

US EPA ARCHIVE DOCUMENT

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: \_\_\_\_\_

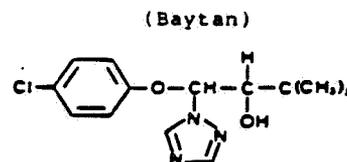
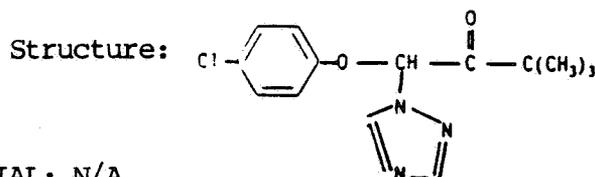
Deferrals To: \_\_\_\_\_ Ecological Effects Branch

X Health Effects Division

1. Chemical: Common names: triadimefon

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

Trade name: Bayleton®



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:

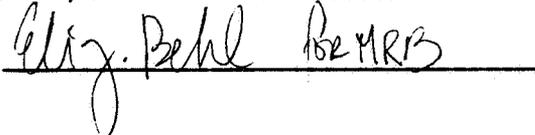
John H. Jordan, Microbiologist  
OPP/EFED/EFGB/Ground-Water Section

Signature: 

Date: 10/23/90

6. APPROVED BY:

Michael R. Barrett, Acting Head  
OPP/EFED/EFGB/Ground-Water Section

Signature: 

Date: 11/8/90

7. CONCLUSIONS:

Triadimenol (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).

$$\begin{aligned} \text{The reference dose (RfD)} &= \frac{\text{daily dose NOEL}(2.5 \text{ mg/kg/day})}{100 \text{ (safety factor)}} \\ &= 0.025 \text{ mg/kg/day} \end{aligned}$$

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

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

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 volatilization 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 <sup>1</sup>	Baytan <sup>2</sup>	Guidelines <sup>3</sup>
Adsorption Partition Coefficient	3.5 - 9.3 <i>1.8 - 6.9 - (low)</i>	0.5 - 3.7	<5.0; usually <1.0 or 2.0
Solubility (ppm)	70 @ 20°C <i>1/91</i>	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

<sup>1</sup>EFGWB Pesticide Environmental Fate One line Summary, 6/22/89

<sup>2</sup>EFGWB Pesticide Environmental Fate One Line Summary, 1/27/84

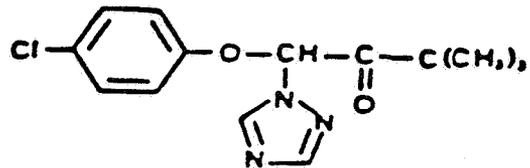
<sup>3</sup>Cohen, S.Z., S.M. Creeger, R.F. Carsel, and C.G. Enfield, "Potential Pesticide Contamination of Groundwater from Agricultural Uses, in Treatment and Disposal of Pesticide Wastes", ACS Symposium Series #259, R.F. Krueger and J.N. Seiber, ed., American Chemical Society, Washington, D.C., 1984.

11. ONE-LINER:

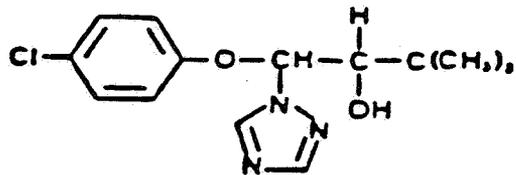
No new environmental fate data were submitted for the one-liner; the new toxicology data will be entered on the toxicology one-liner.

12. CBI:

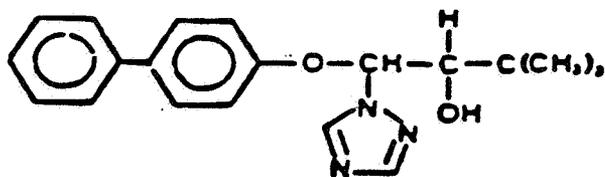
The new toxicology data are CBI at present and were confirmed by the Health Effects Division's Peer Review Committee on June 6, 1990.



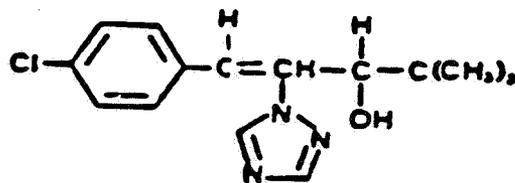
Triadimefon  
(Bayleton)



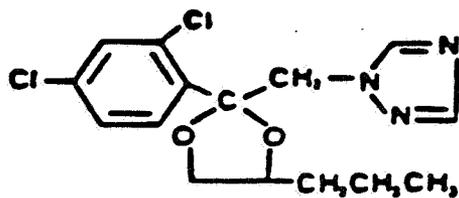
Triademenol  
(Baytan)



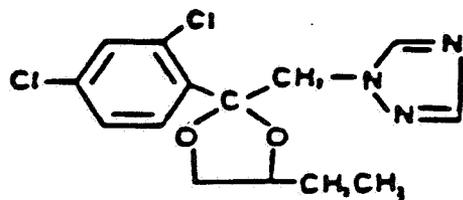
Bitertanol  
(Baycor)



Uniconazole  
(Prunit)



Propiconazole  
(Tilt)



Etaconazole  
(Vanguard)

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

50335  
EFED

Date Received

4-9-90

1. Product Name Bayleton 50% WP					Chemical Name Triadimefon		
2. Identifying Number 3125-320	3. Record Number 22400	4. Action Code 330	5. MRID/ Accession Number -	6. Study Guideline or Narrative			
7. Reference No. 32	8. Date Rec'd (EPA) 4/5/90	9. Prod/Review Mgr/DCI Lewis/Stone	10. PM/RM Team No. 21	11. Data to HED/ EFED/RD/BEAD 4/9/90	12. Proj Return Date 6/23/90	13. Date Returned to RD/SRRD	

Instructions

Is there now groundwater concerns for proposed tomato use? ~~Data to team~~ Evergen's review dated 2/15/85 of original submission.

This Section Applies to Review of Studies Only

14. Check Applicable Box				15. No. of Individual Studies Submitted	
<input type="checkbox"/> Adverse 6(a)(2) Data (405)	<input checked="" type="checkbox"/> Generic Data (Reregistration) (660)	<input type="checkbox"/> Special Review Data (870)		<input type="checkbox"/> Product Specific Data (Reregistration) (655)	
16. Have any of the above studies (in whole or in part) been previously submitted for review?				17. Related Actions	
<input type="checkbox"/> Yes (Please identify the study(ies))				<input type="checkbox"/> No	

18.	To	Type of Review	19. Reviews Also Sent to	20. Data Review Criteria
HED		Science Analysis & Coordination	<input type="checkbox"/> SAC <input type="checkbox"/> PC	A. Policy Note No. 31 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria <input type="checkbox"/> 2 = data of particular concern from registration standard <input type="checkbox"/> 3 = data necessary to determine tiered testing requirements
		Toxicology/HFA	<input type="checkbox"/> TOX/HFA <input type="checkbox"/> PL	
		Toxicology/IR	<input type="checkbox"/> TOX/IR	
		Dietary Exposure	<input type="checkbox"/> DEB <input type="checkbox"/> EA	
EFED	<input checked="" type="checkbox"/>	Ecological Effects	<input type="checkbox"/> NDE <input type="checkbox"/> AC	B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18
	<input checked="" type="checkbox"/>	Environmental Fate & Groundwater	<input type="checkbox"/> EEB <input type="checkbox"/> BA	
SRRD		Special Review	<input type="checkbox"/> EFGWB	C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert
		Reregistration	<input type="checkbox"/> SR	
		Generic Chemical Support	<input type="checkbox"/> RER	
RD		Insecticide-Rodenticide	<input type="checkbox"/> GSC	
		Fungicide-Herbicide	<input type="checkbox"/> IR	
		Antimicrobial	<input type="checkbox"/> FH	
		Product Chemistry	<input type="checkbox"/> AM	
BEAD		Precautionary Labeling		
		Economic Analysis		
		Analytical Chemistry		
		Biological Analysis		

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

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:

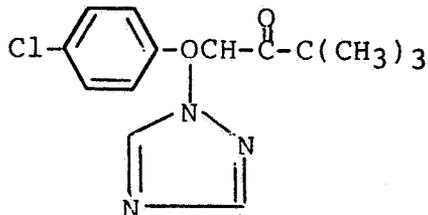
Ecological Effects Branch

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 applicable3.0 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

*Soobok Hong*  
February 15, 1985  
Section 1/EAB/HED

Environmental Chemistry Review

6.0 APPROVED BY:

Samuel M. Creeger, Chief  
Supervisory Chemist

*Samuel M. Creeger*

FEB 15 1985

Environmental Chemistry Review Section 1/EAB/HED

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