

US EPA ARCHIVE DOCUMENT



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

2-8-85

004276

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: TILT Fungicide; Petition Nos. 4F3007 (Pecans), 4E3026 (Bananas),
4F3074 (Rice, Wheat, Barley, Rye), 4G3075 (Rice, Wheat, Barley, Rye);
Caswell No. 323EE.

TO: Henry Jacoby
Product Manager #21
Registration Division (TS-767C)

THRU: Christine F. Chaisson, Ph.D. *C F Chaisson 2/1/85*
Head, Review Section IV
Toxicology Branch
Hazard Evaluation Division (TS-769C)

FROM: Alan C. Katz, M.S., D.A.B.T. *Alan Katz 2/8/85*
Toxicology Branch
Hazard Evaluation Division (TS-769C)

The Toxicology Branch has conducted a preliminary review of the 90-day rat feeding study with triazole alanine (THS 2212; Bayer AG Institute of Toxicology, Wuppertal-Elberfeld, Report no. 12397; EPA Accession Nos. 072207, and 073114), including the histopathological data which was submitted to this Agency by CIBA-GEIGY Corporation on November 29, 1984. The following deficiencies have been noted:

- 1) Except for the histopathology section, the final report is not signed by responsible personnel and does not contain a Quality Assurance statement by the sponsor or contractor.
- 2) Clinical observations are not presented for individual animals or summarized according to sex/dose group.
- 3) Results of ophthalmological examinations are not presented.
- 4) Sufficient data to establish purity of the test substance and homogeneity, stability and concentration in the diet are not presented.

The sponsor must address the deficiencies cited above in order for the Toxicology Branch to complete its evaluation of this study.

1/153