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

JUL 25 1991

OFFICE OF
PESTICIDES AND TOXIC

MEMORANDUM

SUBJECT: Thiram Product and Residue Chemistry Reregistration Standard Updates (CBRS # 7480; Barcode No. D159555.).

FROM: E. Zager, Chief
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

TO: Lois Rossi, Chief
Reregistration Branch
Special Review & Reregistration Division (H7508C)

and

Reto Engler, Ph.D., Chief
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

Attached are the updates to the Product and Residue Chemistry Chapters of the Thiram Reregistration Standard as well as a review of cropfield trial data on cottonseed (MRID # 41065001). These updates and review were prepared by Acurex Corporation under supervision of CBRS, HED. They have undergone secondary review in the Branch and have been revised to reflect Agency policies.

Revised data requirement tables are included.

If you need additional input please advise.

Attachment 1: Thiram Product Chemistry Reregistration Standard Update.

Attachment 2: Thiram Residue Chemistry Reregistration Standard Update and a Review of a Cotton Cropfield Trial

Attachment 3: Confidential Appendices A, B, C, D, and E of the Thiram Product Chemistry Update

ATTACHMENT 2

THIRAM
(Chemical Code 079801)

TASK 3

Reregistration Standard Update

Residue Chemistry

June 21, 1991

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

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THIRAM

REREGISTRATION STANDARD UPDATE

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INTRODUCTION

Thiram is a fungicide registered for foliar, soil, and seed-treatment applications. The SP05 Site Listing for thiram dated December, 1990 indicates that multiple foliar applications are permitted on apples, bananas, celery, peaches, strawberries, and tomatoes. Soil treatments are registered for beans (lima, snap, and string), celery (plant bed and seed bed), cotton, onions (bulb), and soybeans. Root-dip applications are permitted to sweet potato sprouts. Thiram is also registered for seed treatment to alfalfa, barley, beans (castor, cowpeas, lima, snap, and string), beets (garden and sugar), broccoli, Brussels sprouts, cabbage, cantaloupes, carrots, cauliflower, chard, clover, collards, corn (field and sweet), cotton (acid and machine delinted, fuzzy, and reginned), cucumber, eggplant, endive, flax, grasses, kale, kohlrabi, legumes (small seed), lentils, lettuce, millet, mustard, oats, okra, onions, peas, peanuts (shelled), peppers, pumpkin, radishes, rice, rye, safflower, sesame seed, sorghum, soybeans, spinach, squash, sunflower, Swiss chard, tomatoes, triticale, turnips, watermelon, and wheat. Formulations registered for the treatment of seed of food and feed crops include the 2.9 lb/gal soluble concentrate/liquid (SC/L), the 2.9 and 4 lb/gal flowable concentrate (FLC), the 50% wettable powder (WP), and the 1.2 lb/gal ready-to-use (RTU). Use directions for seed treatments were obtained from the Gustafson, Inc., product labels and are summarized in Table 1.

Thiram was the subject of a Residue Chemistry Chapter dated February 3, 1984, and a Guidance Document dated June 29, 1984, in which additional data were required for plant and animal metabolism, residue analytical methods, storage stability data, and residues in or on numerous crops, including those with only seed treatments, should those uses be categorized as food uses. Subsequently, preliminary plant metabolism data showed residue uptake into the leaf and stem parts of tested plants, and the Agency concluded that these uses are considered food uses (memorandum of April 14, 1987 conference, R.Quick, CBRS).

In response to these requirements, Gustafson, Inc., submitted data concerning metabolism in goat and poultry (1989; MRIDs 41006201 and 41006202) that were reviewed by CBRS (C. Deyrup, CBRS No. 5168 dated August 7, 1989), and metabolism in cotton, soybean, and wheat (1986; MRID 00162142 and 1987 MRID; 40216502) that were reviewed by CBRS (R. Perfetti, CBRS No. 6733 dated March 20, 1991). Gustafson, Inc., also submitted 12 studies (1988; MRID 41065001 under CBRS No. 7480 and MRIDs 41065001 to -07; 1989-1990; MRIDs 41503601 to -05) concerning residues of thiram in beets, cotton, corn (field and sweet), beans (succulent and dry), lettuce, peas, safflower, soybeans, sugar beets, and wheat grown from treated seed.

Table 1. Summary of registered application of thiram to seed.

Product Formulations/ EPA Reg. Nos. Registered for Use on Seed	Crop	Application Rate to Seed	
		Oz. ai/cwt.	Oz. ai/bu.
4 lb/gal FlC EPA Reg. No. 7501-14 2.9 lb/gal FlC EPA Reg. No. 7501-17 2.9 lb/gal SC/L EPA Reg. No. 7501-64 50% WP EPA Reg. No. 7501-105 1.2 lb/gal RTU EPA Reg. No. 7501-123	Alfalfa	1.8-4	
	Barley	1.16-2.05	1
	Beans (snap, dry, cowpeas)	1	0.6
	Beans (lima)	1.4-1.5	
	Beets (garden, sugar)	2.40-4	
	Broccoli	2.40-4	
	Brussels sprouts	2.40-4	
	Cabbage	2.40-4	
	Cantaloupe	1.28-2.25	
	Carrots	2.40-4	
	Castor beans	2.25	
	Cauliflower	2.40-4	
	Clover	1.8-4	
	Collards	2.40-4	
	Corn (field)	0.75-1.5	0.75
	Corn (sweet)	1.47-2.5	
	Cotton	0.86-2.25	
	Cucumber	1.28-2.25	
	Eggplant	1.79-3.25	
	Endive	2.40-4	
	Flax	1.40-2.65	1.5
	Grasses	2.40-4	
	Kale	2.40-4	
	Kohlrabi	2.40-4	
	Legumes (small seeded)	1.8-4	

(continued)

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Table 1. (continued)

Product Formulations/ EPA Reg. Nos. Registered for Use on Seed	Crop	Application Rate to Seed	
		Oz. ai/cwt.	Oz. ai/bu.
4 lb/gal FlC EPA Reg. No. 7501-14 2.9 lb/gal FlC EPA Reg. No. 7501-17 2.9 lb/gal SC/L EPA Reg. No. 7501-64 50% WP EPA Reg. No. 7501-105 1.2 lb/gal RTU EPA Reg. No. 7501-123	Lentils	1.49	
	Lettuce	2.40-4	
	Millet	1.22-2	1
	Mustard	2.40-4	
	Okra	3	
	Onions	1.79-3	
	Peanuts (shelled)	0.30-2.25	
	Peas	1.4-1.5	
	Peppers	2.40-4	
	Pumpkin	1.28-2.25	
	Radish	2.40-4	
	Rice	0.75-3.18	0.75
	Rye	0.98-1.89	1
	Safflower	0.98-2	1
	Sesame	1.5	
	Sorghum	1.22-1.55	1
	Soybeans	0.72-1.65	0.6
	Spinach	2.40-4	
	Squash	1.28-2.25	
	Sunflower	1	
	Swiss chard	2.40-4	
	Tomato	1.79-3	
	Turnip	2.40-4	
	Watermelon	1.28-2.25	
	Wheat	0.92-1.65	1

Tolerances for residues in or on food and feed commodities are expressed in terms of thiram per se (40 CFR §180.132), and have been established for apples, bananas, celery, onions (bulb), peaches, strawberries, and tomatoes.

SUMMARY

The following additional residue chemistry data are required:

- Additional data from cotton, wheat, and soybean metabolism studies. If any registrant wishes to support the registered foliar and soil uses, metabolism studies on additional crops will be required.

- Additional information from the submitted seed treatment studies. Further testing is required for certain commodities. Data from processing of pertinent commodities.

QUALITATIVE NATURE OF THE RESIDUE IN PLANTS

The Thiram Guidance Document dated June, 1984 requested data concerning the uptake, translocation, and metabolism of [^{14}C]thiram in a small grain crop, a root crop, and a leafy vegetable. It specified that the plants were to be subjected to soil and subsequent foliar treatments. In addition, the registrant was required to provide data depicting the uptake and translocation of [^{14}C]thiram in a small grain crop, soybean, and cotton grown from treated seed to determine whether seed treatments should be considered non-food uses or whether tolerances should be required for residues in or on commodities grown from treated seed.

In response to the request for data reflecting seed treatment, Uniroyal Chemical Co. submitted data on wheat, cotton, and soybean commodities grown from treated seed in MRID 00162142 (1986) and MRID 40216502 (1987). The latter reference contains work conducted with soybean tissue culture metabolism of [^{14}C]thiram to aid in the identification of metabolites in the other tissues. These data were reviewed by R. Perfetti (CBRS No. 6733; March 20, 1991), who concluded that the data were insufficient because only immature plants were used for extraction and characterization studies. Furthermore, he noted that discrepancies in data reporting prevented conclusive determination of the total radioactive residues (TRR) in samples used for extraction and characterization procedures and that no efforts were made to characterize unextracted residues. He noted that identification of metabolites from plant matrices based on comparison with the chromatographic patterns of the residues produced by soybean callus was invalid without quantitative supporting data. Although glycoside (dimethyldithiocarbamoyl- and dimethylthioocarbamoyl-glucoside) and amino acid (cystiene) conjugates were found, the reviewer pointed out that the moiety conjugated to the sugar or amino acid was not fully characterized. The reviewer recommended that a new study be conducted using mature plant commodities. No additional

data have been submitted. The following requirement, repeated from CBRS No. 6733, remains outstanding:

- o New data are required regarding the qualitative nature of the residues in mature plant parts of soybeans, cotton, and wheat plants grown from seed treated with [^{14}C]thiram at rates high enough to permit characterization of ^{14}C-residues. The data should depict the extractability of the total radioactive residues (TRR) and characterization of residues expressed as total radioactive counts, percentage of total recovered radioactivity, and equivalent concentration in the matrix (ppm). Unextractable residues must be characterized, and the moieties in glycoside and amino acid conjugates must be identified. Residues must be characterized on the basis of analysis of the plant extracts themselves. If work with tissue culture is necessary to support the results of plant matrix analysis, a full complement of quantitative data must be provided.

Although insufficient, the available data indicate that residues of thiram in plants may be conjugated to sugars and amino acids.

References (used):

MRIDs: 00162142. 40216502.

Discussion of the data:

N/A.

QUALITATIVE NATURE OF THE RESIDUE IN ANIMALS

The Thiram Guidance Document dated June, 1984 requested data concerning the metabolism of [^{14}C]thiram in ruminants and poultry. In response, Gustafson, Inc. submitted data concerning metabolism of [^{14}C]thiram in goats (1989; MRID 41006201) and hens (1989; MRID 41006202) that were reviewed by the Agency (C. Deyrup, CBRS No. 5168; August 7, 1989). The data from the goat study were deemed insufficient because unextractable residues accounting for almost 30% of the TRR in liver were not characterized and because the only residue component characterized was a glucuronide conjugate that was tentatively identified. Furthermore, none of the residues in milk or other tissues was identified. With regard to the poultry study, the reviewer noted that 30-35% of the radioactivity in eggs and tissues was lost following attempts to separate components using ion exchange. No attempts to characterize ^{14}C-residues in poultry were made. The reviewer noted that these submissions represented progress reports and that additional data were forthcoming. The final reports have not been received.

The following additional data are required:

- o Additional data are required from the study with goats reported in MRID 41006201 (Report No. 89-005). The registrant must present data characterizing ^{14}C-residues in milk and tissues. It is recommended that the samples from animals dosed at 10x be used, because the total radioactive residues levels in these samples are high enough to permit separation and identification of the residues.

- o Additional data are required from the study with poultry reported in MRID 41006202 (Report No. 89-006). The registrant must present data characterizing ^{14}C-residues in eggs and tissues. It is recommended that the samples from animals dosed at 10x be used. Complete characterization of residues in liver is required, including solubilization and identification of unextracted residues. The final report should contain an explanation of the loss of liver radioactivity from the fraction subjected to ion-exchange chromatography. ^{14}C-Residues in the other tissues and eggs that total <0.05 ppm should be partitioned with organic and polar solvents and subjected to TLC or HPLC analysis.

- o Representative samples from metabolism studies must be analyzed using current enforcement methodology to ascertain that all residues of concern can be recovered.

References (used):

MRIDs: 41006201. 41006202.

RESIDUE ANALYTICAL METHODS

Conclusions:

The Thiram Guidance Document dated June 1984, required validated methods (preferably GC) which can be used to enforce the established tolerances for residues of thiram per se in or on apples, celery, peaches, strawberries, tomatoes, bananas, and onions. A validated confirmatory method (preferably MS) was also required. In addition, the Guidance Document noted that if the required metabolism studies reveal additional metabolites of concern, then additional adequate regulatory methods may be required. Also indicated was that the available plant metabolism data, though insufficient, indicate that residues will not be restricted to the surfaces of treated crops. Therefore, surface stripping extraction procedures will not be acceptable. The Residue Chemistry Chapter discussed several colorimetric methods (including the PAM Vol, II methods) that were deemed inadequate because they are general methods for dithiocarbamates and will not selectively quantitate thiram.

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Gustafson, Inc. submitted (1988; MRID 40495201) the description of a colorimetric method (AM-88), and GLC methods used to generate residue data offered in response to the Guidance Document requirements for seed uses (MRIDs 41065001, 41065002, 41065003, 41065004, 41065005, 41065006, 41065007, 41503601, 41503602, 41503603, 41503604, 41503605). The data collection methods separately quantified thiram, its dithioglucoside metabolite (dimethyldithiocarbamoyl-glucoside), and its monothicglucoside metabolite (dimethylthiocarbamoyl-glucoside).

The Pestrack Data Base (PAM Vol. I Appendix) dated November 6, 1990, indicated that it is not likely that thiram is recoverable through any of the FDA Multiresidue Protocols. The Pestrack also indicated that special surveys have occurred, with methods other than the five Multiresidue Methods. The results of these surveys were not available.

The nature of the residue in plants and animals is not adequately understood. Following review of the required plant and animal metabolism studies, the specific requirements for data collection and enforcement methodology will be determined. It should be noted that current enforcement methodology is nonspecific for carbon disulfide (CS_2) generating compounds. The enforcement of tolerances for residues of thiram per se requires methodology capable of quantifying thiram per se and distinguishing it from other CS_2 generators (e.g., EBDCs).

References (used):

MRIDs: 40495201. 41065001. 41065002. 41065003. 41065004. 41065005. 41065006. 41065007. 41503601. 41503602. 41503603. 41503604. 41503605.

Discussion of the data:

Gustafson, Inc., submitted (1988; MRID 40495201) the description of a colorimetric method (AM-88) and GLC methods used to generate residue data in response to the Guidance Document requirements for seed uses (MRIDs 41065001, 41065002, 41065003, 41065004, 41065005, 41065006, 41065007, 41503601, 41503602, 41503603, 41503604, 41503605).

The colorimetric method AM-88 submitted by the registrant is similar to the colorimetric methods discussed in the Residue Chemistry Chapter of 1984 and is not adequate for enforcement purposes because it is a general method for dithiocarbamates and will not selectively quantitate thiram.

Residues in cotton, field and sweet corn, succulent and dry beans, soy beans, wheat, lettuce, peas, safflower, and sugar and table beets were determined by methods designated as modifications to Hazelton Laboratories America, Inc., (HLA) methods MP-THIR-MA, MP-DITH-MA, and MP-MOTH-MA.

The modification of method (MP-THIR-MA) for determining CS_2 generators (including thiram) involves refluxing the sample in a tin chloride/hydrochloric acid solution. Evolved carbon disulfide is carried by gas stream through a purification absorber containing sulfuric acid to remove volatile interferences and through a CS_2 absorber to trap the CS_2 in ethanol at dry-ice temperature. The carbon disulfide is measured by GLC using a 10% SP-1000 column and flame photometric detection.

The method (MP-DITH-MA) for determining the dithioglucoside residues involves extraction into HCl (1 N). The sample is then filtered and washed with chloroform, which removes thiram and other organic soluble CS_2 generators. The aqueous phase is refluxed in the presence of tin chloride to liberate CS_2, which is purified and absorbed in ethanol as for thiram. The CS_2 is then measured by GLC using a 10% SP-1000 column and flame photometric detection in the sulfur mode.

The method (MP-MOTH-MA) for determining the monothioglucoside residues involves drying the sample with magnesium sulfate and then extracting into ethyl acetate in the presence of sulfate. The extract is concentrated and cleaned up using silica Sep-Pak columns. The residues are collected and converted to trimethylsilyl derivatives. The derivatization procedures were not clearly described. A reference cited for this procedure described a different derivatization, but a correlation between the two procedures was not explained. The residue derivatives were analyzed by GLC using a 3% OV-17 column and flame photometric detection in the sulfur mode.

Methods MP-THIR-MA and MP-DITH-MA were modified only by changing the GLC column packing material and temperatures to optimize chromatographic conditions. Method MP-MOTH-MA was modified only by increasing solvent volumes for extracting residues from dried straw samples.

Recovery and validation data are included in Table 2.

The limits of detection were reported as follows: 0.03 ppm for thiram, 0.05 ppm for dithioglucoside, and 0.10 ppm for monothioglucoside in each commodity.

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Table 2. Recovery of thiram and metabolites from plant commodities.

Commodity	Compound Added	Fortification (ppm)	Percent Recovery
Cotton seed	Thiram	0.03	115, 117
		0.15	89, 94
		0.30	79, 92
	Monothioglucoside	0.10	99, 140
		0.50	110, 110
		1.00	77, 96
	Dithioglucoside	0.05	96, 101
		0.25	71, 80
		0.50	78, 84
Lettuce	Thiram	0.03	109, 118
		0.15	93, 102
		0.30	79, 85
	Monothioglucoside	0.10	93, 116
		0.50	116, 116
		1.00	112, 116
	Dithioglucoside	0.05	88, 97
		0.25	104, 118
		0.50	79, 94
Soybean	Thiram	0.03	89, 102
		0.15	91, 98
		0.30	74, 75
	Monothioglucoside	0.10	109, 109
		0.50	87, 94
		1.00	85, 94
	Dithioglucoside	0.05	78, 93
		0.25	101, 114
		0.50	104, 107

(continued)

Table 2. (Continued)

Commodity	Compound Added	Fortification (ppm)	Percent Recovery
Wheat forage	Thiram	0.03	98, 102
		0.15	79, 92
		0.30	77, 87
	Monothioglucoside	0.10	71, 100
		0.50	74, 79
		1.00	91, 103
	Diothioglucoside	0.05	104, 113
		0.25	76, 80
		0.50	92, 98
Wheat grain	Thiram	0.03	93, 93
		0.15	89, 87
		0.30	87, 92
	Monothioglucoside	0.10	65, 65
		0.50	83, 93
		1.00	72, 74
	Diothioglucoside	0.05	93, 131
		0.25	86, 90
		0.50	82, 94

The methods used for collection of data in the current submissions as well as current enforcement methodology are non-specific for CS_2 generating compounds. The enforcement of tolerances for residues of thiram per se requires methodology capable of quantifying thiram per se and distinguishing thiram from other CS_2 generators (e.g., EBDCs). At this time, the nature of the residue in plants and animals is not adequately understood. Therefore, following review of the required plant and animal metabolism studies, the specific requirements for data collection and enforcement methodology for thiram will be determined.

STORAGE STABILITY DATA

Conclusions:

The Thiram Guidance Document of June, 1984 required data demonstrating the stability of thiram residues in or on representative plant and animal samples stored at freezing temperatures for intervals up to one year or for a period approximately that used for the available or required residue studies. The Agency also requires that the storage intervals and conditions be reported for all samples for which data are submitted. No data have been submitted. The following requirements remain outstanding:

- o Data are required depicting the stability of thiram residues of concern in or on all commodities for which data have been submitted or are required to support existing or needed tolerances. Samples bearing weathered residues or fortified samples should be analyzed immediately after harvest or fortification and thereafter at regular intervals and under the conditions corresponding to those of the samples in the submitted residue tests. In addition, all requested residue data must be accompanied by information regarding sample handling and the intervals and conditions of sample storage.

References (used):

N/A.

Discussion of the data:

N/A.

MAGNITUDE OF THE RESIDUE IN PLANTS

Thiram was the subject of a Residue Chemistry Chapter dated February 3, 1984 and a Guidance Document dated June 29, 1984, in which additional data were required for residues in or on numerous crops, including those with only seed treatments, should those uses be categorized as food uses. Subsequently, preliminary plant metabolism data showed residue uptake into the leaf and stem parts of tested plants, and the Agency concluded that these uses are considered food uses (memorandum of April 14, 1987 conference, R.Quick, CBRS).

Gustafson, Inc. submitted a plan for conducting residue testing on seed treatment of dry beans, field corn, lettuce, peas, safflower, soybeans, succulent beans, sugar beets, sweet corn, table beets, and wheat. These data are discussed in the following section. In reviewing the planned tests, the Agency concluded that the representatives of the bulb vegetables, brassica leafy vegetables, cucurbit vegetables, fruiting vegetables, grasses and non-grass animal feeds needed to be tested as well (M.Bradley, CBRS Nos. 1302, 1303, and

2336; July 1, 1987). No data on crops from these groups have been submitted. Additional data are required.

No data have been submitted reflecting multiple foliar applications that are permitted on apples, bananas, celery, peaches, strawberries, and tomatoes, for soil treatments registered for beans (lima, snap, and string), celery (plant bed and seed bed), cotton, onions (bulb), and soybeans, or root-dip applications are permitted to sweet potatoes.

Crops With Seed Treatment Uses Only

Tolerances:

Tolerances have not been established for residues of thiram in or on dry beans, field corn, lettuce, peas, safflower, soybeans, succulent beans, sugar beets, sweet corn, table beets, or wheat.

Use directions and limitations:

The seed treatment uses registered for Gustafson products are summarized in Table 1.

Conclusions:

The Thiram Guidance Document dated June, 1984 indicated that residue data might be required reflecting seed treatments if these were judged to be food uses. The Agency has since decided that seed treatments of thiram on food/feed crops are food uses requiring residue data and tolerances. In response to the Guidance Document, Gustafson, Inc. submitted data (1988; MRIDs 41065002, 41065003, 41065004, 41065005, 41065006, 41065007, 41503602, 41503603, 41503604, 41503605, and 41503601) regarding residues in or on edible commodities of dry beans, field corn, lettuce, peas, safflower, soybeans, succulent beans, sugar beets, sweet corn, table beets, and wheat grown from treated seed. These data indicate that detectable residues of thiram occurred in or on cotton forage; dry bean forage and hay; dry peas, pea forage, and pea hay; succulent bean forage and fodder; sweet corn forage; and wheat forage and straw, and that detectable residues of the dithioglucoside metabolite occurred in or on dry bean forage; pea forage and hay; sweet corn forage; and wheat forage. Otherwise, these residues were below the limit of detection, <0.03 and <0.05 ppm for thiram and its monothioglucoside metabolite respectively. Residues of the monothioglucoside metabolite were <0.1ppm (non-detectable) in or on all of the commodities tested.

The following is required: tolerances need to be established for thiram residues of concern in or on commodities of dry beans, field corn, lettuce, peas, safflower, soybeans, succulent beans, sugar beets, sweet corn, table beets, and wheat grown from thiram-treated seed.

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Appropriate tolerance levels will be decided upon when the residues to be regulated in plants are determined and sufficient data reflecting registered uses are available.

The following additional data are required regarding the individual commodities that were analyzed in the seed treatment studies:

- For cotton, additional information is required from the test described in MRID 41065001. The analytical methods must be validated at the limits of detection with cotton forage.

- For dry beans, additional information is required from the test described in MRID 41065005. Raw validation data are needed for the dithioglucoside metabolite from the forage analysis. For samples from ID, the storage conditions for the 10 days from sampling to storage must be reported. Also, the registrant must explain how the seeds were cleaned prior to analysis. Additional data are required from CO and MI.

- For lettuce, additional information is needed from the test described in MRID 41503601. All data are required regarding thiram residues in or on the samples without wrapper leaves.

- For peas, additional information is required from the test described in MRID 41503602. Data are required regarding thiram residues in or on pea straw. For samples from ID, the storage conditions for the 12 days from sampling to storage must be reported. For samples from CA, MN, and MY the amount of time used to dry the seed and forage between sampling and storage and the associated storage conditions must be reported. The raw data sheets from Hazelton Labs show calculations for thiram that may be incorrect. The registrant should explain these calculations or submit corrections.

- For succulent beans, additional information is required from the test described in MRID 41065004. Sample reports are required regarding the vine samples from tests conducted in CA.

- For sugar beets, additional information is required from the test described in MRID 41503604. All of the sample reports are needed from MN, and data and sample reports for tops at 45 days after planting are needed from tests conducted in CA.

- For sweet corn, additional information is required from the test described in MRID 41065003. All of the data regarding thiram residues on corn kernels is required. Additional geographic representation is needed. Data from tests conducted in CA regarding analysis of the forage are required.

- For wheat, additional information is required from the test described in MRID 41065007. For samples from KS and OH, all of the storage conditions are required. For samples from MS, the storage conditions for the 16 days that occurred between sampling and storage are required. Tolerances above the detection limit may be needed for forage and straw. Data reflecting treatment at 1x (if different from 2.25 oz ai/CWT) will be needed to set the tolerance at the appropriate level.

References (used):

MRIDs: 41065001. 41065002. 41065003. 41065004. 41065005. 41065006. 41065007. 41503601. 41503602. 41503603. 41503604. 41503605.

Discussion of the data:

Gustafson, Inc. submitted data pertaining to the residues of thiram and its monothioglucoside and dithioglucoside metabolites that result from seed treatments using the 4 lb/gal and the 2.7 lb/gal formulations. Residues above the limit of detection occurred in or on cotton forage; dry bean forage and hay; pea seed, forage, and hay; succulent bean forage and fodder; sweet corn forage; and wheat forage and straw. The results are summarized in Table 3.

Table 3. Residues of thiram and metabolites in or on commodities grown from thiram-treated seed.

Crop/Commodity	Rate (oz ai/CWT)	Thiram	Dithioglu-coside	Monothioglu-coside	Number of Samples	Test States
Cotton (MRID 41065001)	3		<0.05	<0.1		CA, AZ, MS, TX, OK
seed		<0.03			18	
forage		0.56			16	
Dry Beans (MRID 41065005)	1			<0.1		CA, ID, ND, NY
forage		<0.03-0.13	0.10, 0.13		13	
bean		<0.03	<0.05		12	
hay		0.1	<0.05		10	
Field Corn (MRID 41065002)	1.5	<0.03	<0.05	<0.1		IA, IL, MO, OH, OK, VA, NY
forage					22	
ear with husk					21	
fodder (milk stage)					21	
grain					18	
fodder (harvest)					18	
Lettuce (MRID 41503601)	4	<0.3	<0.5	<0.1	14	NY, MI, CA
head with wrapper leaves						

(continued)

Table 3. (Continued)

Crop/Commodity	Rate (oz ai/CWT)	Thiram	Dithioglu-coside	Monothioglu-coside	Number of Samples	Test States
Peas (MRID 41503602)	1.65			<0.1		CA, MN, ID, NY
succulent peas with pod		<0.3	<0.05		12	
dry peas		0.04	<0.05		11	
pea forage		<0.03-0.04	<0.05-0.09		11	
pea hay		<0.03-0.15	<0.05-0.16		11	
Safflower (MRID 41503603)	2.8	<0.03	<0.05	<0.1	10	CA, ND, AZ
seed						
Soybeans (MRID 41065006)	1.65	<0.03	<0.05	<0.1		VA, GA, MS, IL, IA, MN, OH, MO
forage					24	
bean					24	
hay					24	
straw					9	
Succulent Beans (MRID 41065004)	1		<0.05	<0.1		CA, FL, ID, NY, WI, VA
forage		<0.03-0.25			19	
bean with pod		<0.03			19	
fodder		0.05			19	

(continued)

Table 3. (Continued)

Crop/Commodity	Rate (oz ai/CWT)	Thiram	Dithioglu-coside	Monothioglu-coside	Number of Samples	Test States
Sugar Beets (MRID 41503604) beets tops (45 days after planting) tops (harvest)	4.2	<0.03	<0.05	<0.1	 14 9 11	MN, CA, ID, ND
Sweet Corn (MRID 41065003) forage ears with husk fodder	4	<0.03-0.76 <0.03 <0.03	0.17, 0.24 <0.05 <0.05	<0.1	 12 12 12	CA, FL, ID, MN
Table Beets (MRID 41503605) beets tops (45 days after planting) tops (harvest)	4.3	<0.03	<0.05	<0.1	 16 12 16	TX, CA, ID, WI, NY
Wheat (MRID 41065007) forage grain straw hay	2.25	<0.03-4.36 <0.03 0.04 <0.03	<0.05-1.06 <0.05 <0.05 <0.05	<0.1	 28 33 34 15	ID, ND, OH, NY, KS, OR, VA, MS, CA, MT

Samples were analyzed at Hazelton Laboratories America, Inc. (HLA) for thiram residue with a modification of HLA method MP-THIR-MA. This method utilizes gas chromatographic determination by carbon disulfide evolution. In this method, thiram is decomposed to carbon disulfide (CS_2) by refluxing with dilute hydrochloric acid. The CS_2 is then measured by gas chromatography using a flame-photometric detector in the sulfur mode. The limit of detection was 0.03 ppm. If CS_2 was detected by this method, the sample was analyzed for the dithioglucoside metabolite. The analysis for this metabolite was conducted with a modification of HLA method MP-DITH-MA. This method also utilizes gas chromatographic determination by carbon disulfide evolution. Dithioglucoside was extracted with hydrochloric acid, and the non-aqueous generators of CS_2 were removed by extracting with chloroform. CS_2 was then generated and measured as stated above. The limit of detection was 0.05 ppm.

All of the samples were analyzed for monothioglucoside with a modification of HLA method MP-MOTH-MA. This method utilizes gas chromatographic determination of the trimethyl silyl derivatives. In this method, the sample was dried with magnesium sulfate, extracted with ethyl acetate, and sent through silica cleanup to remove interfering compounds. The sample was eluted from the column, dried, and derivatized. The derivative was then analyzed by gas chromatography using a flame-photometric detector in the sulfur mode. Recovery data are summarized in Table 4.

Table 4. Recovery of thiram and metabolites from fortified samples.

Commodity	MRID	Compound Added	Fortification (ppm) (# of samples)	Percent Recovery
Cotton	41065001			
- stalks		Thiram	0.30 (5)	90-102
- stalks		Monothioglucoside	1.00 (1)	81
- seed			1.00 (3)	80-114
Dry beans	41065005			
- bean with pod		Thiram	0.30 (2)	93, 103
- forage			0.30 (4)	73-107
- forage		Monothioglucoside	1.00 (4)	92-106

(continued)

Table 4. (Continued)

Commodity	MRID	Compound Added	Fortification (ppm) (# of samples)	Percent Recovery
Field corn	41065002			
- grain at harvest		Thiram	0.30 (2)	87, 107
- ear w/husk			0.30 (2)	100, 100
- forage			0.30 (6)	70-113
- ear w/husk		Monothioglucoside	1.00 (11)	61-108
Lettuce	41503601			
- head with wrapper leaves		Thiram	0.30 (1)	100
		Monothioglucoside	1.00 (4)	81-118
Peas	41503602			
- pea with pod		Thiram	0.30 (5)	80-103
- vines			0.30 (1)	90
- dried peas			0.30 (4)	90, 100
- vines		Monothioglucoside	1.00 (4)	79-99
- green peas with pod			1.00 (1)	79
- dried peas		Dithioglucoside	0.50 (2)	62, 90
Safflower	41503603			
- seed		Thiram	0.30 (2)	93, 100
- seed		Monothioglucoside	1.00 (1)	91

(continued)

Table 4. (Continued)

Commodity	MRID	Compound Added	Fortification (ppm) (# of samples)	Percent Recovery
Soybeans	41065006			
- forage		Thiram	0.30 (8)	78-100
- beans			0.30 (4)	67-93
- forage		Monothioglucoside	1.00 (12)	58-100
Succulent beans	41065004			
- vines		Thiram	0.30 (5)	94-112
- bean with pod			0.30 (4)	80-97
- vines		Monothioglucoside	1.00 (5)	72-117
- bean with pod			1.00 (1)	98
Sugar beets	41503604			
- tops (45 days)		Thiram	0.30 (3)	120-129
- beets			0.30 (2)	97, 100
- tops at harvest		Monothioglucoside	1.00 (4)	66-126

(continued)

Table 4. (Continued)

Commodity	MRID	Compound Added	Fortification (ppm) (# of samples)	Percent Recovery
Sweet corn	41065003			
- fodder		Thiram	0.30 (1)	99
- ear w/husk			0.30 (5)	87-107
- forage (45 days)			0.30 (4)	71-112
- fodder		Monothioglucoside	1.00 (1)	77
- ear w/husk			1.00 (1)	96
- forage (45 days)			1.00 (5)	61-80
Table beets	41403605			
- tops		Thiram	0.30 (4)	90-120
- beets			0.30 (1)	100
- tops		Monothioglucoside	1.00 (5)	60-113
Wheat	41065007			
- hay		Thiram	0.30 (1)	84
- grain			0.30 (15)	73-114
- forage (45 days)			0.30 (3)	75-105
- grain		Monothioglucoside	1.00 (1)	64
- forage (45 days)			1.00 (9)	77-124
- straw			1.00 (6)	77-105

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The test conditions and geographic representation for the individual commodities are listed below.

Cotton (1988; MRID 41065001): Cottonseed samples were stored for 339-434 days. Forage samples were stored for 339-434 days. All samples were stored at room temperature to -27 °C. Geographic representation is adequate. The test states of CA (22%), OK (1.5%), AZ (5.7%), TX (25%), and MS (13%) account for 67% of the U.S. cotton production (Agricultural Statistics 1990, p. 62).

Dry beans (1988; MRID 41065005): Forage (entire plant harvested 45 days after planting) samples were stored for 181-493 days. Bean-with-pod samples were stored for approximately 398-428 days (the storage period from CA could not be determined). Forage-at-harvest samples were stored for 398-422 days. All samples were stored at -18 °C to -26 °C. Geographic representation was not adequate. The test states of CA (14%), ID (14%), ND (10%), and NY (1.8%) accounted for only 40% of the 1989 U.S. dry bean production (Agricultural Statistics 1990, p. 241). Additional data from CO (13%) and MI (18%) are needed.

Field corn (1988; MRID 41065002): Forage samples were stored for 446-507 days. Grain samples were stored for 362-448 days. Ear-with-husk samples were stored for approximately 437-474 days (the storage period from IA could not be determined). Fodder-at-harvest samples were stored for 363-446 days. Fodder-at-milk-stage samples were stored for 394-477 days. All samples were stored at -24 °C to -4 °C (freezer data for OH was not given). Geographic representation was adequate. The test states of IA (19%), IL (17%), MO (2.9%), OH (4.5%), OK (0.1%), VA (0.5%), and NY (0.7%) accounted for over 70% of U.S. field corn grain production considering that IA is representative of MN (9%) and NE (11%) and IL can represent IN (9%) (Agricultural Statistics 1990, p. 33).

Lettuce (1990; MRID 51503601): Samples of heads with wrapper leaves were stored for 171-498 days at approximately -17 °C to -23 °C (temperature data was not submitted from either of the CA tests). Geographic representation was adequate. The test states of NY (0.6%), MI (0.3%), and CA (76%) account for 77% of the U.S. lettuce production (Agricultural Statistics 1990, p. 155).

Peas (1989; MRID 41503602): Green peas-with-pod samples were stored for approximately 208-447 days (the storage period for the NY samples cannot be determined due to insufficient data). Dried peas were stored for approximately 432-454 days (the storage period for the CA samples cannot be determined due to insufficient data). The dry forage/harvest samples were stored for approximately 454-484 days (the storage period for the CA samples cannot be determined due to insufficient data). Green forage/harvest samples were stored for approximately 447-462 days (the storage period for the CA samples cannot be determined due to insufficient data). Most samples were stored at approximately -20 °C to -23 °C (temperature data were not submitted from CA, MN, or ID). Hay samples collected in CA were dried prior to storage; the duration and conditions during this period

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are unknown. Dry harvest samples from ID were dried for 12 days prior to storage; the conditions maintained during this period are unknown. Geographic representation was adequate. The test states of CA (0.5%), MN (22%), NY (3.3%) and ID (<1.0%) account for 26% of the 1989 U.S. pea production. However, MN is representative of WI (26%) and ID is representative of WA (19%). Together, all of these states account for 70% of the 1989 U.S. pea production (Agricultural Statistics 1990, p. 158).

Safflower (1989; MRID 41503603): Seed was stored for 262-472 days. Samples were stored at temperatures of approximately room temperature (26 °C) (temperature data were not submitted from CA, and the AZ data stated only that prior to shipment, the sample was stored at room temperature). The test state of ND is the primary producer of safflower seed.

Soybeans (1988; MRID 410656006): Forage was stored for 408-503 days. Beans were stored for 241-396 days. Hay was stored for 326-459 days. All samples were stored at approximately -4 °C to -28 °C (temperature data for storage prior to shipment was not submitted from OH). Geographic representation was adequate. The test states of VA (0.9%), GA (1.5%), MS (2.1%), IL (18%), IA (17%), MN (9.6%), OH (6.6%), and MO (6.4%) represent the major regions of U.S. soybean production (Agricultural Statistics 1990, p. 123).

Succulent beans (1988; MRID 41065004): Forage samples harvested 45 days after planting were stored for 128-491 days. Bean pod samples were stored for 111-477 days. Forage-at-harvest samples were stored for 110-486 days. All samples were stored at -4 °C to -33 °C. Geographic representation is adequate. The test states of CA (0.5%), FL (O.5%), ID (0.5%), NY (8%), WI (32%) and VA (<1.0%) accounted for approximately 70% of U.S. succulent bean production considering that ID is representative of OR (20%) and WI is representative of IL (9%) succulent bean production (Agricultural Statistics 1990, p. 147).

Sugar beets (1990; MRID 41503604): Samples of tops harvested 45 days after planting were stored for 241-510 days. Samples of tops-at-harvest were stored for 391-413 days. The samples of beets were stored for 391-4096 days. All samples were stored at approximately -18 °C to -20 °C (temperature data were not given for CA or ID). Geographic representation is adequate. The test states of MN (21%), CA (18%), ID (16%), and ND (11%) account for approximately 70% of the 1989 U.S. sugar beet production (Agricultural Statistics 1990, p. 74).

Sweet corn (1988; MRID 41065003): Forage samples were stored for 435-502 days. The fodder/harvest samples were stored for 367-432 days. Ear-with-husk samples were stored for 367-432 days. All samples were stored at -15 °C to -32 °C. Geographic representation is adequate. The test states of CA (3%) and FL (32%) account for 45% of the 1989 U.S. sweet corn production for the fresh market and the test states of ID (6%) and MN (22%) accounted for 28% of the 1989 U.S. sweet corn production for processing (Agricultural Statistics 1990, p. 153). Therefore, the test states represent over 70% of U.S. sweet corn production.

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Table beets (1989; MRID 41503605): Samples of tops harvested 45 days after planting were stored for 385-490 days. Samples of tops taken at harvest were stored for approximately 461-493 days (the storage period for the CA and WI samples cannot be determined due to insufficient data). Beet samples were stored for approximately 461-462 days (the storage period for the CA and WI samples cannot be determined due to insufficient data). All of the samples were stored at approximately -20 °C to -23 °C (temperature data for CA and ID were not given). Geographic representation is adequate. The test states TX (5.8%), CA (5.1%), ID (<1%), WI (36%) and NY (27%) accounted for 73.9% of the U.S. table beet acreage (1987 Census of Agriculture; part 51, p. 356).

Wheat (1988; MRID 41065007): Forage samples were stored for 143-499 days. Grain samples were stored for 91-446 days. Straw samples were stored for 79-173 days. All samples were stored at 0.5 °C to -34 °C. Geographic representation was adequate. The test states of ID (4.5%), ND (12%), OH (3.1%), NY (0.28%), KS (10%), OR (2.6%), VA (0.6%), MS (0.75%), CA (2.6%), and MT (7%) are resentative of the major U.S. wheat production regions, including the represented states of MN (4%), OK (8%) and WA (5%)(Agricultural Statistics 1990, p. 5).

MAGNITUDE OF THE RESIDUE IN MEAT, MILK, POULTRY, AND EGGS

Tolerances:

No tolerances have been established for residues of thiram in animal commodities.

Conclusions:

The qualitative nature of the residue in animals is not adequately understood. Therefore, the residues of concern in animal commodities cannot yet be determined. Furthermore, tolerances are needed but not currently established for residues in or on feed commodities from crops with registered seed treatments. In addition, it is not known whether the established tolerances for residues in commodities (e.g., apples and tomatoes) that have processed feed items are to be supported or revoked. Therefore, the maximum theoretical dietary burdens for ruminants and poultry cannot be estimated.

TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues in or on food and feed commodities are currently expressed in terms of thiram per se. However, the nature of the residues in plants is not adequately understood and, therefore, the tolerance definition is subject to change.

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No data have been submitted to support the established tolerances for residues of thiram in or on apples, bananas, celery, onions (bulb), peaches, strawberries, or tomatoes. If no registrant elects to submit the required supporting residue data, these tolerances will be revoked.

Tolerances need to be established for thiram residues of concern in or on commodities of dry beans, field corn, lettuce, peas, safflower, soybeans, succulent beans, sugar beets, sweet corn, table beets, and wheat grown from thiram-treated seed. Appropriate tolerance levels will be decided upon when the residues to be regulated in plants are determined and sufficient data reflecting registered uses are available.

The available data on animal metabolism, though insufficient to satisfy data requirements, indicate that residues transfer from feed to meat, milk, and eggs. After review of the requested animal metabolism data and when appropriate tolerance levels for residues in or on feed items are determined, the requirements for feeding studies to set tolerance levels in animal products will be specified.

MASTER RECORD IDENTIFICATION NUMBERS

MRID documents containing data which have been previously reviewed by the Agency are designated in bold print in the following bibliographic listing of Residue Chemistry Citations (used). A summary of the subject memoranda and their associated MRID documents is presented below.

AGENCY MEMORANDA

CBRS No. none
Subject: Memo of Conference April 14, 1987
From: Jerome Rockwell
To: Paul Larson
Dated: April 14, 1987
MRID(s): none

CBRS No. 1302, 1303, 2336
Subject: 7501-20 - Thiram Registration Standard Followup Accession Nos. 264021, 264146
From: Martha J. Bradley
To: Lois A. Rossi
Dated: July 1, 1987
MRID(s): none

CBRS No. 5168
Subject: Followup to the Thiram Registration Standard - Livestock Metabolism

From: Cynthia Deyrup
To: Susan Lewis
Dated: August 7, 1989
MRID(s): 41006201. 41006202.

CBRS No. 6733
Subject: Uniroyal Chemical Company: Response to the Thiram Reregistration Standard: Plant Metabolism Studies
From: R.B. Perfetti
To: Reto Engler
Dated: March 20, 1991
MRID(s): 40216502. 00162142

Residue Chemistry Citations (used):

00143803 Thiram Task Force (19??) (Residue Tolerance and Allowable Daily Intake Information on Thiram). 12 p.

00143860 Tewari, S.; Singh, R. (1979) Thin-layer chromatographic techinque for the separation and identification of carbamate pesticides in post mortem material. Journal of Chromatography 172:528-530.

00154758 Koeppe, M. (1985) Crop Rotation Study with :Carbon-14:-DPX-Y6202 in the Greenhouse: Doc. No. AMR-218-84, Revision 1. Unpublished study prepared by E. I. du Pont de Nemours & Co., Inc. 27 p.

00158665 Warren, J.; Drury, P.; Connor, S. (1986) Determination of Adsorption/Desorption Constants of :Carbon-14:-Thiram: ABC Final Report #33573. Unpublished study prepared by Analytical Bio- Chemistry Laboratories, Inc. 334 p.

00162015 UCB Chemicals Corp. (1986) Validation of Analytical Method: Thiram Technical. Unpublished compilation. 11 p.

00162142 Harned, W.; Tortora, N. (1986) Uptake and Distribution of :Carbon-14: Thiram in Cotton, Soybean and Wheat: Project No. 8565-A. Unpublished study prepared by Uniroyal Chemical. 25 p.

00162909 Taylor, W. (1986) Letter sent to H. Jacoby dated Aug 6, 1986: Data call-in Thiram .... Prepared by Vanderbilt Co., Inc. 20 p.

00165338 Uniroyal Chemical Co., Inc. (1983) The Results of the Amount of Residue Remaining: :Vitavax in Safflower Seed:. Unpublished compilation. 15 p.

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40216502 **Nowakowski, M. (1987) Identification of Metabolites in Cotton, Wheat and Soybean Seedlings Grown from :Carbon 14:Thiram Treated Seeds: Uniroyal Project ID No. 8565-C. Unpublished study prepared by Uniroyal Chemical Co., Inc. 47 p.**

40294601 Tucker, D. (1987) 14 Month Storage Stability Study for Thiram 65WP: Laboratory Project ID: MICRO-FLO THI65-EU-1. Unpublished study prepared by Chempax. 4 p.40294701 Tucker, D. (1987) 14 Month Storage Stability Study for Thiram 75WP: Lab. proj. ID TH175-EU-1. Unpublished study prepared by Chempax. 4 p.

40495200 Pennwalt Corp. (1988) Submission of Data in Response to EPA Product Chemistry and Residue Chemistry Data Call-In for Ziram. Transmittal of 1 study.

40495201 **Keppel, G.E. (1971) Collaborative study of the determination of dithiocarbamate residues by a modified carbon disulfide evolution method. Journal of the Association of Official Analytical Chemists 54(3):528-532. (Also ~In~unpublished submission received April 15, 1981 under 100-607; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 070023-A)**

40016900 California Dept. of Food and Agriculture (1985) Data Submitted to Fulfill the Registration Requirements: Compound 1080. Compilation of 99 Studies.

40857601 U.S. Environmental Protection Agency (1984) GS 122/Thiram: RS: Administrative Record. Unpublished compilation [with confidential attachment!. 361 p.

41006201 **Norris, K. (1989) Determination of the Metabolic Fate of [Carbon-Thiram Orally Administered to Lactating Goats: ADC Project No. 1057. Unpublished study prepared by Analytical Development Corporation in cooperation with Colorado State Univ., Metabolic Laboratory. 56 p.**

41006202 **Norris, K. (1989) Determination of the Metabolic Fate of [Carbon-Thiram Orally Administered to Laying Hens: ADC Project No. 1058. Unpublished study prepared by Analytical Development Corp. in cooperatin with Colorado State Univ., Metabolic Laboratory. 42 p.**

41065001 **Ball, J. (1988) Residue of Thiram and its Monothioglucoside and Dithioglucoside in Cotton: Project ID: 01483; 6111-126J. Unpublished study prepared by Gustafson International Laboratory in cooperation with Hazelton Laboratories. 262 p.**

41065002 Ball, J. (1988) Residue of Thiram and its Monothioglucoside and Dithioglucoside in Field Corn: Project ID: 01486; 6111-126B. Unpublished study prepared by Gustafson International Research Laboratory in cooperation with Hazelton Laboratories. 374 p.

41065003 Ball, J. (1988) Residue of Thiram and its Monothioglucoside and Dithioglucoside in Sweet Corn: Project ID: 01487; 6111-12A. Unpublished study prepared by Gustafson International Research Laboratories. 282 p.

41065004 Ball, J. (1988) Residue of Thiram and its Monothioglucoside and Dithioglucoside in Succulent Beans: Project ID: 01484; 6111-126E. Unpublished study prepared by Gustafson International Research Laboratory in cooperation with Hazelton Laboratories. 249 p.

41065005 Ball, J. (1988) Residue of Thiram and its Monothioglucoside and Dithioglucoside in Dry Beans: Project ID: 01493; 6111-126F. Unpublished study prepared by Gustafson International Research Laboratory in cooperation with Hazelton Laboratories. 244 p.

41065006 Ball, J. (1988) Residue of Thiram and its Monothioglucoside and Dithioglucoside in Soybeans: Project ID: 01494; 6111-126C. Unpublished study prepared by Gustafson International Research Laboratory in cooperation with Hazelton Laboratories. 384 p.

41065007 Ball, J. (1988) Residue of Thiram and its Monothioglucoside and Dithioglucoside in Wheat: Project ID: 01492; 6111-126D. Unpublished study prepared by Gustafson International Research Laboratory in cooperation with Hazelton Laboratories. 608 p.

41503601 Rockwell, J. (1990) Residues of Thiram and its Metabolites in Lettuce: Lab Project Number: HLA 6111-126K: 01488: 90-007. Unpublished study prepared by Gustafson International Research Laboratory in association with Hazleton Laboratories America, Inc. 141 p.

41503602 Rockwell, J. (1989) Residues of Thiram and its Metabolites in Peas: Lab Project Number: 90-008: HLA 6111-126G: 01489. Unpublished study prepared by Gustafson International Laboratories in association with Hazleton Laboratories, Inc. 213 p.

41503603 Rockwell, J. (1989) Residues of Thiram and its Metabolites in Safflower: Lab Project Number: 90-009: HLA 6111-126L: 01490. Unpublished study prepared by Gustafson International Laboratory in association with Hazleton Laboratories America, Inc. 137 p.

41503604 Rockwell, J. (1990) Residues of Thiram and its Metabolites in Sugar Beets: Lab Project Number: 90-010: HLA 6111-126H: 01491. Unpublished study prepared by Gustafson International Research Laboratory in association with Hazleton Laboratories, America, Inc. 181 p.

41503605 Rockwell, J. (1989) Residues of Thiram and its Metabolites in Table Beets: Lab Project Number: 90-011: HLA 6111-126I: 01485. Unpublished study prepared by Gustafson International Research Laboratory in association with Hazleton Laboratories America, Inc. 184 p.

TABLE A. GENERIC DATA REQUIREMENTS FOR THIRAM RESIDUE CHEMISTRY.[1]

Data Requirement		Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.240 Residue Chemistry					
171-2.	Chemical Identity[4]				
171-3.	Directions for Use	EP	Partially		Yes[5]
171-4.	Nature of the Residue (Metabolism)				
	Plants	PAIRA	Partially	00162142 40216502	Yes[6]
	Livestock	PAIRA & Plant Metabolites	Partially	41006201 41006202	Yes[7]
171-4.	Residue Analytical Methods	TGAI & Metabolites	Partially	40495201 41065001 41065002 41065003 41065004 41065005 41065006 41065007 41503601 41503602 41503603 41503604 41503605	Reserved[8]
171-4.	Storage Stability	TEP & Metabolites	No	N/A	Yes[9]
171-4.	Magnitude of the Residue in Plants				

(Continued, Footnotes Follow)

TABLE A. (Continued)

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
Bulb Vegetables				
- Onions (dry bulb)	TEP	Partially	N/A	Yes[10]
Leafy Vegetables				
- Celery	TEP	Partially	N/A	Yes[10]
Fruiting Vegetables				
- Tomatoes	TEP	Partially	N/A	Yes[10]
(processed commodities)		No	N/A	Yes[11]
Pome Fruits				
- Apples	TEP	Partially	N/A	Yes[10]
(processed commodities)		No	N/A	Yes[12]
Stone Fruits				
- Peaches	TEP	Partially	N/A	Yes[10]
Small Fruits and Berries				
- Strawberries	TEP	Partially	N/A	Yes[10]

(Continued, Footnotes Follow)

TABLE A. (Continued)

Data Requirement		Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
Miscellaneous Commodities					
- Bananas		TEP	Partially	N/A	Yes[10]
171-4.	Crops with Seed Treatment[13]	TEP	Partially	41065002 41065003 41065004 41065005 41065006 41065007 41503601 41503602 41503603 41503604 41503605	Yes[14]
	(processed commodities)		No	N/A	Yes[15]
171-4.	Magnitude of the Residue in Milk/Meat/Poultry/Eggs	TGAI or Plant Metabolites	No	N/A	Reserved[16]

[1]Gustafson, Inc. has partially responded to requirements for data on plant and animal metabolism and residues on crops grown from treated seed, specified in the 6/84 Guidance Document. The data gaps included for those topics in this update address specific deficiencies, if any in the submitted data. Guidance Document requirements to which there has been no response are carried over in this update.

[2]Test substance: TGAI = technical grade of the active ingredient; PAI = purified active ingredient; PAIRA = purified active ingredient, radiolabeled; TEP = typical end-use product; EP = end-use product.

(Continued, Footnotes Follow)

TABLE A. (Continued)

[3]These references were submitted in response to the Thiram Guidance Document dated June, 1984. Underlining indicates documents that have been reviewed for this update.

[4]The same chemical identity data are required under 40 CFR 158.150-190, with emphasis on impurities that could constitute residue problems. Refer to product chemistry data requirements tables.

[5]The use patterns discussed in this Residue Chemistry Update are based on labels for the products of the basic producer, Gustafson, Inc. When end-use product DCIs are developed (e.g, at issuance of the RED), RD should require that all end-use product labels (e.g., any unamended basic producer labels, SLNs, and products covered under generic data exemptions) be amended such that they are consistent with the amended basic producer labels.

[6]Uniroyal Chemical Co. submitted data on wheat, cotton, and soybean commodities grown from treated seed. These data have been deemed inadequate by CBRS. New data are required regarding the qualitative nature of the residues in mature plant parts of soybeans, cotton, and wheat plants grown from seed treated with [^{14}C]thiram at rates high enough to permit characterization of ^{14}C-residues. The data should depict the extractability of the total radioactive residues (TRR) and characterization of residues expressed as total radioactive counts, percentage of total recovered radioactivity, and equivalent concentration in the matrix (ppm). Unextractable residues must be characterized, and the moieties in glycoside and amino acid conjugates must be identified. Residues must be characterized on the basis of analysis of the plant extracts themselves. If work with tissue culture is necessary to support the results of plant matrix analysis, a full complement of quantitative data must be provided.

[7]Gustafson, Inc. submitted data concerning metabolism of [^{14}C]thiram in goats. These data have been judged inadequate by CBRS. Additional data are required from the study with goats reported in MRID 41006201 (Report No. 89-005). The registrant must present data characterizing ^{14}C-residues in milk and tissues. It is recommended that the samples from animals dosed at 10x be used, since the total radioactive residues levels in these samples are high enough to permit separation and identification of the residues.

[8]The nature of the residue in plants and animals is not adequately understood. Following review of the required plant and animal metabolism studies, the specific requirements for data collection and enforcement methodology will be determined. It should be noted that current enforcement methodology is non specific for carbon disulfide (CS_2) generating compounds. The enforcement of tolerances for residues of thiram per se requires methodology capable of quantifying thiram per se and distinguishing thiram from other CS_2 generators (e.g., EBDCs).

TABLE A. (Continued)

[9]No data on storage stability have been submitted. Data are required depicting the stability of thiram residues of concern in or on all commodities for which data have been submitted or are required to support existing or needed tolerances. Samples bearing weathered residues or fortified samples should be analyzed immediately after harvest or fortification and thereafter at regular intervals and under the conditions corresponding to those of the samples in the submitted residue tests. In addition, all requested residue data must be accompanied by information regarding sample handling and the intervals and conditions of sample storage.

[10]No data have been submitted to support the established tolerances for residues of thiram in or on apples, bananas, celery, onions (bulb), peaches, strawberries, or tomatoes. If no registrant elects to submit the required supporting residue data, these tolerances should be revoked.

[11]No data have been submitted in response to the Guidance Document. Data are required depicting the concentration of thiram residues of concern in juice, dry pomace, catsup, and puree processed from tomatoes bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate food/feed additive tolerance must be proposed.

[12]No data have been submitted in response to the Guidance Document. Data are required depicting the concentration of thiram residues of concern in juice and dry pomace processed from apples bearing measurable weathered residues. If residues concentrate in either commodity, an appropriate food/feed additive tolerance must be proposed.

[13]Gustafson, Inc. submitted data from tests pertaining to the residues of thiram and its monthio and dithioglucoside metabolites that result from seed treatments using the 4 lb/gal and the lb/gal formulations. Residues occurred on cotton forage; dry bean forage and hay; pea seed, forage, and hay; succulent bean forage and fodder; sweet corn forage; and wheat forage and straw. Residues were below the limit ofmdetection in or on other commodities. Tolerances need to be established for thiram residues of concern in or on commodities of dry beans, field corn, lettuce, peas, safflower, soybeans, succulent beans, sugar beets, sweet corn, table beets, and wheat grown from thiram-treated seed. Appropriate tolerance levels will be decided upon when the residues to be regulated in plants are determined and sufficient data reflecting registered uses are available.

[14]For cotton, additional information is required from the test described in MRID 41065001. The analytical methods must be validated at the limits of detection with cotton forage.

For dry beans, additional information is required from the test described in MRID 41065005. Raw validation data are needed for the dithioglucoside metabolite from the forage analysis. For samples from ID, the storage conditions for the 10 days from

TABLE A. (Continued)

sampling to storage must be reported. Also, the registrant must explain how the seeds were cleaned prior to analysis. Additional data are required from CO and MI.

For lettuce, additional information is needed from the test described in MRID 41503601. All data are required regarding thiram residues in or on the samples without wrapper leaves.

For peas, additional information is required from the test described in MRID 41503602. Data are required regarding thiram residues in or on pea straw. For samples from ID, the storage conditions for the 12 days from sampling to storage must be reported. For samples from CA, MN, and MY the amount of time used to dry the seed and forage between sampling and storage and the associated storage conditions must be reported. The raw data sheets from Hazelton Labs show calculations for thiram that may be incorrect. The registrant should explain these calculations or submit corrections.

For succulent beans, additional information is required from the test described in MRID 41065004. Sample reports are required regarding the vine samples from tests conducted in CA.

For sugar beets, additional information is required from the test described in MRID 41503604. All of the sample reports are needed from MN, and data and sample reports for tops at 45 days after planting are needed from tests conducted in CA.

For sweet corn, additional information is required from the test described in MRID 41065003. All of the data regarding thiram residues on corn kernels is required. Additional geographic representation is needed. Data from tests conducted in CA regarding analysis of the forage are required.

For wheat, additional information is required from the test described in MRID 41065007. For samples from KS and OH, all of the storage conditions are required. For samples from MS, the storage conditions for the 16 days that occurred between sampling and storage are required. Tolerances above the detection limit may be needed for forage and straw. Data reflecting treatment at 1x (if different from 2.25 oz ai/CWT) will be needed to set the tolerance at the appropriate level.

[15]No data have been submitted in response to the Guidance Document. Data are required depicting the concentration of thiram residues of concern in the following processed commodities: (i) meal, hulls, crude oil, refined oil, and soapstock processed from cottonseed; (ii) starch, crude oil and refined oil from wet milling and flour, grits, crude oil, and refined oil from dry milling of corn grain; (iii) meal, crude oil, and refined oil processed from safflower seed; (iv) meal, hulls, crude oil, refined oil, and

TABLE A. (Continued)

soapstock processed from soybeans; and (v) dried pulp, molasses, and refined sugar processed from sugar beets. The RACs must bear measurable weathered residues; application at exaggerated rates may be necessary. If residues concentrate in any commodity, an appropriate food/feed additive tolerance must be proposed.

[16]No data are required at this time. The available data on animal metabolism, though insufficient to satisfy data requirements, indicate that residues transfer from feed to meat, milk, and eggs. After review of the requested animal metabolism data and when appropriate tolerance levels for residues in or on feed items are determined, the requirements for feeding studies to set tolerance levels in animal products will be specified.