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

JUL 17 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Thiabendazole - Comprehensive Data Call-In Notice - Merck and Company - EPA Registration No. 618-67

MRID No.: 410835-01
DEB No.: 5399

FROM: Gobind P. Makhijani, Chemist
Dietary Exposure Branch
Health Effects Division (H7509C)

TO: Jay Ellenberger/R. White, PM Team 50
Special Review Branch
Special Review and Reregistration Division (H7508C)

and

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

THRU: William J. Boodee, Section Head
Reregistration Section
Dietary Exposure Branch
Health Effects Division (H7509C)

In response to the comprehensive Data Call-In (DCI) Notice for Thiabendazole, Merck and Company has submitted Product Chemistry Data (MRID No. 410835-01, dated May 2, 1989) to partially fulfill the requirements for its Thiabendazole Technical (EPA Registration No. 618-67).

These data and our conclusions are discussed below.

62-1 - Preliminary Analysis of Product Samples

The registrant has provided preliminary analyses of 10 batches of Thiabendazole Technical manufactured during 1986 and 1987. The results of analysis of these 10 batches are discussed in Confidential Appendix A.

Some further clarification is needed regarding the impurities reported previously by the registrant (MRID No. 408355-01).

A data gap still exists here.

62-2 - Certification of Limits

The registrant has submitted information giving only the lower limits for the active ingredient and a combined upper limit for the two impurities. These limits are discussed in Confidential Appendix B. The upper and lower limits for the active ingredient and upper limits for each impurity present at $\geq$ 0.1 percent (w/w) must be provided and certified on EPA Form 8570 (Rev. 2-85).

A data gap still exists here.

63-3 - Analytical Methods to Verify Certified Limits

The registrant has submitted methods for the quantitation of thiabendazole active ingredient and the impurities in the technical product. These procedures are discussed in Confidential Appendix C.

All the analytical methods have been validated by the registrant for accuracy, precision, and linearity.

No further information is needed on this topic.

Note to the Product Manager

The registrant (Samuel F. Richard of Merck and Company) has informed us by telephone on July 6, 1989 that sections 61-1, 61-2, and 61-3 were submitted to EPA on September 29, 1988 (MRID No. 408355-01). DEB has not received these data at this time.

Attachment I: Confidential Appendices A, B, & C (3 pages)

cc: Thiabendazole Registration Standard, SF, Reviewer, RRP PMSD/ISB (E. Eldredge), Ellenberger (PM 50), Toxicology (Coberly).

cc: Thiabendazole Registration Standard, SF, RF, Reviewer, PMSD/ISB (E. Eldredge), Ellenberger (PM 50), RF, Circu. Toxicology (Coberly).

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