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

JUN 13 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No. 618-67. Thiabendazole.
[RD Data Review Record ID No.: 060101]
§63-13 Data Submitted in Response to DCI.
DEB#: 5187 HED#: 9-1223 MRID#: 410250-01

FROM: Maxie Jo Nelson, Ph.D., Chemist
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Health Effects Division (H7509C)

THRU: Robert S. Quick, Section Head
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Health Effects Division (H7509C)

TO: J. Ellenberger/R. Whiters, PM Team 50
Generic Chemical Support Branch
Special Review & Reregistration Division (H7508C)

BACKGROUND

PM Team 50 has sent to DEB for review a study (MRID# 410250-01) submitted to the Agency by Merck & Co., Inc. in partial response to the Agency's 3/24/88 Comprehensive Generic Data Call-In (DCI) Notice on Thiabendazole.

The study is entitled, "Thiabendazole: Stability of 2-(4-Thiazolyl) benzimidazole", by J. Justin, Merck & Co., Inc., 2/19/89, Lab Project ID CHEM-89, and is intended to fulfill the data requirements of 40 CFR 158.190 (Product Chemistry Data Requirements for Registration: Physical and Chemical Characteristics) Guideline reference §63-13 (Stability) of Subdivision D (Product Chemistry) of the Pesticide Assessment Guidelines.

§63-13 requires the following information on the stability of the technical grade of each active ingredient (TGAI) in each manufacturing use product (MUP) and end-use product (EUP) to support their registration: sensitivity to metal ions and metal; stability at normal and elevated temperatures; and, sensitivity to sunlight. §63-13 also provides a listing of suggested test methods.

DISCUSSION

Merck has provided data to demonstrate the stability of thiabendazole (TGAI) when stored at room temperature (25° ± 10°C) for up to 61 months, or at an elevated temperature (40° ± 1°C) for up to 19 months.

The storage stability values reported for thiabendazole samples ranged from 98.3 to 100.6% during this test period.

Thiabendazole samples were analyzed per the assay procedure (colorimetric) described in the U.S. Pharmacopeia, Volume XXI, p. 1045. (Merck reported none of the suggested test methods of §63-13 were applicable to the assay of thiabendazole, which is a water-insoluble powder.)

No information was provided re the sensitivity of thiabendazole (TGAI) to metal ions, metal, or sunlight. Merck states these data requirements should not apply to thiabendazole since, in the interval between manufacture and processing into end-use formulations, the dry TGAI is stored in polyethylene bags, sealed in draft board drums, and never exposed to metals, metal ions, or sunlight.

DEB does not agree to a data waiver of the required information under §63-13 re the sensitivity of thiabendazole (TGAI) to metal ions, metal, and sunlight. The need for this information remains a data gap.

CONCLUSIONS

1. Merck has provided data to demonstrate the stability of thiabendazole (TGAI) when stored at room temperature (25° ± 10°C) for up to 61 months, or at an elevated temperature (40° ± 1°C) for up to 19 months.

2. DEB does not agree to a data waiver of the required information under §63-13 re the sensitivity of thiabendazole (TGAI) to metal ions, metal, and sunlight. The need for this information remains a data gap.

cc: M. Nelson, **Reading File**, Circulation (7), Thiabendazole Subject File, R. Schmitt, ISB/PMSD (E. Eldredge).

H7509C:DEB:Reviewer(MJN):CM#2:Rm804:557-7423:typist(mjn):6/9/89.
RDI:SecHead:RSQuick:6/9/89:BrSrScientist:RALoranger:6/13/89.