



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

OFFICE OF
PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES

MEMORANDUM

Date: February 28, 2006

Subject: TCMTB. Summary of Analytical Chemistry and Residue Data for the Reregistration Eligibility Decision (RED) Document.

DP Barcode: D322617
40 CFR §:180.288

PC Code:035603
Chemical Class: Benzothiazole

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Executive Summary

As an antimicrobial pesticide, TCMTB [(2-benzothiazolylthio)methyl thiocyanate] is used largely as a wood preservative. It is also used as a microbiocide/microbiostat and bacteriocide/bacteriostat in industrial processes and water systems, as well as in industrial materials, as a preservative. As an agricultural pesticide, TCMTB is a fungicide used as a seed treatment on barley, corn, cotton, oat, rice, safflower, sorghum, sugar beet, and wheat.

The reregistration of TCMTB is being supported by Bayer CropScience (Bayer) and Wilbur-Ellis Company (Wilbur-Ellis). TCMTB food/feed end-use products are marketed in the United States under the trade names Busan[®], Cotguard[®], Nusan[®], and Nu-Flow[®]. The Bayer and Wilbur-Ellis TCMTB formulations registered for food/feed uses include emulsifiable concentrate (EC) and soluble concentrate (SC). For food/feed uses, Bayer is supporting TCMTB use on cotton only, while Wilbur-Ellis is supporting uses on barley, cotton, oat, rice, wheat, safflower, and sugar beet. The technical registrant of TCMTB, Buckman Laboratories, Inc. (Buckman) has requested cancellation of all food/feed uses. Therefore, use on corn and sorghum is no longer being supported. Bayer and Wilbur-Ellis will be responsible for providing the Agency with the appropriate data needed to maintain the supported uses on their product labels.

Tolerances are established for residues of the fungicide 2-(thiocyanomethylthio)benzothiazole in/on barley (grain and straw), sugar beets (roots and tops), corn (forage, grain, and stover), cotton (forage and undelinted seed), oats (forage, grain, hay, and straw), rice (grain and straw), safflower (seed), sorghum (forage, grain, and stover), and wheat (forage, grain, hay, and straw) at 40 CFR §180.288. The permanent tolerances for residues in plant commodities are established at the limit of quantitation (LOQ) of 0.1 ppm (N). The "N" designation, denoting "negligible" residues must be deleted from 40 CFR §180.288.

The reregistration requirements for plant metabolism have not been fulfilled. Data have been submitted depicting the uptake of TCMTB in corn, cotton, safflower, and wheat and were found to be inadequate due to lack of identification and/or characterization of parent and/or metabolites. Additional metabolism studies conducted with tomatoes and melons have been submitted and briefly reviewed; however, translation to the currently registered crops is not adequate for reregistration purposes. Confirmatory metabolism data should be submitted depicting the nature of residues in wheat, cotton, and sugar beets. Adequate identification and/or characterization of parent and/or metabolites should be conducted as required by OPPTS 860 Series Guidelines. The Risk Assessment Review Committee (RARC) met and determined that the interim residue of concern for tolerance expression and risk assessment is TCMTB in/on plants (P. Deschamp, Report of the RARC, 1/11/2006). This is a preliminary decision and the additional confirmatory plant metabolism data should be submitted in a timely manner.

No livestock metabolism studies have been submitted for review. Livestock metabolism studies may be required if the requested plant metabolism studies show uptake of residues. If livestock metabolism studies are required, the registrant must provide poultry and ruminant metabolism studies following OPPTS 860 Series Guidelines.

A tolerance enforcement method is available for determining thiobenzothiazole-containing residues in barley, corn, cotton, oat, rice, safflower, sugar beet, and wheat. This method was originally submitted with Pesticide Petition (PP) 0F0954 by Buckman. Residues are converted to 2-chlorobenzothiazole, which is determined by a gas-liquid chromatography (GLC) method

using an electron capture detector (ECD). The quantitation limit of the method has been determined at 0.10 ppm. This method is listed as Method B in PAM Vol. II. The method is outdated and uses toxic reagents; therefore, if an additional method that is adequate for tolerance enforcement is available, it should be submitted immediately for review.

Two data-collection methods are available for determining thiocyanate-containing residues. The first method was originally submitted with PP 0F0954 by Buckman for the determination of residues in barley, corn, cottonseed, oat, rice, and wheat. The method is listed as Method I in PAM Vol. II. The second method was originally submitted with PP 5F1613 by Buckman for the determination of residues in safflower seed, sorghum grain and foliage, and sugar beet and foliage. The method is listed as Method A in PAM Vol. II. Residues are converted from thiocyanate to cyanogen bromide; then the cyanogen bromide is treated with pyridine-benzidine reagent to form an intensely colored dye. The absorbance of the dye solution is determined at 532 nm. In a method tryout (Method I), the Agency obtained recoveries of 90% and 110% (duplicate samples) at the 0.10 ppm fortification level and 105% and 115% (duplicate samples) at the 0.20 ppm fortification level. The quantitation limit of both methods has been determined at 0.10 ppm.

If the requested metabolism studies show additional residues are of concern and the current enforcement method does not capture these additional residues, development of a method capable of doing so will be required.

The requirement of a tolerance enforcement method for livestock is put on reserve pending the results from the requested plant metabolism studies, and, if required, the livestock metabolism studies.

The FDA PESTDATA database dated 11/2001 (PAM Volume I, Appendix I) indicates that TCMTB *per se* is completely recovered (>80%) using Multiresidue Methods Section 302 (Luke Method), but is only partially recovered (50-80%) using 303 (Mills, Onley, Gaither Method) and 304 (Mills fatty food Method). If additional residues of concern are determined from the requested metabolism studies, all additional residues of concern for tolerance expression will need to be tested through Multiresidue Methods.

Storage stability data for TCMTB in/on barley, cotton, oat, rice, wheat, safflower, and sugar beet have not been submitted by the registrant. No data were provided on how long samples from the submitted field trials were stored prior to analysis; therefore, storage stability data for the previously submitted field trials are required and should be submitted immediately. Additionally, if field trials are required or additional uses are requested, concurrent storage stability data will be required under this guideline topic.

TCMTB is not intended for application to livestock and no livestock feeding studies have been submitted. The grain crops, their byproducts and forages, are livestock feed items. It is therefore necessary to consider if TCMTB residues are transferred to meat, milk, poultry, and eggs of livestock through ingestion of the residue bearing commodities. It has been indicated in the foregoing considerations that the nature of residue in plants has not been adequately described. In the absence of such data, the residue level is unclear. If the requested residue data show finite residues in the feed items, livestock feeding studies would be essential to an evaluation of the transfer of residues to milk, meat, poultry, and eggs. Therefore, no valid conclusions relative to 40 CFR §180.6 (the necessity of tolerances in livestock commodities) can be made in the

absence of livestock feeding studies.

The available field trial data are not adequate according to current OPPTS 860 Series Guidelines. The correct number of field trials, number of samples collected, and locations of trials are all insufficient. Additionally, no storage stability data was submitted with the field trial studies and the application rates are unknown for the barley, corn, oat, rice, and wheat studies. The method used for determining residues in barley, corn, oat, rice, and wheat is the data-collection method which only determines the thiocyanate ion (Method I or A in PAM Vol. II). The method used for determining residues in cotton is the tolerance enforcement method which determines thiobenzothiazole-containing residues (Method B in PAM Vol. II). If the requested metabolism studies show additional metabolites of concern are expected, new field trials should be conducted using a method which is capable of determining all residues of concern as determined by the tolerance expression. Additionally, tolerances should be proposed in/on barley hay and cotton gin byproducts as these are now considered significant livestock feed items according to Table 1 of OPPTS 860.1000. Field trial data are not available for sugar beets; therefore, magnitude of residue data in sugar beets should be submitted following all OPPTS 860 Series Guidelines.

No processing studies have been submitted. Once the requested metabolism studies have been submitted, reviewed, and the metabolites of concern are determined, data should be submitted which show whether residues concentrate in the byproducts of the registered raw agricultural commodities.

No confined accumulation data in rotational crops are available; however, soil persistence studies are available. The registrant should provide confirmatory method data along with storage stability data in order for the data to be considered scientifically adequate. Contingent upon the adequacy of the storage stability and method data, soil persistence is not likely to be a concern with respect to follow-up crops. However, the method used is unknown and the exact compounds that make up the residues found is unknown; therefore, this data requirement is put on reserve awaiting submission of the requested data and pending the results from the plant metabolism studies.

Residue Chemistry Deficiencies and Regulatory Guidelines

1. Confirmatory metabolism data should be submitted depicting the nature of residues in wheat, cotton, and sugar beets.
2. The available enforcement method (Method B in PAM Vol. II.) is outdated and uses toxic reagents; therefore, if an additional method that is adequate for tolerance enforcement is available, it should be submitted immediately for review.
3. Storage stability data were not included with the original field trial data submissions; therefore, storage stability data for the previously submitted field trials are required and should be submitted immediately.
4. Storage stability and method data were not provided with the original soil persistence studies summarized under OPPTS 860.1850 in this document. Storage stability and method data are required and should be submitted immediately.
5. Application rates in lbs a.i./100 lbs seed for all the submitted field trial studies should be

provided.

6. Tolerances for barley hay and cotton gin byproducts should be proposed once the requested metabolism data are submitted and reviewed.
7. Data should be submitted which show whether residues concentrate in the byproducts of the registered raw agricultural commodities.
8. Magnitude of residue data in sugar beets following all OPPTS 860 Series Guidelines should be submitted.
9. Additionally, numerous OPPTS 860 Series Guidelines have been placed on reserve pending the requested plant metabolism data (see Table 4).

Background

The TCMTB Phase 4 Review dated 3/11/1991 summarized the status of available residue chemistry data for the reregistration of TCMTB. The Phase 4 Review requested plant metabolism data on corn or wheat, cotton, and sugar beet. Data requirements for livestock metabolism, residue analytical methods, storage stability, and magnitude of the residue in plants were put on reserve status pending the results from the plant metabolism studies. This document presents an overall and up-to-date Residue Chemistry Science Assessment with respect to the reregistration of TCMTB. The PC Code and nomenclature of TCMTB are listed below in Table 1 and the physicochemical properties are listed in Table 2. The structure of TCMTB and metabolites/degradates of concern are presented in Table 3.

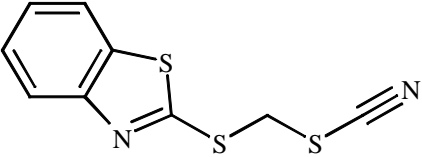
Table 1. TCMTB Nomenclature.	
Chemical structure	
Common name	TCMTB or TCMB
Molecular formula	C ₉ H ₆ N ₂ S ₃
IUPAC name	2-(thiocyanomethylthio)benzothiazole
CAS name	(2-benzothiazolythio)methyl thiocyanate
CAS number	21564-17-0
PC Code	035603
Supported food/feed site uses	barley, cotton, oat, rice, safflower, sugar beet, and wheat

Table 2. Physicochemical Properties of TCMTB		
Parameter	Value	Reference
Molecular weight	238.35 g/mol	Merck Index 12 th Edition
Melting point/range	Not applicable (NA) for liquids	NA
Boiling point/range	Decomposed at 191 °C at 741.9 mm Hg	C. Jiang, D322899, 11/17/05
pH	5.99 (1:100 dilution in water)	C. Jiang, D322899, 11/17/05
Density	1.3761 g/cm ³	C. Jiang, D322899, 11/17/05

Table 2. Physicochemical Properties of TCMTB

Parameter	Value	Reference
Water solubility	45 mg/L	C. Jiang, D322899, 11/17/05
Vapor pressure	1.45 x 10 ⁻⁴ mm Hg at 20°C 1.72 x 10 ⁻⁴ mm Hg at 25°C	C. Jiang, D322899, 11/17/05
Vapor pressure ¹	2.44 x 10 ⁻¹⁰ mm Hg at 20°C 4.04 x 10 ⁻¹⁰ mm Hg at 25°C	C. Jiang, D322899, 11/17/05
Dissociation constant, pK _a	NA	NA
Octanol/water partition coefficient	log K _{ow} of 3.23 at 20°C	C. Jiang, D322899, 11/17/05
Viscosity	352.4 cSt	C. Jiang, D322899, 11/17/05

1. Tests done with pure active ingredient (PAI).

Table 3. Chemical Names, Metabolism Data, and Structures of TCMTB and Its Metabolites/Degradates.

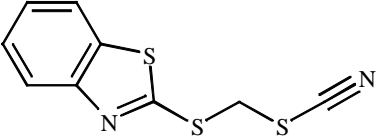
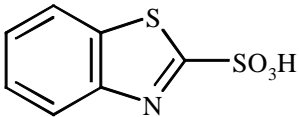
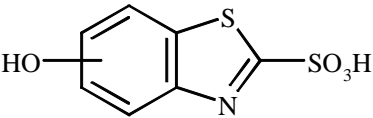
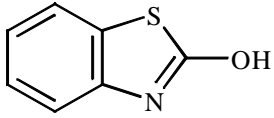
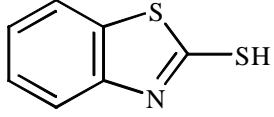
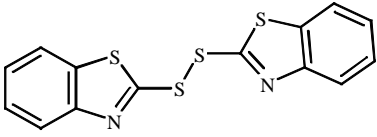
Chemical Name	Commodity	Percent TRR ¹		Structure
		Major Residue (>10% TRR)	Minor Residue (<10% TRR)	
TCMTB [2-benzothiazolylthio)methyl thiocyanate] CAS number: 21564-17-0	Melon fruit		ND ²	
	Melon plant		0.9%	
	Tomato fruit		ND	
	Tomato plant		ND	
	Aerobic soil (58 DPT ³)		0.6%	
2-BTSA [2-benzothiazolesulfonic acid]	Melon fruit	31.9%		
	Melon plant	14.0%		
	Tomato fruit	61.7%		
	Tomato plant	32.6%		
	Aerobic soil (58 DPT)	70.8%		
OH-2-BTSA ^{4,5} [2-(hydroxybenzothiazolyl)sulfonic acid]	Melon fruit		8.4%	
	Melon plant		2.6%	
	Tomato fruit		8.5%	
	Tomato plant	21.2%		
2-OH-BT [2-hydroxybenzothiazole] or BTOL [2-benzothiazolol] CAS number: 934-34-9	Melon fruit		1.3%	
	Melon plant		2.5%	
	Tomato fruit		ND	
	Tomato plant		ND	
	Aerobic soil (21 DPT)		7.0%	
2-MBT or 2-SH-BT [2-mercaptobenzothiazole] CAS number: 149-30-4	Melon fruit		0.7%	
	Melon plant		0.1%	
	Tomato fruit		ND	
	Tomato plant		ND	
	Cotton forage		ND	
	Aerobic soil (1.5 DPT)	30.3%		
	Aerobic soil (14-21 DPT)		0.3-0.4%	

Table 3. Chemical Names, Metabolism Data, and Structures of TCMTB and Its Metabolites/Degradates.

Chemical Name	Commodity	Percent TRR ¹		Structure
		Major Residue (>10% TRR)	Minor Residue (<10% TRR)	
2,2'-DTBB or DBB [2,2'-dithiobis(benzothiazole) CAS number: 120-78-5	Aerobic soil (maximum at 1 DPT)		6.7%	

1. TRR = Total radioactive residue.

2. ND = Not detected.

3. DPT = Days post-treatment.

4. Two isomers make up 2-(hydroxybenzothiazolyl)sulfonic acid. The exact position of the hydroxyl group was not determined. The numbers presented in the table are the summation of the two isomers. The following is the breakdown of TRR for each isomer (in parenthesis) following each individual commodity: melon fruit: 8.4% (1.1% and 7.3%); melon plant: 2.6% (1.4% and 1.2%); tomato fruit: 8.5% (6.9% and 1.6%); and tomato plant: 21.2% (6.7% and 14.5%).

Summary of Science Findings

A tabular summary of the residue chemistry science assessments for reregistration of TCMTB is presented below in Table 4. The conclusions listed in Table 4 regarding the reregistration eligibility of TCMTB food/feed uses are based on the use patterns being supported by Bayer and Wilbur-Ellis. When end-use product data-call-ins (DCIs) are developed (e.g., at issuance of the RED), the Registration Division (RD) should require that all end-use product labels (e.g., MAI labels, special local needs (SLNs), and products subject to the generic data exemption) be amended such that they are consistent with labels registered to Bayer and Wilbur-Ellis.

Table 4. Residue Chemistry Science Assessment for the Reregistration of TCMTB.

GLN Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References
860.1200 Directions for Use	Not applicable (NA)	No	None
860.1300 Plant Metabolism	NA	Yes ⁴	42376801 ¹ , 20431471 ² , 44654101 ³ , 44654102 ³
860.1300 Livestock Metabolism	NA	Reserved	None
860.1340 Residue Analytical Methods			
Plant commodities	NA	Yes ⁶	PP 5F1613, PP 0F0954, FDA PAM Vol. II
Livestock commodities	NA	Reserved ⁷	None
860.1360 Multiresidue Methods	NA	Reserved ⁸	None
860.1380 Storage Stability Data			
Plant commodities	NA	Yes ⁵	None
Processed commodities	NA	Reserved	None

Table 4. Residue Chemistry Science Assessment for the Reregistration of TCMTB.			
GLN Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References
Livestock commodities	NA	Reserved	None
860.1400 Water, Fish, and Irrigated Crops	NA	No	None
860.1460 Food Handling	NA	No	None
860.1480 Meat, Milk, Poultry, and Eggs	NA	Reserved ⁷	None
860.1500 Crop Field Trials			
<u>Root and Tuber Vegetables Group</u>			
Beet, sugar, roots	0.1(N) [§180.288(a)]	Reserved ⁹	None
<u>Leaves of Root and Tuber Vegetables Group</u>			
Beet, sugar, tops	0.1(N) [§180.288(a)]	Reserved ⁹	None
<u>Cereal Grains Group</u>			
Barley, grain	0.1(N) [§180.288(a)]	Reserved ⁹	00117874 ¹²
Corn, field, grain and aspirated grain fractions	0.1(N), grain [§180.288(a)]	No ¹¹	00117874 ¹²
Corn, pop, grain	None established	No ¹¹	None
Corn, sweet, K+CWHR	None Established	No ¹¹	None
Oat, grain	0.1(N) [§180.288(a)]	Reserved ⁹	00117874 ¹²
Rice, grain	0.1(N) [§180.288(a)]	Reserved ⁹	00117874 ¹²
Sorghum, grain, grain and aspirated grain fractions	0.1(N), grain [§180.288(a)]	No ¹¹	None
Wheat, grain and aspirated grain fractions	0.1(N), grain [§180.288(a)]	Reserved ⁹	00117874 ¹²
<u>Fodder, Forage, Hay, and Straw of Cereal Grains Group</u>			
Barley, hay and straw	0.1(N), straw [§180.288(a)]	Reserved ⁹	00117874 ¹²
Corn, field, forage and stover	0.1(N) [§180.288(a)]	No ¹¹	00117874 ¹²
Corn, pop, stover	None established	No ¹¹	None
Corn, sweet, forage and stover	None established	No ¹¹	None
Oat, forage, hay, and straw	0.1(N) [§180.288(a)]	Reserved ⁹	00117874 ¹²
Rice, straw	0.1(N) [§180.288(a)]	Reserved ⁹	00117874 ¹²

Table 4. Residue Chemistry Science Assessment for the Reregistration of TCMTB.			
GLN Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References
Sorghum, grain, forage and stover	0.1(N) [§180.288(a)]	No ¹¹	None
Wheat, forage, hay, and straw	0.1(N) [§180.288(a)]	Reserved ⁹	00117874 ¹²
<u>Miscellaneous Commodities</u>			
Cotton, undelinted seed and gin byproducts	0.1(N), undelinted seed [§180.288(a)]	Reserved ⁹	00004239 ¹³
Safflower, seed	0.1(N) [§180.288(a)]	Reserved ⁹	None
860.1520 Processed Food/Feed			
Barley	None established	Yes	None
Beet, sugar	None established	Yes	None
Corn, field	None established	No ¹¹	None
Cotton	None established	Yes	None
Oat	None established	Yes	None
Rice	None established	Yes	None
Safflower	None established	Yes	None
Sorghum	None established	No ¹¹	None
Wheat	None established	Yes	None
860.1650 Submittal of Analytical Reference Standards	NA	Yes ¹⁰	None
860.1850 Confined Rotational Crops	NA	Reserved ⁹	None
860.1900 Field Rotational Crops	None established	Reserved ⁹	None

1. F. Fort, D187529, MRID 42376801, 00/00/0000.

2. M. Perry, D221887, MRID 20431471, 5/11/1998.

3. Both studies (MRID 44654101 and 44654102) are summarized in this chemistry summary document. Full review of both studies is currently underway.

4. Confirmatory metabolism data should be submitted depicting the nature of residues in wheat, cotton, and sugar beets.

5. Storage stability data was not included with the original field trial data submissions, therefore, it is required.

6. The available enforcement method (Method B in PAM Vol. II.) is outdated and uses toxic reagents; therefore, if an additional method that is adequate for tolerance enforcement is available, it should be submitted immediately for review. Additionally, if the requested metabolism studies show additional residues are of concern and the current enforcement method does not capture these additional residues, development of a method capable of doing so will be required.

7. This requirement is put on reserve pending the results from the requested plant metabolism studies, and if required, the livestock metabolism studies.

8. If additional residues of concern are determined from the requested metabolism studies, all additional residues of concern for tolerance expression will need to be tested through Multiresidue Methods.

9. This requirement is put on reserve pending the results from the requested metabolism studies.

10. Analytical standards must be replenished as requested by the Repository. If additional residues are included in the tolerance expression based on the requested metabolism data, analytical reference standards should be submitted and replenished as requested by the Repository.

11. The registrants are not supporting use of TCMTB on corn and sorghum; therefore, all tolerances associated with those uses should be revoked.

12. MRID 00117874 was reviewed in PP 2F1264.

13. MRID 00004239 was reviewed in PP 0F0954.

860.1200 Directions for Use

Product List

There are two Bayer and two Wilbur-Ellis end-use products containing the active ingredient TCMTB, which are registered for use on domestically grown food/feed crops as indicated in Table 5.

EPA Reg. No.	Formulation ¹	Registrant	Product Name	Supported Seed Treatment Use Sites
264-965	30% EC	Bayer CropScience	Busan [®] 30A	cotton
264-983 ²	5% EC	Bayer CropScience	Cotguard [®]	cotton
2935-389	30% EC	Wilbur-Ellis Co.	Nusan [®] 30 EC	barley, cotton, oat, rice, safflower, sugar beet, and wheat
2935-413 ³	9% SC	Wilbur-Ellis Co.	Nu-Flow [®] ND	cotton on farm

1. EC = Emulsifiable Concentrate and SC = Soluble Concentrate.

2. Formulation also contains Carboxin (PC Code 090201) at 14.35% and Metalaxyl (PC Code 113501) at 2.4%.

3. Formulation also contains Chloroneb (PC Code 027301) at 23.5%.

Use Patterns

As an agricultural pesticide, TCMTB is a fungicide used as a seed treatment on barley, corn, cotton, oat, rice, safflower, sorghum, sugar beet, and wheat. It is used in commercial and on-farm settings. For food/feed uses, Bayer is supporting TCMTB use as a seed treatment on cotton only, while Wilbur-Ellis is supporting uses on barley, cotton, oat, rice, wheat, safflower, and sugar beet (K. Jakob, TCMTB Use Closure Memo, 1/30/2006). Use on corn and sorghum are not being supported. The technical registrant of TCMTB, Buckman, has requested cancellation of all food/feed uses (K. Jakob, TCMTB Use Closure Memo, 1/30/2006). An analysis of the current labeling and available use information was completed by HED. A summary of directions for the use of TCMTB is presented below in Table 6.

EPA Reg. No.	Product Name	Formulation	Crop	Application Equipment	Max. App. Rate (fl oz/100 lbs of seed)	Max. App. Rate (lbs ai./100 lbs of seed)
264-965	Busan [®] 30A	30% EC	cotton	commercial treater	4.5 fl oz/100 lbs of seed	0.093 lbs ai./100 lbs of seed
264-983	Cotguard [®]	5% EC	cotton	commercial treater	9.0 fl oz/100 lbs of seed	0.032 lbs ai./100 lbs of seed
2935-389	Nusan [®] 30 EC	30% EC	cotton	commercial treater	5.0 fl oz/100 lbs of seed	0.10 lbs ai./100 lbs of seed
			barley, oat, rice, wheat	commercial treater	1.25 fl oz/100 lbs of seed	0.026 lbs ai./100 lbs of seed
			safflower, sugar beet	commercial treater	2.0 fl oz/100 lbs of seed	0.041 lbs ai./100 lbs of seed

Table 6. Summary of Maximum Application Rates for Registered TCMTB Food/Feed Seed Treatment Uses.						
EPA Reg. No.	Product Name	Formulation	Crop	Application Equipment	Max. App. Rate (fl oz/100 lbs of seed)	Max. App. Rate (lbs ai/100 lbs of seed)
2935-413	Nu-Flow® ND	9% SC	cotton	commercial treater	19.7 fl oz/100 lbs of seed	0.13 lbs a.i./100 lbs of seed
				on-farm treater	8.0 fl oz/100 lbs of seed	0.051 lbs a.i./100 lbs of seed

860.1300 Nature of the Residue - Plants

The reregistration requirements for plant metabolism have not been fulfilled. In the Phase 4 review (3/11/1991) the registrant, Buckman, was instructed to provide three new plant metabolism studies, one each on corn or wheat, cotton and sugar beets, to determine if any uptake occurred in the aerial portion and/or edible root portion of the growing crop. Based on this information, a determination would be made as to whether TCMTB uses are food or nonfood. Data have been submitted depicting the uptake of TCMTB in corn, cotton, safflower, and wheat and were found to be inadequate due to lack of identification and/or characterization of parent and/or metabolites. Additional metabolism studies conducted with tomatoes and melons have been submitted; however, translation to the currently registered crops is not adequate for reregistration purposes. Confirmatory metabolism data should be submitted depicting the nature of residues in wheat, cotton, and sugar beets. Adequate identification and/or characterization of parent and/or metabolites should be conducted as required by OPPTS 860 Series Guidelines.

The Risk Assessment Review Committee (RARC) met and determined that the interim residue of concern for tolerance expression and risk assessment is TCMTB in/on plants (P. Deschamp, Report of the RARC, 1/11/2006). This is a preliminary decision dependent on the results from the requested metabolism data. For drinking water, the RARC decided that the residues of concern for risk assessment are TCMTB and 2-MBT. Summary of the preliminary decisions concerning the residues of concern in plants and drinking water are presented below in Table 7.

Table 7. Summary of TCMTB Residues to be Included in the Risk Assessment and Tolerance Expression.			
Matrix		Residues Included in Risk Assessment	Residues Included in Tolerance Expression
Plants	Primary crop - barley, cotton, oat, rice, safflower, sugar beet, and wheat	TCMTB	TCMTB
	Rotational crop	NA = not applicable	NA
Livestock	Ruminant	NA	NA
	Poultry	NA	NA
Drinking water		TCMTB and 2-MBT	NA

All submitted studies are summarized below. No data have been submitted depicting the uptake of TCMTB in sugar beets.

Corn, Cotton, Safflower, and Wheat (MRID 42376801 and 43147201)

Buckman submitted a study (MRID 42376801) entitled "Uptake and Translocation of ¹⁴C-Busan

30A Used in Seed Treatment Combustion Analysis Phase".

Uniformly labelled ^{14}C -TCMTB in the benzene ring was applied (as a solution of unknown concentration in an unspecified solvent) to four seed types, corn, cotton, safflower, and wheat at the maximum application rate at the time. No data were submitted depicting residues in/on sugarbeets. The specific activity and radiopurity of the test substance were determined to be 45,600 dpm/ug (5.26 mCi/mmol) and 100%, respectively. Seeds were added to amber bottles that contained the radioactive material and placed on a roller for an hour to insure uniform coating. Acetonitrile washes of ten seeds were analyzed by liquid scintillation counting (LSC) and the washed seeds were combusted to determine the rate of application. The remaining seeds were planted. Samples were taken from the aerial portion of the plant at various growth stages. Corn silage, haylage, grain and stover; wheat forage, hay, grain and straw; safflower forage, seed, thinnings, and stalk; and cotton forage samples were obtained. Control samples showed some uptake of radioactivity which increased with time. The registrant concluded that this was a result of housing the control samples in the same greenhouse with the treated plants. The Health Effects Division (HED) previously concurred with this assumption; however, some of the control samples contained higher radioactive residues than its treated counterpart. The treated samples were stored frozen before processing and were analyzed by high-performance liquid chromatography (HPLC) using an ultraviolet detector (UV).

Radioactive residues were found in all plant parts with the least amount of residue in corn commodities (0.0011-0.0021 ppm). The highest residues were found in cotton forage samples (2.7856 ppm). Cotton forage samples were analyzed for the presence of 2-MBT. No 2-MBT residues were found in the aqueous or organic cotton forage extracts. During the HPLC analysis of both the aqueous and organic extracts, a peak was noted to elute with a retention time similar to that of TCMTB. The identity of this peak was not confirmed by alternative means. Additionally, the registrant stated that subsequent analyses for the presence of 2-MBT in other plant extracts were being performed; however, no additional data have been submitted to the Agency for review.

Buckman submitted an addendum (MRID 43147201) to the previous study report (MRID 42376801) evaluating the uptake and translocation of C^{14} -TCMTB in seed treatment of corn, wheat, safflower and cotton. This addendum includes the results of combustion analysis of radioactive residues in cotton seed, lint, and stalk. These results were not included in the previous study report because the treated cotton plants were not mature when the report was prepared. Table 8 below presents the results of the initial study and the addendum report.

Crop	Harvest Point	Days Harvested After Planting	Total DPM/G ¹	Corrected ppm ²
Corn	Haylage	62 days	68.4	0.0015
	Silage	114 days	95.8 ³	0.0021
	Grain	139 days	54.7	0.0012
	Stover	139 days	50.2	0.0011
Cotton	Forage	52 days	127000	2.7856
	Seed	211 days	192	0.0041
	Lint	211 days	264	0.0058
	Stalk	211 days	502	0.0110

Table 8. Radioactivity in Corn, Cotton, Safflower, and Wheat.				
Crop	Harvest Point	Days Harvested After Planting	Total DPM/G ¹	Corrected ppm ²
Safflower	Forage	49 days	948.5	0.0208
	Seed	147 days	478.8	0.0105
	Stalk	147 days	1860	0.0408
Wheat	Forage	22 days	18660	0.4092
	Hay	63 days	1158	0.0254
	Grain	141 days	538.1	0.0118
	Straw	141 days	3083	0.0676

1. Total dpm/g = corrected ppm X specific activity.
2. Corrected for machine recovery and matrix recovery.
3. Sample was combusted twice. Number represents average of both combustions.

Residues of 0.0011 ppm to 2.7856 ppm total radioactivity (TCMTB equivalents) were found demonstrating uptake of TCMTB residues in crop parts. Identification and/or characterization of parent and/or metabolites were not performed. The solvent and TCMTB concentration in the treatment solution was not provided as well as the seed treatment rate. Both of these should be comparable with the commercial/agricultural practices. Residues were found above 0.005 ppm, which is the trigger value for food-use classification. Additional metabolism studies should be conducted with corn or wheat, cotton, and sugar beets where identification and/or characterization of parent and/or metabolites are completed.

Melon (MRID 44654101)

Transplanted melon plants were grown in two confined plots. The treated plot received two soil-drench applications of ¹⁴C-TCMTB containing 20.0 mCi and supplementary unlabelled TCMTB in blank formulation of Busan 30 WB, so that the applications were equivalent to approximately 5.0 lb a.i./A. The applications were made at the time of transplanting and again 14 days later. Immature melons (0.78 kg) were sampled at a preliminary sampling, at 29 days after last application. At the sampling at maturity, approximately 5.4 kg of melons was sampled and 0.59 kg of mature plant material was also taken. At all sampling events, the plant material was promptly frozen. It was stored frozen and shipped frozen to the analytical laboratory. The melons were stored and shipped under refrigeration to facilitate handling and chopping at the analytical laboratory.

On receipt at Xenobiotic Laboratories, the fruit and plant material were frozen and homogenized and samples were taken for determination of the total radioactive residue (TRR) of each matrix. No radioactivity was detected in any of the untreated samples (<0.001 ppm). The immature treated melons contained 0.304 ppm and the immature plant material contained 0.532 ppm and the mature plant material contained 8.00 ppm of radioactivity as TCMTB-equivalents.

The parent compound, TCMTB, was found only in the plant material and at very low concentration, 0.073 ppm. One principle metabolite, 2-BTSA, was found in both the fruit and plant material. It was present in the fruit at 0.170 ppm and in the plant material at 1.12 ppm. 2-OH-BT and 2-MBT were also detected, but at <0.01 ppm in fruit and at 0.203 ppm and 0.010 ppm in the plant, respectively. Two positional isomers of OH-2-BTSA were also detected, but primarily in the plant at 0.113 ppm and 0.097 ppm. In addition, ¹⁴C incorporation was also detected in sucrose, fructose, and glucose at more than 27% of TRR. Table 9 presents the results

of the melon metabolism study.

Table 9. Major TCMTB Metabolites Found in Melons.

Compound	Residue			
	Melon Fruit		Melon Plant	
	ppm	%	ppm	%
TCMTB	<0.001	0	0.073	0.9
2-BTSA	0.170	31.9	1.12	14.0
2-OH-BT	0.007	1.3	0.203	2.5
2-MBT	0.004	0.7	0.010	0.1
OH-2-BTSA ¹	0.006	1.1	0.113	1.4
OH-2-BTSA ¹	0.039	7.3	0.097	1.2
Sugars ²	0.144	27.1	0.032	0.4
Totals	0.370	69.4	1.65	20.5
Post-Extraction Solids	0.109	20.5	5.80	72.5
Grand Totals	0.479	89.9	7.45	93.0

1. Two positional isomers of hydroxy-2-benzothiazolesulfonic acid were detected. The exact position of the hydroxyl group could not be determined.

2. Sucrose + glucose + fructose with ¹⁴C incorporation.

Tomato (MRID 44654102)

Transplanted tomato plants were grown in two confined plots. The treated plot received two soil-drench applications of ¹⁴C-TCMTB containing 20.0 mCi and supplementary unlabelled TCMTB in blank formulation of Busan 30 WB, so that the applications were equivalent to approximately 5.0 lb a.i./A. The applications were made at the time of transplanting and again 14 days later. Immature tomatoes (0.24 kg) were sampled at a preliminary sampling, at 29 days after last application. Tomatoes were sampled twice at maturity, approximately 1.0 kg of ripe tomatoes was sampled at 56 days after last application and 1.5 kg of ripe tomatoes as well as 1.2 kg of green tomatoes were sampled two weeks later. In addition, approximately 1.0 kg of mature plant material was also taken. Samples were taken from the untreated control plants on the same schedule. At all sampling events, the plant material was promptly frozen. It was stored frozen and shipped frozen to the analytical laboratory. The tomatoes were stored and shipped under refrigeration to facilitate handling and chopping at the analytical laboratory.

On receipt at Xenobiotic Laboratories, the fruit and plant material were frozen and homogenized and samples were taken for determination of the total radioactive residue (TRR) of each matrix. No radioactivity was detected in any of the untreated samples (<0.001 ppm). The immature (29 day sampling) treated tomatoes contained 0.298 ppm and the immature plant material contained 6.41 ppm of radioactivity as TCMTB-equivalents. The mature (56 day sampling) treated tomatoes contained 0.221 ppm and the mature plant material contained 4.08 ppm of radioactivity as TCMTB-equivalents.

The parent compound, TCMTB, was not found in the tomato fruit or in the plant material, <0.001 ppm. One principle metabolite, 2-BTSA, was found in both the fruit and plant material. It was present in the fruit at 0.136 ppm and in the plant material at 1.33 ppm. Two positional isomers of OH-2-BTSA were also detected, but only in significant quantities in the plant material (0.272 ppm and 0.590 ppm). In addition, ¹⁴C incorporation was also detected in sucrose, fructose, and glucose at more than 18% of TRR. Table 10 presents the results of the tomato metabolism study.

Table 10. Major TCMTB Metabolites Found in Tomatoes.

Compound	Residue			
	Tomato Fruit		Tomato Plant	
	ppm	%	ppm	%
TCMTB	<0.001	0	<0.001	0
2-BTSA	0.136	61.7	1.33	32.6
OH-2-BTSA ¹	0.015	6.9	0.272	6.7
OH-2-BTSA ¹	0.004	1.6	0.590	14.5
Sugars ²	0.031	14.1	0.193	4.7
Unidentified	0.008	3.6	0.494	12.1
Totals	0.194	87.9	2.88	70.6
Post-Extraction Solids	0.017	7.8	0.927	22.7
Grand Totals	0.211	95.7	3.81	93.3

1. Two positional isomers of hydroxy-2-benzothiazolesulfonic acid were detected. The exact position of the hydroxyl group could not be determined.

2. Sucrose + glucose + fructose with ¹⁴C incorporation.

The reregistration requirements for plant metabolism have not been fulfilled. Data have been submitted depicting the uptake of TCMTB in corn, cotton, safflower, and wheat and were found to be inadequate due to lack of identification and/or characterization of parent and/or metabolites. Additional metabolism studies conducted with tomatoes and melons have been submitted; however, translation to the currently registered crops is not adequate for reregistration purposes. Confirmatory metabolism data should be submitted depicting the nature of residues in wheat, cotton, and sugar beets. Adequate identification and/or characterization of parent and/or metabolites should be conducted as required by OPPTS 860 Series Guidelines. The Risk Assessment Review Committee (RARC) met and determined that the interim residue of concern for tolerance expression and risk assessment is TCMTB in/on plants (P. Deschamp, Report of the RARC, 1/11/2006). This is a preliminary decision and additional confirmatory data should be submitted in a timely manner. For drinking water, the RARC decided that the residues of concern for risk assessment are TCMTB and 2-MBT.

The determination of the residues of concern in plant commodities is based on the tomato and melon metabolism studies and the available toxicity data. 2-BTSA was found at significant levels (62% in tomato fruit); however, it should be excluded as a residue of concern because it is expected to be less toxic than the parent TCMTB. 2-BTSA is likely to not contribute significantly to the chronic toxicity of the parent based on the following considerations:

1. 2-BTSA has a very polar structure lacking the structural features of the parent (TCMTB) that might lead to toxicologically significant species. Although the mode of toxic action of the parent is not known, its thiocyanomethylthio group is likely to be metabolized to toxic species. This group is not present in 2-BTSA. Thus, 2-BTSA cannot contribute to toxicity via this group.
2. If the benzimidazole ring of TCMTB is involved in its toxic effects by biotransformation to electrophilic species, 2-BTSA is not likely to undergo this type of biotransformation. 2-BTSA, being a sulfonic acid, is expected to undergo little or no metabolism. Small-molecule sulfonic acids generally undergo little or no biotransformation. For example, methanesulfonic, benzenesulfonic, and naphthylaminesulfonic acids are excreted untransformed in laboratory animals (Biological Basis of Detoxication, Caldwell J. & Jakoby W.B. [eds], 1984, p. 162).

3. In a chemical with a mercapto group (-SH), oxidation of the mercapto group to the corresponding sulfonic acid is known to produce a marked decrease in toxicity. For example, phenyl mercaptan (i.e. benzenethiol) is a fairly toxic chemical producing neurotoxicity, liver toxicity, and other effects and has a rat acute oral LD₅₀ of 46 mg/kg (McCord & Witheridge, 1949, cited in NIOSH website). In contrast, the oxidized form, benzenesulfonic acid is reported as having a rat acute oral LD₅₀ of 890 mg/kg (Benzenesulfonic acid MSDS). This marked decrease of toxicity can be attributed to polarity resulting from the replacement of the -SH group with a sulfonic acid group.
4. 2-BTSA is the oxidized (sulfonic acid) form of 2-MBT; thus, it is expected to be equally or less systemically toxic than 2-MBT by analogy with the benzenethiol/benzenesulfonic acid pair of compounds. Barring high-dose effects such as gastrointestinal effects, the chronic RfD for 2-MBT of 0.6 mg/kg/day set by the HED RfD/Peer Review suggests that the chronic toxicity of 2-BTSA is much smaller than that of the parent TCMTB with a chronic RfD of 0.013 mg/kg/day. Although there are concerns for the carcinogenic potential of 2-MBT (Group C), there are no such concerns for 2-BTSA due to its very high polarity and probable absence of metabolism.

Additionally, 2-MBT and other TCMTB metabolites were not found at significant levels to be considered residues of concern. Therefore, only TCMTB should be considered a residue of concern in plant commodities.

For drinking water, the residues of concern should include TCMTB and 2-MBT and is based on the available aerobic soil metabolism study (MRID 43532201). 2-BTSA was found at 71% TRR; however, it should be excluded as a residue of concern for reasons noted in the above section. 2-MBT was found at 30% TRR after 1.5 days post-treatment and should be considered a residue of concern. 2-MBT is distinctly less toxic than the parent; however, it can not be ruled out as a residue of concern and should be included in the dietary risk assessment. All other metabolites were not found at significant levels; therefore, they should not be considered residues of concern.

860.1300 Nature of the Residue – Livestock

Livestock metabolism studies may be required if the requested plant metabolism studies show uptake of residues. If livestock metabolism studies are required, the registrant must provide poultry and ruminant metabolism studies following OPPTS 860 Series Guidelines.

860.1340 Residue Analytical Methods – Plants

A tolerance enforcement method is available for determining thiobenzothiazole-containing residues in barley, corn, cotton, oat, rice, safflower, sugar beet, and wheat. This method was originally submitted with Pesticide Petition (PP) 0F0954 by Buckman. Residues are extracted by blending with water and the extract is refluxed with NaOH. After partition with CH₂Cl₂, glacial acetic acid and sulfuryl chloride are added to convert the residues to 2-chlorobenzothiazole, which is determined by a gas-liquid chromatography (GLC) method using an electron capture detector (ECD). The quantitation limit of the method has been determined at 0.10 ppm. This method is listed as Method B in PAM Vol. II. The method is outdated and uses toxic reagents; therefore, if an additional method that is adequate for tolerance enforcement is available, it

should be submitted immediately for review.

Two data-collection methods are available for determining thiocyanate-containing residues. The first method was originally submitted with PP 0F0954 by Buckman for the determination of residues in barley, corn, cottonseed, oat, rice, and wheat. Residues are extracted with benzene and the extract is cleaned up with liquid-liquid extractions (isooctane to H₂SO₄-water and then H₂SO₄-water to CH₂Cl₂). The TCMTB residue is heated with sodium polysulfide solution to liberate thiocyanate ion. Bromine is added to convert the thiocyanate to cyanogens bromide; then the cyanogen bromide is treated with pyridine-benzidine reagent to form an intensely colored dye. The absorbance of the dye solution is determined at 532 nm. In a method tryout, the Agency obtained recoveries of 90% and 110% (duplicate samples) at the 0.10 ppm fortification level and 105% and 115% (duplicate samples) at the 0.20 ppm fortification level. The quantitation limit of the method has been determined at 0.10 ppm. The method is listed as Method I in PAM Vol. II.

The second method was originally submitted with PP 5F1613 by Buckman for the determination of residues in safflower seed, sorghum grain and foliage, and sugar beet and foliage. TCMTB is extracted from samples by blending with acetone. The extract is filtered and cleaned up on a Florisil column, and TCMTB is eluted with benzene. After liquid-liquid partitioning, the same procedure described above for Method I is followed. Samples of safflower seed, sorghum grain and foliage, and sugar beet and foliage were fortified with 0.10 ppm to 0.30 ppm TCMTB and recoveries ranged from 70% to 93%. The quantitation limit of the method has been determined at 0.10 ppm. The method is listed as Method A in PAM Vol. II.

If the requested metabolism studies show additional residues are of concern and the current enforcement method does not capture these additional residues, development of a method capable of doing so will be required.

860.1340 Residue Analytical Methods - Livestock

This requirement is put on reserve pending the results from the requested plant metabolism studies, and if required, the livestock metabolism studies.

860.1360 Multiresidue Methods

There is no information in the review documents regarding submittal of data for FDA Multiresidue Methods by the petitioner. However, the FDA PESTDATA database dated 11/2001 (PAM Volume I, Appendix I) indicates that TCMTB *per se* is completely recovered (>80%) using Multiresidue Methods Section 302 (Luke Method), but is only partially recovered (50-80%) using 303 (Mills, Onley, Gaither Method) and 304 (Mills fatty food Method).

If additional residues of concern are determined from the requested metabolism studies, all additional residues of concern for tolerance expression will need to be tested through Multiresidue Methods.

860.1380 Storage Stability

Storage stability data for TCMTB in/on barley, cotton, oat, rice, wheat, safflower, and sugar beet have not been submitted by the registrant. No data were provided on how long samples from the

submitted field trials were stored prior to analysis; therefore, storage stability data for the previously submitted field trials are required and should be submitted immediately. Additionally, if field trials are required or additional uses are requested, storage stability data will be required under this guideline topic.

860.1400 Water, Fish, and Irrigated Crops

TCMTB is not intended for direct use on water and aquatic food and feed crops; therefore, no residue chemistry data are required under this guideline topic.

860.1460 Food Handling

TCMTB is not intended for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

860.1480 Meat, Milk, Poultry, and Eggs

TCMTB is not intended for application to livestock. The grain crops, byproducts, and forages are livestock feed items. It is therefore necessary to consider if TCMTB residues are transferred to meat, milk, poultry, and eggs of livestock through ingestion of the residue-bearing commodities.

It has been indicated in the foregoing considerations that the nature of residue in plants has not been adequately described. In the absence of such data, the residue level is unclear.

No livestock feeding studies have been submitted. If the requested residue data show finite residues in the feed items, livestock feeding studies would be essential to an evaluation of the transfer of residues to milk, meat, poultry, and eggs. Therefore, no valid conclusions relative to 40 CFR §180.6 (the necessity of tolerances in livestock commodities) can be made in the absence of livestock feeding studies.

860.1500 Crop Field Trials

The available field trial data are not adequate according to current OPPTS 860 Series Guidelines. The correct number of field trials, number samples collected, and locations of trials are all insufficient. Additionally, no storage stability data were submitted with the field trial studies and the application rates are unknown for the barley, corn, oat, rice, and wheat studies. The method used for determining residues in barley, corn, oat, rice, and wheat is the data-collection method which only determines the thiocyanate ion (Method I or A in PAM Vol. II). The method used for determining residues in cotton is the tolerance enforcement method which determines thiobenzothiazole-containing residues (Method B in PAM Vol. II). If the requested metabolism studies show that additional metabolites of concern are expected, new field trials should be conducted in which the method samples for all residues of concern as determined by the tolerance expression. Field trial data are not available for sugar beets; therefore, magnitude of residue data in sugar beets should be submitted following all OPPTS 860 Series Guidelines.

Cotton (MRID 00004239)

Cotton: Four studies reflecting seed treatments of 2-3 oz of Busan 72/100 lbs seed are reported.

The exact application rate in lbs a.i./100 lbs of seed is unknown. Control values ranged from 0.01 ppm to 0.04 ppm, with values from treated samples ranging from 0.01 ppm to 0.09 ppm. These data are inadequate to determine whether or not real residues are present. Additionally, no data on cotton gin byproducts have been provided and are currently required.

Barley, Corn, Oat, Rice, and Wheat (MRID 00117874)

Barley: Grain and foliage samples were obtained from crops in Wisconsin, Tennessee, and North Dakota which had received seed treatments of 0.7x to 5.6x the original application rate. Apparent residues in grain or foliage were 0.01-0.04 ppm. Untreated grain or foliage samples had residues of 0.01-0.04 ppm.

Corn: Grain and foliage samples were obtained from crops in Indiana, Illinois, Kansas, Missouri, and Wisconsin which had received seed treatments of 1x to 1.5x the original application rate. Apparent residues in grain or foliage were 0.01-0.04 ppm. Untreated grain and foliage samples had residues of 0.01-0.05 ppm.

Oat: Grain and foliage samples were obtained from crops in Arkansas and Wisconsin which had received seed treatments of 0.6x to 1.4x the original application rate. Apparent residues in grain and foliage were 0.02-0.04 ppm. Residues in untreated grain and foliage samples were 0.02-0.04 ppm.

Rice: Grain and foliage samples were collected from crops in Arkansas and Louisiana which had received seed treatments of 1x to 2.4x the original application rate. Apparent residues in grain and foliage were 0.02-0.04 ppm. Residues in untreated grain or foliage were 0.02-0.04 ppm.

Wheat: Samples of grain and foliage were taken from crops in Arkansas and North Dakota which had received seed treatments of 1.2x to 5.6x the original application rate. Apparent residues in grain and foliage were 0.02-0.04 ppm. Residue in untreated grain and foliage samples were 0.02-0.04 ppm.

A comparison of the data for the field studies of all the crops indicates that there is no significant difference between residue levels for the treated and untreated crops (grain or foliage). It may be concluded that no residues of the parent compound, TCMTB, are likely to occur in the grain or foliage of barley, cotton, corn, oats, rice, and wheat from the current use pattern. Thus, the tolerance level of 0.1 ppm represents the analytical method's sensitivity rather than determinable residues.

The above conclusions apply only to the residues of the parent compound. No data have been submitted indicating if plant residues contain components other than the parent compound. If additional metabolism data show the presence in the residue of components other than the parent compound in significant quantities, then residue data on the subject crops may be necessary.

860.1520 Processed Food and Feed

No processing studies have been submitted. Once the requested metabolism studies have been submitted, reviewed, and the metabolites of concern are determined, data should be submitted which show whether residues concentrate in the byproducts of the registered raw agricultural commodities. If concentration occurs, and the concentrated residue levels exceed the proposed

tolerance, then food additive tolerances to cover such residues will be necessary.

860.1650 Submittal of Analytical Reference Standards

An analytical reference standard for TCMTB was submitted by Buckman in February of 2002 and expires February of 2012. The standard is available at the EPA National Pesticide Standards Repository. If additional residues are included in the tolerance expression based on the requested metabolism data, analytical reference standards should be submitted and replenished as requested by the Repository.

860.1850 Confined Accumulation in Rotational Crops and 860.1900 Field Accumulation in Rotational Crops

TCMTB treated seeds were planted in silt loam and yellow clay loam soils. The seeds were treated at 0.75-4.5 fl oz/100 lbs seed. Less than 0.10 ppm of TCMTB residues were noted in the soils at intervals of 30 days and beyond.

Loess and clay loam soils were treated in-furrow or broadcast at 1.2-1.6 lbs a.i./100 lbs seed (9x the current maximum seed treatment rate). Residues were 1.1-1.7 ppm at 30 days, 0.6-1.0 ppm at 100 days, less than 0.10-1.0 ppm at 189 days, and less than 0.10 ppm at 215 days.

Sandy loam and silt loam soils were treated at 0.72-4.32 lb a.i./100lbs seed. Residues were less than 0.10-1.0 ppm at 30 days and less than 0.10 ppm at 60 days.

It is unclear which method was used to determine residue levels in the above soil persistence studies. The registrant should provide method data along with storage stability data in order for the data to be considered scientifically adequate. However, with the exception of storage stability and method data, soil persistence is not likely to be a concern with respect to follow-up crops. However, the method used is unknown and the exact compounds that make up the residues found is unknown; therefore, this data requirement is put on reserve awaiting submission of the requested data and pending the results from the plant metabolism studies.

Tolerance Reassessment Summary

Tolerances for residues in/on plant livestock commodities have been established under 40 CFR §180.288. The tolerances for residues of TCMTB in/on plant commodities is expressed in terms of residues of TCMTB *per se* [(2-benzothiazolylthio)methyl thiocyanate].

Tolerances Established Under 40 CFR §180.288

Confirmatory metabolism data conducted with wheat, cotton, and sugar beet are requested to determine the nature of residues in plants. Depending on the results from the requested confirmatory metabolism studies, additional guideline requirements may be requested for: livestock metabolism; enforcement and data-collection methods; multiresidue methods; storage stability; and livestock, crop, processed commodity, and rotational crop magnitude of residue studies. A summary of the TCMTB tolerance reassessment is presented below in Table 11.

Tolerances To Be Proposed Under 40 CFR §180.288

Because of changes to Table 1 (OPPTS 860.1000), tolerances for barley hay and cotton gin byproducts must be proposed.

Table 11. Tolerance Reassessment Summary for TCMTB.			
Commodity	Current Tolerance	Tolerance Reassessment	Comment/[Correct Commodity Definition]
Tolerances Established Under 40 CFR §180.288:			
Barley, grain	0.1 (N) ¹	TBD ²	
Barley, straw	0.1 (N)	TBD	
Beet, sugar, roots	0.1 (N)	TBD	
Beet, sugar, tops	0.1 (N)	TBD	
Corn, grain	0.1 (N)	Revoke	The registrants do not intend to support use of TCMTB on corn.
Corn, forage	0.1 (N)	Revoke	The registrants do not intend to support use of TCMTB on corn.
Corn, stover	0.1 (N)	Revoke	The registrants do not intend to support use of TCMTB on corn.
Cotton, forage	0.1 (N)	Revoke	No longer considered a significant livestock feed item.
Cotton, undelinted seed	0.1 (N)	TBD	
Oat, forage	0.1 (N)	TBD	
Oat, grain	0.1 (N)	TBD	
Oat, hay	0.1 (N)	TBD	
Oat, straw	0.1 (N)	TBD	
Safflower, seed	0.1 (N)	TBD	
Sorghum, grain, forage	0.1 (N)	Revoke	The registrants do not intend to support use of TCMTB on sorghum.
Sorghum, grain, grain	0.1 (N)	Revoke	The registrants do not intend to support use of TCMTB on sorghum.
Sorghum, grain, stover	0.1 (N)	Revoke	The registrants do not intend to support use of TCMTB on sorghum.
Wheat, forage	0.1 (N)	TBD	
Wheat, grain	0.1 (N)	TBD	
Wheat, hay	0.1 (N)	TBD	
Wheat, straw	0.1 (N)	TBD	
Tolerances To Be Proposed Under 40 CFR §180.288:			
Barley, hay	None established	TBD	
Cotton, gin byproducts	None established	TBD	

1. N = Negligible. The "N" designation must be removed from all tolerances.

2. TBD = To be determined. Tolerances cannot be determined at this time because additional data are required.

Codex Harmonization

There are no Codex maximum residue limits (MRLs) for TCMTB; therefore, no questions of compatibility with U.S. tolerances exist.

Bibliography

Agency Memoranda Citations

Date	DP Barcode	PP No.	From	To	MRID Nos.	Subject
12/16/1993	D187529	None	F. Fort	V. Dietrich and B. Sidwell	42376801	TCMB. Uptake of ¹⁴ C from Seed Treatment. Case No. 2625. Chemical No. 035603. MRID No. 42376801. CBRS No. 11294. DP Barcode D187529.
5/11/1998	D221887	None	M. Perry	M. Swindell	20431471	TCMTB. Uptake of ¹⁴ C from seed treatment. Case No. 2625. Chemical No. 035603. MRID No. 43147201. DP Barcode D221887.
7/31/1970	None	0F0954	A. Rathman	None	None	PP #0F0954: TCMTB on cotton, as amended. Evaluation of analytical method and residue data.
9/23/1972	None	2F1264	A. Smith	None	None	PP #2F1264. TCMTB in small grain crops.

Master Record Identification Numbers

00004239 Wilbur-Ellis Company (1979) Residue Data Summary. Unpublished study including letter dated Oct 16, 1978 from J.H. Stoner to Dave T. Schulteis, received Feb 6, 1979 under 2935-413; pre-pared in cooperation with Stoner Laboratories; CDL:237334-A

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