12-9-91 R.F.

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

December 9, 1991

MEMORANDUM

SUBJECT: Amendment to PP#9G3817, Tebuconazole on Grapes and Peanuts
Mobay Response to Deficiencies related to Temporary Tolerance and EUP (Mobay letter of 11/19/90)
[MRID Nos. 417174-00 to -05 and -07 to -10, DEB No. 7512, HED No. 1-0417, DP Barcode D159779

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In response to our review of their temporary tolerance petition and associated EUP's for the use of tebuconazole on peanuts and grapes (PP#9G3817, 3125-EUP-ROO and 3125-EUP-ENN, C. L. Olinger, 6/8/90), the petitioner, Mobay, has submitted additional data and comments responding to those deficiencies. The petitioner states that this submission responds only to those deficiencies related to their EUP on peanuts. Additionally, revised Sections B and F are included. Mobay also requests answers to several questions.

One formulation is included in the revised Section B. Folicur 3.6F is to be used on peanuts (3125-EUP-ENN). An earlier Section B also included ELITE 45 DF to be used on grapes (3125-ROO).

Section B now includes a feeding restriction for peanut forage and Hay. Section F no longer has tolerance proposals for livestock commodities. It does, however, still include a proposal for a tolerance on peanut hay at 50 ppm. A food additive tolerance is now proposed for raisin waste at 6 ppm; peanut oil (crude or refined) and peanut soapstock at 0.5 ppm;

and peanut hulls at 4 ppm; however, there is no H petition number, nor any indication that the H petition fee has been paid. Additional residue data for peanuts are also provided, reflecting aerial application. (Aerial application is not permitted on the EUP label.)

Since the previous review, CB has met with the petitioner twice (C. Olinger memo of 7/26/90 and G. Otakie memo of 7/29/91) to discuss deficiencies, responded to questions and reviewed feeding study protocols (F. Toghrol memos of 2/7/91 and 4/1/91). In the last meeting, Mobay indicated a willingness to delete temporary tolerance proposals for grapes.

Copending petitions for permanent tolerances for tebuconazole residues on peanuts and grapes have recently been reviewed by CB (PP#9F3724, 9F3818/9H5575, G. Otakie, 4/30/91, CB Nos. 5567, 5597-9, 6021, 6405-6, 6613-4). Those permanent petitions remain in reject status with numerous outstanding deficiencies.

CONCLUSIONS

Deficiencies 1a, 2a, 2b, 8d, and 12a pertaining to grapes remain outstanding. These deficiencies could be resolved by deleting use directions for grapes and deleting tolerance proposals for grape commodities.

Deficiencies 4, 6b, 6c, 6d, 8e, and 8f, pertaining to peanuts remain outstanding.

4. Additional questions have been raised about the metabolism of tebuconazole in livestock commodities. The amended report contains different results with no explanation and insufficient data to verify the calculations. There is also a discrepancy between the ratio of radiolabeled tebuconazole and metabolites in liver extract. A corrected copy of the poultry metabolism report is needed, along with complete calculations to support all results.

6b., 6c., 6d. Peanut forage and hay feeding restrictions are acceptable, but peanut meal, hulls, and soapstock are livestock feed items which are not under grower control. Additionally, this petition includes proposed temporary tolerances for grape commodities, which are not under grower control. Therefore, tolerances and analytical methods are still needed for meat, milk, poultry and eggs.

We could accept the petitioner's argument that the expected residues would be too low to measure and could conclude that the use would be in Category 3 of 40 CFR

180.6(a) for the purpose of temporary tolerance only, if peanut hulls, meal, and soapstock were the only livestock feed items. Thus, if tolerance proposals and use directions for grapes were deleted, we could consider this deficiency resolved for the purpose of the temporary tolerance. For a permanent tolerance on peanuts only, tolerances would still be needed for livestock commodities, although they may be set at the limit of detection of the analytical method.

8e, 8f. The petitioner did not respond to these deficiencies. Storage stability data are needed for eggs and milk. Additional information is needed about the poultry commodity storage stability study: residue levels in ppm as well as relative percentages, and the detector used in the study.

Deficiencies 5a and 5b are resolved for the purpose of this temporary tolerance only. A revised method with better precision may be required for a permanent tolerance on peanut processed commodities. An independent method validation is still needed for the permanent tolerance and must be submitted before we can initiate a PMV. The sampling instructions should als obe revised since they still refer to a German manual.

Deficiencies 8a, 8b, and 8c are resolved for the purpose of this temporary tolerance. The petitioner should note our suggestions in the body of this review for conducting future storage stability studies.

Deficiencies 9b, 11b, and 12b are resolved.

Additional conclusions and deficiencies are numbered below starting with 13.

13. There is no evidence of an H petition number, nor any indication that the temporary food additive petition fee has been paid. This will be required before this temporary tolerance can be established.

14. A new Section F is needed deleting the temporary tolerance proposal for peanut hay, and including temporary tolerance proposals for the livestock commodities which were deleted, along with a revised Section B including use directions for grapes. Alternatively, a new section F may be submitted deleting the temporary tolerance proposal for peanut hay and all grape commodities.

15. The additional residue data for peanuts reflecting ground and aerial application (MRID No. 417174-09) were not required and have not been reviewed at this time. The data will be needed for any future temporary tolerance if aerial application is desired

and should also be reviewed for the purpose of the copending permanent tolerance request.

The petitioner's questions are answered at the end of this review.

SUMMARY OF REMAINING DEFICIENCIES

- H petition number

- All deficiencies pertaining to grapes, which were not addressed in this amendment, and a revised Section B, including use directions for grapes and peanuts.

- Questions about livestock metabolism calculations, analytical methodology for livestock commodities, storage stability for milk and eggs, and questions about storage stability studies in other livestock commodities. A corrected copy of the poultry metabolism report, along with complete supporting calculations.

- Revised Section F, deleting the temporary tolerance proposal for peanut hay and requesting temporary tolerances for the livestock commodities which were deleted in this amendment.

ALTERNATIVE REMAINING DEFICIENCIES (assuming grape use is removed)

- H petition number

- Revised Section F, deleting the temporary tolerance proposals for peanut hay, and all grape commodities.

RECOMMENDATIONS

We recommend that the petitioner be advised to correct the remaining deficiencies. We recommend that this review be sent to the petitioner in its entirety.

The petitioner should reference the metabolism data (MRID Nos. 417174-01, -02, and -04) and the new field trial data for peanuts (MRID No. 417174-09) in their next submission for the copending permanent tolerance (9F3818/9H5575). They should include both the temporary petition number (9G3817) and the MRID Numbers (417174-01 to -05 and -07 to -10) for those studies.

Detailed Considerations

The deficiencies are restated below as they are numbered in our previous review of 6/8/90, followed by Mobay's response and our comments. Deficiencies 1a, 2a, 2b, 8d, and 12a pertain only

to grapes (3125-EUP-ROO) and will not be discussed in this review. These deficiencies remain outstanding. Our responses to Mobay's questions are found at the end of this review.

Deficiency #3

"Contingent upon submission of storage information, for the purposes of a temporary tolerance, the residue of concern is the parent, tebuconazole, for both peanuts and grapes."

In our memo dated 6/8/90, under metabolism of tebuconazole in peanuts, we also made the following statements:

> "It was unclear that tebuconazole was applied three times at 6, 8, and 10 weeks for a total of 0.225 lb ai/A, or if three pots were sprayed at different intervals.
>
> "A new metabolism study with multiple applications must be submitted to support a permanent tolerance. Tebuconazole should be labeled in the chlorophenyl ring. Samples storage and preparation should be adequately described. Report documentation should explain the identification of metabolites in detail and the concentration of each metabolite in addition to the percent of total radioactive residue should be reported. If the new metabolism studies reveal similar results, it may be necessary to include HWG 2061 in the tolerance expression."

Mobay response to Deficiency #3

Mobay has provided a revised report on the metabolism of tebuconazole in peanuts (Mobay Report No. 87043, MRID No. 417174-01) in which the number of applications of labeled tebuconazole and the dates of harvest and extraction of peanut foliage, nutmeat, and hulls have been provided. This revised report consists of four additional pages (pp 34-37) added to the previous submission and corrections on four pages between page 7 and 11. Mobay has requested that the revised metabolism study report replace the previous submission (Mobay report No. 87043, MRID 409959-24).

According to the submission, radiolabeled tebuconazole was applied three times, at 6, 8, and 10 weeks after planting. The rate used was the maximum field rate of 0.25 kg ai/ha (0.225 lb ai/A). Mobay has now provided the dates of harvest and extraction for the peanut forage, nutmeat and hull samples from the metabolism study. The samples were analyzed within 190, 147, and 146 days, respectively.

The distribution of triazole-^{14}C tebuconazole and its metabolites in peanut foliage, nut meat and hulls were reported

previously on the basis of percent only. In this revised report, residues are reported as ppm, as well as % TRR. (See Tables I, II, and III.) Total radioactive residues were 29.2 ppm tebuconazole equivalents in the foliage, 1.19 ppm in the nutmeat, and 0.16 ppm in the hulls.

Table I Distribution of triazole-^{14}C tebuconazole and its metabolites in peanut foliage.

Fraction	Residue (ppm tebuconazole equiv.	% TRR
Organic		
Tebuconazole	17.05	58.4
HWG 2061	4.41	15.1
Other *	4.00	13.7
Aqueous **	1.87	6.4
Unextractable **	1.87	6.4
		100.0

* analyzed by TLC or HPLC
** Includes TLC origin, diffused activity, and cleanup losses
*** Includes aqueous silanized silica and acidic partition

Table II. Distribution of triazole-^{14}C tebuconazole and its metabolites in peanut nutmeats.

Fraction	Residue (ppm tebuconazole equiv.	% TRR
Organic *	0.02	1.5
Aqueous **		
triazole	0.11	9.0
TA	0.55	46.4
TLA	0.10	8.5
Diffuse	0.32	26.9
1N HCl released	0.08	7.1
Unextractable	0.01	0.6

* Includes hexane, chloroform, and methanol fractions
** Analyzed by TLC or HPLC
TA = triazole alanine
TLA = triazole lactic acid

Table III. Distribution of triazole-^{14}C tebuconazole and its metabolites in peanut hulls.

Fraction	Residue (ppm tebuconazole equiv.)	% TRR
Organic		
tebuconazole	0.02	13.2
HWG 2061	0.01	3.4
Diffuse	0.02	11.4
Aqueous		
Tebuconazole	<0.01	2.4
TA	<0.01	2.6
not identified (separate fractions listed)	0.05	38.5
6N HCl released (not identified)	0.01	8.6
Not extracted	0.03	19.9
		100.0

Mobay indicates that a new metabolism study with chlorophenyl ^{14}C tebuconazole for peanuts in progress and will be submitted to the Agency.

CBRS Comments

For the purpose of this temporary tolerance only, this deficiency is resolved. Storage information and storage stability data for the peanut metabolism study are discussed under deficiencies 8a, 8b, and 8c.

For the purpose of this temporary tolerance and EUP only, we will consider the residue of concern to be tebuconazole, per se, in grapes and peanuts. However, if the new metabolism study for chlorophenyl ^{14}C tebuconazole in peanuts reveals similar results or identifies new metabolites of toxicological concern, it may be necessary to include HWG 2061 and any other newly identified metabolites in the permanent tolerance expression. The new metabolism study should include sample calculations and sufficient detail so that CB may verify all of the petitioner's calculations.

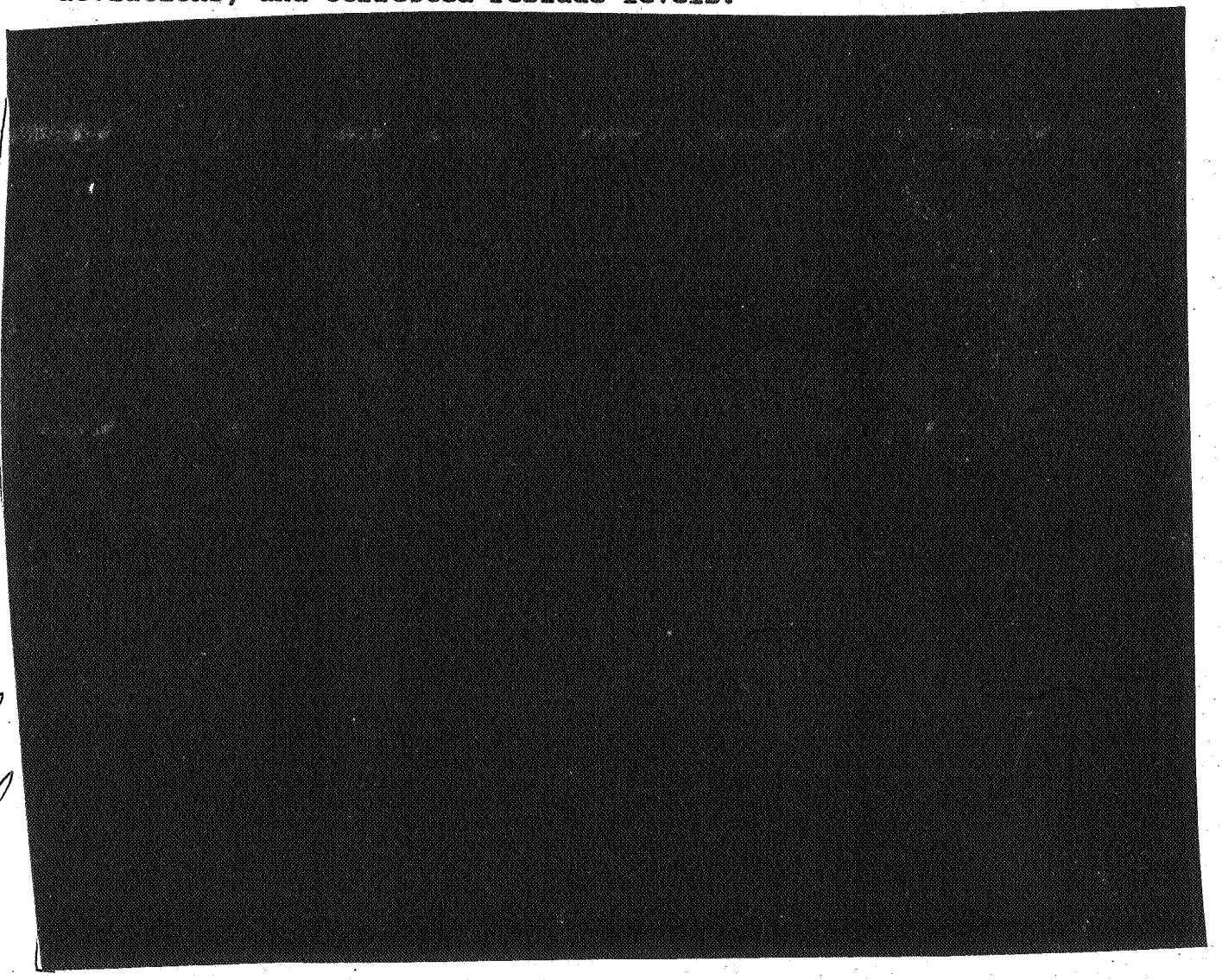
Deficiency 4

"Contingent upon submission of adequate storage stability data, the residues of concern in animal matrices are the parent, tebuconazole, and the t-butyl hydroxy metabolite, HWG 2061." Although the petitioner proposed to regulate only the parent compound, significant quantities of HWG 2061 (2-49% of the TRR)

and its conjugate (11-93% of the TRR) were found in cattle and poultry tissues in the cattle and poultry metabolism studies.

Mobay response to Deficiency 4

Mobay has submitted a revised report for the metabolism study for chlorophenyl ^{14}C tebuconazole in poultry and has requested that the revised report (Mobay Report No. 87156, MRID No. 417174-02) replace the previously submitted report (Mobay report No. 87156, MRID No. 409959-30). Mobay states that the revised report includes the tissue analysis dates, standard deviations, and corrected residue levels.



Goat Metabolism. Mobay has also submitted a revised report for their metabolism study of chlorophenyl ^{14}C tebuconazole in dairy goats. They request that the revised report (Mobay Report No. 94882, MRID No. 417174-04) replace the previous submission

(Mobay Report No. 94882, MRID No. 409959-29). Mobay states that, since the analysis of goat tissues and milk were done within four months, and poultry tissues are stable for that time, therefore the tissue analysis for the goat metabolism study is supported by the poultry storage stability data. They state that a milk storage stability study is in progress and will be submitted in December, 1990.

The petitioner's letter explains that the feeding level of 15 mg/kg body weight/day is equivalent to approximately 500 mg/kg tebuconazole in the feed because goats eat approximately 3% of their body weight per day.

CBRS Comments

This deficiency remains outstanding. The amended report raises additional questions. The results of the study have been revised. Different figures are presented for the total radioactive residue, with no explanation, and insufficient data to verify the calculations. Some of the tabulated results are higher and some are lower than previously reported. The metabolism study report should contain sufficient data along with a complete sample calculation so that we may verify the petitioner's calculations. Mobay should submit a complete copy of the poultry metabolism report, along with complete supporting calculations.

We also noticed a discrepancy between the ratio of radiolabeled tebuconazole and metabolites in poultry liver extract. The peak sizes in the HPLC radiochromatogram (Figure 6) do not match the tabulated results in Table 4 of the previous submission. The peak ratios for the kidney extract (figure 7) have the same relative ratio as the previously tabulated results. This discrepancy must be explained. Calculations must be provided to support all results.

We have not received the milk storage stability study to date. This study should be submitted.

Deficiency #5a

"Contingent upon submission of a revised analytical method incorporating subsequent modifications, an analytical method is available for the determination of tebuconazole in grapes and peanuts and associated processed commodities, with the exception of peanut oil and soapstock."

Mobay Response to Deficiency 5a

Mobay submitted a revised analytical method, entitled Modification of Folicur Residue Method for peanut meat and peanut hay" (Mobay Report No. 94295, Addendum 1, page 31 and 32, MRID

No. 417174-03). Mobay requests that the revised analytical method replace the previous submission (Mobay Report No. 94295, MRID No. 407009-63).

The modifications are: (a) in the extraction procedure, three times more sodium sulfate is used for drying the dichloromethane solution; (b) in the cleanup procedure, the gel permeation chromatography is performed prior to the silica gel column chromatography; and (c) in the gas chromatography, to avoid interference of natural constituents a third temperature ramp is added to the GC program.

The method still refers to a German Manual (DFG) for sampling instructions.

CB Comments

This deficiency is resolved for the purpose of the temporary tolerance. This amendment includes most of the changes required in our review of the permanent petition (9F3818/9H5575, G. Otakie, 5/9/91). However, the sampling instructions still need revision because they still refer to a German manual.

Deficiency 5b

"An analytical method for peanut oil and soapstock must be submitted before a temporary tolerance can be granted." "An independent method validation as described in PR Notice 88-5 must be submitted as well for a permanent tolerance."

Mobay Response

Mobay submitted a revised analytical method, entitled Modification of Folicur Residues in processed peanut products" (Mobay Report No. 94295, Addendum 2, page 33 to 36, MRID No. 417174-03). Mobay requests that the revised analytical method replace the previous submission (Mobay Report No. 94295, MRID No. 407009-63). The percent recovery of tebuconazole in fortified processed peanut products ranged from 50 to 110 % for soapstock at the 0.02 to 0.40 ppm fortification levels. The recovery of tebuconazole in fortified refined oil and crude oil at the 0.02 ppm fortification level ranged from 84 to 134 % and 101 to 117 %, respectively.

CBRS Comments

This deficiency is resolved for the purposes of this temporary tolerance only. The analytical method has a large percent recovery variation for tebuconazole in processed peanuts products. Therefore the revised method may not be suitable for enforcement purposes. A revised analytical method with good

recoveries for tebuconazole in processed peanut products may be required for a permanent tolerance. An independent method validation will still be required for a permanent tolerance and must be submitted before we can initiate a PMV.

Deficiencies 6b, 6c, and 6d

"The analytical method submitted may be adequate for the determination of tebuconazole in bovine kidney and poultry skin and HWG 2061 in bovine liver contingent upon justification of data variability."

The method as submitted is not adequate for determination of tebuconazole in eggs and milk, and for determination of HWG 2061 in eggs, milk, poultry liver, and poultry fat. A new modified method must be submitted for a temporary tolerance."

Good recoveries were obtained by an independent lab for the determination of tebuconazole and HWG 2061 in bovine liver. Based on the laboratory's experience with the method, a modified method should be submitted, incorporating their recommendations."

Mobay Response

Mobay indicates that since they are in the process of redoing the analytical method for animal tissues, milk, and eggs, and will repeat the animal feeding studies for the permanent tolerance, they wish to request an exemption of the requirement for a temporary tolerance in animal tissues, milk, and eggs. Mobay also requests a waiver of the requirement for an analytical method and residue feeding studies in livestock for this EUP for the following reasons:

1. Mobay will restrict the feeding and grazing of peanut vines and hay.

2. This restriction will limit the potential residues in animal tissues, milk, and eggs to a level far below the limit of detection of the analytical method, assuming residues at the proposed tolerance level for peanut hulls, meal and soapstock. Mobay estimates that the maximum residues, based on the TRR from their ^{14}C tebuconazole feeding studies, would not exceed 0.0012 ppm in poultry tissues, 0.00003 ppm in eggs, 0.0025 ppm in bovine tissue, and 0.00002 ppm in milk.

3. Based on this restriction, they have revised their Section F for the temporary tolerance petition (PP#9G3817) and EUP for tebuconazole on peanuts by removing the proposed tolerances for eggs, meat, and milk.

The complete calculation for Mobay's estimate was included in their letter of 11/19/90.

CB Comments

These deficiencies remain outstanding.

The analytical method for tebuconazole and HWG 2061 is not suitable. The percent recovery for tebuconazole in poultry tissues, when fortified at 0.05 to 0.1 ppm ranged from 61 to 126%, and in eggs, at fortification levels from 0.01 to 0.1 ppm, ranged from 66 to 130%. The percent recovery for tebuconazole metabolite HWG 2061, when fortified at 0.05 to 0.1 ppm in poultry tissues ranged from 27 to 80% and in eggs, when fortified at 0.01 to 0.1 ppm, ranged from 30 to 180%. The percent recovery of this method makes it unsuitable for enforcement purposes.

Peanut forage and hay feeding and grazing restrictions are acceptable, but peanut meal, hulls, and soapstock are livestock feed items which are not under grower control. Therefore, this feeding restriction does not eliminate the need for tolerances in meat, milk, poultry and eggs. Finite residues were found in peanut vines, hulls and nutmeat, although nutmeat residues were near the limit of detection of the analytical method.

We could accept the petitioner's argument that the expected residues would be too low to measure and could conclude that the use would be in Category 3 of 40 CFR 180.6(a) for the purpose of a temporary tolerance only, if these peanut commodities were the only livestock feed items, However, this petition includes proposed temporary tolerances for grapes and processed grape commodities. This increases the dietary burden to livestock.

If tolerance proposals and use directions for grapes were deleted from this temporary tolerance petition, we could consluder this deficiency resolved for the purpose of the temporary tolerance.

Deficiencies 8a, 8b, and 8c

"Tebuconazole is stable in peanut foliage for up to six months; storage stability data up to eight months must be submitted to support the residue data."

"Tebuconazole is stable up to 4.5 months in peanut meat; data up to eight months must be submitted to support the residue data."

No storage stability data for peanut hulls are available."

Mobay Response

According to Mobay, storage stability studies using triazole ^{14}C tebuconazole in peanuts indicated that tebuconazole was stable in peanut foliage from three weeks (85.9%) up to 189 days (83.8%), as reported in Mobay report 95679, MRID No. 409959-40.

Mobay has submitted a revised Storage Stability Study Report (Mobay Report No. 95679, MRID No. 417174-05) to replace the previously submitted Storage Stability Report (Mobay Report No. 95679, MRID No. 409959-40). In this experiment, peanut foliage from the peanut metabolism study was harvested on 10/14/86, which contained a total radioactive residue (TRR) of 29.2 ppm tebuconazole equivalents. Samples were stored at -10 C for 182 weeks and analyzed periodically. Extracted radioactive residue from peanut foliage was partitioned into chloroform and were separated by TLC using an acetone/methanol/acetic acid (95:5:1) solvent system. These data indicate that no decomposition of tebuconazole in peanut foliage occurred for up to 179 weeks (1253 days). See Table V below.

Table V Stability of Triazole ^{14}C Tebuconazole residues in peanut foliage following frozen storage.

Time (weeks)	Residue (ppm tebuconazole equivalents) TRR in chloroform fraction	tebuconazole by TLC
3	17.2	12.75
26	21.09	16.87
27	20.33	16.97
30	19.65	16.46
182	19.72	16.80

The information provided was insufficient to verify the petitioner's calculations.

Mobay also submitted a revised peanut storage stability study report (Mobay report No. 98493, MRID No. 417174-08) to replace their previously submitted report (Mobay Report No. 98493, MRID No.. 410685-02). The report includes frozen storage stability data from tebuconazole in barley, grapes, and peanuts. The study was done by ABC Laboratories, the same laboratory who did the analyses for the field trial samples.

Samples with detectable field incurred residues were analyzed initially and then stored frozen at -20 C for 138 to 909 days and reanalyzed at one or two intervals after frozen storage. For peanut hulls, treated samples were taken from a number of field studies over a two year period of time and all reanalyzed at the same time.

Frozen Storage Stability of Tebuconazole in Peanuts, Peanut Hulls, Grapes, Barley Grain, Barley Forage, and Barley Straw			
Matrix	Storage Time (days)	Residue (ppm Tebuconazole)	% Remaining
Peanuts	0	0.08	
	138	0.11	138%
	510	0.13	163%
Peanut Hulls	0	0.54	
	225	0.57	106%
	0	0.49	
	225	0.43	88%
	0	0.56	
	233	0.43	77%
	0	0.37	
	233	0.64	173%
	0	2.02	
	569	4.15	205%
	0	2.15	
	569	1.86	87%
	0	0.54	
	569	0.45	83%
	0	0.71	
	569	1.01	142%
	0	0.49	
	895	0.34	69%
	0	0.99	
	895	0.89	90%
	0	0.20	

908	0.28	140%
0	0.89	
908	0.81	91%

[redacted]

These data show that residues of tebuconazole in peanut nutmeat may be stable up to 510 days (17 months) and in peanut hulls up to 233 days (7 months). However, the results are quite variable.

We note that the initial analyses are included in a number of reports and the analyses after storage were done using a GC/NPD with a computer recording system which used only a single point calibration curve. The samples were diluted varying amounts so that the resulting peak was similar in size to the standard peak. Controls and fortified samples of each matrix being analyzed were not used; e.g., only barley forage control and fortified samples were used in one analytical run with peanut, grape, and barley grain, forage, and straw. The amount of information in the report was sufficient to verify the calculations.

CB Comments

For the purpose of this temporary tolerance, these deficiencies are resolved.

A better design for a frozen storage stability study would be to reanalyzed the same samples at a number of intervals, e.g., 2 weeks, 1 month, 3 months, 6 months, 12 months, 2 years, 3 years, etc....

Deficiencies 8e and 8f

"No storage stability data for eggs and milk are available."

"Contingent on submission of additional experimental information, tebuconazole and HWG 2061 are stable in poultry kidney, muscle, and fat for twelve months, and in poultry liver for six months." Relative percentages were reported. The residue level in ppm should be reported. The detector used should be specified as well.

Mobay Response

Mobay did not respond to this deficiency. No storage stability data for tebuconazole in milk and eggs were provided with this submission. Mobay states that storage stability studies for tebuconazole in eggs and milk are in progress and will be submitted to the Agency in December, 1990.

No additional information on the poultry commodity storage stability studies was submitted.

CB Comments

Deficiencies 8e and 8f remain outstanding.

We have not received the storage stability studies for tebuconazole and metabolites in milk or eggs to date. The petitioner should submit these studies. For the poultry commodity storage stability studies, we still need residue levels in ppm as well as relative pecentages, and the identiry of the detector used in the study.

Deficiency 9a

"Contingent upon submission of adequate storage stability data, the peanut residue data are adequate for a temporary tolerance only."

Mobay Response

Mobay provided a revised report for the storage stability study in peanut nutmeat, foliage, and peanut hulls. See the discussion under deficiencies 8a, 8b, and 8c.

CB Comments

For the purpose of this temporary tolerance only, this deficiency is resolved. For more information, see the discussion under 8a, 8b, and 8c.

Deficiencies 9b, 11b, and 12b

"The proposed tolerance for peanut hulls should be increased to 4 ppm."

"Section F should be revised to include the following temporary tolerances: peanut oil (crude or refined), 0.5 ppm; peanut soapstock, 0.5 ppm."

The tolerances for wet and dry grape pomace should be incorporated into a single tolerance: grape pomace (dry and wet), 12 ppm. A tolerance for raisin waste should be proposed, since there was greater concentration of tebuconazole in raisin waste than raisins."

Mobay Response

Mobay has submitted a revised Section F and has proposed the temporary tolerances in or on peanuts at 0.1 ppm , peanut hulls at 4.0 ppm, peanut hay at 50.0 ppm, grapes at 2.0 ppm, grape pomace (dry or wet) at 12 ppm, raisins at 3.0 ppm, raisin waste at 6.0 ppm, peanut oil (crude or refined at 0.5 ppm, and peanut soapstock at 0.5 ppm. Mobay has deleted tolerance proposals for livestock commodities.

CB Comments

For the purpose of this temporary tolerance, these deficiencies are resolved, but new deficiencies are created. We note that a feeding restriction is proposed for peanut forage and hay, but there is a tolerance proposal for peanut hay. This tolerance is not needed if there is a feeding restriction, and the proposal should be deleted.

Peanut forage and hay feeding restrictions are acceptable, but peanut meal, hulls, and soapstock are livestock feed items which are not under grower control. Additionally, this petition includes proposed temporary tolerances for grape commodities, which are not under grower control. Therefore, tolerances and analytical methods are still needed for meat, milk, poultry and eggs.

We could accept the petitioner's argument that the expected residues would be too low to measure and could conclude that the use would be in Category 3 of 40 CFR 180.6(a) for the purpose of temporary tolerance only, if peanut hulls, meal, and soapstock were the only livestock feed items. Thus, if tolerance proposals and use directions for grapes were deleted, we could consider this deficiency resolved for the purpose of the temporary tolerance. For a permanent tolerance on peanuts only, tolerances would still be needed for livestock commodities, although they may be set at the limit of detection of the analytical method.

Thus, a new Section F is needed deleting the temporary tolerance proposal for peanut hay, and reproposing the temporary tolerances for livestock commodities which were deleted. Alternatively, a new Section F is needed deleting the temporary tolerance proposals for peanut hay and all grape commodities, along with a new Section B deleting use directions for grapes.

Deficiencies 13b and 13c

"The dairy cow and laying hen feeding studies are inadequate due to unresolved method problems and the lack on concurrent fortification and storage stability data."

The tolerance expression for all animal matrices should include the parent tebuconazole and the hydroxy metabolite, HWG 2061. Method sensitivity to tolerance proposed should be revised to the combined limits of detection for tebuconazole and HWG 2061."

Mobay response

In response to these deficiencies, the petitioner has agreed to repeat the ruminant and poultry feeding studies. Protocols entitled "Feeding Study - Dairy Cow" and Poultry Feeding" were submitted.

CB Comments

The feeding study protocols referenced in the petitioner's letter were reviewed in a previous memo (F. Toghrol, 4/1/91). The protocols were very general. We recommencded that the petitioner be provided with a copy of sour Standard Evaluation Procedures for Feeding studies to aid them in the conduct of the study.

Additional Field trial data - peanuts

Mobay has also submitted a study (Mobay report No. 100073, MRID NO. 417174-09), entitled, "Tebuconazole Magnitude of the Residue on Peanuts, 3.6F." Seven applications of tebuconazole 3.6F were made to peanuts at the rate of 3.6 oz ai/A/application using aerial or ground application.

CB Comments

These data were not required and will not be reviewed at this time because aerial application is not allowed on the ETU label. If Section B is later amended to include aerial application, then the data will be reviewed. These data should also be considered in connection with the copending permanent petition 9F3818/9H5575.

Other

Mobay has submitted storage stability data for tebuconazole in soil (Mobay Report No. 100244, MRID No. 417174-10). This study was not required by CB. It is under the purview of EFGWB and should be referred to them for review.

Mobay has asked several questions in their letter. The questions are stated below, followed by our response.

Question 1

"Will restricting the feeding of peanut vines and hay eliminate the need for temporary tolerances of any kind in meat, milk, and eggs?"

CB Response

Restricting the feeding of peanut vines and hay eliminates the need for tolerances in peanut forage and hay. This feeding restriction would be considered practical for a Section 3 registration. Whether this restriction would eliminate the need for temporary tolerances in meat, milk, poultry, and eggs, depends on whether we can conclude that the use would be in Category 3 of 40 CFR 180.6(a). We would need to conclude that there would be no reasonable expectation of residues in meat, milk, poultry, and eggs.

In this case, there is a reasonable expectation of residues because the livestock metabolism studies show that residues will transfer to meat, milk, poultry, and eggs; however, those residues are likely to be below the limit of detection. By the petitioner's calculations, based on the TRR from the metabolism studies, if residues in peanut feed commodities are at the proposed tolerance levels and registration is sought only in peanuts, residues in livestock commodities are expected to be an order of magnitude below the limit of detection.

We could condlude that the use would be in Category 3 of 40 CFR 180.6(a) for the purpose of a temporary tolerance only. For a permanent petition, a tolerance would be needed at the limit of detection for livestock commodities, even if peanuts are the only site for which tebuconazole is to be registered.

Question 2

"Relative to the permanent tolerance expressions for any crops, how many sites would DEB consider necessary for a minimal program to repeat the required crop field trial studies for representative analysis of metabolite residues only?"

CB Response

CB has responded to this question several times. We tailored our response to this petition, for peanuts and grapes. Basically, we would require the field trials to be repeated and all samples to be analyzed for all components of the total toxic residue (i.e., those that need to be included in the tolerance expression). Because the ratios of the parent compound and metabolites may vary, we do not consider it appropriate to analyze for metabolites only, unless the parent compound is not included in the tolerance expression. Regarding the number of field trials required, the number needs to be sufficiently representative of all of the major growing areas of the crop, with larger numbers of field trials in the growing areas where the greater percentage of the crop is grown, and a minimum of two field trials in minor growing areas.

Question 3

"For residue studies and storage stability, will DEB allow data from wheat to cover the requirements for barley, apples to cover pears, etc?"

CB response

For storage stability data requirements, generally, only one study is necessary for each crop group or even two crop groups. For example, apple storage stability data would be sufficient for tree fruits, grape storage stability data for small fruits; wheat storage stability data for small grains; potato storage stability data for root crops; spinach storage stability data for leafy greens, etc. If the pesticide and/or metabolites are unstable in frozen storage, however, then concurrent sotrage stabolity studies would be requried each time a residue field treial or processing study is done.

For residue data requirements, the same is not true. Residue data are generally translated only when there are residue data for the representative commodities in the crop group, and then only if the ratio between the residue levels in field trials for the representative crops is less than 5. The crop groupings were established to reduce the amount of residue data required for a large number of crops. Occasionally, some exceptions are made; e.g., raspberry data would cover requirements for blackberries and other similar berries if the uses are the same or if the other berries have a lower application rate, provided that sufficient raspberry data have been provided and the data are representative of the areas where all of the berries are grown.

cc:R.F., circu, PP#9G3817, PP#9G3818, S. Hummel, G. Otakie, B. Cropp-Kohlligian, FOD/PIB
RDI:FBS:12/09/91:DE:12/09/91
H7509C:DEB:SVH:svh:RM810:CM#2:x77324:12/09/91
FILE:TEBUCON.PP