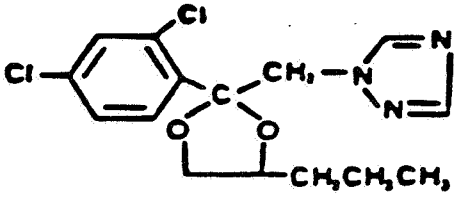
Triademenol
(Baytan)



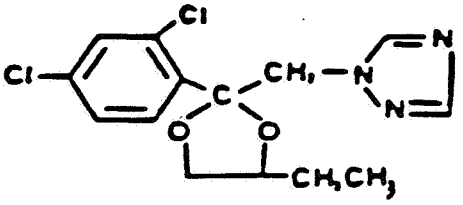
Bitertanol
(Baycor)



Uniconazole
(Prunit)



Propiconazole
(Tilt)



Etaconazole
(Vangard)

Chemicals Structurally Related to Triadimefon
(Bayleton)

Use this form for individual studies & to submit pesticide applications.

United States Environmental Protection Agency
Office of Pesticide Programs
Washington, DC 20460

Data Review Record

Confidential Business Information - Does not contain National Security Information (E.O. 12065)

Pack Number	Date Received
50335 EFED	4-9-90

1. Product Name: Bayleton 50% WP

Chemical Name: triadimefon

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
3125-320	22400	330	–	–

7. Reference No.	8. Date Rec'd (EPA)	9. Prod/Review Mgr/DCI	10. PM/RM Team No.	11. Date to HED/ EFED/RD/BEAD	12. Proj Return Date	13. Date Returned to RD/SRRD
32	4/5/90	Lewis / Stone	21	4/9/90	6/23/90	

Instructions

Is there now groundwater concerns for proposed tomato use? ~~Refer to Sam Creegan~~'s review dated 2/15/85 of original submission

This Section Applies to Review of Studies Only

14. Check Applicable Box

- [ ] Adverse 6(a)(2) Data (405)
- [ ] Special Review Data (870)
- [ ] Generic Data (Reregistration) (660)
- [ ] Product Specific Data (Reregistration) (655)

15. No. of Individual Studies Submitted

16. Have any of the above studies *(in whole or in part)* been previously submitted for review?

- [ ] Yes *(Please identify the study(ies))*
- [ ] No

17. Related Actions

18.	To	Type of Review	19. Reviews Also Sent to	
HED		Science Analysis & Coordination	SAC	PC
		Toxicology/HFA	TOX/HFA	PL
		Toxicology/IR	TOX/IR	
		Dietary Exposure	DEB	EA
		Nondietary Exposure	NDE	AC
EFED		Ecological Effects		BA
	X	Environmental Fate & Groundwater	EEB	
SRRD		Special Review	EFGWB	
		Reregistration		
		Generic Chemical Support	SR	
RD		Insecticide-Rodenticide	RER	
		Fungicide-Herbicide	GSC	
		Antimicrobial		
		Product Chemistry	IR	
		Precautionary Labeling	FH	
BEAD		Economic Analysis	AM	
		Analytical Chemistry		
		Biological Analysis		

20. Data Review Criteria

A. Policy Note No. 31

- [ ] 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria
- [ ] 2 = data of particular concern from registration standard
- [ ] 3 = data necessary to determine tiered testing requirements

B. Section 18

- [ ] 1 = data in support of section 3 in lieu of section 18

C. Inert Ingredients

- [ ] 1 = data in support of continued use of List 1 inert

- [ ] Confidential Statement of Formula (EPA Form 8570-4) Attached *(Trade Secrets)*
- [ ] Label Attached

EPA Form 8570-17 (Rev. 11-88)
Previous editions are obsolete.

White - Data Coordinator
Yellow - Data Review Section
Pink - PM/RM/DCI
Green - Return with completed review

RIN 5712-93

PC 109901 TRIADIMEFON REVIEW

Page 8 is not included in this copy.

Pages _____ through _____ 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.

Shaughnessy No.: 109901

Date Out EAB: FEB 15 1985

TO: H. Jacoby
Product Manager # 21
Registration Division
TS-767

FROM: Samuel M. Creeger, Chief
Environmental Chemistry Review Section No. 1
Exposure Assessment Branch
Hazard Evaluation Division

Attached please find the environmental fate review of:

Reg./File No.: 3125-320

Chemical: Triadimefon

Type Product: Fungicide

Product Name: BAYLETON 50 % WP

Company Name: Mobay

Submission Purpose: Amend label - add new use on tomatoes

Action Code: 330

Date In: 12/5/84

EAB # 5177

Date Completed: FEB 15 1985

TAIS (Level II)	Days
63	0.25

Deferrals To:

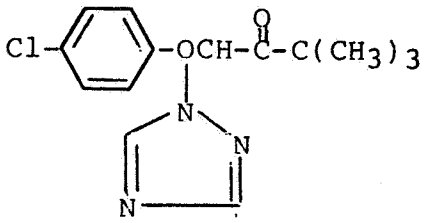
_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

1.0 CHEMICAL:

- o Common name: triadimefon
- o Trade name: BAYLETON 50 % Wettable Powder FUNGICIDE
- o Chemical name: 1-(4-chlorophenoxy-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone
- o Chemical structure:



2.0 TEST MATERIAL: Not applicable

3.0 ACTION TYPE:

Label amendment for BAYLETON 50 % Wettable Powder FUNGICIDE to include use on tomatoes.

4.0 STUDY IDENTIFICATION:

No new data were submitted.

5.0 REVIEWED BY:

Soobok Hong, Ph.D.
Chemist
Environmental Chemistry Review Section 1/EAB/HED

Soobok Hong
February 15, 1985

6.0 APPROVED BY:

Samuel M. Creeger, Chief
Supervisory Chemist
Environmental Chemistry Review Section 1/EAB/HED

Samuel M Creeger
FEB 15 1985

7.0 CONCLUSION:

EAB file reveals that all the environmental fate data requirements on Bayleton have been satisfied to support the proposed use.

8.0 RECOMMENDATION:

The current rotational crop restriction still applies.

9.0 BACKGROUND:

A. Introduction

Mobay is requesting an amendment of its label for BAYLETON