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

MAR 6 1992

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **PP#9G3817.** Mobay's Response to Deficiencies Concerning the Temporary Tolerance Petition and Experimental Use Permits (Section 5) for the Fungicide Tebuconazole on Grapes (3125-EUP-ROO) and Peanuts (3125-EUP-ENN).
CBRS Nos. 8731 and 8732.
DP Barcode Nos. D169681 and D169684.
MRID Nos. 42125801 and 41717407.

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Mobay's applications for temporary tolerances under PP#9G3817 and two associated experimental use permits (EUPs) for applications of tebuconazole on peanuts and grapes were rejected by DEB (see memo C. Olinger dated 6/8/90) after review of residue chemistry data submitted in support of the requests (MRID Nos. 407009-01 through -03, and -63; 409959-01, -24, -25, -26, -29 through -36, -40 through -43, and -46 through -49; 411827-02; 4138835-01; 410685-01 and -02; 412633-18).

One EUP request involved applications of FOLICUR 3.6 F to over 475 acres of peanuts distributed over 8 states using a total of

208 gallons of formulation to gather efficacy, yield and ground verses aerial application comparison data (3125-EUP-ENN). The other EUP involved applications of ELITE 45 DF to over 235 acres of grapes distributed over 10 states using a total of 470 lb. of formulation to generate similar efficacy, yield and application method comparison data (3125-EUP-ROO).

In response to the rejection of their original requests for temporary tolerances and associated EUP's, the registrant submitted additional data and comments to address the specified deficiencies (MRID Nos. 417174-00 to -05 and -07 to -10). These data and comments have been reviewed and CBRS has concluded that several deficiencies remain outstanding (see S. Hummel memo dated 12/9/91).

In the current submission (Mobay letter dated 9/26/91), Mobay has written to inform the Agency that they are withdrawing their application for an EUP for the use of ELITE 45 DF on grapes (3125-EUP-ROO) and revising PP#9G3817 by deleting the temporary tolerance requests for all grape commodities without prejudice to a future filing. The registrant has submitted a revised Section F for PP#9G3817 (dated 9/26/91) in which grape, grape pomace (dry and wet), raisin, and raisin waste have been deleted. Below is the information supplied in the revised Section F (dated 9/26/91).

> Tolerances are proposed for residues of the fungicide tebuconazole (α-[2-(4-Chlorophenyl)ethyl]-α-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol) in or on the following commodities:

Commodity	PHI (days)	Proposed Tolerance (ppm)
Peanuts	14	0.1
Peanut hulls	14	4.0
Peanut hay	14	50.0
Food Additive Tolerance		
Peanut oil (crude or refined)		0.5
Peanut soapstock		0.5

The registrant still intends to pursue the application for an EUP for the use of FOLICUR 3.6 F on peanuts (3125-EUP-ENN) as originally requested and has submitted a letter and revised Section F (dated 9/26/91), a revised EUP draft label (dated 10/1/91), and a new report entitled, "Storage Stability of Tebuconazole and HWG 2061 in Egg and Milk" (MRID No. 42125801). These new data and comments, they feel, address all of the remaining peanut residue chemistry data deficiencies that were identified in the temporary tolerance petition review completed

by DEB (see C. Olinger memo dated 6/8/90).

Deficiencies as numbered in the previous temporary tolerance petition review completed by DEB (see C. Olinger memo dated 6/8/90) and addressed by the registrant in the current submission (Mobay letter dated 9/26/91) are restated below, followed by Mobay's verbatim response to the deficiency and CBRS's comments.

DETAILED CONSIDERATIONS

Deficiency 1a.

The name of the product on the CSF should be changed to ELITE 45 DF to reflect the name on the requested EUP. The CSF should be corrected so that the total weight percent of the ingredients is 100%, not 108.8%.

Registrant's Response to Deficiency 1a.

A revised CSF for ELITE 45 DF is no longer needed since Mobay has withdrawn the pending ELITE 45 DF grape EUP with this letter (dated 9/26/91).

CBRS's Conclusion Concerning Deficiency 1a.

With the withdrawal of the pending ELITE 45 DF grape EUP (3125-EUP-ROO) and the deletion of proposed temporary tolerances for tebuconazole residues in/on grape commodities in the revised Section F (dated 9/26/91) of PP#9G3817, deficiency 1a. is rendered moot. Under these circumstances, the resolution of deficiency 1a is not a prerequisite to the approval of the proposed temporary tolerances for peanut commodities under PP#9G3817 or the requested EUP for the use of FOLICUR 3.6 F on peanuts (3125-EUP-ENN).

Deficiency 1c.

The discrepancy on the CAS numbers reported in the CSF and the technical specification sheet should be clarified.

Registrant's Response to Deficiency 1c.

In response to the discrepancy concerning the CAS numbers on the CSF and the technical specification sheet, enclosed is a revised CSF for FOLICUR 3.6 F in which the CAS numbers [CAS 80443-41-0 and CAS (±)-107534-96-3] are listed for BAY HWG 1608 Technical. The CAS number 80443-41-0 was originally chosen and is more generic in nature. It represents a substance for which the stereochemical information is not specified and thus unknown.

This CAS number is only associated with the chemical name.

The CAS number 107534-96-3 represents a substance, which was described in the source document, as a racemic mixture of two enantiomers "+" and "-". The synonyms FOLICUR, RAXIL, and BAY HWG 1608 are associated with this registry number, as well as the chemical name.

CBRS's Conclusion Concerning Deficiency 1c.

Deficiency #1c is resolved for the purposes of this temporary tolerance petition (PP#9G3817) and the associated EUP on peanuts (3125-EUP-ENN) only.

This issue is not sufficiently resolved for the purposes of the copending permanent tolerance petitions (PP#9F3724/9F3818 and FAP#9H5575). Since FOLICUR, RAXIL, and BAY HWG 1608 are associated with both CAS numbers, the registrant must provide details concerning the chemical purity and enantiomer ratio of the substances represented by CAS Nos. 80443-41-0 and 107534-96-3 in a future submission for the permanent tolerance petition.

Deficiencies 2a. and 2b.

The application instructions for grapes should be clarified so that termination of application is expressed in terms of a PHI only, and not to Brix stage or berry coloring.

The curative application instructions for grapes should be clarified.

Registrant's Response to Deficiencies 2a. and 2b.

Application instructions are no longer needed since Mobay has withdrawn the pending ELITE 45 DF grape EUP with this letter (dated 9/26/91).

CBRS's Conclusion Concerning Deficiencies 2a. and 2b.

With the withdrawal of the pending ELITE 45 DF grape EUP (3125-EUP-ROO) and the deletion of proposed temporary tolerances for grape commodities in the revised Section F (dated 9/26/91) of PP#9G3817, deficiencies 2a and 2b are rendered moot. Under these circumstances, the resolution of deficiencies 2a and 2b are not prerequisite to the approval of the proposed temporary tolerances for peanut commodities under PP#9G3817 or the requested EUP for the use of FOLICUR 3.6 F on peanuts (3125-EUP-ENN).

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.

Registrant's Response to Deficiency 3.

In response to the request for storage stability data, Mobay Report No. 87043 on peanuts was revised and submitted to the Agency 11/19/90 and assigned EPA MRID No. 41717401. Our [Mobay] 11/19/90 letter also indicated that a new peanut metabolism study was in process to replace Mobay Report No. 98425 (EPA MRID No. 41182703). This study has been completed, submitted to the Agency on 8/9/91 under Mobay Report No. 101289, and assigned EPA MRID No. 41980201.

Data on grapes are no longer needed since the proposed EUP on grapes has been with drawn.

CBRS's Conclusion Concerning Deficiency 3.

Concering the proposed temporary tolerances for peanut RACs/processed products and the associated EUP for the use of FOLICUR 3.6 F on peanuts (3125-EUP-ENN), deficiency #3 is resolved and tebuconazole, per se, is the residue of concern. Storage stability data are discussed under deficiencies 8a, 8b, and 8c.

The revised report concerning the metabolism of tebuconazole in peanuts (Mobay report No. 87043; MRID No. 41717401) was reviewed by CBRS and deemed adequate for the temporary tolerance only (see S. Hummel memo dated 12/9/91).

The new peanut metabolism study (Mobay Report No. 101289;MRID No. 41980201) is currently undergoing review by CBTS in support of the permanent tolerance petition (PP#9F3724/9F3818/FAP#9H5575) and will not be discussed here. However, if the new peanut metabolism study provides results similar to previous metabolism studies or identifies new metabolites of concern, it may be necessary to include these metabolites in the permanent tolerance expression.

With the withdrawal of the pending ELITE 45 DF grape EUP (3125-EUP-ROO) and the deletion of proposed temporary tolerances for grape commodities in the revised Section F (dated 9/26/91) of PP#9G3817, the requirements for grape metabolism and storage stability data are rendered moot.

Deficiencies 4 and 8f.

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.

Contingent upon 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 6 months.

Registrant's Response to Deficiencies 4 and 8f.

In our letter of 11/19/90, revised Mobay Reports 87156 (poultry) and 94882 (goat) with the requested storage stability data were submitted. These revised reports were assigned EPA MRID Nos. 41717402 and 41717404, respectively.

CBRS's Conclusion Concerning Deficiencies 4 and 8f.

Deficiency 4 remains outstanding. Deficiency 8f is resolved for the purposes of this temporary tolerance petition (PP#9G3817) and the associated EUP on peanuts (3125-EUP-ENN) only.

Concerning deficiency #4, the tebuconazole animal metabolism studies (MRID Nos. 41717402 and 41717404) were reviewed and deemed inadequate for the purpose of the temporary tolerances (see S. Hummel memo dated 12/9/91). However, CBRS may agree to grant an exemption from the requirement for temporary tolerances in animal tissue, milk, and eggs if the registrant submits an amended Section F (as draft dated 9/26/91) of PP#9G3817 deleting the tolerance in/on peanut hay (50.0 ppm) to be consistent with the concomitant peanut hay (and vine) feeding restriction as per the proposed label (draft dated 10/1/91). These deficiencies would then be resolved for the purposes of the proposed temporary tolerances in/on peanut commodities and the associated EUP for the use of FOLICUR 3.6 F on peanuts (3125-EUP-ENN) only.

Regarding deficiency #8f, the registrant submitted a revised chicken tissue storage stability study (Mobay Report 98420; MRID No. 417174-07) to replace a previous report (Mobay Report 98420; MRID No. 409959-41). Several deficiencies/concerns were identified in the original study (see memo C. Olinger dated 6/8/90). These deficiencies/concerns included the absence of reported residue concentrations (ppm), discrepancies in the reported stability of HWG 2443 throughout the original report, and the appearance of significantly increased activity of HWG 2443 and the sulfate conjugate of HWG 2061 over the storage interval in several tissues. The revised report includes residue concentrations (ppm of FCLICUR and metabolites; TABLE I, page 12 of 19), a new conclusion concerning the stability of certain metabolites under storage conditions, and an explanation of the observed increases in activity of HWG 2443 and the sulfate

conjugate of HWG 2061 in certain poultry tissues.

Below are the residue concentrations (ppm) provided in TABLE I of the revised storage stability report (MRID 417174-07). Concentration values have been highlighted to show the length of stability of residues in poultry tissues as proposed by the registrant in the current submission (MRID 417174-07).

Ppm Distribution of FOLICUR and its metabolites in the Organic Fractions of Various Chicken Tissues Held in Frozen Storage.

	Residues in Organic Extract[1] (ppm)			
Tissue and Residue	1 Month	3 Month	6 Month	12 Month
Liver				
FOLICUR	**2.13**	**1.81**	**2.34**	0.82
HWG 2061	**1.41**	**1.31**	**1.70**	0.92
HWG 2443	**0.81**	**0.88**	**1.03**	1.71
Metabolite A[2]	**1.37**	**1.31**	**1.02**	2.04
Unknown[3]	1.52	1.43	1.00	0.87
Kidney				
FOLICUR	**1.75**	**3.04**	**2.33**	**2.99**
HWG 2061	**0.39**	**0.55**	**0.61**	**0.51**
HWG 2443	**0.95**	**0.89**	**0.97**	**1.01**
Metabolite A[2]	**0.53**	**0.51**	0.23	0.20
Unknown[3]	1.67	1.18	1.45	0.22
Muscle				
FOLICUR	**0.32**	**0.33**	**0.27**	**0.33**
HWG 2061	**0.15**	**0.16**	**0.12**	**0.15**
HWG 2443	N.D.	N.D.	N.D.	N.D.
Metabolite A[2]	N.D.	N.D.	N.D.	N.D.
Unknown[3]	0.06	0.07	0.11	0.01
Fat				
FOLICUR	**1.03**	**0.99**	**0.88**	**0.75**
HWG 2061	**0.14**	**0.14**	**0.13**	0.09
HWG 2443	N.D.	N.D.	N.D.	N.D.
Metabolite A[2]	**0.07**	**0.09**	0.12	0.11
Unknown[3]	0.07	0.10	<0.01	0.01

[1] Organic extracts analyzed on silica gel 60 F-254 thin-layer plates using acetonitrile/methanol/acetic acid (90:10:1) solvent system.

[2] Metabolite A has a higher Rf than the parent on tlc. This metabolite was tentatively identified as the sulfate conjugate of HWG 2061.

[3] Total of all other tlc bands which did not co-chromatograph with available standards.

N.D. Not Detected.

These data satisfy the requirement that concentrations as well as percentages of radioactivity for residues in all tissues must be provided (see memo C. Olinger dated 6/8/90).

The registrant has also revised the conclusions drawn from this study. The conclusions are as follows:

> "Residues of FOLICUR and its metabolites HWG 2061 and HWG 2443 in chicken liver were found to be stable for 12 months. Although increased levels of FOLICUR and HWG 2061 were observed after the 1 month analysis of kidney extracts, these compounds may still be stable up to 12 months in this tissue. Both FOLICUR and HWG 2061 showed 12 month stability in muscle. In fat, FOLICUR and HWG 2061 were stable up to 12 months and 6 months, respectively. An unknown metabolite, tentatively identified as the sulfate conjugate of HWG 2061, was stable for 6 months in the liver and 3 months in the kidney and fat."

These conclusions, while consistent throughout the revised report, vary on several points from assertions made by the registrant in the original study submission. However, with the single exception of HWG 2061 in fat, the registrant's conclusions concerning length of storage stability of residues now coincide with those presented in the original temporary tolerance petition (see memo C, Olinger 6/8/90).

Apparent increases in concentrations of FOLICUR and HWG 2061 in stored kidney tissue over time (1 to 3 months) are attributed to matrix variation or experimental error during the 1-month kidney analysis.

The significant increase in the level of HWG 2443 in the liver at 12-months is attributed to oxidation of both FOLICUR and HWG 2061. The registrant observed that the levels of both the parent and the alcohol significantly decreased at 12-months, whereas the concentration of HWG 2443 increased.

The registrant has also revised their conclusion concerning the identification of the sulfate conjugate of HWG 2061 and now refers to it as Metabolite A (a possible unknown). According to the registrant a metabolite with a higher Rf than the parent on silica gel 60 F-254 developed in ACN/MeOH/acetic acid (90:10:1) was detected in chicken liver, kidney and fat (see Table above). This metabolite (now called Metabolite A) was tentatively identified as a sulfate conjugate of HWG 2061. According to the registrant, in the metabolism study, the conjugate was isolated from a polar fraction of excreta, liver and kidney extracts by HPLC and was not detected in the muscle and fat. Mobay contends that the apparent nonpolar nature of Metabolite A in the TLC system suggests it may be an unknown. Metabolite A is reportedly stable up to 3 months in the kidney and fat and 6 months in the

liver.

With the submission of the residue concentrations (ppm) as in TABLE I of the revised report (MRID 417174-07) and the explanation of the apparent increases in concentrations of FOLICUR and HWG 2061 in stored kidney tissue over time (1 to 3 months) as provided by the registrant, deficiency #8F is resolved for the purposes of the temporary tolerances only. The revised poultry storage stability study (MRID 417174-07) demonstrates that tebuconazole and HWG 2061 are stable in poultry kidney, muscle, and fat for 12-months, and in poultry liver for 6-months.

The explanation concerning the increases in concentration of FOLICUR and HWG 2061 in stored kidney tissue may not be sufficient for the permanent tolerance petition. Rationale provided by the registrant concerning similar occurrences in other metabolites (HWG 2443 and Metabolite A) have been reiterated here but have not been discussed fully since under current circumstances (see CBRS's Conclusions Concerning Deficiencies 6b and 6c) these explanations do not impinge on the approval of the temporary tolerances for the peanut commodities or the associated EUP (3125-EUP-ENN). The registrant is directed to reference this revised storage stability study (MRID-417174-07) in their next submission for the copending permanent tolerance petitions (PP#9F3724/9F3818/FAP#9H5575).

Deficiency 5b.

An analytical method for peanut oil and soapstock must be submitted before a temporary tolerance can be granted.

Registrant's Response to Deficiency 5b.

With our letter of 11/19/90, we submitted revised Mobay Report No. 94295 which contained a detailed description of the method used in the analysis of the oil and soapstock. This revised report was assigned EPA MRID No. 41717103.

CBRS's Conclusion Concerning Deficiency 5b.

Deficiency #5b is resolved for the purposes of this temporary tolerance petition (PP#9G3817) and the associated EUP on peanuts (3125-EUP-ENN).

The revised analytical method (Mobay Report No. 94295; MRID 41717103) entitled, "Modification of Folicur Residues in Processed Peanut Products" was reviewed by CBRS and deemed adequate for the determination of tebuconazole residues in peanut oil and soapstock (see S. Hummel memo dated 12/9/91).

Deficiencies 6b. and 6c.

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 the determination of HWG 2061 in eggs, milk, poultry liver, and poultry fat. A new or modified method must be submitted for a temporary tolerance.

Registrant's Response Concerning Deficiencies 6b. and 6c.

In our 11/19/90 letter, we indicated that we were in the process of redoing the analytical method for animal tissues, milk, and eggs, and would repeat the animal feeding studies for the permanent tolerance. We also requested an exemption from temporary tolerances in animal tissues, milk and eggs and requested a waiver of requirements for an analytical method and residue feeding studies in livestock for the EUP on peanuts. These reasons are reiterated below.

1. Mobay has submitted revised draft labeling, dated 11/8/90, restricting the feeding/grazing of peanut vines/hay. This has been done by adding the following to the Remarks column under Recommended Applications.

   "Do not feed or graze green peanut vines or peanut vine hay. Do not hog down treated peanut fields."

2. This feeding restriction will limit the potential residues in tissues, milk, and eggs to levels far below required limits of determination of analytical methods by limiting the peanut matrices which can be used in animal feed to hulls, meal, and soapstock. If the expected tolerances for each of these matrices and the dietary percentage which each of these can be fed to animals is taken into consideration, the total residues to be expected in tissues, milk, and eggs will be much less than 0.01 ppm (0.0025 ppm to 0.00002 ppm) based on the total radioactivity residues detected in the poultry and goat metabolism studies (Mobay Report Nos. 87156 and 94832;EPA MRID Nos. 41717402 and 41717404, respectively). This conclusion is reached in the following manner:

   a. In the poultry metabolism study, poultry were fed at 10 mg/kg body wt or approximately 250 mg/kg of feed (based on eating 4% of body wt/day).

      Goats were fed in the metabolism study at 15 mg/kg body wt or approximately 500 mg/kg of feed (based on eating

3% of body wt/day).

The highest <u>total</u> radioactive residues were 8.29 ppm (poultry liver) and 5.19 ppm (goat liver).

b. Using the proposed tolerances (hulls, 4 ppm; meal, 0.1 ppm; soapstock, 0.5 ppm) and the percentages of peanut matrices in animal feed (Table II, EPA Guidelines, Subpart O), the following maximal residues might be expected in animal feed:

Poultry: 10% meal (0.1 ppm) + 5% soapstock (0.5 ppm) + 85% regular feed (0 ppm) = 0.35 ppm or 0.035 mg/kg of feed.

Bovine: 5% hulls (4 ppm) + **15%** meal (0.1 ppm) + 5% soapstock (0.5 ppm) + 75% regular feed (0 ppm) = 0.24 ppm or 0.24 mg/kg of feed.

c. Comparing the expected maximal residues in animal feed with the feeding levels used in the poultry and goat metabolism studies, the following factors are derived:

Poultry: 250 mg/kg ÷ 0.035 mg/kg = 7143

Bovine: 500 mg/kg ÷ 0.24 mg/kg = 2083

These factors, which were divided into the total tissue, milk and egg residue levels found in the metabolism studies, yield residue levels expected in those matrices from consumption of maximally treated feed from the proposed EUP use.

d. Hence, for poultry total residues (not just tebuconazole) would not be expected to exceed 0.0012 ppm in tissues or 0.00003 in eggs. For bovine, total residues (not just tebuconazole) would not be expected to exceed 0.0025 ppm in tissues or 0.00002 ppm in milk. In each circumstance, the residues of tebuconazole or tebuconazole plus HWG 2061 would be even lower.

3. Based on the above and the fact that we have withdrawn our application for an EUP on grapes, enclosed is a revised Section F, dated 9/26/91, for Pesticide Petition No. 9G3817 in which the proposed tolerances for eggs, meat, milk, grapes, grape pomace (dry and wet), raisins, and raisin waste have been removed.

<u>CBRS's Conclusion Concerning Deficiencies 6b. and 6c.</u>

These deficiencies remain outstanding. However, CBRS would consider an exemption from the requirement for temporary

tolerances in animal tissues, milk and eggs as well as the requirement for an analytical method and residue feeding studies in livestock for the purposes of this EUP only, if the registrant will delete the tolerance for peanut hay from the revised Section F (draft date 9/26/91) of the PP#9G3817 petition.

The registrant has deleted all temporary tolerance proposals for grape commodities in the revised Section F (dated 9/26/91) of PP#9G3817 and has submitted a revised EUP label (draft dated 10/1/91) which restricts peanut vine/hay feeding/grazing which are under the growers' control. Therefore, the proposed temporary tolerance for peanut hay as specified in the revised Section F (dated 9/26/91) of PP#9G3817 is not needed. Since peanut commodities such as peanut meal, hulls, and soapstock will be the only livestock feed items, residues are expected to be too low to measure in livestock commodities. Given the low importance of these feed items, the expected nondetectable livestock residues, and the small scale of the proposed EUP (<0.03% of the 1989 peanut acreage), CBRS concludes that an exemption from the requirement of livestock tolerances is appropriate for the subject EUP only.

The registrant must further revise the Section F (dated 9/26/91) of PP#9G3817 by deleting the proposed temporary tolerance for peanut hay since a feeding restriction is imposed on the proposed EUP label (drafted 10/1/91).

Deficiency 8a.

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.

Registrant's Response to Deficiency 8a.

These data were submitted to the Agency with our letter, dated 11/19/90, and are contained in revised Mobay Report No. 95679 (EPA MRID No. 41717405). This revised report contains storage stability data showing no decomposition of tebuconazole out to 176 weeks following harvest. In addition, this study was further revised to convert relative percentages to actual concentrations (ppm) and the detector used has been specified.

CBRS's Conclusion Concerning Deficiency 8a.

Deficiency #8a is resolved for the purposes of this temporary tolerance petition (PP#9G3817) and the associated EUP on peanuts (3125-EUP-ENN).

The storage stability data on peanut forage (Mobay Report No. 95679;MRID No. 41717405) were reviewed by CBRS and deemed

adequate for the purpose of the temporary tolerances (see S. Hummel memo dated 12/9/91).

Deficiencies 8b. and 8c.

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.

Registrant's Response to Deficiencies 8b. and 8c.

These data were submitted to the Agency with our letter, dated 11/19/90, and are contained in revised Mobay Report No. 98493 (EPA MRID No. 41717408). This revised report contains storage stability data on peanut meat to approximately 18 months and also includes storage stability data on peanut hulls.

CBRS's Conclusion Concerning Deficiencies 8b. and 8c.

Deficiencies #8b and #8c are resolved for the purposes of this temporary tolerance petition (PP#9G3817) and the associated EUP on peanuts (3125-EUP-ENN).

The storage stability data for peanuts and peanut hulls (Mobay Report No. 95679;MRID No. 41717405) were reviewed by CBRS and deemed adequate for the purpose of the temporary tolerances (see S. Hummel memo dated 12/9/91).

Deficiency 8e.

No storage stability data for eggs and milk are available.

Registrant's Response to Deficiency 8e.

Storage stability data on eggs and milk are contained in the enclosed Mobay Report No. 101340 entitled "Storage Stability of Tebuconazole and HWG 2061 in Egg and Milk".

In addition, with our letter of 11/19/90, we submitted revised Mobay Report No. 98420 (EPA MRID No. 41717407) which now contains concentrations (ppm) as well as percentages and information on the stability of metabolites in tissues.

CBRS's Conclusion Concerning Deficiency 8e.

This deficiency remains outstanding. However, CBRS would consider an exemption from the requirement for temporary tolerances in animal tissues, milk and eggs as well as the requirement for storage stability data for eggs and milk for the

purposes of this EUP (3125-EUP-ENN) only, if the registrant will delete the tolerance for peanut hay from the revised Section F (draft date 9/26/91) of the PP#9G3817 petition. See also CBRS's Conclusion Concerning Deficiencies 6b and 6c for additional comments.

In the newly submitted storage stability study (MRID No. 42125801), fresh homogenized milk and egg samples (20 grams each) were treated with [triazole-UL-^{14}C] tebuconazole (α[2-(4-chlorophenyl)ethyl]-α-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol) at 1.00 to 1.02 ppm or with [triazole-UL-^{14}C] HWG 2061 [5-(4-chlorophenyl)-2,2-dimethyl-3-(1H-1,2,4-triazole-1-ylmethyl)pentan-1,3-diol] at 0.46 to 0.47 ppm. Samples were analyzed immediately at zero time before storage and after 1-month, 3-months, 6-months and 12-months of storage in a walk-in freezer at -24°C ± 1°C. Radioactive residues were extracted into methanol. Triplicate aliquots (1.0 ml) of extract were removed for radioassay (LSC). The remaining extract was analyzed by Radio-TLC using TLC plates developed in chloroform/methanol (9:1 or 4:1).

Below in Tables 1 and 2 are the storage stability data concerning radiolabeled tebuconazole and HWG 2061 residues in stored milk and egg samples measured by LSC.

Table 1: Radioactivity recoveries in extracts of milk and egg samples after treatment with [^{14}C] FOLICUR.

Storage Time	Sample	[^{14}C] FOLICUR Fortification Level (dpm)	[^{14}C]FOLICUR Level Found (dpm)[1]	FOLICUR Recovery (%)
Zero Time	Milk A	2502937	2435709	97
	Milk B	2502937	2420896	97
	Egg A	2554131	2485496	97
	Egg B	2554131	2483446	97
1-Month	Milk A	2502937	2389476	95
	Milk B	2502937	2263116	90
	Egg A	2554131	2598497	102
	Egg B	2554131	2559829	100
3-Month	Milk A	2502937	2274552	91
	Milk B	2502937	2287023	91
	Egg A	2554131	2437659	95
	Egg B	2554131	2427604	95
6-Month	Milk A	2502937	2367471	95
	Milk B	2502937	2320447	93
	Egg A	2554131	2409018	94
	Egg B	2554131	2430030	95
12-Month	Milk A	2502937	2188796	87
	Milk B	2502937	2133107	85
	Egg A	2554131	2354063	92
	Egg B	2554131	2413524	95

[1] dpm values are an average of triplicate measurements.

Table 2: Radioactivity recoveries in extracts of milk and egg samples after treatment with [^{14}C] HWG 2061.

Storage Time	Sample	[^{14}C]HWG2061 Fortification Level (dpm)	[^{14}C]HWG2061 Level Found (dpm)[1]	HWG2061 Recovery (%)
Zero Time	Milk A	3951020	3987138	101
	Milk B	3951020	4085343	103
	Egg A	3937163	3904105	99
	Egg B	3937163	3863446	98
1-Month	Milk A	3951020	3910233	99
	Milk B	3951020	3943552	100
	Egg A	3937163	3864267	98
	Egg B	3937163	3918521	100
3-Month	Milk A	3951020	3697153	94
	Milk B	3951020	3666476	93
	Egg A	3937163	3841924	98
	Egg B	3937163	3788460	96
6-Month	Milk A	3951020	3841847	97
	Milk B	3951020	3842211	97
	Egg A	3937163	3856939	98
	Egg B	3937163	3816535	97
12-Month	Milk A	3951020	3654378	92
	Milk B	3951020	3656805	93
	Egg A	3937163	3676255	93
	Egg B	3937163	3767479	96

[1] dpm values are an average of triplicate measurements.

Extraction of samples fortified with [^{14}C] FOLICUR recovered 85 to 95% and 92 to 102% of the applied radioactivity in stored milk and eggs, respectively. Extraction of samples fortified with [^{14}C] HWG 2061 recovered 92 to 100% and 93 to 100% of the applied radioactivity in stored milk and eggs, respectively.

The submitted storage stability study (MRID No. 42125801) does not provide sufficient confirmatory data/information to assure that the recovered radioactivity levels that were measured by LSC are actually the spiked parent or metabolite (HWG2061). The registrant should provide milk and egg recovery data for extracts analyzed by Radio-TLC using the chloroform/methanol (9:1 and/or 4:1) as well as the proposed data collection/enforcement method. Reported recovery results should include concentrations as ppm of the parent or HWG 2061 metabolite and percent recovery for each spiked species.

The registrant is directed to reference the storage stability study, once it has been appropriately revised as recommended above, in their next submission for the copending permanent tolerance petitions (PP#9F3724/9F3818/FAP#9H5575).

Revised Mobay Report No. 98420 (MRID No. 41717407) has not been reviewed here. Acceptance of these data, which concerns storage stability in animal tissues other than milk and eggs, has no bearing on the resolution of deficiency 8e.

Deficiency 9a.

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

Registrant's Response to Deficiency 9a.

Additional storage stability data for peanuts are described under items 8a, 8b, and 8c. In addition, with our letter, dated 11/19/90, additional residue data from aerial applications were submitted to the Agency in Mobay Report No. 100073 (EPA MRID No. 41717409).

CBRS's Conclusion Concerning Deficiency 9a.

For the purpose of the temporary tolerances on peanut commodities (PP#9G3817) and the associated EUP for the use of FOLICUR 3.6 F on peanuts (3125-EUP-ENN), deficiency 9a is resolved. Storage stability data were discussed under deficiencies 8a, 8b, and 8c.

The aerial data (MRID No. 41717409) have not been reviewed and will not be reviewed here because aerial applications are not allowed on the revised EUP label (dated 10/1/91) although generating ground vs aerial data was given as one of the purposes of requesting the original EUP for use of FOLICUR 3.6 F on peanuts (3125-EUP-ENN). If the label is later amended to include aerial applications, then the data will be reviewed.

The registrant should reference the aerial field trial data (MRID

No. 417174-09) in their next submission for the copending permanent tolerance petitions (PP#9F3724/9F3818 and FAP#9H5575).

Deficiencies 9b. and 11b.

The proposed tolerance for peanut hulls should be increased to 4.0 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.

Registrant's Response to Deficiencies 9b. and 11b.

Enclosed is a revised Section F, dated 9/26/91 in which proposed tolerances for peanut hulls, peanut oil (crude or refined) and peanut soapstock are now 4.0, 0.5 and 0.5 ppm, respectively.

CBRS's Conclusion Concerning Deficiencies 9b. and 11b.

Deficiencies 9b. and 11b. are satisfied. However, since a feeding restriction is proposed for peanut forage and hay, Section F (dated 9/26/91) must be further revised by deleting the proposed temporary tolerance for residues of tebuconazole in/on peanut hay.

Deficiencies 12a. and 12b.

The grape processing study is inadequate due to insufficient documentation of processing procedures.

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.

Registrant's Response to Deficiencies 12a. and 12b.

These items are no longer needed since with this letter (dated 9/26/91) we are withdrawing our application for an EUP for ELITE 45 DF on grapes.

CBRS's Conclusion Concerning Deficiencies 12a. and 12b.

With the withdrawal of the pending ELITE 45 DF grape EUP (3125-EUP-ROO) and the deletion of proposed temporary tolerances in/on grape commodities in the revised Section F (dated 9/26/91) of PP#9G3817, deficiencies 12a and 12b are rendered moot. Under these circumstances, the resolution of deficiencies 12a and 12b

are not prerequisite to the approval of the proposed temporary tolerances for peanut commodities under PP#9G3817 or the requested EUP for the use of FOLICUR 3.6 F on peanuts (3125-EUP-ENN).

Deficiencies 13b. and 13c.

The dairy cow and laying hen feeding studies are inadequate due to unresolved method problems and the lack of 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 tolerances proposed should be revised to the combined limits of determination for tebuconazole and HWG 2061.

Registrant's Response to Deficiencies 13b. and 13c.

Mobay is in the process of redoing the animal feeding study and will submit these to the Agency at a later date in support of our petition for permanent tolerances. As explained in our response to items 6b. and 6c., we wish to request an exemption from temporary tolerances in animal tissues, milk and eggs for the FOLICUR peanut EUP.

CBRS's Conclusion Concerning Deficiencies 13b. and 13c.

These deficiencies remain outstanding.

See "CBRS's Conclusions Concerning Deficiencies 6b and 6c" for additional comment.

REMAINING DEFICIENCIES CONCERNING TEMPORARY TOLERANCES FOR PEANUT COMMODITIES (PP#9G3817) AND ASSOCIATED EUP (3125-EUP-ENN).

1. The registrant must submit a revised Section F (as drafted 9/26/91) of PP#9G3817 deleting the proposed temporary tolerance for tebuconazole residues in/on peanut hay.

2. The registrant must establish an H petition for the temporary food/feed additive tolerances. Also the registrant must further revise the Section F (dated 9/26/91) specifying a Food Additive Tolerance in Peanut Oil (delete reference to "crude or refined") at 0.5 ppm and a Feed Additive Tolerance in Peanut Soapstock at 0.5 ppm for the parent compound, tebuconazole, only.

3. The registrant needs to specify the duration of the EUP for the use of FOLICUR 3.6 F on peanuts (3125-EUP-ENN) so the

expiration of the proposed temporary tolerances for peanut commodities can be established. The time frame specified in the original application for the EUP was from May 1 through December 31 of 1990.

4. The registrant should be aware that aerial applications have not been approved for the use of FOLICUR 3.6 F on peanuts since they are not included in the EUP label (draft dated 10/1/91) although aerial applications were specified in the original EUP application (3125-EUP-ENN). The registrant should make clear their intent concerning aerial applications.

   The registrant should reference the existing aerial field trial data (MRID No. 417174-09) in their next submission for the copending permanent tolerance petitions.

RECOMMENDATIONS

CBRS recommends in favor of the proposed EUP and temporary tolerances provided that the remaining deficiencies (1-4, above) are resolved.

Note to the PM: The registrant should be directed to reference their storage stability studies (MRID Nos. 42125801 and 41717407) in their next submission for the copending permanent tolerance petitions (PP#9F3724/9F3818/FAP#9H5575). These studies need additional clarification (see CBRS's Conclusion Concerning Deficiencies 4 and 8f and CBRS's Conclusion Concerning Deficiency 8e) and may not be sufficient for the permanent tolerance petitions in their present form.

cc: BLCKohlligian (CBRS), G. Otakie (CBTS), Tebuconazole SF, PP#9G3817, RF, C. Furlow (FOD/PIB), Circulate (7).

RDI: WJHazel:2/28/92 EZager:3/4/92

H7509C:CBRS:BLCKohlligian:CM#2:Rm 803:703-305-7462:12/31/91.