

Shaughnessy No.: 109901

Date Out of EFBWB: JUNE 22, 1990

TO: Rebecca Cool
Product Manager #41
Registration Division (H7505C)

FROM: Henry Nelson, Ph.D., Acting Section Chief *H Nelson*
Environmental Chemistry Review Section #3
Environmental Fate & Ground Water Branch/EFED (H7507C)

THRU: Hank Jacoby, Chief *Hank Jacoby*
Environmental Fate & Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Attached, please find the EFGWB review of...

Reg./File # : 90-PR-02

Chemical Name: Triadimefon

Type Product : Fungicide

Product Name : BAYLETON DF

Company Name : Puerto Rico Dept of Agriculture (Mobay Corp)

Purpose : Review request for additional applications in
connection with a Section 18.

Date Received: 5/31/90 EFGWB#: 900615

Action Code: 513 Total Review Time (days): 2.0

Deferrals to: _____ Ecological Effects Branch, EFED
_____ Science Integration & Policy Staff, EFED
_____ Non-Dietary Exposure Branch, HED
_____ Dietary Exposure Branch, HED
_____ Toxicology Branch I, HED
_____ Toxicology Branch II, HED

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

50596

Date Received

6/4/90

1. Product Name

Bayleton DP

Chemical Name

Triadimenol

2.

Identifying Number

90-PR-02

3.

Record Number

264861

4. Action

Code

513

5. MRID/

Accession Number

6.

Study Guideline or Narrative

7. Reference No.

8. Date Rec'd (EPA)

5/22/90

9. Prod/Review Mgr/DCI

Cool/Pemberton

10. PM/RM Team No.

41

11. Date to HED/

5/31/90

12. Proj Return Date

6/1/90

13. Date Returned

to RD/SRRD

Instructions

Please see attached instruction

This Section Applies to Review of Studies Only

14. Check Applicable Box

☐

Adverse 6(a)(2) Data (405)

☐

Generic Data (Reregistration)(660)

15. No. of Individual Studies Submitted

☐

Special Review Data (870)

☐

Product Specific Data (Reregistration)(655)

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

20. Data Review Criteria

HED

Science Analysis & Coordination

Toxicology/HFA

Toxicology/IR

Dietary Exposure

Nondietary Exposure

☐ SAC

☐ PC

☒ TOX/HFA

☐ PL

☐ TOX/IR

☒ DEB

☐ EA

☐ NDE

☐ AC

☐ EEB

☐ BA

☒ EFGWB

☐ SR

☐ RER

☐ GSC

☐ IR

☐ FH

☐ AM

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

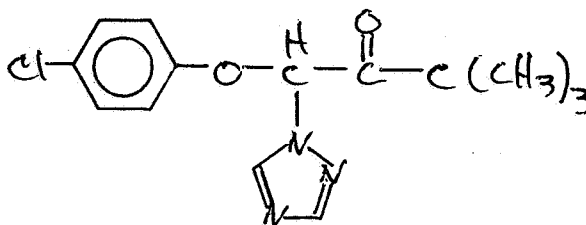
1.0 CHEMICAL:

Common Name- Triadimefon (Bayleton)

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

Trade Name- BAYLETON 50DF

Chemical Structure-



2.0 TEST MATERIAL: Not applicable.

3.0 STUDY/ACTION TYPE: The Puerto Rico Dept of Agriculture is requesting authorization to use BAYLETON 50DF (soil drench application) and/or BAYLETON 50WP to coffee trees in completing its 1989 Section 18 (Emergency Exemption). They were granted an exemption for 1990 to complete the foliar applications started in 1989.

4.0 STUDY/DOCUMENT IDENTIFICATION:

1. Letter dated 23 Mar 1990 from the Puerto Rico Dept of Agriculture to OPP (Office of Pesticide Programs) requesting the authorization to use an additional BAYLETON formulation (soil drench).

2. Letter dated 31 Jan 1990 from Mobay Corp to the Puerto Rico Dept of Agriculture giving the use directions for the soil drench formulation (BAYLETON 50DF).

3. Letter from the OPP dated 23 Feb 1990 granting an exemption to Puerto Rico to complete the four applications started in 1989.

5.0 REVIEWED BY:

Herbert L. Manning, Ph.D.
Microbiologist, EFGWB/EFED

Signature: *Herbert L. Manning*
Date:

6.0 APPROVED BY:

Henry Nelson, Ph.D.
Acting Chief, Section 3, EFGWB/EFED

Signature: *HV Nelson*
Date: 6/22/90

7.0 CONCLUSION:

- 7.1 The EFGWB concludes that we have _____ ground water concerns with Puerto Rico using a soil drench formulation (BAYLETON 50DF) in addition (possibly) to a foliar application (BAYLETON 50WP) for the following reasons:

1. Baytan is a degradation product of Bayleton, with the aldehyde group being converted to a hydroxyl group. Baytan is the degradate of concern in the environment, since it has the potential to leach ($K_d = 0.5-3.7$) and is persistent in aerobic soil ($t_{1/2} = 8-9$ months).

2. Movement of Baytan below the root zone or into ground water, where anaerobic conditions prevail, would increase its half-life of beyond the aerobic half-life of 8-9 months.

3. In using the soil drench formulation (BAYLETON 50DF), rainfall is needed to carry the chemical into the root zone for uptake by tree roots and the use directions specify that applications must be made at the start of the spring or fall rainy season.

4. The current emergency exemption (allowing the completion of the 1989 exemption) for the foliar application permits treatment of 60,000 acres, which apparently would be the acreage that would receive the soil drench treatment if authorization to use it is granted.

Thus, the combination of a leachable, persistent pesticide being used over a large area before a rainy season starts would greatly increase the likelihood of the pesticide leaching to ground water.

5. Table 1 (shown below) was taken from the initial EFGWB review (19 Sep 1989, EFGWB #90441) of the 1989 request for exemption and gives the leaching assessment (fate data compared to guideline triggers) for triadimefon.

TABLE 1
LEACHING ASSESSMENT FOR TRIADIMEFON

Property	Bayleton ¹	Baytan ²	Guidelines ³
Adsorption Partition Coefficient	3.5 - 9.3	0.5 - 3.7	<5.0, <1.0 or 2.0
Solubility (ppm)	70 @ 20° C	49 - 95° C	>30 ppm
Hydrolysis half-life	relatively 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	>>8-9 months	>2-3 weeks

¹EFGWB Pesticide Environmental Fate One Line Summary, 6/22/89.

²EFGWB Pesticide Environmental Fate One Line Summary, 1/27/84.

³Cohen, S.Z., S.M. Creeger, R.F. Carsel, and C.G. Enfiel, "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.

8.0 RECOMMENDATIONS:

8.1 We have no specific recommendations; however, our position on Puerto Rico's authorization request is stated above (Section 7.1).

9.0 BACKGROUND:

A. Introduction- Puerto Rico was granted an Emergency Exemption (Section 18) in 1989 (apparently) to use BAYLETON 50WP as a foliar application on coffee rust disease on coffee trees. However, because of tropical storms, they only made one foliar application in 1989. Subsequently, they received another Emergency Exemption for 1990 to complete the 4 applications permitted under the 1989 exemption.

The present submission concerns a request to use a preventative, soil drench formulation (BAYLETON 50DF) on

coffee tree acreage (before symptoms appear) in addition to possibly using the foliar formulation (BAYLETON 50WP).

B. Directions for Use- See the attached letters.

10.0 DISCUSSION OF INDIVIDUAL STUDY: Not applicable.

11.0 COMPLETION OF ONE-LINER: Not applicable.

12.0 CBI APPENDIX: There is no CBI in this review.

Reviews Please Note:

While a specific exemption was authorized for the 89 season - only 1 of the authorized 4 applications were made due to several hurricanes in 89. A specific exemption was again authorized in 90 with the provision that acreage treated last yr would only be treated 3x so as not to exceed the 4 appl. originally approved. Now Puerto Rico wishes to add DF applications to the program this will be applied to the same acreage which may already have been treated up to 4x with the WP. Please comment on use of this additional material

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Enclosure 2

March 23, 1990

Mr. Douglas D. Campt
Director
Office of Pesticide Programs
CA - 2 Room 115-C
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Bayleton

Re: Section 18 Specific Exemption
90-PR-02

Dear Mr. Campt:

Thank you for the approval of the above referenced specific Exemption which allows us to continue the foliar application of Bayleton to control the "coffee rust" in Puerto Rico.

As mentioned to you during our February 20 meeting, we need, and hereby request, your authorization for the additional use of Bayleton (EPA Reg. No. 3125-320) in soil drench application.

We have kept in close communication with the registrant. Mobay is in the process of conducting residue studies for both foliar and soil drench application of the product in Puerto Rico, in coordination with the P.R. Agricultural Experiment Station. Soil drench applications of this product are successfully being made in Honduras, Costa Rica, Guatemala, Mexico and Brazil. According to data obtained by Mobay, there is no residue problem with the soil drench application.

This request for soil drench application is based on the recommendations to the effect made by Mobay as stated in the attached letter from Dr. Richard Rudolph of January 31, 1990 (Enclosure 1). As per said recommendation, we are proposing that foliar application of the product will be made where coffee rust infection of 5% or less is present before treatment. The soil drench treatment will be used as follows:

Preventative Treatment:

Mix 1.0 pounds of Bayleton in 14.0 gallons of water. Apply 2.0 fluid ounces of this solution around the base of each coffee tree at the start of the spring or fall rainy season. The application must be made to the soil, not to the vegetation which might be growing under the trees. The applications must be made before disease symptoms are present on the leaves of the coffee trees.

Page 2 of 2

- 2 -

A second application can be made four months later if needed. The fall application should be made either after harvest, or, 30 days before harvest. Rainfall is required to carry Bayleton into the root zone for uptake by tree roots. Therefore, application of the Bayleton to the soil must be made at the beginning of either the spring or fall rainy seasons, or at both times, i.e., late March and April or July and August, or at both times, if necessary.

Curative Treatment:

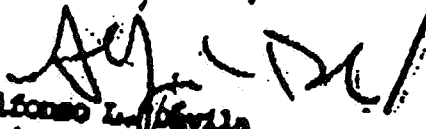
Where coffee rust infection is present on trees, a soil application may be made only after a foliar spray of 7.1 ounces of Bayleton has been used to control the existing infection. A soil application as described above can be made 4 weeks after the rust infection has been brought under control with 1 to 2 foliar sprays.

Our request is also based on additional economic and practical reasons. Coffee is grown in the mountain areas in the central part of Puerto Rico. The foliar application of Bayleton is made by ground application using knapsack sprayers. The dilution is prepared by mixing 7.1 ounces of the product with up to 100 gallons of water. This solution is applied in 0.97 acres, or approximately 1,000 trees. It takes one worker a whole day to treat half an acre of coffee trees. Since the water or solution must be hand carried up the mountains under a hot sun, it makes progress slow and cumbersome. On the other hand, the soil drench application being requested involves mixing 1.0 pounds of Bayleton in 14.0 gallons of water. The application is made by spraying 2 ounces of solution to the soil around the base of each tree with a meterjet spray gun attached to the knapsack sprayer. This method of application will treat 883 trees using only 14 gallons of water. One worker would be able to apply up to 2 acres daily. Consequently, there would be an increase in efficiency of almost 400%.

For the foregoing reasons we request that the Puerto Rico Department of Agriculture be granted authorization to use Bayleton in accordance to the use pattern recommended by Mobay, and petitioned herein.

Thank you for your kind attention and assistance in this matter. Please feel free to let me know if you have any questions, since we would like to initiate the soil drench application as soon as possible.

Sincerely,


Alfonso L. Méndez
Undersecretary of Agriculture

Mobay

Bayer



Mobay Corporation

A Bayer USA INC. COMPANY

Agricultural Chemicals Division

January 31, 1990

1587 Phoenix Boulevard #6
Atlanta, Georgia 30349-5503
Telephone: 404/997-7466

Mr. Hector Munez
Puerto Rico Dept. of Agriculture
P. O. Box 10163
Santurce, Puerto Rico 00908

Dear Mr. Munez:

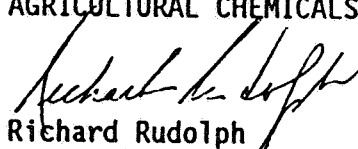
The enclosed use directions for BAYLETON 50DF as a soil drench application are sent to you at the request of Mr. Raphael Montalvo-Zapata. MOBAY recommends the soil drench application of BAYLETON DF rather than the use of granules due to the significant cost difference. A 5% granule would require shipment of ten times as much material to obtain the equal amount of active ingredient as the current BAYLETON 50% DF. Also, there is no commercial production of a 5% granule which contains only EPA approved ingredients. To produce such a product for use in Puerto Rico would be very expensive since current manufacturing facilities produce only the DF formulation. Currently only small amounts of BAYLETON 5% granule are produced in laboratory facilities. Thus, the increased production and shipping cost of a 5% granule make BAYLETON 50DF soil applications a much better option at this time. We are searching for someone to formulate a granule for us in Puerto Rico, this would make a significant reduction in the cost. Research and commercial use in Central America has shown soil drench applications to perform equal to granule treatments. Thus, the use of BAYLETON 50DF as a drench is more economical and equally effective as a BAYLETON granule.

When mixed and applied according to the enclosed directions, 1.01b of BAYLETON 50DF will treat 883 trees using only 14 gallons of water. A Meterjet spray-gun, manufactured by Spray Systems, can be used to accurately apply 2 ounces liquid per tree. This applicator can be attached to almost any type sprayer. This applicator applies the same volume of liquid each time the trigger is squeezed, thus uniform application without measuring from a bucket and pouring is easily done.

For 1990, MOBAY recommends asking EPA to approve a Section 18 use of BAYLETON for foliar application as was done in 1989, and asking for the soil drench application as described in the enclosed proposed use. The foliar application will be needed where coffee rust infection of 5% is present before treatment. The soil treatment should be used as a preventative treatment only.

Sincerely,

MOBAY CORPORATION
AGRICULTURAL CHEMICALS DIVISION



Richard Rudolph
Regional Development Manager
Eastern Region

RR:mc

Enclosure

USE DIRECTIONS FOR BAYLETON 50 DF APPLIED AS A SOIL
DRENCH FOR THE CONTROL OF COFFEE RUST IN PUERTO RICO:

1) PREVENTATIVE TREATMENT:

Mix 1.0 lb. BAYLETON 50DF in 14.0 gallons of water. Apply 2.0 fl. ounces of this solution around the base of each tree at the start of the spring or fall rainy season. The application must be made to the soil, not to vegetation which might be growing under trees. Applications must be made before disease symptoms are present on the leaves of coffee trees. A second application can be made four months later if needed. The fall application should be made either after harvest, or, 30 days before harvest. Rainfall is required to carry BAYLETON into the root zone for uptake by tree roots. Therefore, application of BAYLETON 50DF to the soil must be made at the beginning of either the spring or fall rainy seasons, or at both times.

2) CURATIVE TREATMENT:

Where coffee rust infection is present on trees, a soil application should be made only after a foliar spray of 7.2 oz./A BAYLETON 50DF has been used to control the existing infection. A soil application as described above can be made 4 weeks after the rust infection has been brought under control with 1-2 foliar sprays.

Reg. II
EPA9281
Dave Andreassan

/INT

Puerto Rico Department of Agriculture
P.O. Box 10163
Santurce Puerto Rico 00908,

231990

/INT

Agricultural Services Administration
P.O. Box 9200
Santurce Puerto Rico 00908,

/ZIP

Regional Director HFR-21
Food and Drug Administration
830 3rd Avenue
Brooklyn NY 11232,

/ZIP

Branch Chief HFF-314
FDA/CFSAN
200 C Street S.W.
Washington D.C. 20204,

/INT

Luis Izquierdo-mor M.D.
Secretary of Health
Call Box 70184
Dept of Health Bldg. A
San Juan (Puerto Rico)+

Attention: Alfonso L. Davila

The Environmental Protection Agency hereby grants a specific exemption under the provisions of section 18 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, to the Puerto Rico Department of Agriculture for use of Bayleton (triadimefon) to control coffee rust on coffee. This specific exemption is subject to the following conditions and restrictions:

1. The Puerto Rico Department of Agriculture is responsible for ensuring that all provisions of this specific exemption are met. It is also responsible for providing information in accordance with 40 CFR 166.32. This information must be submitted to EPA Headquarters.

2. The product Bayleton 50% WP Fungicide (EPA Reg. No. 3125-320) may be used. All applicable precautions, directions and restrictions on the EPA-registered product label must be followed.
3. A maximum rate of 3.55 ounces active ingredient per acre per application may be used.
4. A maximum of 4 applications are authorized. Acreage which was treated with Bayleton last year may only be treated a maximum of 3 times this year.
5. All applications will be made with ground equipment.
6. A 30 day pre-harvest interval will be observed.
7. A maximum of 60,000 acres of coffee may be treated.
8. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes).
9. This chemical can travel (seep or leach) to ground water that is used for drinking water. Users are advised to be careful in mixing and handling this chemical to avoid spills. This product must not be mixed/loaded, or used within 50 feet of sink holes or wells, including abandoned wells and drainage wells. Do not use in hydrogeologically vulnerable conditions defined as having very permeable (sandy) soils, ground water less than 30 feet, and/or soil conditions conducive to preferential flow conditions (e.g. karst terrain). Do not over irrigate. Avoid use during periods of heavy rain.
10. The use of triadimefon is prohibited in areas that may result in exposure of endangered species to triadimefon. Prior to use, the Endangered Species Specialist, U.S. Fish and Wildlife Service, Puerto Rico (809-851-7297), must be notified. Triadimefon may not be used in any area in which the Fish & Wildlife Service determines that endangered species may be adversely impacted.
11. Applications made in accordance with the above provisions are not expected to result in residues of triadimefon and its metabolites containing chlorophenoxy and triazole moieties (expressed as the fungicide) in or on coffee (coffee beans, roasted or instant) in excess of 0.01 ppm. Analytical methodology is available in PAM-II. The Food and Drug Administration, DHHS, has been advised of this action.

12. The EPA shall be immediately informed of any adverse effects resulting from use of Bayleton in connection with this program.

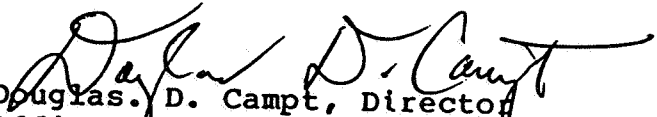
13. A final report summarizing the results of this program must be submitted by February 28, 1991.

14. This specific exemption expires on August 31, 1990.

Any future correspondence in connection with the exemption should refer to file symbol: 90-PR-02.

This is the second year that this use has been requested under section 18 of FIFRA. The decision of whether future requests for this use are approved will depend, in part, on progress made towards registration. It would be to your advantage to keep current on such progress.

Any request for soil drench application or involving additional applications to acreage which has already been treated four times previously (total use history, not just per season) will require an in depth review and should be requested well in advance of the needed use season.


Douglas D. Campt, Director
Office of Pesticide Programs

FEB 26 1990

Date: _____