

US EPA ARCHIVE DOCUMENT

S554461

DATE OUT: 03/FEB/1999

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [X] End-Use Product []**
BARCODE No.: 252511 EPA RECEIVED DATE: 31/DEC/1998 REG./File Symbol No.: 618-109
PRODUCT NAME: Mertect Fungicide, 98.5% Thiabendazole MRID.: 447246-01 & -02
COMPANY NAME: Merck & Co., Inc. Action Code: 345

FROM: Sami Malak, Chemist *Sami Malak*
Technical Review Branch/RD (7505C)

TO: 22 Cynthia Giles-Parker/Maria Rodriguez
Fungicide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 30/DEC/1998, Jellineck, Schwartz & Connolly, Inc., on behalf of Merck & Co., Inc. requests review for acceptability an alternate formulation for subject product, CSF dated 30/DEC/1998. The applicant included some product chemistry data, certification with respect to citation of data, and data matrix.

FINDINGS:

- 1a. The alternate formula, CSF dated ³⁰~~22~~/DEC/1998, is manufactured in India as opposed to the currently approved basic formulation, CSF dated 20/AUG/1998, which is manufactured the USA.
- 1b. The alternate formulation is identical in composition to the currently approved basic formulation. This was supported by data included with this submission on the manufacturing process, discussion of formation of impurities and certified limits.
- 1c. Product's label for the basic formulation is the same as that for the alternate formulation, Reg. No. 618-109, accepted on 30/OCT/1998. The product is to be used for formulating fungicidal formulations.
- 1d. For future data submission of TGAI's, it is preferable to comply with PR Notice 97-6 by citing impurities as "Other Ingredients" on product's label rather than "Inert Ingredients" as is the case with this label.
- 2. The submitted product's CSF, an alternate formulation dated 30/DEC/1998, was filled out correctly and completely and the nominal concentration of the active ingredient agrees with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2).

CONCLUSIONS:

✓ The submitted product's CSF, an alternate formulation dated 30/DEC/1998 is acceptable. To CRM: Please note Finding 1(d) above.

S. Malak and Central File (Reg. No. 618-109).
7505C:RD:TRB:CM-2:Rm.268:s.m.:03/FEB/1999:703-308-9365: <618-109 >

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