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

OCT 25 1994

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: PP#3F4167 - Permanent Tolerance Petition -
Tebuconazole (Elite 45 DF®), Fungicide on Bananas -
Evaluation of Amendments Dated August 19, 1993. MRID
Nos. 429098-01 thru 03. CBTS No. 13483. DP Barcode:
D201313.

FROM: Gary F. Otakie, P.E., Chemist
Tolerance Petition Section II
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Health Effects Division (H7509C)

Gary F. Otakie

THRU: Richard A. Loranger, Ph.D., Acting Chief
Chemistry Branch I - Tolerance Support
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R. Loranger

TO: Leonard Cole (Acting)/Benjamin Chambliss, PM Team 21
Fungicide - Herbicide Branch
Registration Division (H7505C)

and

Albin Kocialski, Section Head
Registration Section
Chemical Coordination Branch
Health Effects Division (H7509C)

Background

In the subject petition Mobay has submitted analytical method and residue data to support proposed permanent tolerances for the new chemical tebuconazole on bananas at 0.05 ppm. Permanent tolerances for tebuconazole on peanuts and peanut hulls (PP#9F3724) were approved August 3, 1994 per 40 CFR 180.474. CBTS's most recent review for the proposed use on bananas (see April 26, 1993 memo of G. Otakie) noted four deficiencies remain unresolved.

In the previous submission, the petitioner (i.e. Miles Inc.) provided a revised Section F proposing the following permanent tolerance for the new chemical fungicide tebuconazole (i.e., Folicur, HWG-1608) (alpha-[2-(4-chloro-phenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol):

<u>Commodity</u>	<u>Preharvest Interval (Days)</u>	<u>Proposed Tolerance (ppm)</u>
<u>TOLERANCE PROPOSAL</u>		
bananas	0	0.05

Revised Section B

Revised labels dated 7/9/93 for Elite 45 DF Foliar Fungicide® have been submitted which include revisions needed for compliance with Worker Protection Standards, and revisions to the Environmental Hazards label section and the following use restriction for non-bagged bananas:

Do not apply Elite 45 DF to non-bagged bananas.

Conclusions

1. CBTS is satisfied that the batch analysis data of the TGAI previously submitted represents the commercial full scale production process rather than bench or pilot scale production.
2. The nature of the residue in grapes is adequately understood, and the residue consists of only the parent, tebuconazole. Metabolism data from grapes is translatable to other fruits such as bananas.
3. PAM II includes an acceptable enforcement method for tebuconazole in/on bananas.
4. The banana residue data support the proposed permanent tolerance of 0.05 ppm for tebuconazole in/on bananas.

Recommendations

TOX considerations permitting CBTS recommends in favor of the proposed permanent tolerance of 0.05 ppm for tebuconazole in/on bananas. See "Detailed Considerations" for additional information.

Detailed Considerations

The deficiencies follow the numbering of CBTS's previous review of PP#3F4167 (see 4/26/93 review of G. Otakie).

Deficiency No. 1

A deferral request is required to include an acceptable schedule for submission of analysis results representing five different production runs of the final full scale production process together with a revised CSF with certified limits reflecting these data.

Petitioner's Response to Deficiency No. 1

Per a 4/19/94 letter from John Thornton of Miles Inc. the petitioner has verified that the TGAI analysis results of each of the five batch analyses previously submitted to EPA represented a day's full scale commercial production of 20,000 to 30,000 pounds Folicur Technical which was shipped to Germany as a pesticide not registered for use in the United States of America.

CBTS Comments/Conclusions re: Deficiency No. 1

The following are the conclusions of CBTS's review of PP#9F3724 (see 6/15/94 memo of G. Otakie):

CBTS is satisfied that the batch analysis data of the TGAI previously submitted represents the commercial full scale production process rather than bench or pilot scale production.

This deficiency is resolved.

Deficiency No. 2

A final decision on the adequacy of the grape metabolism study is deferred pending resolution of the deficiencies discussed in Detailed Considerations - Nature of the Residue.

Petitioner's Response to Deficiency No. 2

The petitioner's response to deficiencies in the tebuconazole grape metabolism study as iterated in CBRS's review of PP#9G3817 (see 6/8/90 memo of C. Olinger) is included as Attachment 1.

CBTS Comments/Conclusions re: Deficiency No. 2

In the grape metabolism study over 90% of the TRR was characterized as parent reflecting aged residues with PHI's up to 28 days. Surface residues account for most of the parent residue with a small portion also identified in the methanol extract from fruit homogenization. Attachment 2 (i.e. page 10 from C. Olinger's 6/8/90 review of PP#9G3817) summarizes the grape metabolism residue data. CBTS notes that the major portion of the residue in the methanol extract was **not** identified and the HPLC results in the current submission indicates the likely presence of **unidentified** metabolites (see Attachment 1; Figures 5 and 6). However, this fraction represented less < 10% of the TRR and therefore in accordance with the 7/16/92 memo of E. Zager and D. Edwards (Additional Guidance for Conducting Plant and Livestock Metabolism Studies) their identification is not required since each metabolite also represents < 10% TRR.

The nature of the residue in grapes is adequately understood, and the residue consists of only the parent, tebuconazole. Metabolism data from grapes is translatable to other fruits such as bananas.

This deficiency is resolved.

Deficiency No. 3

A decision concerning the acceptability of the proposed analytical methodology for tebuconazole on bananas is deferred pending the results of the EPA Permanent Method Validation for peanuts and resolution of outstanding deficiencies in the grape metabolism study. A separate copy of the final method for tebuconazole on bananas will be required so it can be submitted as a letter method to FDA.

Petitioner's Response to Deficiency No. 3

The petitioner has submitted "Gas Chromatographic Method for Determination of Residues of Tebuconazole in Crops, Processed Products, Soil and Water" dated 1/15/93 including Addendum 5; Miles Report Number 101341, MRID No. 429098-01.

CBTS Comments/Conclusions re: Deficiency No. 3

Per CBTS's 3/31/94 review of PP#9F3724 the tebuconazole Petition Method Validation for peanuts was successfully completed by ACL/BEAD (see 6/10/93 memo of E. Hayes). Per a 9/6/94 letter to FDA the subject analytical method for tebuconazole (i.e. Miles Report No. 101341) was forwarded as a new entry in PAM II.

CBTS notes that the subject method includes a section on the extraction of bananas under the subheading 3.2.2.3 Plant Material

with High Water Content, and therefore a separate method for bananas is not needed. Also, the method (i.e. Addendum 5) includes instructions for the use of an alternate GC column as was recommended in the Method Validation Report.

PAM II includes an acceptable enforcement method for tebuconazole in/on bananas.

This deficiency is resolved.

Deficiency No. 4

A final decision on the adequacy of the tebuconazole field trial data on bananas is deferred pending resolution of the nature of the residue in grapes and whether the field trial residue data reflect bagged or unbagged bananas.

Petitioner's Response to Deficiency No. 4

The petitioner submitted an additional report: Tebuconazole - Magnitude of the Residue on Banana; by R. N. Burger; 12/14/92; Report No. 99827-1; MRID No. 429098-02 including the results of three additional field trials (i.e. four field trials were included in the original submission). Five foliar applications of Folicur 45DF in oil were made to banana trees using ground equipment at a rate of 100 grams ai/hectare/application (i.e. approx. 3.2 ounces Elite 45 DF per acre) with spray volumes of approximately 20 gallons per acre. The interval between applications ranged from 14 to 15 days. Samples were collected at 0, 7 and 14 days following the last application.

Approximately 50% of the whole fruit were washed and allowed to drip dry and the other 50% were unwashed following harvest. Bananas whose pulp and peel were separated in the field were recombined for analysis, based on the weight percent of each component, since separate analysis of pulp and peel was deemed unnecessary due to minimum non-detectable residues in the previous field trials. All untreated banana control samples contained <0.01 ppm of tebuconazole.

Banana samples were held in frozen storage for a maximum period of 307 days before extraction. Residue data were obtained using the analytical procedure described in Miles Report No. 101341 (MRID No. 42209505) with modifications. Sample size was decreased from 100 to 50 grams, amount of sodium sulfate added to the sample extract was decreased from 150-200 to 30 grams with a larger amount of sodium sulfate used to filter the extract (150-200 vs. 30 grams), gel permeation chromatography was not used for banana, tebuconazole was eluted from the c-18 column with 20 ml

of methanol:water (85:15 v:V) in place of 10 ml methanol:water (7:3) and the final volume of extract for GC analysis was changed from 4 ml to 2 ml. Fortifications of 0.01, 0.02, 0.05 and 10 ppm in the control banana matrix resulted in tebuconazole recoveries ranging from 80 to 111%. The limit of determination was 0.01 ppm.

The petitioner also noted some errors in the previous EPA summary of residue data. The following table from the report (Attachment 3) includes all the tebuconazole banana gross residue data (i.e. four original field trials and three new field trials).

The petitioner responded to a questions concerning the fact that residue levels in the unwashed Keaau samples from the first report at a 7 and 14 day PHI were higher than at 0 day PHI. Analytical variability is not uncommon when measuring residues at or near the limit of determination. Additionally, it is possible that a slight amount of contamination occurred during sampling or processing.

The petitioner also responded to the question on whether the field trial data reflect bagged or unbagged bananas. The residue data for the first four field trials reflect bagged bananas (the response did not specifically address the last three field trials). The decision to exclude unbagged bananas from the study was based on the fact that virtually all commercially grown bananas are bagged. Additionally, the petitioner has submitted a revised label restricting the use on unbagged bananas (see Revised Section B).

The Conclusion of the field trial report indicates that the maximum tebuconazole residue level in banana was 0.04 ppm and therefore recommends a tolerance of 0.1 ppm, with a 0 day PHI. However, a revised Section F was not included with the submission.

CBTS Comments/Conclusions re: Deficiency No. 4

CBTS notes some discrepancies in the petitioner's summary of residue data (see Attachment 3) and residue data used by CBTS below (i.e. data on unwashed bananas from Keaau, HI from Table 4 of MRID No. 425178-01 and the 0.04 ppm residue occurred on unwashed bananas per Table 3 of MRID No.429098-02).

The following table summarizes all the tebuconazole banana field trial residue data resulting from five applications of ELITE 45DF at 100 grams ai/hectare/application:

Tebuconazole Residues in Banana (seven field trials)

Study Location	PHI Days	Washed/ Unwashed	Tebuconazole Residue (PPM)		
			Pulp	Peel	Combined*
Wymanolo, HI	0	Washed	<0.01	<0.01	<0.01
"	7	Washed	<0.01	<0.01	<0.01
"	14	Washed	<0.01	<0.01	<0.01
"	0	Unwashed	<0.01	0.01	<0.01
"	7	Unwashed	<0.01	0.01	<0.01
"	14	Unwashed	<0.01	<0.01	<0.01
Keaau, HI	0	Washed	<0.01	<0.01	<0.01
"	7	Washed	0.01	0.02	0.01
"	14	Washed	<0.01	<0.01	<0.01
"	0	Unwashed	<0.01	<0.01	<0.01
"	7	Unwashed	0.01	0.02	0.02
"	14	Unwashed	0.02	0.02	0.02
Santa Isabel, PR	0	Washed	<0.01	<0.01	<0.01
"	7	Washed	<0.01	<0.01	<0.01
"	14	Washed	<0.01	<0.01	<0.01
"	0	Unwashed	<0.01	<0.01	<0.01
"	7	Unwashed	<0.01	<0.01	<0.01
"	14	Unwashed	<0.01	<0.01	<0.01
Santa Isabel, PR	0	Washed	<0.01	<0.01	<0.01
"	7	Washed	<0.01	<0.01	<0.01
"	14	Washed	<0.01	<0.01	<0.01
"	0	Unwashed	<0.01	<0.01	<0.01
"	7	Unwashed	<0.01	0.01	<0.01
"	14	Unwashed	<0.01	<0.01	<0.01

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Three Additional Banana Field Trials (Combined Only)					
Waimanalo, HI	0	Unwashed			0.03
"	0	Washed			0.03
"	7	Unwashed			0.03
"	7	Washed			0.03
"	14	Unwashed			0.04
"	14	Washed			0.03
Keaau, HI	0	Unwashed			<0.01
"	0	Washed			<0.01
"	7	Unwashed			<0.01
"	7	Washed			<0.01
"	14	Unwashed			<0.01
"	14	Washed			<0.01
Rio Piedras, PR	0	Unwashed			<0.01
"	0	Washed			<0.01
"	7	Unwashed			<0.01
"	7	Washed			<0.01
"	14	Unwashed			<0.01
"	14	Washed			<0.01

* Combined residue = Pulp Residue (PPM) x Wt. Fraction + Peel Residue (PPM) x Wt. Fraction

CBTS on 10/17/94 received a memo from J. A. Alsadek (EAB/BEAD) which indicated that approximately 100% of the bananas imported from Ecuador, Mexico and other Latin American Countries get bagged while they are growing on the banana plants (See Attachment 4). CBTS also notes that the revised label includes a statement prohibiting use on unbagged bananas. Accordingly, CBTS does not object to the absence of residue data on unbagged bananas.

The maximum residue from the field trials (i.e. 1X) was 0.04 ppm gross residue in washed whole fruit at a 14 day PHI with the concurrent method recovery for banana fortified at 0.1 ppm tebuconazole reported at 84%. In general the residues levels in the field trials appear to be independent of the PHI or whether the bananas were washed or unwashed. However, since the majority of residue samples were <0.01 ppm (limit of determination for tebuconazole) conclusions regarding the effect of PHI or washing the bananas on tebuconazole residue levels are not possible or necessary. The banana residue data support the proposed tolerance of 0.05 ppm for tebuconazole in/on banana.

This deficiency is resolved.

Attachment 1 - Metabolism of Tebuconazole on Grapes (Addendum pages 7-17); 6/29/92; Miles Report No. 88728-1; MRID No. 429098-03.

Attachment 2 - page 10 from C. Olinger's 6/8/90 review of PP#9G3817

Attachment 3 - Table 2 from 8/19/93 Amended Application for Registration.

Attachment 4 - 10/17/94 Memo Received 10/17/94 from J. A. Alsadek (EAB/BEAD) On Banana Cultural Practices.

cc with Attachments: Reviewer-Otakie, RF, Circu, PP#3F4167, E. Haeberer.
RDI: EHaeberer:10/20/94 MFlood:10/24/94

TEBU CONAZOLE

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Pages 10 through 23 are not included in this copy.

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_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

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FIFRA registration data.

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_____ 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.

Summary of Tebuconazole Metabolism Study in Grapes

Interval	Fraction	Tebuconazole		Unidentified Organosoluble		Unidentified Water soluble		Insoluble		Totals	
		%	ppm	%	ppm	%	ppm	%	ppm	%	ppm
0 Day	Rinse	99.1	6.84	-	-	-	-	-	-	99.1	6.84
	MeOH Ext. Solids	-	-	0.8	0.06	-	-	-	-	0.8	0.06
	Totals	99.1	6.84	0.8	0.06	-	-	0.1	0.007	100.0	6.9
3 Day	Rinse	97.5	7.70	-	-	-	-	-	-	97.5	7.70
	MeOH Ext. Solids	2.0	0.16	-	-	0.1	0.008	-	-	2.1	0.166
	Totals	99.5	7.86	-	-	0.1	0.008	0.4	0.032	100.0	7.9
7 Day	Rinse	93.9	3.76	-	-	-	-	-	-	93.9	3.76
	MeOH Ext. Solids	3.7	0.15	-	-	0.9	0.04	-	-	4.6	0.18
	Totals	97.6	3.90	-	-	0.9	0.04	1.5	0.06	100.0	4.0
14 Day	Rinse	89.1	5.97	-	-	-	-	-	-	89.1	5.97
	MeOH Ext. Solids	6.3	0.42	-	-	1.8	0.12	-	-	8.1	0.54
	Totals	95.4	6.39	-	-	1.8	0.12	2.8	0.19	100.0	6.7
21 Day	Rinse	84.5	2.54	-	-	-	-	-	-	84.5	2.54
	MeOH Ext. Solids	7.3	0.22	-	-	3.3	0.10	-	-	10.6	0.32
	Totals	91.8	2.75	1.1	0.03	2.4	0.072	1.4	0.04	100.0	3.0
28 Day	Rinse	87.6	2.01	-	-	-	-	-	-	87.6	2.01
	MeOH Ext. Solids	4.3	0.10	-	-	3.5	0.08	-	-	7.8	0.18
	Totals	91.9	2.11	0.5	0.01	2.7	0.06	1.4	0.03	100.0	2.3

Reported as tebuconazole equivalents.
All ppm values were calculated from the total ppm and percent radioactivity values.

Table 2. Summary of all available tebuconazole residue data for bananas (whole fruit) taken from Miles reports 99827 and 99827-1.

Miles Report No.	Location (Experiment No.)	Washed / Unwashed	Tebuconazole Whole Fruit Residues (ppm)		
			0-Day PHI	7-Day PHI	14-Day PHI
99827 ¹	Wymanolo, HI (458-FR057-88D)	Washed	<0.01	<0.01	<0.01
		Unwashed	<0.01	<0.01	<0.01
	Keaau, HI (458-FR058-88D)	Washed	<0.01	0.01	<0.01
		Unwashed	<0.01	0.01	0.02
	Santa Isabel, PR (750-FR059-88D)	Washed	<0.01	<0.01	<0.01
		Unwashed	<0.01	<0.01	<0.01
	Santa Isabel, PR (750-FR060-88D)	Washed	<0.01	<0.01	<0.01
		Unwashed	<0.01	<0.01	<0.01
99827-1	Hawaii (458-FR007-91D)	Washed	0.03	0.03	0.04
		Unwashed	0.03	0.03	0.03
	Hawaii (458-FR008-91D)	Washed	<0.01	<0.01	<0.01
		Unwashed	<0.01	<0.01	<0.01
	Puerto Rico (750-FR009-91D)	Washed	<0.01	<0.01	<0.01
		Unwashed	<0.01	<0.01	<0.01

¹Whole Fruit Residue = Pulp Residue (ppm) X Wt. Fraction + Peel Residue (ppm) X Wt Fraction.



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

Received
10/17/94
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: Bananas - Cultural Practices. Bagged versus Unbagged Bananas.

From: Jihad A. Alsadek, Ph.D., Economist *Jihad A. Alsadek*
Economic Analysis Branch
Biological and Economic Analysis Division (7503W)

Through: Edward Brandt, Acting Section Leader *Ed Brandt*
Economic Analysis Branch
Biological and Economic Analysis Division (7503W)

To: Michael T. Flood, Ph.D.
Acting Branch Senior Scientist
Chemistry Branch, Tolerance Support
Health Effects Division (7505C)

In response to your memo to Robert Esworthy EAB's Chief, dated September 14, 1994, regarding the establishment of import tolerances for various fungicides on bananas; I have the following to report:

I had two personal telephone conversations with Robert Moore, the President of International Banana Association, for almost an hour. Mr. Moore said that approximately 100 percent of the bananas imported from Ecuador, Mexico, and other Latin American Countries get bagged while they are still growing on the banana plants. He added that 90 percent of the imported bananas to the U.S. come in boxes with no consumer plastic bags on them; while 10 percent of the imports get bagged when displayed for sale in supermarkets.

The only State in the U.S. that grows bananas is Hawaii, but because of the oriental fruit fly the rest of the U.S. does not get bananas from Hawaii. Hence we import almost 100 percent of the bananas from Latin America. We import about 190 million pounds of bananas each year and the banana per capita consumption is 27 lbs. versus 22 lbs. for apples.

Plantains compose less than two percent of the banana imports; they are usually sold in the ethnic communities of Los Angeles, New York, Miami, and Houston. American importers buy plantains from the small local farmers who are unsophisticated when it comes to spraying

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and the usage of pesticides. Despite this fact and the small imported amount of plantains; the banana tolerance would be adequate for plantains, because the banana tolerance level is stringent enough to ensure the protection of the public and the environment from any risks.

Based on my conversations with Mr. Moore; BEAD determines that almost all of the imported bananas sold in the U.S. supermarkets are bagged when pesticides are applied, and the same conclusion can be drawn with respect to plantains found in gourmet or ethnic supermarkets.

cc. Rob Esworthy, EAB Chief
Ed. Brandt, RASPS Acting Section Leader