CONFIDENTIAL

R.T.

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

MAY 9 1991

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#9F3724/9F03818 and FAP#9H5575 - Permanent Tolerance Petitions - New Chemical - Tebuconazole, Fungicide on Peanuts, Grapes, Wheat, Barley, Oats, and Seed Grass (CB Nos. 5667, 5597, 5598, 5599, 6021, 6405, 6406, 6613, and 6614) Evaluation of Analytical Methods, Residue, and Processing Data (MRID Nos. 407009-01 through -03, and -63; 409959-01, -24, -25, -26, -28, and -29 through -36, -40 through -49; 411827-02; 413835-01; 410685-01 and -02; 412633-10 through -19; and 414502-01)

FROM: Gary F. Otakie, P.E., Chemist
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Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

Gary F. Otakie

TO: Susan Lewis, PM 21
Fungicide-Herbicide Branch
Registration Division (H7505C)

and

Toxicology Branch
Health Effects Division (H7509C)

THRU: Richard D. Schmitt, Ph.D., Chief
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

Richard D. Schmitt

In the subject petitions, Mobay is proposing the following permanent tolerances 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) in the following commodities:

Commodity	Preharvest Interval (Days)	Proposed Tolerance (ppm)
TOLERANCE PROPOSAL		
Barley, grain	28	2.0
Barley, green forage	14	5.0
Barley, straw/hay	28	18.0
Oat, grain	Seed Treatment	0.01
Oat, green forage	Seed Treatment	0.01
Oat, straw	Seed Treatment	0.01
Oat, hay	Seed Treatment	0.05
Grapes	14	2.0
Grass, seed cleanings (including hulls)	5	25.0
Grass, seed straw (including chaff)	5	30.0
Grass, forage (i.e., grazable regrowth)	118	0.20
Peanuts	14	0.10
Peanut hulls	14	3.5
Peanut hay/vines	14	50.0
Raisins	14	3.0
Wheat, grain	28	0.40
Wheat, green forage	14	5.0
Wheat, straw/hay	28	19.0
FOOD ADDITIVE TOLERANCE PROPOSAL		
Barley, milled fractions (except flour)		1.0
Wheat, milled fractions (except flour)		1.0
Peanut crude oil		0.45
Peanut refined oil		0.35
Peanut soapstock		0.40
Grape pomace (wet)		4.0
Grape pomace (dry)		12.0
Raisin waste		6.0

and for the combined residues of tebuconazole and its 1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol metabolites in the following commodities:

Commodity	Proposed Tolerance (ppm)
Eggs	0.02
Meat, fat, and meat byproducts of poultry	0.05
Meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep	0.15
Milk	0.01

A request for temporary tolerances under PP#9G3817 for tebuconazole on peanuts, grapes, processed products, and animal commodities has also been reviewed by CB and was rejected because of numerous deficiencies (see June 8, 1990 review of Christine L. Olinger).

Conclusions

1a. Product chemistry data have been submitted representing the small scale manufacture of the TGAI. To achieve registration the petitioner must satisfy product-chemistry requirements (61-1, -2, -3, 62-1, -2, -3, 63-2 through -21 and 64-1) for the TGAI from the full scale production process or submit a deferral request in accordance with the PAG Subdivision D - Product Chemistry, October 1982 (pages 42, 43, 44, 50, and 51) with the proposal of an acceptable schedule for submission of these data.

1b. Also, clarification of the inconsistency in the CAS Number for tebuconazole reported in the CSF and technical specification sheet and additional data on the TGAI per 63-5, 63-13 and 64-1 are required before any permanent tolerances can be issued.

2. Revised labels for all the proposed formulations are required responding to the deficiencies noted under Proposed Uses (e.g., deletion of aerial application, adjuvants and 10 gal/A spray volume or submission of additional data; clarification of the use directions for grapes and a statement precluding the use of more than one formulation without appropriate instructions).

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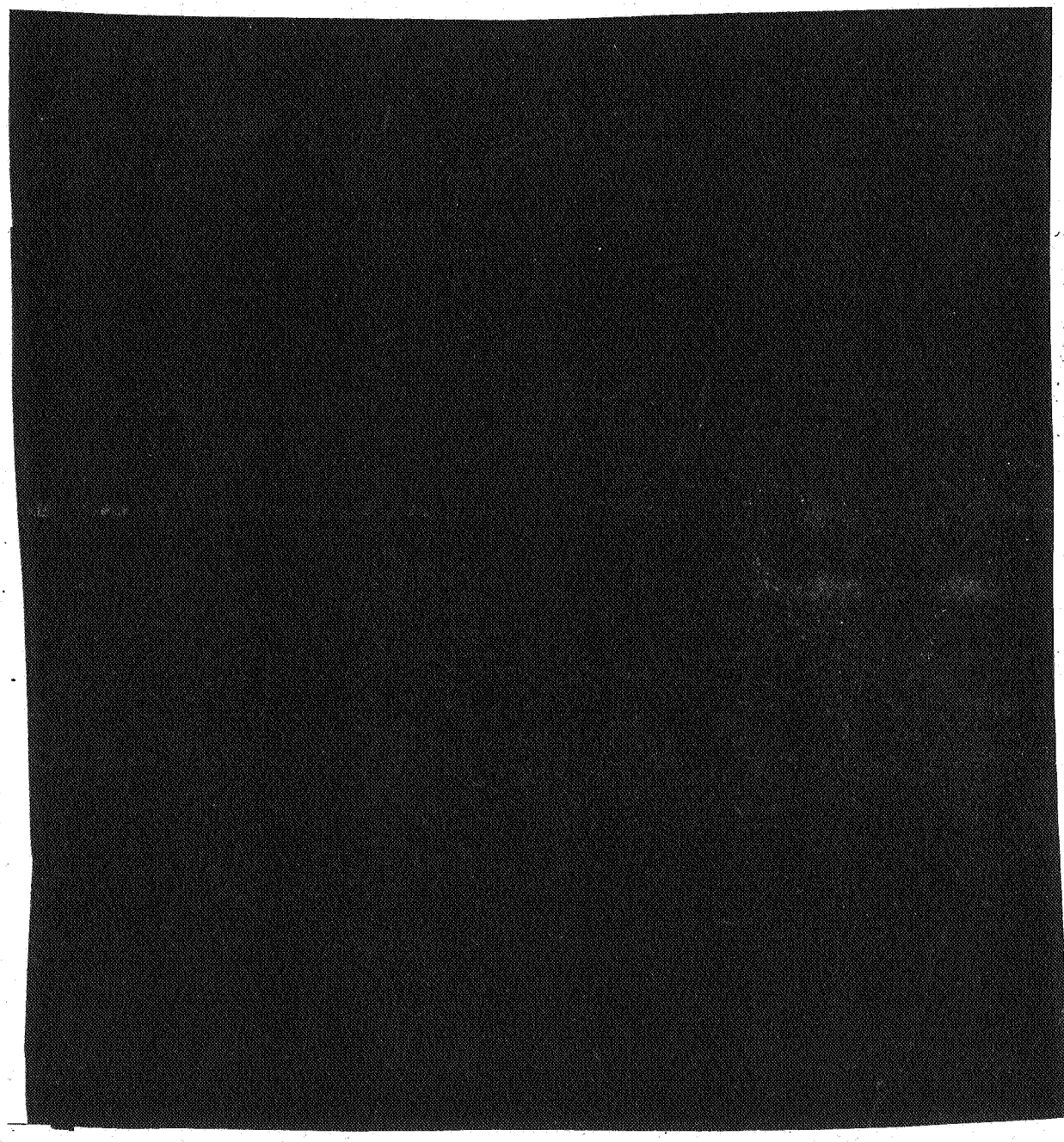


5. The proposed analytical methodology with minor revisions appears tentatively acceptable for all the plant matrices except peanuts. Satisfactory independent method validations have been completed and have indicated the need for minor method revisions. Although data on radiolabeled validation of the proposed analytical methodology must be provided for representative matrices, EPA will conduct a Petition Method Validation (PMV) on wheat, grapes and peanuts, once three non-proprietary copies of the revised method have been

submitted. Peanuts will be included in the PMV to evaluate the adequacy of the methodology for the parent (additional methodology for metabolites may yet be required).

6. The nature of the residue in peanuts is not currently adequately understood. A new peanut metabolism study with tebuconazole labeled in the chlorophenyl ring and including multiple applications at an exaggerated application rate is required. Tebuconazole metabolites may need to be added to the tolerance expression for peanuts.

7. A decision on the need for new analytical methodology for peanuts and a new independent method validation are deferred until the nature of the residue in peanuts is known.

8. Revised analytical methodology for tebuconazole and significant metabolites in peanut oil and soapstock is required (see Detailed Considerations - Peanut Processing Studies).

[redacted]

10. The nature of the residue in poultry and ruminants is tentatively adequately understood and the primary residues are tebuconazole and its t-butyl hydroxy metabolite (HWG-2061). A final decision on the nature of the residue in animals is deferred pending resolution of the deficiencies discussed under Detailed Considerations - Nature of the Residue in Animals.

11. The proposed analytical methodology for residues in animals appears unacceptable as an enforcement method. Method recoveries for tebuconazole and HWG-2061 were for many of the animal matrices, either highly variable and/or low. An independent method validation done on only liver failed the first three attempts before acceptable recoveries were obtained, and 3.5 work days were required to

complete the analysis. Revised proposed enforcement analytical methodology with radiolabeled validation of the proposed methodology for all regulated ruminant and nonruminant matrices; and an independent method validation for both liver and milk are required before EPA can conduct a PMV.

12. Interference data on 94 pesticides subjected to the proposed plant analytical methodology indicated possible interference from norflurazon and sethoxydim. Accordingly, a confirmatory method is required.

13. Interference data on 102 pesticides subjected to the proposed animal analytical methodology indicated possible interference problems from some pesticides. As detailed in the Analytical Methods section of this review, clarification of hydrolysis and derivatization procedures are required and additional interference analyses may be needed if the revised animal analytical methodology is significantly different from that tested.

14. Multiresidue method data for tebuconazole and HWG-2061 have been submitted. The results of the Florisil column evaluation require clarification and if adequate recoveries can be obtained, Protocol D and E method validations need to be repeated for tebuconazole with EC detection. Also, testing of HWG-2061 through Protocol B is required.

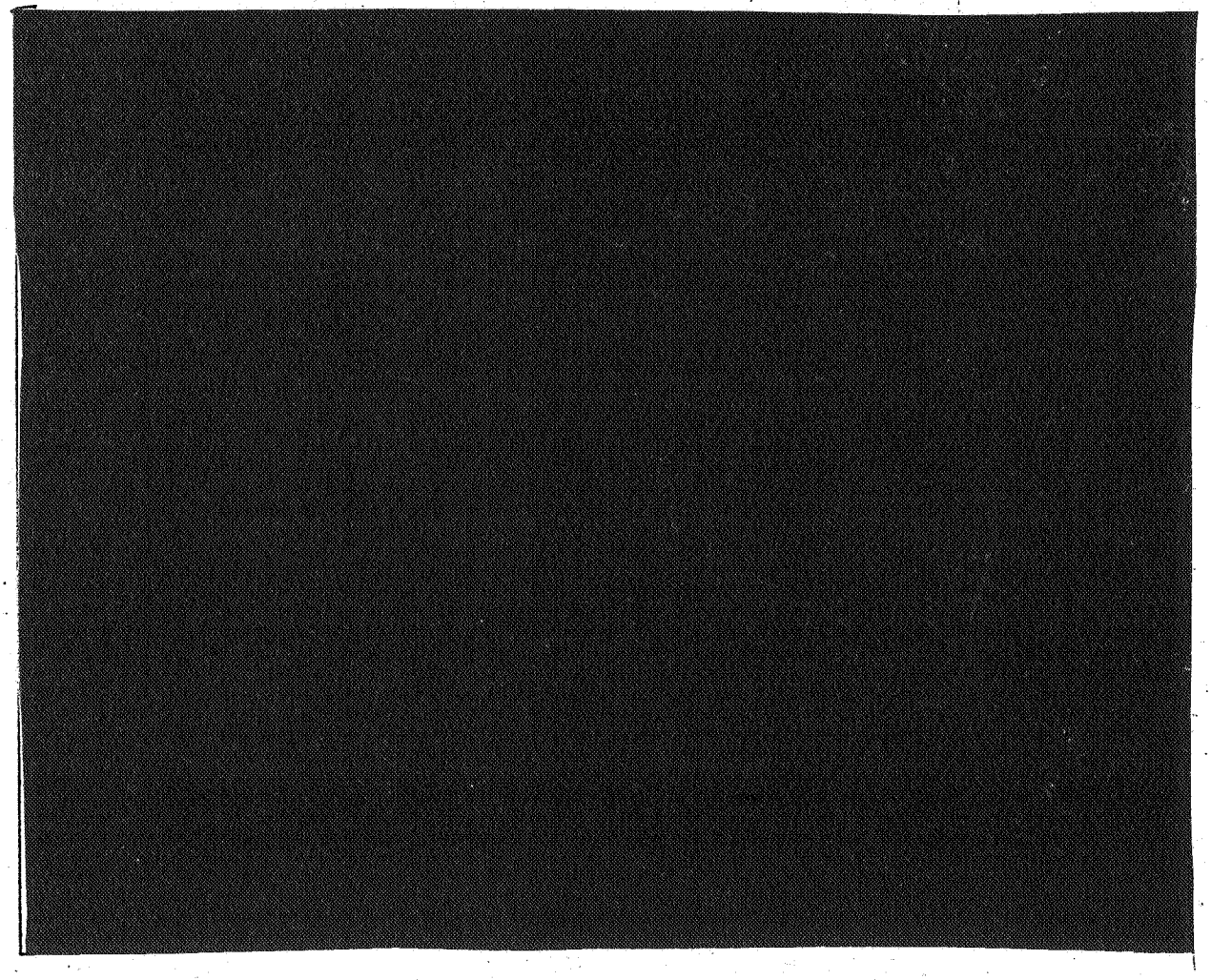
15. Available RAC storage stability data indicate tebuconazole is stable in peanut meat for up to 4.5 months, peanut foliage up to 6 months [redacted] when stored under frozen conditions. Up to 8 months storage stability data on peanut foliage and peanut meat are required to support the field trial data. Also, referenced storage stability data from Mobay Report No. 98494 are required.

16. [redacted] However, additional storage stability data on tebuconazole and HWG-2061 in milk for up to 8 months and in eggs for up to 6 months are required.

PENDING REGISTRATION INFORMATION IS NOT INCLUDED

17. Tebuconazole storage stability data are currently not available for any processed products. Storage stability data on processed peanut and grape matrices are required. Storage stability data on processed wheat products are not required since storage stability data on tebuconazole in barley can be translated to processed wheat matrices.

18. A decision on the adequacy of the field trial data on peanuts and the proposed tolerances must be deferred until the nature of the residue in peanuts is determined and requested experimental (see Residue Data - Field Trials section of this review) and storage stability data submitted. Additional field trials will be necessary if any moieties other than the parent need to be included in the tolerance expression for peanuts. Nevertheless, existing field trial data on tebuconazole alone indicate the proposed tolerance on peanut hulls should be revised to 4.0 ppm.



Reviewable Reviewed

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The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

__✓__ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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27. A decision on the adequacy of the peanut processing study and proposed concentration factors must be deferred until the nature of the residue in peanuts is known and storage stability data and revised analytical methodology for the processed peanut products are submitted. A new peanut processing study will be needed if the tolerance expression for peanuts includes any tebuconazole metabolites. In either case a revised Section F will be required. The revised Section F should not include crude or refined peanut oil since our present policy is to set food additive tolerances on just peanut oil (using data for refined oil).

28. Additional information on the grape processing study must be submitted so a determination can be made as to whether the study adequately reflects commercial grape processing procedures (see Detailed Considerations - Grape Processing Study). A revised Section F including feed additive tolerances for grape pomace (dry or wet) and raisin waste of 12.0 and 6.0 ppm, respectively, is also required.

29. A decision on the adequacy of the poultry and ruminant feeding studies must be deferred until the issues iterated in the Detailed Considerations (i.e., Poultry and Dairy Cattle Feeding Studies) are resolved.

30. Proposed meat, milk, poultry, and egg tolerances are not acceptable. Based on the current feeding studies a revised Section F is required with proposed tolerances for the combined residues of tebuconazole and HWG-2061 in cattle, goats, hogs, horses, and sheep fat and meat of 0.10 ppm; cattle, goats, hogs, horses, and sheep mbyp of 0.50 ppm; in milk of 0.03 ppm; in poultry meat, fat and mbyp of 0.10 ppm; and in eggs of 0.10 ppm. All the revised tolerances, with the exception of cattle, goats, hogs, horses, and sheep mbyp and milk are based on the combined limits of quantitation for tebuconazole and HWG-2061 from the analytical methodology used in the feeding studies. Further revisions in proposed meat, milk, poultry, and egg tolerances and/or new feeding studies may be necessary if the outstanding issues pertaining to the feeding and metabolism studies and required revised enforcement analytical methodology are not satisfactorily resolved.

Summary of Deficiencies that Need to Be Resolved

1. A proposed schedule for submission of product chemistry data reflecting the TGAI from the full scale production process is required.

2. Revised labels for all the proposed product formulations are needed.

3. Additional data on the wheat and grape metabolism studies are required.

4. A new peanut metabolism study, radiolabeled validation of proposed analytical methodology, and a successful EPA PMV are required for peanuts.

5. Additional experimental data on the poultry and ruminant metabolism studies are required.

6. Additional product chemistry data on the TGAI (i.e., 63-5, 63-13, 64-1) are required.

7. Revised copies of the proposed analytical methodology for residues of tebuconazole in plants (i.e., except peanuts), radiolabeled method validation and a successful EPA PMV are needed.

8. Revised enforcement analytical methods for residues of tebuconazole and its hydroxy metabolites (HWG-2061) in animal matrices, radiolabeled method validation, an independent method validation, and a successful EPA PMV are required.

9. Additional data on the submitted interference studies and appropriate confirmatory methods are required.

10. Additional multiresidue testing data are required.

11. Storage stability data for processed plant products, additional referenced RAC data, and data for milk and eggs are required.

12. Additional field trials for peanuts including the hydroxy metabolite will likely be needed.

13. Additional experimental data to support the seed grass, wheat, barley, grape, and peanut field trials are required.

14. Additional data on the wheat processing study and residue data on grain dust are required.

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15. Additional data on the grape processing study are required.

16. Additional experimental data on the poultry and ruminant feeding studies are required.

17. Additional data on the peanut processing study are required. A new peanut processing study will be needed if the hydroxy metabolite is added to the tolerance expression for peanuts.

18. Revised analytical methodology for tebuconazole and significant metabolites in peanut oil and soapstock is required.

19. Additional experimental data on the poultry and ruminant feeding studies are required.

20. A Section F with revised RAC, processed product and meat, milk, poultry and egg tolerances is required.

Recommendations

At this time CB recommends against establishing the proposed permanent tolerances for tebuconazole and its hydroxy metabolite for the reasons cited under Conclusions Nos. 1 through 3b, 5 through 8, and 10 through 30.

Detailed Considerations

Product Chemistry

The Product Chemistry Data Requirements are listed in 40 CFR 158.120. Each of those data requirements is cross-referenced to the Product Chemistry Guidelines Reference Number (GRN) in the Pesticide Assessment Guidelines (PAG), Subdivision D, Product Chemistry (October 1982; EPA-540/9-82-018), which provide detailed information on the types and minimum amounts of data/information an applicant must submit in support of registration.

CB will review the data/information pertaining to the technical grade of the active ingredient (TGAI). Data/information pertaining to the formulation proposed for use will be reviewed only as they relate to the potential for

residue concerns. The kind of data required by 40 CFR 158.120 for the technical product and the Product Chemistry GRNs are summarized below:

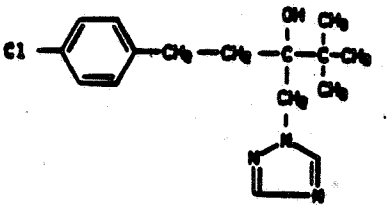
40 CFR 158.120 Data Requirements	GRNs
Product Identity and Composition	61-1 thru -3
Analysis and Certification of Product Ingredients	62-1 thru -3
Physical and Chemical Characteristics	63-2 thru -13

Information Sources

MRID Nos. 407009-03, 407009-02c, 407009-2, 407009-01c, and 407009-01.

61-1 - Product Identity and Disclosure of Ingredients

The structure of tebuconazole is depicted below:



Chemical Name/Chemical Abstracts Service (CAS): alpha-[2-(4-Chlorophenyl) ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2-4-triazole-1-ethanol

Product Name: Folicur, Raxil, Elite

Company Code Name: HWG-1608

Molecular Weight: 307.8

Empirical Formula: $C_{16}H_{22}ClN_3O$

CAS Registry No.: 107534-96-3

CB concludes that the CSF submitted is acceptable for registration of tebuconazole, provided the registrant proposes on acceptable schedule for submission of a revised CSF, reflecting analyses of five representative samples, from full-scale (i.e., commercial) production (see GRN 62-1).

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61-2 - Description of Beginning Materials and Manufacturing Process

A description of the beginning materials and the manufacturing process for small-scale batch production of tebuconazole is included in the Confidential Appendix.

CB concludes the following information, representing the full-scale (i.e., commercial) production process, is required to achieve full registration:

1. Beginning Materials (i.e., for the full-scale production process)

   a. The name and address of the manufacturers or suppliers of each beginning material.

   b. Copies of all available technical specifications, data sheets, and other documents by which the composition, properties, or toxicity are described.

   c. All other information concerning the qualitative and quantitative composition of the beginning materials.

2. Manufacturing Process (i.e., on the full-scale production process)

   a. Statements of whether the steps in the process are batch and/or continuous.

   b. The amounts (e.g., weight) of the beginning materials and the order in which they are added.

   c. A flowchart with chemical equations of each intended chemical reaction occurring at each step of the process, together with a complete description of the equipment used to produce and purify the product (e.g., reaction vessels, mixers, distillation and purification equipment, etc.).

   d. A complete description of the physical conditions and control parameters (e.g., temperature, pressure, humidity, mixer RPM, etc.) must be provided for each step of the process, together with a discussion of the acceptable parameter range and influence on the purity and the relative amounts and/or identity of impurities, variation of these control parameters can cause.

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e. A statement of the intended chemical reactions (if any) together with a flow chart with the chemical equations for each chemical reaction occurring at each step of the process.

f. The approximate time (e.g., duration) of each step in the production process.

g. A discussion of the measures taken to assure the quality of the final product.

Note: The required information on the beginning materials and manufacturing process may be deferred until after full-scale production commences, in accordance with an approved schedule for submission of the data (see GRN 62-1).

61-3 - Discussion of Formation of Impurities

Data has been submitted by the registrant on the small-scale production process, in response to this requirement. To achieve full registration, the petitioner must discuss the following information based on the full-scale production process for the technical or propose an acceptable schedule for submission of these data (see GRN 62-1):

1. For each impurity which may be present in the product at a level equal to or greater than 0.1 percent (1000 ppm) based on knowledge of:

   a. The composition of each beginning material and intentionally added inert ingredient;

   b. Impurities which are known to be present from other information;

   c. The substances which result from the intended reactions of the manufacturing process;

   d. Degradation or postproduction reactions of any of the product's ingredients;

   e. Contamination of the product from earlier use of the same production equipment to produce other substances or contamination from packaging materials; and

   f. Process control, purification, and quality control procedures used.

2. Any other impurity which was found to be present in any analysis of the product.

62-1 - Preliminary Analysis

The results of analyses of five small-scale production batches are contained in the Confidential Appendix. Details of the analytical methods used to determine the active ingredient and the impurities are discussed under GRN 62-3.

To achieve full registration, the applicant must provide the following information:

- Analysis of five samples representing five different production runs of the final full scale production process for the active ingredient and each impurity. Data on the size of each production run (i.e., pounds or gallons of product produced) must also be provided. If the product is produced by a batch process, each sample should be taken from a different batch of the product and if the product is produced by a continuous process, samples should be taken at intervals sufficiently spaced to provide data on any variation in product content.

Alternatively, if the applicant considers it impractical to construct facilities to produce the proposed product in commercial quantities prior to receiving full registration so that the required preliminary product analyses on the full-scale production process can be provided, a deferral request must be submitted in accordance with the PAG Subdivision D - Product Chemistry, October 1982 (see pages 42, 43, 49, 50, and 51), with the proposal of an acceptable schedule for submission of these data.

62-2 - Certification of Limits

Certified limits of the active ingredients and the known impurities present at levels $\geq$ 0.1 percent in the technical from the small-scale batch production process are listed in the CSF dated June 22, 1988. No N-nitrosamines are expected at concentrations greater than 1 ppm, since there are no nitrosation steps or nitrated products. No tetra- chloro-p-benzodioxins or tetrachlorobenzofurons are expected since there are no conditions in the process to cause their formation. To achieve full registration, data on the preliminary analysis (see GRN 62-1) of the technical from the full-scale production with proposed certified limits reflecting these data will be required. The applicant needs to propose an acceptable schedule for submission of these data (see GRN 62-1). Clarification of the CAS Number for the TGAI is also required.

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62-3 - Analytical Methods to Verify Certified Limits

According to the CSF (see Confidential Appendix) [redacted] components are present in the TGAI at certifiable levels.

The following methods were used for the analyses: gas chromatography (GLC), high performance liquid chromatography (HPLC), mass spectrometry (MS) and its coupling with chromatographic methods (GC/MS, HPLC/MS), atomic absorption spectroscopy (AAS) as well as titrations. The components were quantitatively determined by calibration with reference standards of known content. The identity of the reference standards was secured by MS or NMR.

CB tentatively concludes that no additional information is required, to satisfy requirements under GRN 62-3, pending submission of five samples representing five different production runs of the final full-scale production process (see GRN 62-1).

63-2 Through 63-21 - Physical and Chemical Characteristics

The physical/chemical properties of the TGAI are given below. Note that CB no longer addresses the physical/chemical properties of manufacturing-use products.

63-2	- Appearance	Colorless to tan
63-3	- Physical State	Crystalline solid
63-4	- Odor	PAI: Odorless to mildly aromatic TGAI: Odorless to mildly aromatic
63-5	- Melting Point, °C	PAI: 104.7
63-6	- Boiling Point, °C	N/A, Too high
63-7	- Density, g/mL @ 20 °C	1.202
63-8	- Solubility	
	Water, 20 °C, g/100 mL	PAI: 0.0032
	Solvents, 20 °C, g/L	
	n-hexane	2 to 5
	dichloromethane	> 200
	toluene	50 to 100

63-8 - Solubility (cont'd)		
	2-propanol	100 to 200
	Other, percent	
	Dipropylene glycol	0 °C: 10.7 10 °C: 11.6, 13.6 40 °C: 22.3, 26.2
	Propylene glycol	0 °C: 5.2 10 °C: 5.6 40 °C: 9.3
	Glycerine	0 °C: 0.125, 0.108 10 °C: 0.11, 0.15 40 °C: 0.17, 0.20
	Water	0 °C: - 10 °C: 21 ppm 40 °C: 52 ppm
63-9 - Vapor Pressure at 20 °C, mbar		PAI: 7.2×10^{-9}
63-10 - Dissociation Constant		N/A, Does not dissociate.
63-11 - Octanol Water Partition Coefficient at 20 °C		PAI: 5000
63-12 - pH		N/A, Not soluble enough.
63-13 - Stability		
	Metals	Stable with most materials of construction.
	Light	Relatively stable to sunlight in aqueous solution or on soil
	pH	Stable at sterile aqueous buffers at pH 5, 7, and 9.
	Thermal	No loss of active ingredient after 1 year at warehouse temperatures.

63-14 - Oxidation Reduction	N/A, Does not have oxidative or reductive characteristics.
63-15 - Flammability	N/A, Solid
63-16 - Explodability	No impact explosive characteristics.
63-17 - Storage Stability	Very good chemical stability with a shelf life projected to 2 years.
63-18 - Viscosity	N/A, Solid
63-19 - Miscibility	N/A, Technical
63-20 - Corrosion Characteristics	Compatible with most materials of construction.
63-21 - Dielectric Breakdown Voltage	N/A, Technical

CB concludes that additional information/data on the stability of Folicur Technical, exposed to metals and at elevated temperatures, and the melting point of TGAI are required to fulfill the data requirements of GRNs 63-13 and 63-5.

A decision on the acceptability of the data on the remaining physical and chemical characteristics in this submission (with the exception of data on the PAI for 63-8 - Solubility, 63-9 - Vapor Pressure, 63-10 - Dissociation Constant, and 63-11 - Octanol/Water Partition Coefficient) cannot be made since the manufacturing process for the TGAI is still in the developmental stage and may change. Accordingly, data on the final manufacturing process (61-2) and preliminary analysis of the final product (62-1) are required to determine if the TGAI will be substantively changed before the adequacy of the above data can be determined.

Other Product Chemistry Requirements

64-1 - Submittal of Samples

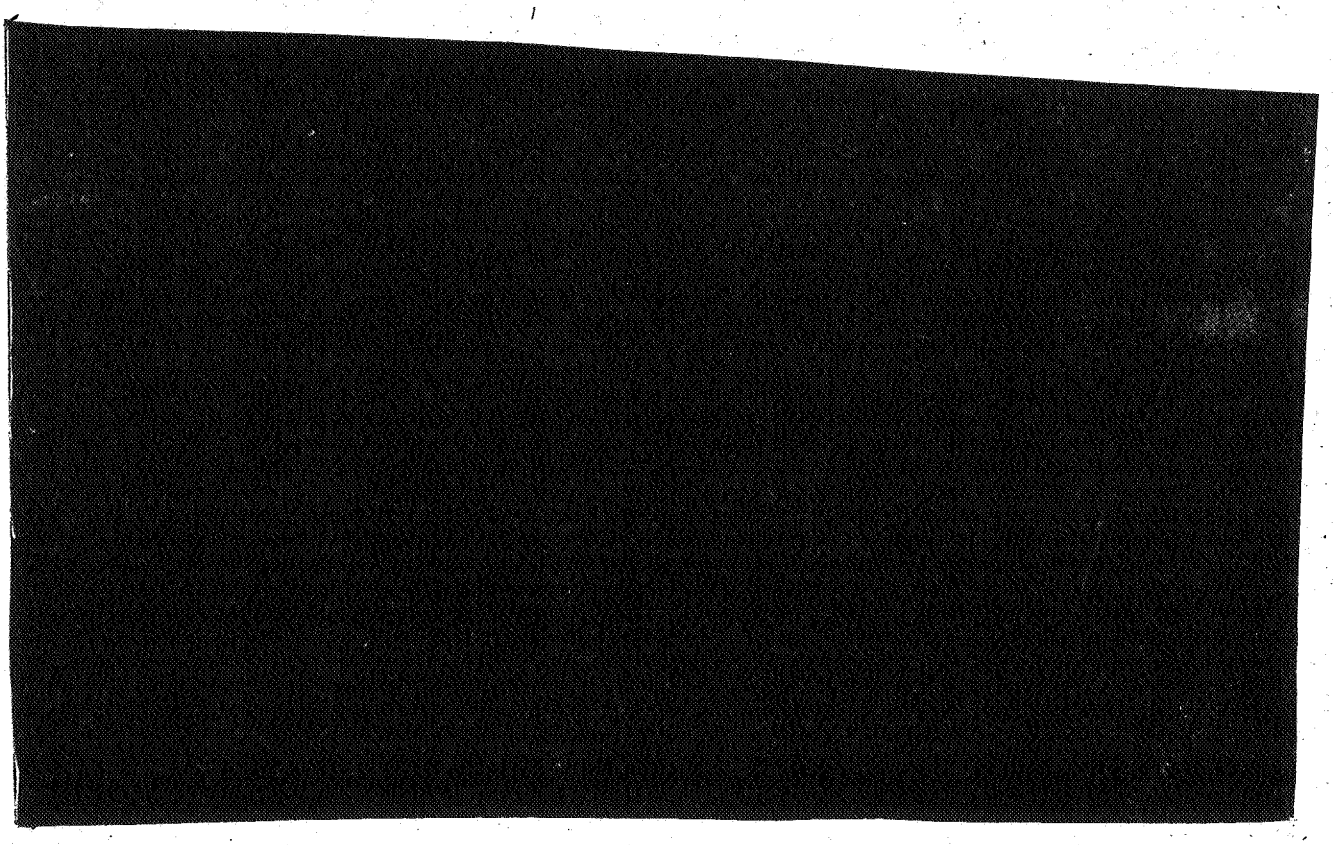
To achieve full registration, the applicant must submit samples of the TGAI (200 g) and PAI (5 g) along with the analytical method for the active ingredient to the following address:

Active Ingredients Program
Attn: Head, Analytical Chemistry Section
Analytical Chemistry Branch
Benefits and Economic Analysis Division
Office of Pesticide Programs
Environmental Protection Agency
Building 306, BARC East
Beltsville, MD 20705

Residue Chemistry

Proposed Uses

PENDING REGISTRATION INFORMATION IS NOT INCLUDED



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____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

✓ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

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[redacted]

Peanuts

Folicur 1.2 EC (i.e., 1.2 lb ai/gal), Elite 45 DF (i.e., a granular formulation, 45% by weight), and Folicur 3.6 F (i.e., 3.6 lb ai/gal) are proposed for use as a fungicide on peanuts. A maximum of 168 fl oz of Folicur 1.2 EC, 56 oz of Elite 45 DF, or 56 fl oz of Folicur 3.6 F (i.e., 1.58 lb ai/A) may be applied per acre per season. Application rates of from 20 to 24 fl oz of Folicur 1.2 EC, 8 oz of Elite 45 DF, or 6 2/3 to 8 fl oz of Folicur 3.6 F per acre are recommended beginning 5 weeks after planting and at 14-day intervals, with a minimum PHI of 14 days.

CB concludes the following label revisions and information are necessary:

1. Until field trials are conducted representing aerial application, label instructions for aerial application should be deleted from all proposed labels.

2. Unless the petitioner can demonstrate that adjuvants or wetting agents were used in the field trials, statements on the proposed labels recommending their use must be deleted, until additional field trials providing bridging data as to whether the use of these agents affects crop residue levels are submitted.

3. The petitioner should explain why a minimum spray volume of 20 gal/A by ground spray is recommended for grasses grown for seed, while a minimum spray volume of 10 gal/A by ground spray is recommended for wheat, barley, peanuts, and grapes, when a majority of the field trials were conducted at spray volumes of $\geq$ 20 GPA.

[redacted]

6. Since registration of multiple formulations is proposed, all the labels should have a statement precluding use of more than one formulation on any individual crop, unless appropriate instructions are provided to ensure that the maximum application rate is not exceeded.

Nature of the Residue in Plants

[redacted]

Weed clearance

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[redacted]

Metabolism of Tebuconazole in Peanuts (MRID Nos. 409959-24 and -25, Mobay Report Nos. 87043 and 98428)

The nature of the residue in peanuts was reviewed in PP#9G3817 in response to a temporary tolerance request on peanuts (see C.L. Olinger, memorandum of June 8, 1990 for a detailed review).

In brief, two similar metabolism studies, one labeled in the triazole ring and one labeled in the chlorophenyl ring were submitted. In both studies C_{14} tebuconazole was applied three times (i.e., at 6, 8 and 10 weeks after planting with harvest at 17 weeks) at the maximum single application rate (i.e., 0.225 lb. ai/A or .4X) while the proposed use provides for up to seven such single applications or a total maximum application of 1.58 lb. ai/A.

PENDING REGISTRATION INFORMATION IS NOT INCLUDED

The following table and paragraph from the review of the temporary tolerance summarize the results of the metabolism study labeled in the triazole ring:

	Foliage	Peanut Meat	Hulls
"Total ppm[1]	29.2	1.19	0.16
Percent Radioactivity			
Tebuconazole	58.4	ND	15.6[8]
HWG 2061	15.1	ND	3.4
Unid. organic[2]	13.7	1.5	11.4
Triazole	N/A	9.0	ND
TA	N/A	46.4	2.6
TLA	N/A	8.5	ND
1 N HCl[3]	N/A	7.1	N/A
6 N HCl[4]	N/A	N/A	8.6
Bound[5]	N/A	N/A	15.8
Unid. Aqueous[6]	6.4	26.9	22.7
Unextractable Residue	6.4	0.6	19.9
Total Recovered[7]	103.2	116.5	106.3

[1]Results expressed as tebuconazole equivalents.
[2]Includes material at TLC origin, diffusion activity, and clean-up losses.
[3]Radioactivity released upon refluxing with 1 N HCl.
[4]Radioactivity released upon refluxing with 6 N HCl.
[5]Material in aqueous phase after C_{18} clean-up.
[6]Includes aqueous silanized silica clean-up, acidic partition, diffusion activity.
[7]Actual total recovery; all results normalized to 100 percent.
[8]Includes 3.4 percent conjugated tebuconazole.
N/A = not applicable; ND = None detected;
TA = Triazolylalanine; TLA = Triazolylalanine acid.

"Most of the residue was found in the foliage and was comprised primarily of tebuconazole and the t-butyl hydroxy metabolite (HWG 2061). Triazole, triazolyl alanine, and triazolyl alanine acid were found in the peanut meats. A considerable amount of residue was unidentified. Almost 20 percent of the radioactivity in the hulls was identified as tebuconazole and the hydroxy metabolite. Even after refluxing with 6 N HCl, a considerable amount of activity was unextractable."

The following table and paragraph from the review of the temporary tolerance summarize the results of the metabolism study labeled in the chlorophenyl ring:

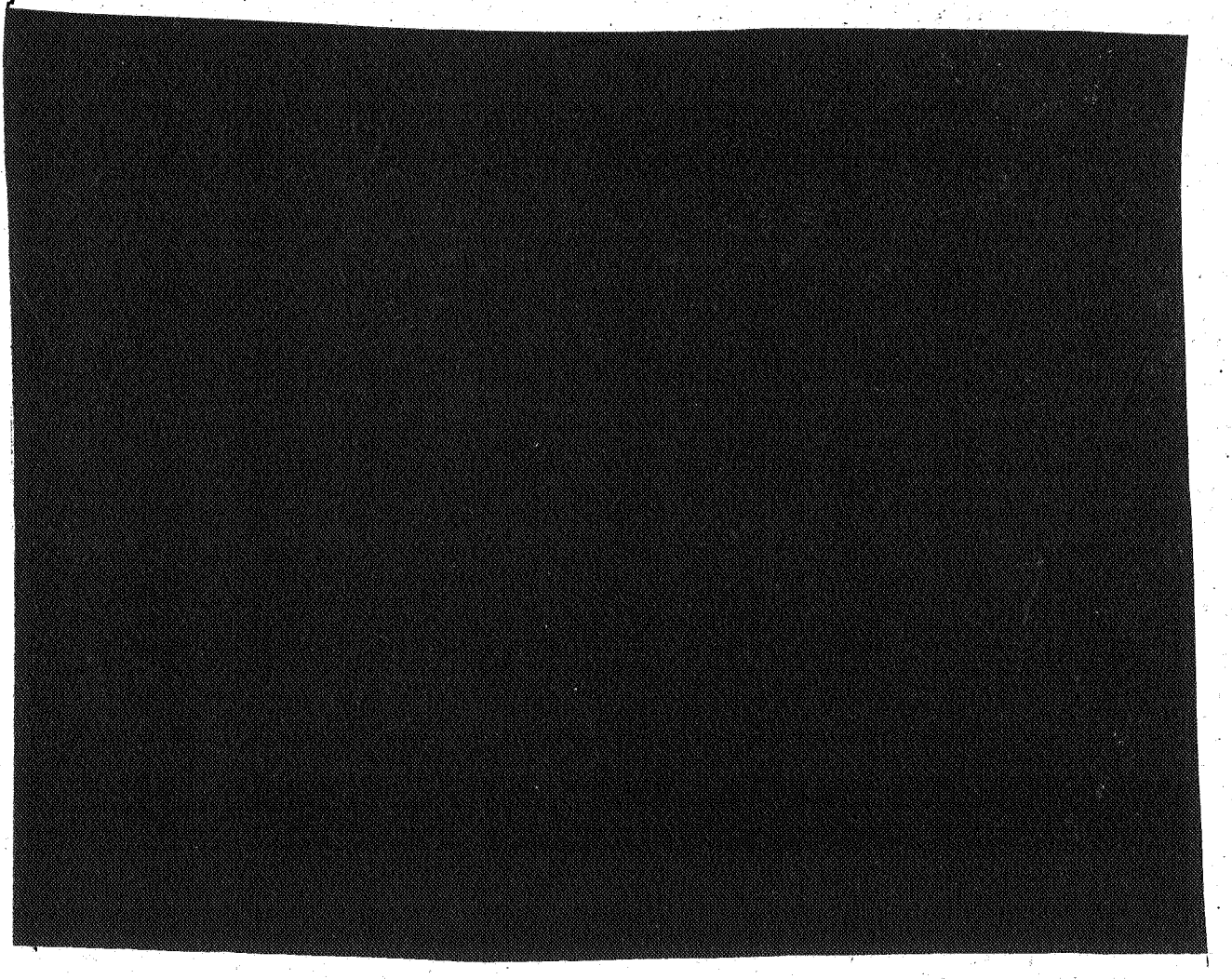
	Foliage	Peanut Meat	Hulls
"Total ppm[1]	22.6	0.09	0.27
Percent Radioactivity			
Tebuconazole	59.6	ND	15.9
HWG 2061	13.2	ND	3.9
Unid. organic[2]	17.7	N/A	18.2
Lipid fraction	N/A	46.0[7]	N/A
1 N HCl[3]	N/A	42.4	8.6
6 N HCl[4]	N/A	8.2	5.9
Unid. Aqueous[5]	4.0	N/A	19.3
Unextractable Residue	5.5	3.4	28.2
Total Recovered[6]	107.6	85.8	90.8

[1]Results expressed as tebuconazole equivalents.
[2]Includes material at TLC origin, diffusion activity, and clean-up losses.
[3]Radioactivity released upon refluxing with 1 N HCl.
[4]Radioactivity released upon refluxing with 6 N HCl.
[5]Includes aqueous silanized silica clean-up, acidic partition, diffusion activity.
[6]Actual total recovery; all results normalized to 100 percent.
[7]From hexane Soxhlet and extracted fraction.
N/A = Not applicable; ND = None detected.

"The total ppm radioactivity found is generally in good agreement with that found in the triazole labeled study, with the exception of the peanut meat. The relative proportions of tebuconazole to HWG 2061 were in good agreement with the triazole study for both the foliage and shells. Residues from the lipid fraction from the peanut meat did not significantly partition into acetonitrile. Attempts to isolate the radioactive material from the lipid fraction using GPC, Florisil, and silica column chromatography, silica HPLC, preparative TLC, saponification, and methylation were unsuccessful. Therefore no metabolites in the peanut meat from the chlorophenyl labeled metabolism study were identified."

Although the peanut metabolism studies were determined to be adequate to support a temporary tolerance, a new metabolism study is required to support a permanent tolerance. Assuming triazole residues are not of toxicological concern (see Conclusion No. 4), the study should be conducted with tebuconazole labeled in the chlorophenyl ring with multiple applications at exaggerated application rates to provide sufficient radioactivity for characterization of all metabolites. The study should include a complete sample storage and preparation history and detailed documentation of identified metabolites, their concentration, and percent of the TRR. If the new metabolism study results in similar residues of HWG 2061, this metabolite may need to be added to the tolerance expression, with appropriate analytical methodology also required.

The nature of the residue in peanuts is not currently adequately understood. A new peanut metabolism study is required.



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Pages 32 through 34 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

__✓__ Information about a pending registration action.

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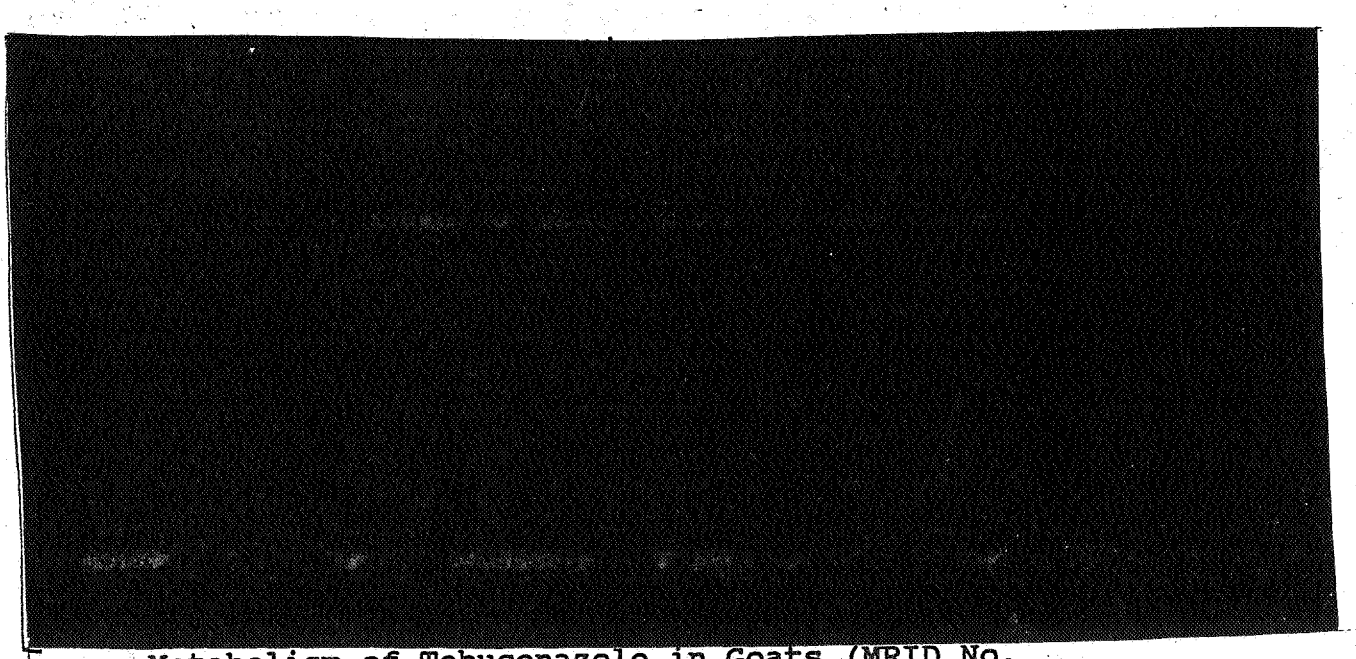

PENDING REGISTRATION INFORMATION IS NOT INCLUDED

Metabolism of Tebuconazole in Goats (MRID No. 409959-29, Mobay Report No. 94882)

The nature of the residue in goats was reviewed in PP#9G3817 in response to a temporary tolerance request (see C.L. Olinger, memorandum of June 8, 1980 for a detailed review).

In brief, one 40 kg dairy goat received three consecutive daily doses of tebuconazole labeled in the chlorophenyl ring (i.e., 25.97 mCi/mmole) at a level of 15 mg/kg of body weight. Milk was collected every morning and evening but the interval between dosing and milking was not reported. The animals were sacrificed 2 hours after the final dose. Data on the storage period between sacrifice and analysis was not reported.

The radioactivity in the tissues and milk were highly extractable. ^{14}C residues were quantified by combustion and liquid scintillation counting and metabolite identification was by either TLC, HPLC, and/or GC/MS.

Acid hydrolysis of tissue samples, and acid and enzyme hydrolysis of liver and kidney samples were necessary to release a conjugate of the t-butyl hydroxy/t-butyl alcohol analog (HWG 2061). ^{14}C residue levels were 5.19, 3.96, 0.15, 0.05, and 0.04 ppm in liver, kidney, fat, muscle, and milk,

respectively. The following tables from the report summarize the results of the study:

Distribution of Radioactivity in Fractions of Tissues and Milk Taken 2 Hours After Administration of the Last of Three Daily Doses of UL-^{14}C-Chlorophenyl-FOLICUR

	Percent of Recovered Radioactivity				
	Liver	Kidney	Fat	Muscle	Milk
Organosoluble	96.6	97.6	90.1	89.0	85.2
MeOH Reflux	1.8	1.8	7.0	11.0	7.9
Unextractable	2.6	0.6	3.0	0.0	6.9
Total	100.0	100.0	100.0	100.0	100.0

Quantitation and Identification of Metabolites in Tissues and Milk After Administration of UL-^{14}C-Chlorophenyl-FOLICUR

	Percent of Total Residue				
Compound	Liver	Kidney	Fat	Muscle	Milk
FOLICUR	12.4	2.5	9.5	0.0	13.6
t-Butyl alcohol	15.3	2.3	12.5	21.4	22.2
t-Butyl alcohol conjugate	67.9	92.8	68.1	67.6	49.4
Total	95.6	97.6	90.1	89.0	85.2

The petitioner's proposed route of metabolism, based on the relative abundance of conjugated material, assumes hydroxylation of tebuconazole to HWG 2061, followed by rapid conjugation of the latter. Hence, the levels of t-butyl hydroxy/t-butyl alcohol derivative never build up to large amounts. Although no urine data were presented, the petitioner indicated that a cursory examination of the urine indicated the presence of the conjugate thus suggesting that it is the terminal residue prior to elimination.

The referenced CB review of the temporary tolerance request made the following conclusions:

"Since it could not be determined how long these samples were stored prior to analysis this study is not adequate. Since storage stability data are available for poultry muscle, liver, kidney, and fat, these may be sued to support the comparable bovine matrices, assuming any deficiencies with that study are addressed. Milk stability data are not

available. For acceptance of this study for temporary tolerance purposes only, the petitioner must demonstrate that the samples were analyzed within an acceptable period and submit storage stability data for milk.

"Assuming the deficiencies noted above are satisfied, additional information must be provided before this study can be considered to support a permanent tolerance. As outlined in the Subdivision O - Data Reporting Guidelines food consumption and milk production data should be provided. If the consumption and production are abnormal, possible explanations should be discussed. The dpm and ppm values for the tissues/organs should be tabulated so CB may confirm some calculations." Also, based on this data the petitioner should estimate the feeding level (ppm) that the 15 mg/kg/day dosing level is equivalent to so a comparison to residue levels detected in the cattle feeding study can be made.

Although, the petitioner proposed to regulate only the parent, tebuconazole in the temporary tolerance request, the tolerance expression for animal commodities in the permanent tolerance request includes its 1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol metabolite (i.e., the hydroxylated t-butyl metabolite).

A final decision on the adequacy of the goat metabolism study cannot be made until the deficiencies noted above from CB's review of the temporary tolerance request are resolved and additional standard and sample HPLC and GLC chromatograms are provided. However, tentatively the residues of concern in ruminants are the parent and its t-butyl hydroxy metabolite (HWG-2061).

Analytical Methods

Analytical Method - Plants (MRID Nos. 407009-63 and 409959-42, Mobay Report Nos. 94295 and 95680)

The analytical method in plants and corresponding interference study were reviewed in PP#9G3817 in response to a temporary tolerance request (see C.L. Olinger, memorandum of June 8, 1990 for a detailed review).

In brief, plant residues are homogenized and extracted with either acetone or for grains and peanuts with 3:1 acetone:water and filtered after the addition of a filter acid. The acetone/water mixture from any plant material is saturated with sodium chloride and partitioned with dechloromethane (DCM) and the aqueous phase discarded. The DCM extract is dried with sodium sulfate, evaporated to dryness and reconstituted in toluene and applied to a slurry packed silica gel column and the column washed with ethyl

acetate and tebuconazole eluted with 2:8 n-hexane:ethyl acetate and applied to a GPC column with 1:1 cyclohexane: ethyl acetate as the mobile phase and the eluent fraction containing tebuconazole evaporated to dryness and reconstituted in ethyl acetate. Two gas chromatography columns are specified; either a 3 percent SP-2100 methyl silicone packed or an HP-5 fused silica capillary column; with a thermionic specific detector, with a linear range for tebuconazole approximately 0.2 to 30 ng, and a detection limit of 0.05 ppm.

Quantitiation is by a single point external standard, however preparation of standard solutions, their stability and criteria for their selection and frequency of analysis are not included in the method. Method recoveries for peanuts, barley, oats, rye wheat and grapes at the tebuconazole fortification level of 0.05 ppm ranged from 82 to 103 percent.

An interference study was submitted for 94 nitrogen and/or phosphorus containing compounds which have a registered tolerance on wheat, grapes, barley, peanuts, and seed grasses. The compounds were injected either individually or in mixtures into a GC equipped with a 3 percent OV-101 glass column and a nitrogen-phosphorus detector. Retention times were compared with 0.10 ppm tebuconazole standards. Four compounds were found to interfere with tebuconazole: disulfoton, malathion, norflurazon and sethoxydim. After subjecting the four compounds to a silica gel cleaning column specified in the tebuconazole analytical method only norflurazon and sethoxydim showed interference. A confirmatory method for tebuconazole thus will be required for a permanent tolerance.

The method appears tentatively acceptable, with comment, to support the proposed permanent tolerances on all plant commodities except peanuts (meat, hulls, and hay). The nature of the residue in peanuts has not yet been established and a new peanut metabolism study is required; an analytical method for HWG 2061, a metabolite in peanuts will be required if included in the tolerance expression. Revisions in the original submitted analytical method, including the reverse order of the GPC and silica column clean up, etc. (see Method Validation Reports) need to be incorporated, the reference to a German manual (not generally available) for sample preparation needs to be revised to reference the FDA PAM Manual or provide specific sample preparation instructions, a discussion provided of the preparation of standard solutions, their stability, criteria for selection and frequency of analysis and three nonproprietary copies of the complete revised analytical methodology are required for a PMV.

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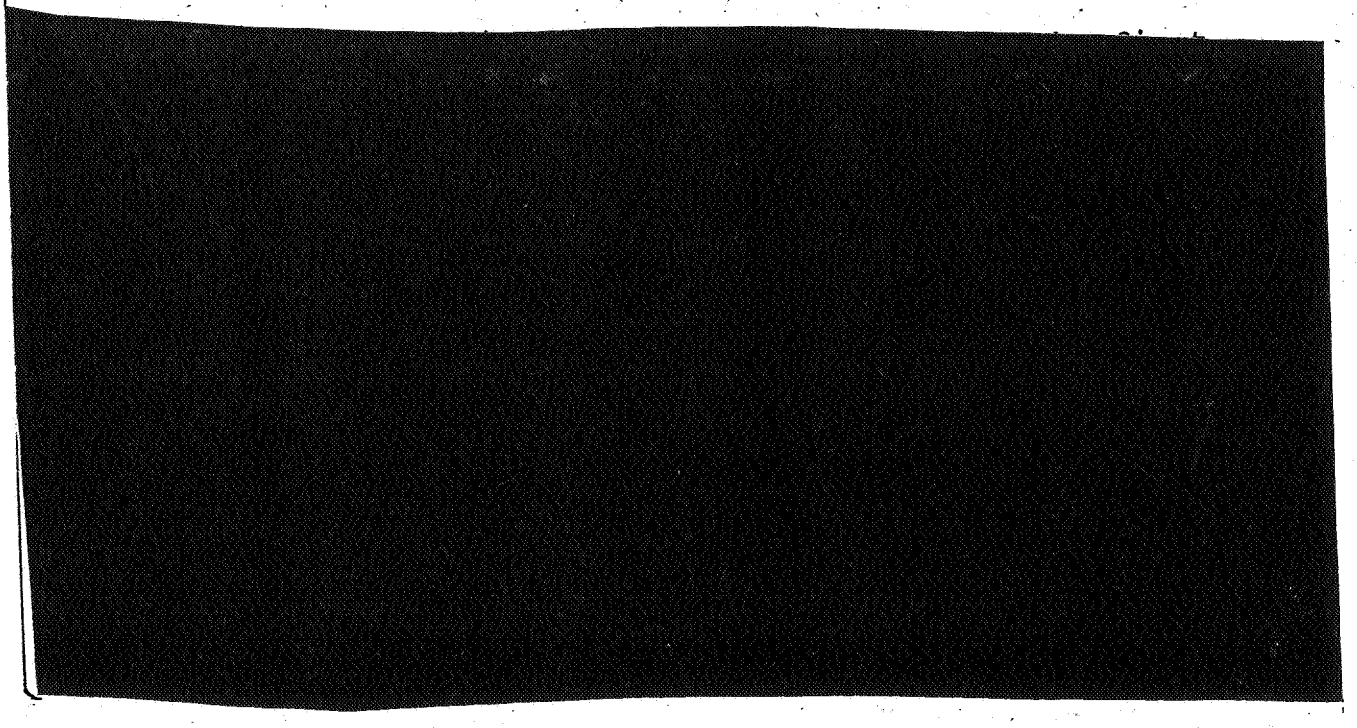
Although EPA will not delay proceeding with the plant PMV, permanent tolerances on crops will not be granted until radiolabeled validation data on the proposed analytical methodology for representative matrices (i.e., wheat, grapes, and peanuts) has been submitted. If radiolabeled validation of the proposed analytical methodology for plants indicates a major portion of the radioactive residue is not recovered and identified by these methods, radiolabeled validation of new proposed analytical methodlogy will be required. When using samples from the metabolism studies held in frozen storage, the petitioner must provide a comparison of the total radioactive residue (TRR) and the residue profile both before and after the sample storage period; and if there is a significant change in the TRR or the residue profile, additional analyses using identical analytical methodology to that used in the metabolism studies and/or the generation of new aged radiolabeled residues may be required.

The petitioner should provide 5 g of analytical grade tebuconazole necessary for the PMV (refer to Product Chemistry 64-1 for the appropriate EPA address).

Independent Method Validation of Plant Method (MRID Nos. 412633-11 and 412633-19, Mobay Report Nos. 98520 and 99624)



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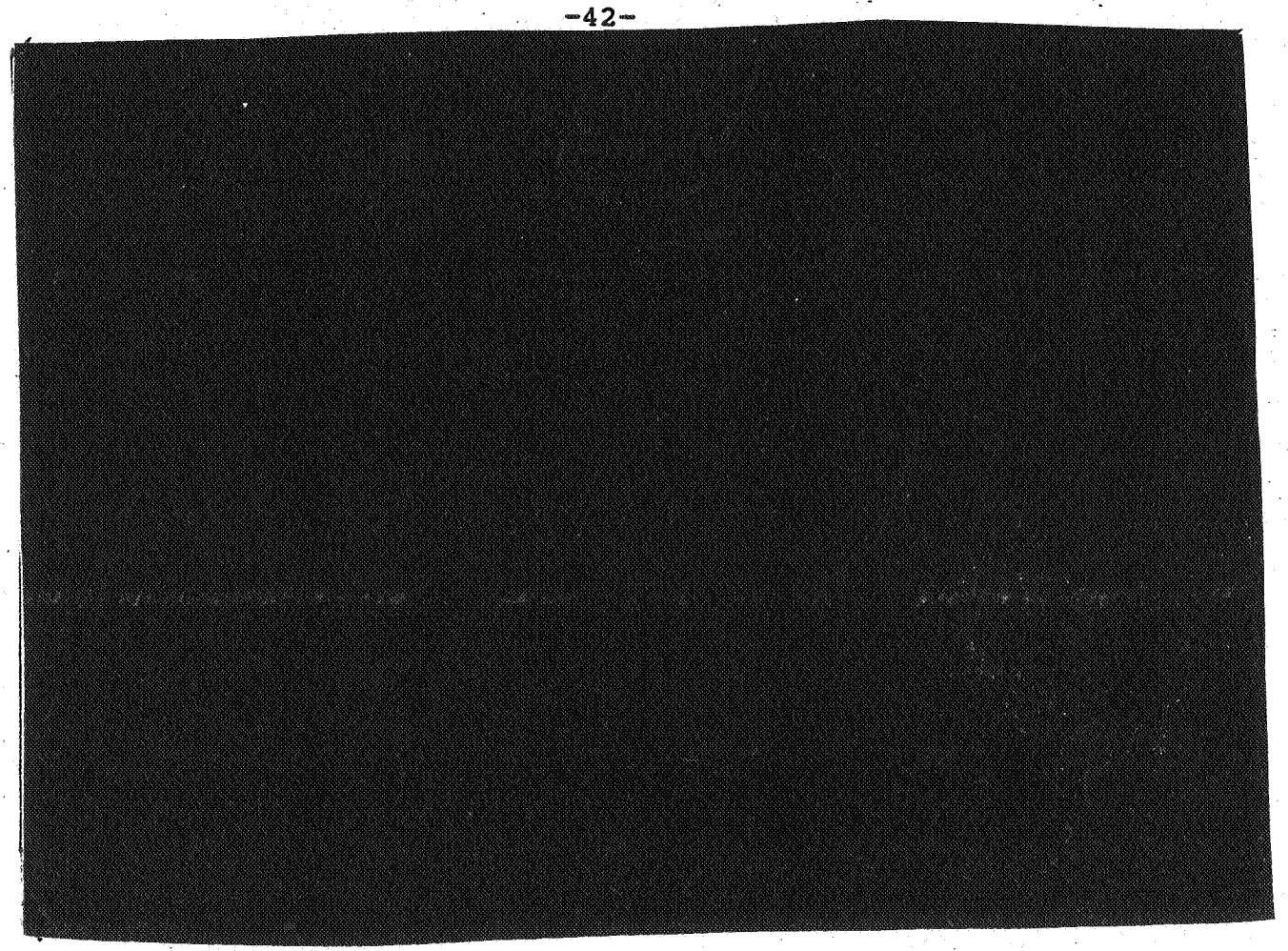

The second method validation report was on peanut meat and hay was dated July 12, 1989 and was performed by Pharmacology and Toxicology Research Laboratory - West in Richmond, California. Residue data were obtained using the analytical procedure described in Mobay Report No. 94295 and accompanying method modifications, which were not specified in the report. The following table summarizes the tebuconazole recoveries obtained:

Tebuconazole Peanut Method Validation

Matrix	Fortification (ppm)	Recoveries (%)
Peanut Meat	0.05 - 0.10	87 - 120
Peanut Hay	50 - 100	80 - 118

Sample GC chromatograms were submitted and indicated some interference in both peanut meat and hay in the same vicinity as the tebuconazole peak. Method revisions included the use of 90 rather than 30 g of sodium sulfate and the addition of a third temperature programmed ramp for the GC to be used with peanut meat. The petitioner should make the

necessary modifications to the tebuconazole analytical methodology for the PMV on peanuts. If the new metabolism study indicates significant residues of HWG 2061, validation of the modified methodology with radiolabeled residues from the peanut metabolism study will be required. With radiolabeled validation of the proposed analytical methodology a new independent method validation for peanuts will only be required if significant method revisions are necessary.

In summary once the petitioner submits a nonproprietary copy of the proposed plant analytical methodology with the needed revisions and modifications, EPA will conduct a PMV on plant matrices (i.e., wheat, grapes and peanuts). A decision on the need for an additional independent method validation and PMV for peanuts, to include metabolites, must be deferred until the required peanut metabolism study with radiolabeled validation of the proposed analytical methodology is submitted.

Analytical Method - Animals (MRID Nos. 409959-31 and 409959-43, Mobay Report Nos. 97468 and 98325)

The analytical method in animals and corresponding interference study were reviewed in PP#9G3817 in response to a temporary tolerance request (see C.L. Olinger, memorandum of June 8, 1990 for a detailed review).

In brief, the method submitted (Report No. 97468) used gas chromatography for the detection of tebuconazole and HWG 2061 and its conjugates in bovine liver, muscle, kidney, milk, and fat and poultry muscle liver, fat, skin and eggs. Liver, muscle, kidney, milk and egg samples are homogenized twice with methanol and filtered (a filter aid is required for milk and egg samples). Egg, liver and kidney samples are partitioned first with hexane and then acetonitrile (ACN), with the ACN extract added to the methanol filtrate with the methanol (ACN) extract evaporated to an aqueous residue. Fat and chicken skin samples use a hexane/ACN extraction scheme.

The aqueous residue from all the bovine matrices is refluxed for 2 hours with 1N HCl and a 16-hour reflux with 2N HCl is required for poultry liver and eggs. The aqueous extract is partitioned three times with DCM dried with sodium sulfate and the DCM evaporated to dryness with the residue reconstituted with 1:1 cyclohexane:ethylacetate and applied to a GPC column with tebuconazole and HWG 2061 eluted with 1:1 ethanol:cyclohexane with the extract subjected to clean up either by silica gel chromatography or Florisil column chromatography with HPLC. Tebuconazole and HWG 2061 are analyzed on a DB-17 and HP-5 capillary column, respectively, with a thermionic specific detector (nitrogen specific) at 300 °C using splitless on-column injection. Copies of sample

chromatograms for standards, controls and residue samples were provided. Confirmation of the GC analyses was done using selected ion monitoring by GC-MS.

To validate the proposed methodology poultry liver and muscle samples from the metabolism study were measured by GC and radiochemical levels measured by TLC. The ppm levels measured by GC vs. tissue radiochemical levels (ppm) for tebuconazole were: liver 2.8 vs. 2.5 and muscle 0.18 vs. 0.28 and for HWG 2061 liver 1.7 vs. 2.7 and muscle 0.19 vs. 0.15.

The following table and narrative from the above referenced review summarizes the methodology recovery results and CB's conclusions:

	Tebuconazole				HWG 2061			
Tissue	Spiking Level (ppm)	Range of Recoveries	Avg. Rec. ± Std. Dev.	No. of Reps.	Spiking Level (ppm)	Range of Recoveries	Avg. Rec. ± Std. Dev.	No. of Reps.
Bovine Tissues								
Liver	0.05-0.1	45-96	70 ± 16	6	0.05-0.1	42-100	70 ± 23	8
Kidney	0.05-0.1	65-130	98 ± 24	7	0.05-0.1	42-134	77 ± 36	5
Muscle	0.05	62-106	88 ± 19	4	0.05	70-120	95 ± 24	4
Fat	0.05-0.5	66-94	78 ± 12	4	0.05	60-78	67 ± 9	3
Milk	0.01-0.05	50-140	88 ± 23	15	0.01-0.05	30-102	57 ± 23	14
Poultry Tissues								
iver	0.05-0.1	61-106	78 + 21	6	0.05-0.1	27-34	32 + 3.1	5
Muscle	0.05	72-98	86 ± 13	3	0.05	72-80	77 ± 4	3
Fat	0.05	70-92	81 ± 11	3	0.05	52-58	56 ± 3	3
Skin	0.05	62-126	100 ± 34	3	0.05	58-68	65 ± 6	3
Eggs	0.01-0.1	66-130	106 ± 25	10	0.01-0.1	30-180	65 ± 51	8

Recoveries reported as percent recoveries and are corrected for any interferences found in the controls.

"All matrices from the poultry and bovine metabolism studies should be analyzed by this and any new analytical methods to ensure extractability and hydrolysis of the conjugated metabolites before a permanent tolerance can be considered.

"Before a temporary tolerance can be granted, a new or modified method must be submitted for the determination of tebuconazole in milk and eggs and HWG 2061 in bovine kidney, milk, poultry liver, and eggs. An explanation for the method variability for the determination of tebuconazole in bovine kidney, poultry skin, and HWG 2061 in bovine liver should be provided.

"For a permanent tolerance more description regarding the standard linearity and calibration should be included in the method. An explanation why hydrolysis is not required in some poultry matrices should be provided since conjugates were found. The tissues, milk, and eggs from any new metabolism studies conducted should be analyzed by this and any new methods submitted to check extractability and hydrolysis of the conjugated metabolite."

Also, for a permanent tolerance, particularly in light of the variable method recoveries obtained in the above table, revised proposed enforcement analytical methodology for all matrices and an independent method validation for both liver and milk are required before EPA can conduct a PMV. If radiolabeled validation of the proposed analytical methodology for animal matrices indicates a major portion of the radioactive residue is not recovered and identified by these methods, radiolabled validation of new proposed analytical methodology will be required. When using samples from the metabolism studies held in frozen storage, the petitioner must provide a comparison of the TRR and the residue profile both before and after the sample storage period; and if there is a significant change in the TRR or the residue profile, additional analyses using identical analytical methodology to that used in the metabolism studies and/or the generation of new aged radiolabeled residues may be required.

An interference study was also submitted on 102 nitrogen or phosphorous compounds to determine if pesticides with existing tolerances on animal products would interfere with the determination of tebuconazole or HWG 2061. The report specified that as in the method, the chemicals were hydrolyzed with 1N HCl and also derivatized with BSTFA to check for interference with HWG 2061. The following is a summary of the results from the report.

"Several mixtures did exhibit peaks which met these criteria. The individual components of these mixtures were taken through the hydrolysis procedure and analyzed separately. None of the individual compounds confirmed an interference. It was suspected that some of the original interfering peaks may have been due to carryover through the auto injector or gas chromatographic system itself."

The report also discusses rehydrolysis and rederivatization of the mixtures and individual chemicals and it is not clear whether the original mixtures were hydrolyzed, or only the individual components hydrolyzed after a mixture exhibited interference, and whether the individual components were again rehydrolyzed when they exhibited interference. Clarification of the hydrolysis and

derivatization procedures are required and additional analyzes of the interferant mixtures and their individual components may be necessary. A decision on the adequacy of the interference study must be deferred until the above data are provided and the required revised animal analytical methodology submitted so a determination can be made if the new methodology is significantly different from that tested.

Independent Method Validation of Animal Method (MRID No. 413835-01, Mobay Report No. 99834)

The independent method validation with beef liver was reviewed in PP#9G3817 in response to a temporary tolerance request (see C.L. Olinger, memorandum of June 8, 1990 for a detailed review).

The following is the Abstract from the report:

"Four attempts were made to validate Mobay method #97468 on beef liver. After recalibration of the GPC column with ^{14}C labeled material, recoveries were 88% to 103% for FOLICUR and varied from 79% to 98% for its metabolite HWG 2061. It was determined that the most important step in the extraction procedure was the acid hydrolysis. A fresh HCl solution should be made prior to hydrolysis of the extract. Incomplete hydrolysis resulted in exceptionally dirty samples which altered the equilibrium time required between each sample when run on the GPC. To aid in equilibration, samples were loaded onto the GPC by alternating solvent filled loops between every two samples. This allowed for complete equilibration if a dirty sample were placed onto the GPC and allowed for complete recovery of the analytes."

The following are CB's conclusions from the referenced review:

"Insufficient information regarding the method problems was provided. Three attempts were made before any contact with the sponsor, but no details about the problems encountered were provided. Before this study can be accepted additional documentation regarding the first three attempts must be submitted.

"CB questions whether this is an appropriate enforcement method. The report states that 3.5 days are required to complete a set of samples. Unless the petitioner can provide a detailed justification for use of this method, a new method which will take considerably less time must be submitted for a permanent tolerance. Other method problems must be resolved as well."

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Revised proposed enforcement analytical methodology with radiolabeled validation of the proposed methodology for all regulated ruminant and nonruminant matrices (see Analytical Method - Animals), and an independent method validation for both liver and milk are required before EPA can conduct a PMV.

Multiresidue Method Testing (MRID Nos. 409959-32 and 409959-33; Mobay Report Nos. 97425 and 98000)

The multiresidue method testing data were reviewed in PP#9G3817 in response to a temporary tolerance request (see C.L. Olinger, memorandum of June 8, 1990 for a detailed review). In brief, multiresidue method evaluations were submitted for tebuconazole and HWG 2061 through Protocols A, C, D, E, and former Protocol B. Tebuconazole can be detected on the OV-101 column and HWG 2061 on the OV-17 column, with NP, EC, and HEC detection. Before a permanent tolerance can be granted the discrepancy of tebuconazole recoveries for the Florisil column evaluation requires clarification and if adequate recoveries can be obtained, Protocol D and E method validations need to be repeated with EC detection. Also, HWG 2061 must be tested through Protocol B.

Residue Data

Storage Stability

Plants (MRID Nos. 409959-40 and 410685-02; Mobay Report Nos. 95679 and 98493)

The above-referenced storage stability studies have been discussed in PP#9G3817 (see Christine L. Olinger, memorandum of June 8, 1990 for a detailed review of the storage stability data on peanuts and grapes); the major conclusions are reiterated here:

1. Tebuconazole is stable in peanut foliage for up to 6 months; storage stability data up to 8 months must be submitted to support the residue data.

2. Tebuconazole is stable up to 4.5 months in peanut meat; data up to 8 months must be submitted to support the residue data.

3. No storage stability data for peanut hulls are available.

[redacted]

[redacted]

Storage Stability - Animals (MRID No. 409959-41; Mobay Report No. 98420)

The above-referenced storage stability study has been discussed in PP#9G3817 (see Christine L. Olinger memorandum of June 8, 1990 for a detailed review); the conclusion is reiterated here:

- Contingent on submission of additional experimental information, tebuconazole and HWG 2061 are stable in poultry kidney, muscle, and fat for 12 months, and in poultry liver for 6 months.

The above-referenced review also noted that HWG 2443 and the sulfate conjugate of HWG 2061 appear to be stable up to 6 months.

CB will accept the above storage stability on poultry matrices as also being representative of stability in the same bovine matrices; however, additional storage stability data on tebuconazole and its metabolites in milk and eggs are required.

Storage Stability - Processed Products

Tebuconazole storage stability data are currently not available for any processed products. The following excerpt in response to NACA comments from October 10, 1989 memorandum of Richard D. Schmitt, Ph.D., Overview of Residue Chemistry Guidelines summarizes CB's current policy on the required storage stability data on processed products:

COMMENT: "If storage stability has been shown in the raw agricultural commodity (RAC), storage stability studies in each of the processed fractions should not be required." EPA RESPONSE: Since some processed fractions (e.g., oils, fruit juices, soapstocks) have matrices quite different from the starting RAC, storage stability data are required for byproducts. However, once storage stability has been demonstrated in a few representative crops and their byproducts, additional data would not be needed, provided storage conditions and duration are similar. Suggested representative crops would be an oilseed (e.g., soybeans), a fruit (e.g., citrus), and a non-oily grain (e.g., wheat).

Accordingly, storage stability data on processed peanut and grape matrices are required. Storage stability data on processed wheat products are not required, since storage stability data on tebuconazole in barley can be translated to processed wheat matrices.

Field Trials

Magnitude of Residue in Peanuts (MRID Nos. 409959-36 and 412633-18; Mobay Report Nos. 96728 and 99129)

The above-referenced residue studies have been discussed in PP#9G3817 (see Christine L. Olinger, memorandum of June 8, 1990, for a detailed review).

In brief, two sets of field trials on peanuts were conducted. The first study was conducted in six States in 1987 with either six or seven foliar spray applications at intervals from 10 to 17 days, of 3.6 oz ai/A of Folicur 1.2 EC or 45 DF (i.e., 1X or 1.58 lb ai/A) and PHIs ranging from 1 to 9 days (14-day PHI proposed). Curing intervals (i.e., time between digging and harvesting) varied from 1 to 14 days; although normal practice is to allow 2 to 3 days for curing (i.e., field drying) some cooperators interpreted the

PHI as the curing time (14 of 22 residue samples reflected curing times of ≥ 7 days). Residue levels of tebuconazole from the two formulations varied from < 0.5 to 3.6 ppm in peanut vines, from < 0.04 to 3.4 ppm in peanut hulls, and from < 0.02 to 0.03 ppm in peanut nutmeat.

The petitioner's narrative indicates that the peanut samples were held in frozen storage for a maximum of 247 days prior to extraction and analysis; however, storage stability of tebuconazole in peanuts has only been demonstrated for up to 4 months and storage stability data for peanut hulls has not been submitted.

In the second study, residue trials were conducted in five States in 1988 with seven applications of 3.6 oz ai/A of Folicur 3.6 F (i.e., 1X) at intervals from 9 to 14 days, with PHIs from 3 to 14 days and curing intervals of 1 to 9 days for peanuts and 1 to 11 days for peanut vines, before harvesting. Residue levels of tebuconazole varied from < 0.01 to 0.08 ppm for peanut meats; from 0.17 to 2.15 ppm for peanut hulls; and from 0.17 to 28.75 ppm for peanut vines with all samples analyzed within 6 months of harvest (i.e., stability data are only available for 4.5 months).

Both residue studies utilized the analytical procedure described in Mobay Report No. 94295; revised such that the silica gel cleanup followed the GPC cleanup. Additionally, in the first study considerably more sodium sulfate was used for drying the extracts than was specified in the method and some samples required an additional C_{18} Cartridge cleanup to reduce the interferences and one interferant up to 0.17 ppm depicted by a large peak immediately after the tebuconazole peak, may invalidate some of the reported nondetectable samples (i.e., Poast/sethoxdim, a reported interferant was also used on some of the control and treated plots). Additionally, in the second study relatively high levels of an interferant were found in untreated peanut vines but a determination of whether the interferant would be due to application of sethoxydim (which has been shown to interfere with tebuconazole) could not be made. Analytical recoveries for both studies ranged from 74 to 118 percent, at representative fortification levels, with the exception of hulls spiked at 0.01 ppm in the first study, where recoveries ranged from 136 to 175 percent.

The petitioner should provide a summary table and corrections of residue levels to reflect residues found in the controls, percent recovery, and interferences detected in controls and discussion of all the field trial data (i.e., both studies depicting the storage intervals and conditions from sampling to both extraction and analysis, with PHIs, curing intervals, and identification of which chromatograms

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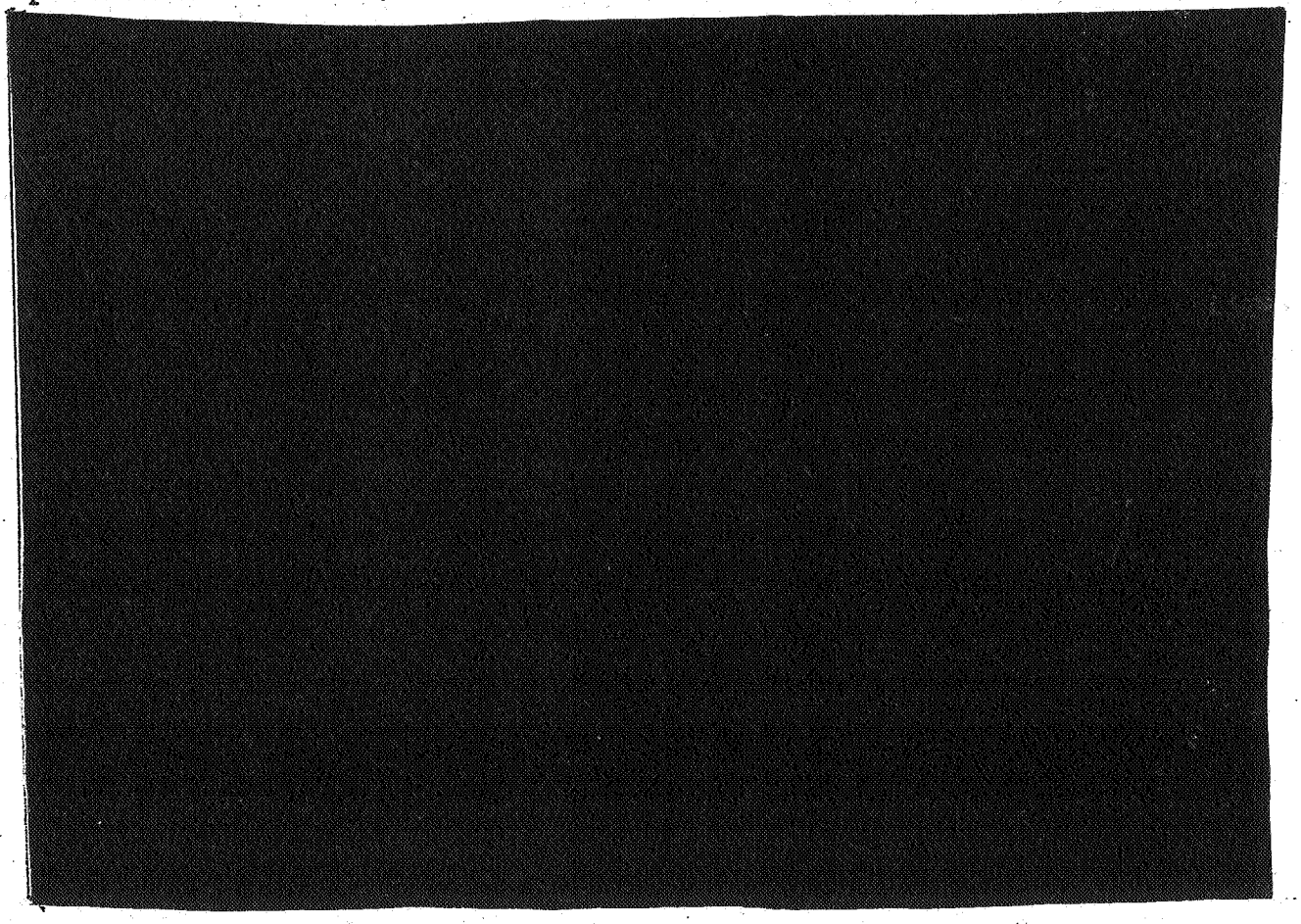
depicted interferences in the vicinity of tebuconazole), for each individual sample for peanuts, hulls, and vines. Until these data and additional storage stability data on peanuts and hulls are available and the nature of the residue in peanuts is known, a decision on the adequacy of the field trials cannot be made. Also, per an October 3, 1990 request for clarification of required crop field trial studies for representative analysis of metabolite residues only, a CB response was issued under PP#9G3817 (see February 7, 1991 memorandum of F. Toghrol). For the permanent tolerance on peanuts the petitioner should conduct field trials in a minimum of five States geographically representative of national peanut production at the maximum proposed use rate with analysis of both the parent and significant metabolites. Although the current field trial data tend to support proposed tolerance levels for tebuconazole in peanuts and peanut hay of 0.10 and 50.0 ppm, respectively, the data support a tolerance level of 4.0 ppm rather than the 3.5 ppm currently proposed in peanut hulls. Additionally, the revised analytical methodology resulting from the peanut field trials should be submitted as the proposed enforcement method and required changes in the limit of detection for peanuts and vines (ibid. PP#9G3817).



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57

Trichlorobenzene

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____ The product confidential statement of formula.

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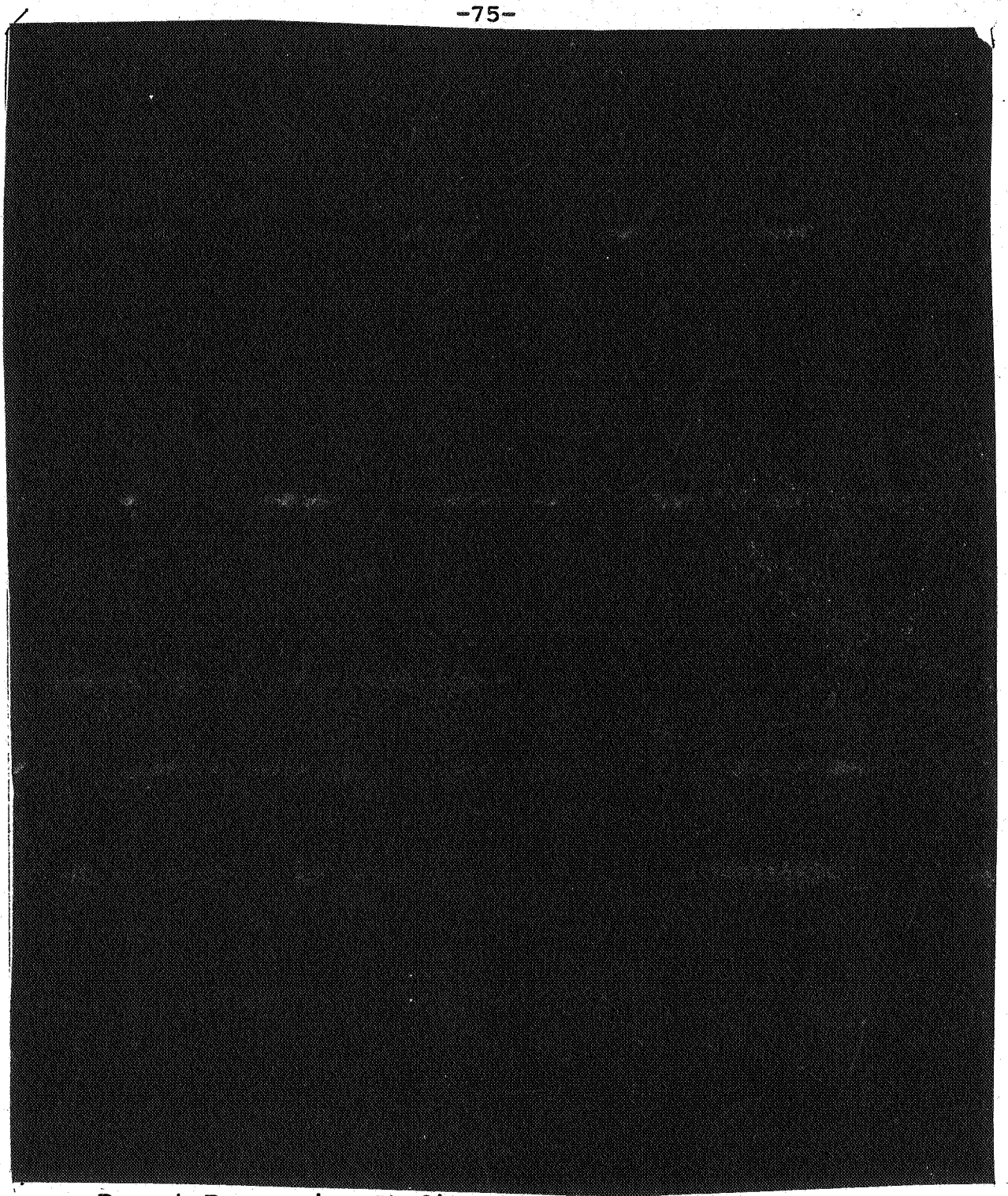

Peanut Processing Studies (MRID Nos. 409959-45 and 414502-01; Mobay Report Nos. 98308 and 98541)

Two peanut processing studies have been submitted and both were reviewed in PP#9G3817 in response to a temporary tolerance request (see C.L. Olinger, memorandum of June 8, 1990 for a detailed review).

In brief, in the first study (September 12, 1988), peanuts from the 1987 field trial conducted in Georgia, where tebuconazole (1.2 EC) was applied seven times at 3.6 oz ai/A at intervals of 14 days for a total application of 1X. The peanuts were dug 19 days after application and after 7 days of field drying were harvested. Peanuts were processed using the procedures described in the Small-Scale Processing of Peanuts from Texas A&M University. Peanut and presscake samples were analyzed by the analytical procedure described in Mobay Report No. 94295, with method modifications necessary for the other peanut processed fractions. Method recoveries although acceptable for peanut meat (74-102%) and presscake (76-120%) were poor or variable for crude oil (52%), refined oil (68-175), and soapstock (55-113%). The peanut meat and all the processed fractions except soapstock contained no detectable tebuconazole residues at a 0.02 ppm quantitation limit (except crude oil quantitation limit 0.05 ppm). Tebuconazole residues in soapstock were found at the quantitation limit of 0.01 ppm.

For the second peanut processing study, February 16, 1989, tebuconazole (1.2 EC) was applied seven times at 18 oz ai/A at intervals of 9 days, with a hand-held plot sprayer for a total application of 5X. The peanuts were dug 3 days following the last application and harvested after additional 3 days of field drying, frozen, and shipped within 3 days to the processor. A gap of 7 days between shipping from the processor to receipt at the analytical lab requires clarification.

Peanuts were processed using the procedures described in the Small-Scale Processing of Peanuts from Texas A&M University. Residue data were obtained using the analytical procedure in Mobay Report No. 94295 and the Method addenda in Appendix C; and method procedures used for peanut processed and refined oil are in Mobay Report No. 98308. The following table and narratives from the referenced CB review summarize the results of the processing study and CB's conclusions:

Matrix	Range of Recoveries, %	ppm Found Control	ppm Found Treated
Peanut Meat	66-93	< 0.02	0.08
Presscake (Meal presscake)	73-74	< 0.01	0.05
Presscake (Meal, Solvent Extracted)	73-74	< 0.01	0.04
Crude Oil (Expeller)	107-112	0.026	0.35
Crude Oil (Solvent Extracted)	101-117	0.059	0.20
Refined Oil	84-134	0.017	0.26
Soapstock	73-80	0.066	0.30

"Tebuconazole concentrates in crude oil, refined oil, and soapstock. The calculated concentration factors are crude oil (expeller), 4.4; crude oil (solvent extracted), 2.5; refined oil, 3.3; and soapstock, 3.8. Mobay has not proposed any tolerances for peanut processed products. Based on these concentration factors and the proposed peanut tolerance, the following tolerances should be proposed: crude oil, 0.5 ppm; refined oil, 0.5 ppm; and soapstock, 0.5 ppm. The section F should be amended to include these tolerances.

"Most of the fortifications were done at or below the level of interference for the oil and the presscake. This is not normally acceptable but will be allowed for the temporary tolerance only.

"Since tolerances in/on soapstock and oil will be enforced nonconfidential method(s) for the analysis of tebuconazole and any metabolites must be available. Since the method which has been submitted does not include oil and soapstock, a new one must be submitted. The reported limit of determination should be at least twice the interference level found in the controls. An independent method validation as described in PR Notice 88-5 must be submitted as well for a permanent tolerance.

"This study is adequate for a temporary tolerance only. Storage stability data for the processed products must be submitted for a permanent tolerance. A new processing study will have to be submitted if any metabolites of concern are found in the new metabolism study."

[redacted]

Waived Agreement

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Meat, Milk, Poultry, and Eggs

Dairy Cattle Feeding Study (MRID Nos. 409959-48 and -49, Mobay Report Nos. 98422 and 98437)

The dairy cattle feeding study was reviewed in PP#9G3817 in response to a temporary tolerance request (see C.L. Olinger memorandum of June 8, 1980 for a detailed review).

In brief, based on an estimated maximum 1X feeding level of 25 ppm, four treatment groups of three dairy cows each and fed 0, 25, 75, 250 ppm tebuconazole daily for 28 days in a gelatin capsule by bolus gun. The concentration of tebuconazole in the capsules was found to be stable for up to 79 days in frozen storage.

Milk samples were taken twice daily and animals were sacrificed within 20 hours of the final dose and samples analyzed utilizing the analytical method described in Mobay Report No. 97468 and discussed in the Analytical Method section of this review. Sample control, standard and residue GC chromatograms were also provided.

Residue samples were stored up to 8 months prior to analysis and no additional storage stability data were submitted. CB considers the available storage stability data on tebuconazole and HWG 2061 in poultry tissue, indicating their stability in poultry kidney, muscle, and fat for up to 12 months and poultry liver up to 6 months sufficient to support their stability in the subject cattle feeding study, in all the matrices except milk (see Storage Stability - Animals). Data for each of 10 cows were reported (i.e., only one control cow was sacrificed) individually including residues of tebuconazole and HWG 2061 in milk, fat, muscle, liver, and kidney.

The following tables from CB's June 8, 1980 review summarize the residue levels reported:

Summary of Residues in Dairy Cow Tissues

Matrix	Dose Level ppm	Tebuconazole ppm Found[1]	HWG 2061 ppm Found[2]	Total Residue ppm[3]
Fat	0	< 0.05	< 0.05	< 0.05;
	25	NA	NA	NA
	75	NA	NA	NA
	250	< 0.05; < 0.05; < 0.05	< 0.05; < 0.05; < 0.05	< 0.05; < 0.05; < 0.05
Muscle	0	< 0.05	< 0.05	< 0.05
	25	NA	NA	NA
	75	NA	NA	NA
	250	< 0.05; < 0.05; < 0.05	< 0.05; < 0.05; < 0.05	< 0.05; < 0.05; < 0.05

[1]Expressed as tebuconazole equivalents.
[2]Expressed as HWG 2061 equivalents.
[3]Expressed as tebuconazole equivalents.
NA = Not Analyzed; no residues were detected in the samples at the highest feeding level.

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Summary of Residues in Dairy Cow Tissues (cont'd)

Matrix	Dose Level ppm	Tebuconazole ppm Found[1]	HWG 2061 ppm Found[2]	Total Residue ppm[3]
Kidney	0	< 0.05	< 0.05	< 0.05
	25	< 0.05; < 0.25; < 0.05	< 0.05; < 0.05; < 0.05	< 0.05; < 0.05; 0.25
	75	< 0.05; < 0.05; < 0.05	0.11; < 0.05; 0.09	0.16; 0.05; 0.08
	250	< 0.05; 0.09; < 0.05	0.87; 0.72; 0.55	0.83; 0.77; 0.54
Liver	0	< 0.05	< 0.05	< 0.05
	25	0.06; 0.07; < 0.05	0.10; 0.08; < 0.05	0.15; 0.14; < 0.05
	75	0.07; 0.06; 0.12	0.10; 0.08; 0.06	0.16; 0.13; 0.17
	250	0.11; 0.20; 0.13	0.28; 0.81; 0.32	0.38; 0.97; 0.44

[1]Expressed as tebuconazole equivalents.
[2]Expressed as HWG 2061 equivalents.
[3]Expressed as tebuconazole equivalents.
NA = Not Analyzed; no residues were detected in the samples at the highest feeding level.

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Summary of Residues in Milk

Dose Level	Day 7 ppm Teb[1]	Day 7 ppm HWG 2061[2]	Day 14 ppm Teb	Day 14 ppm HWG 2061	Day 21 ppm Teb	Day 21 ppm HWG 2061	Day 26 ppm Teb	Day 26 ppm HWG 2061	Day 27 ppm Teb	Day 27 ppm HWG
0	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01
25	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
25	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
25	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
75	NA	NA	NA	NA	NA	NA	< 0.01	< 0.01	< 0.01	< 0.01
75	NA	NA	NA	NA	NA	NA	< 0.01	< 0.01	< 0.01	0.02
75	NA	NA	NA	NA	NA	NA	< 0.01	< 0.01	< 0.01	< 0.01
250	< 0.01	0.03	< 0.01	0.01	< 0.01	0.01	< 0.01	0.02	< 0.01	0.03
250	< 0.01	0.02	0.01	< 0.01	< 0.01	< 0.01	< 0.01	0.01	< 0.01	0.01
250	< 0.01	0.03	0.01	< 0.01	< 0.01	0.01	< 0.01	0.02	*	0.01

[1]Expressed as tebuconazole equivalents.
[2]Expressed as HWG 2061 Equivalents.
*Sample lost.
"\ = Not Analyzed; no residues detected in highest dose level.

In summary, at a reported quantitation level of 0.01 ppm for tebuconazole and HWG 2061 in milk and 0.05 ppm for tebuconazole and HWG 2061 in beef tissues, no residues of either moiety were found in fat or muscle at the 250 ppm dose level. However, a 0.25 ppm residue of tebuconazole and no detectable residue of HWG 2061 (i.e., < 0.05 ppm) or a total residue of 0.30 ppm was the highest reported residue in kidney; and a 0.06 ppm residue of tebuconazole and a 0.10 ppm residue of HWG 2061 or a total residue of 0.16 ppm was the highest reported residue in liver at the 25 ppm dosage level. At the 250 ppm feeding level, residue levels of HWG 2061 plateaued in milk at 0.03 ppm on day 7 with no residues of tebuconazole detected.

A determination of the adequacy of the cattle feeding study to support permanent tolerances cannot be made until the following issues are resolved:

1. Additional data necessary to validate the goat metabolism study are provided.

2. Data requested on the milk analyses are submitted (e.g., samples analyzed were whole or skim milk, and information on whether morning and afternoon milk samples were composited in the ratio of production).

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3. Additional sample chromatograms and concurrent method fortification data for liver and other matrices must be submitted, and residue levels before and after adjustment for average method recoveries depicted. If as indicated in CB's July 26, 1990 memorandum of conference (see PP#9G3817, memorandum of C. Olinger) the petitioner claims the recovery data in Mobay Report No. 97468 (MRID No. 409959-31) represents the concurrent fortification data for the feeding studies; a written explanation including information on the dates and locations of all the analyses, and a discussion of the GPC column calibration and acid hydrolysis problems discussed in Mobay Report No. 99834 (MRID No. 413835-1) are required.

4. Food consumption, animal weights and milk production data should be provided.

5. Storage stability data on tebuconazole and HWG 2061 in milk for a minimum of 8 months are required.

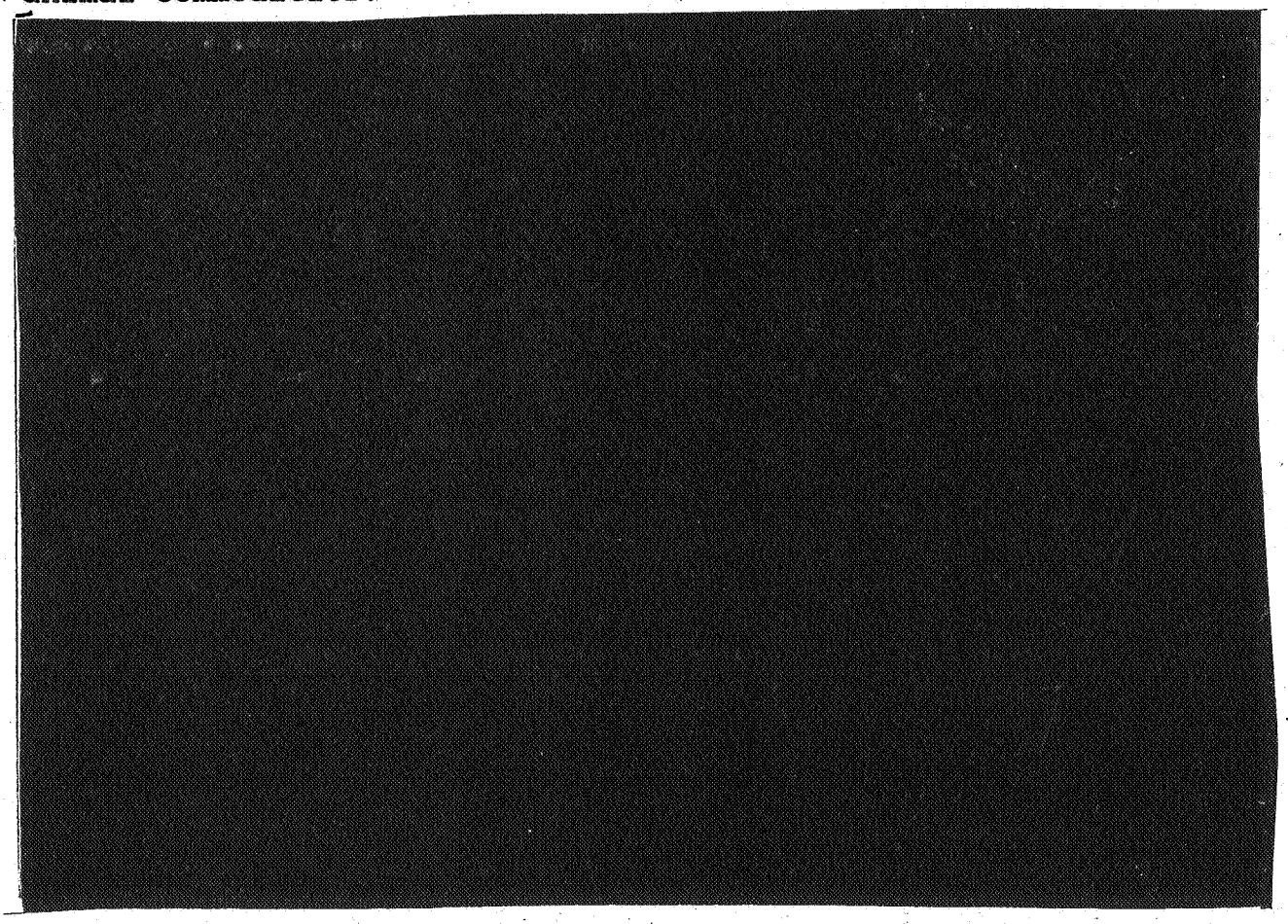
6. The petitioner must provide a comparison of the residue levels detected in the high dose cattle feeding group to average residue levels detected in the C^{14} goat metabolism study, and provide an explanation of nonlinear residue results (i.e., based on the two equivalent feeding levels and method recoveries).

The petitioner should note that questions pertaining to the acceptability of the proposed analytical methodology in animal matrices, as an enforcement method, although applicable to the cattle feeding study may not invalidate the results in consideration of the exaggerated feeding levels and low if any residues detected.

Based on the current proposed uses of tebuconazole, a cattle diet of 60 percent peanut hay at the proposed tolerance level of 50 ppm and 40 percent barley grain at the required tolerance of 3.0 ppm results in a minimum dietary burden of 31.2 ppm. Although the feeding of other animal feed items with tebuconazole residues is possible, the above scenario appears reasonable as a worst case diet. However, the addition of new uses of tebuconazole may change the dietary burden. Proposed tolerances based on the results of the feeding study at the 25 ppm feeding level (i.e., 0.8X) may need to be adjusted accordingly. Also, the proposed tolerances for the animal matrices may need to be adjusted where they are based on no detectable residues, to reflect

the sum of the limits of quantitation for tebuconazole and HWG 2061 (e.g., milk), once the animal analytical methodology deficiencies are resolved and the detection limits are known.

Conditionally, based on the feeding study and current claimed quantitation levels, a revised Section F with proposed tolerances for combined residues of tebuconazole and HWG 2061 in cattle, goats, hogs, horses and sheep, fat, and meat of 0.10 ppm; and in cattle, goats, hogs, horses and sheep mbyp of 0.50 ppm; and in milk of 0.03 ppm would be required. However, adjustment of residue levels to reflect analytical method recoveries and/or the failure to validate the current claimed quantitation limits of enforcement analytical methodology or the need for new feeding studies may necessitate other changes in the proposed tolerances for animal commodities.



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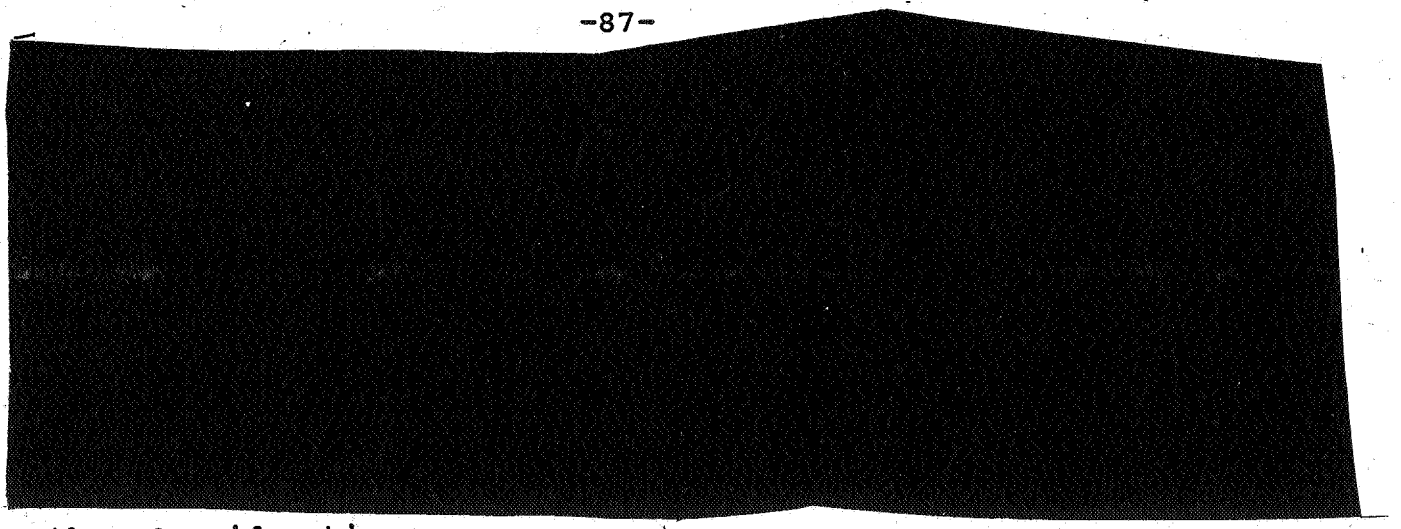

Other Considerations

An International Residue Limit Status sheet is included in this review as Attachment 1. Since no Codex, Canadian, or Mexican limits/tolerances have been established for tebuconazole, there are no compatibility problems at this time.

Attachment 1: International Residue Limit Status Sheet
Attachment 2: Confidential Appendix

cc w/Confidential Appendix: G. Otakie (CBTS), E. Haeberer (CBTS), RF, SF, PP#9G3817K, C.Furlow, PIB/FOD, C.Olinger (CBRS), F. Suhre (CBRS).

H7509C:CBTS:G.Otakie:CM#2:Rm800B:
RDI:E.Haeberer:03/20/91:R.Loranger:03/21/91

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ATTACHMENT 1

INTERNATIONAL RESIDUE LIMIT STATUS

5/4/90

CHEMICAL TEBUCONAZOLE

CODEX NO. _____

CODEX STATUS:

[X] No Codex Proposal Step 6 or above

Residue(if Step 8): _____

Crop(s)	Limit (mg/kg)

CANADIAN LIMITS:

[X] No Canadian limit

Residue: _____

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 9F3704, 9H5575
9F3818, 9G3817

RCB Reviewer OTAMIE

Residue: TEBUCONAZOLE

Crop(s)	Limit (mg/kg)
barley, green forage	5.0
barley, straw/hay	18.0
grass, forage	0.2
grass, seed straw	30.0
oat, straw	0.01
oat, hay	0.05
peanut hulls	3.5
raisins	3.0
wheat, green forage	5.0
barley, milled fraction	1.0
grape pomace (wet)	4.0
raisin waste	6.0
WHEAT SHORTS	1.0

MEXICAN LIMITS:

[X] No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)

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NOTES:

Form revised 1986

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL TEBUCONAZOLE

CODEX NO. ____

J. Otakie 5/4/90

CODEX STATUS:

☒ No Codex Proposal Step 6 or above

Residue(if Step 8): ____

Crop(s)	Limit (mg/kg)

CANADIAN LIMITS:

☒ No Canadian limit

Residue: ____

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 9F3724, 9H5575, 9F3818, 9G3819

RCB Reviewer OTAKIE

Residue: TEBUCONAZOLE

Crop(s)	Limit (mg/kg)
barley, grain	2.0
barley, straw	5.0
grapes	2.0
grass, seed cleanings	25.0
oat, grain	0.01
oat, green forage	0.01
peanuts	0.1
peanut hay	50.0
wheat, grain	0.4
wheat, straw	~~10~~ 20.0 (19)
wheat, milled fraction	1.0
grape pomace (dry)	12.0

MEXICAN LIMITS:

☒ No Mexican limit

Residue: ____

Crop(s)	Limit (mg/kg)

NOTES:

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL TEBUCONAZOLE

CODEX NO. _____

CODEX STATUS:

☐ No Codex Proposal Step 6 or above

Residue(if Step 8): _____

Crop(s)	Limit (mg/kg)

CANADIAN LIMITS:

☐ No Canadian limit

Residue: _____

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 9F3724, 9H5575 9F3818, 9G3817

RCB Reviewer OTAKIE

Residue: TEBUCONAZOLE

Crop(s)	Limit (mg/kg)
Peanut Crude Oil	0.45
Peanut Refined Oil	0.35
Peanut Soapstock	0.40
Eggs	0.02
Milk	0.01
meat fat and meat byproducts of Poultry	0.15
meat, fat and meat byproducts of cattle, goats, hogs horses and sheep	0.01

MEXICAN LIMITS:

☐ No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)

NOTES:

Form revised 1986

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