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

APR 21 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Id. No. 060101. Thiabendazole Data Call-In. Merck's Product & Residue Chemistry responses of 8/15/88 & 9/29/88. MRID Nos. 407898-01, -14, & 408355-01. Branch Nos. 4564 thru 4567 & 4591.

FROM: Kenneth W. Dockter, Chemist
Special Registration Section I
Dietary Exposure Branch
Health Effects Division (H 7509C)

THRU: A.R. Rathman, Section Head
Special Registration Section I
Dietary Exposure Branch
Health Effects Division (H 7509C)

TO: Geraldine W. Werdig/Ruby A. Whiters, PM Team # 50
Generic Chemical Support Branch
Special Review/Reregistration Division (H 7508C)

Merck & Co., Inc. has provided responses in support of reregistration of 5 of their thiabendazole containing MERTECT® products. They are:

Name*	EPA Reg. No.
MERTECT 40	618-58
" ANTIMYCOTIC	67
" 340-F	75
" LSP	84
" DF	92

* on CSFs (see Confidential Appendix)

No Registration Standard for thiabendazole has been issued as of this writing, and none is scheduled. (personal communication from W. Boodee, 11/18/88).

The data and/or non-applicability reasons provided are summarized below. Unless otherwise stated we consider them to be adequate.

61-1 Product identity & disclosure of ingredients: 408355-01: Thiabendazole; 5 CSFs are incomplete as received. (see Confidential Appendix)

61-2 Description of starting materials & manufacturing process: 408355-01: (see Confidential Appendix)

61-3 Discussion of the formation of impurities: 408355-01: (see Confidential Appendix)

Series 63 (except for § 63-6): 407898-01:

63-2 Color: Of 10 lots "assayed", 6 were off white, 3 were light tan, & 1 was yellowish tan. The procedure involved compressing the powder sample gently between 2 layers of clean white paper. Color reference standards of thiabendazole were similarly treated. The reference and assay samples were compared visually to obtain the closest color match. The reference samples ("standards") are periodically replaced by fresh samples that are kept in reserve.

63-3 Physical state: Dry powder at room temperature. We note that test should be conducted at 20°C or 25°C.

63-4 Odor: None distinguishable at room temperature.

63-5 Melting point: 297.6-300.6°C (n=10 lots). The US Pharmacopoeia Method 1A was used. Briefly, using a controlled heating device, like the Thomas Hoover Melting Rate Programmer, the temperature is quickly raised to within 10°C of the expected melting point. The equipment is then programmed to raise the bath temperature at 1°C/minute. At 5°C below the expected melt, a capillary tube, partially filled with test sample is inserted into the heated bath.

63-6 Boiling point: Does not apply, technical is a solid.

63-7 Bulk density: The loose bulk density is 30-37 cc; tapped is 25-30 cc (n=10 lots). The tapped bulk density procedure, which is designed to simulate the density that a powdered product will attain under normal transportation and handling, was used. Briefly, a 50 ml graduate cylinder, i. d. about 18 mm, containing 10.0 g sample was raised and dropped, 10 X, vertically, exactly 2 in. onto a hard rubber mat, and read directly.

63-9 Vapor pressure: Approx. 4×10^{-9} mm Hg at 25°C. A Knudsen effusion cell was used at 181-121°C because of the low vapor pressure of thiabendazole at room temperature. The pressures at 25°C and 49°C were determined by extrapolation of vapor pressure vs. 1/T using a Merck 1/22/73 method titled, "Thiabendazole: Determination of Sublimation Pressure, Heat of Sublimation and Loss of Weight at 25° and 49°C". An adequate description and raw data were provided.

63-11 Octanol/Water partition coefficient: Range 141-285 at 25°C. This was previously submitted, which see K. Dockter 8/14/85; RCB #1222.

63-12 pH: Range 5.16-5.97 (n=10 lots). The procedure involved addition of 50 ml of CO_2 free water to 2 g of thiabendazole in a plastic beaker with a top. The sample was stirred for 15-30 min. using a magnetic stirrer; a completely wet sample is critical. Vigorous shaking would work as well; stirring with a pH probe would not. A pH probe was put into the slurry and stirring continued for 2 min.; the stirring stopped for 30 sec, then the pH reading recorded.

171-2 Chemical identity: 407898-14: (see Confidential Appendix)

171-3 Directions for use: the 7 labels provided in the current package as received by the Branch were:

1. MERTECT® 40 Water Dispersable Antimycotic to retard or control mold growth in reconstituted tobacco leaf; product 47981 - EPA Reg. No. 618-58-AA,

2. MERTECT® Fungicide for use only in the manufacture of EPA registered fungicidal formulations; product 4709? - EPA Reg. No. 618-67-AA, and annotated "NOTE: Copy of label submitted to EPA on 8/1/88 for review and approval." [We note that this technical specifies 98.5% ai; its incomplete CSF shall be discussed in the Confidential Appendix],

3. MERTECT® 340-F Flowable Fungicide (water dispersible suspension); product 48015 - EPA Reg. No. 618-75, and accepted 6/11/88?,

4. MERTECT® 340-F; product 48015 - 6/15/88 Draft Supplemental Labeling for chemigation application,

5. MERTECT® LSP Flowable Fungicide (water dispersible suspension) Wheat Seed treatment to control seed- and soil-borne Common Bunt (Stinking Smut) and Dwarf Bunt of Wheat; product 48009 - EPA Reg. No. 618-84-AA,

6. MERTECT® DF Fungicide (water Dispersible Granular); product 48016 - EPA Reg. No. 618-92, and accepted with comments 1?/11/88?,

and

7. MERTECT® DF; product 48016 - 6/15/88 Draft Supplemental Labeling for chemigation application.

171-4 Magnitude of the residue (including storage stability data) - Crop Field Trials Fumigated Commodities studies: Merck claims that these studies are not applicable; there are no fumigation type uses with "any" thiabendazole products.

171-4 Magnitude of the residue (including storage stability data) - Meat/Milk/Poultry/Eggs (Animal/livestock feeding studies) Premise Use studies: Merck claims that these studies are not applicable; there are no thiabendazole uses which result in: 1) Direct adsorption (dermal or innalation) from sprays, mists, or fogs with animals present, 2) Direct consumption (e.g., by the animal licking surfaces treated with sugar baits, pick up of bait granules by poultry, or contamination of feed, feed troughs, (or water troughs), and 3) Direct contamination of milk from deposition on milking equipment, treatment of milk cows, etc.

171-4 Magnitude of the residue (including storage stability data) - Aquatic Use Sites - Water Residue studies, - Fish & Shellfish Residue studies, & - Irrigated Crop Residue studies: Merck claims that these are not applicable; citrus use is post-harvest, and rice use (label - MERTECT 340-F EPA Reg. No. 618-75) prohibits application directly to water. We can for that label, per se, agree; but then the 6/15/88 draft supplemental labeling for chemigation application is not appropriate. These studies are required to support the addition of chemigation to the label.

71-4 Magnitude of the residue (including storage stability data) - Food Handling studies: Merck claims that these studies are not applicable; not used in food/feed handling establishments nor is it insecticidal.

Conclusions and Recommendations

The following information/data are still needed for filling all the Product and Residue chemistry requirements for Merck's 5 products.

61-1 Product identity & disclosure of ingredients
A completely executed, independent Confidential Statement of Formula for each product. Also, the phrase thereon, "inerts from above" & stated purpose ("Inert") are inadequate. (see Confidential Appendix for specific details)

Series 62 Analysis & certification of product ingredients
All data for Merck's thiabendazole technical, MERTECT® Antimycotic, EPA Reg. No. 618-67. (See Confidential Appendix for specific deficiencies)

63-8 Solubility
Quantitative data determined at 20°C or 25°C on TGAI or PAI in g/100 ml of distilled water and representative polar and non-polar solvents commonly used for pesticides. Report as ppm if sparingly soluble.

63-13 Stability
Discussion of TGAI sensitivity to metal ions, metal, & sunlight, and of TGAI stability at normal and elevated temperatures.

64-1 Submittal of samples
The registrant has not indicated that a sample of thiabendazole has been sent to the EPA Pesticides and Industrial Chemical Repository. They should be reminded to submit a sample if this has not been done.

171-2 Chemical identity
(see Confidential Appendix for specific details)

We presume that Merck intends to provide the rest of the data (i.e., plant & animal metabolism, plant & animal residue analytical methods, storage stability, processing, and feeding) required by the 3/24/88 DCI Notice.

Attachment (Confidential Appendix, 3 pages)

CC with Attachment: Dockter (DEB), Thiabendazole SF, E. Eldredge (ISB/PMSD), RF.

CC without Attachment: D. Schmitt, Circulation (7).

RDI: ARRathman:4/19/89:EZager:4/19/89
H7509C:DEB:CM#2:RM 802:77886:K.W. Dockter:edited by Kd:4/20/89

Page ___ is not included in this copy.

Pages 6 through 8 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

✓ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

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

_____ The document is not responsive to the request.

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