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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#'s 4F3007(Pecan), 4F3026(Banana), 4F3074(Wheat, Barley, Rye, Rice, Meat and Milk). Propiconazole (Tilt® or CGA-64250). Validation of Residues Data for Plant and Animal Commodities. Addendum to RCB memo of 3/13/87.

FROM: Sami Malak and W. T. Chin, Chemists
Tolerance Petition Section III
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Sami Malak, W.T. Chin

THRU: Philip V. Errico, Section Head
Tolerance Petition Section III
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Philip V. Errico

TO: Lois Rossi, PM #21
Fungicide-Herbicide Branch
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

The available residue data submitted in connection with subject petitions were generated mainly with CIBA-GEIGY's methods No. AG-356 (for plant commodities) and No. AG-359 (for animal commodities). Chemical Operations Branch (BUD) and RCB have concluded that these methods are inadequate for method trials as enforcement methods and because of (1) time requirements, (2) unavailability of state of the art instrumentation and (3) poor resolution (see R. F. Thomas's 9/9/86 memo to RCB and A. Smith's 10/9/86 memo).

Upon re-evaluation of the residue data and methods involved, RCB reached the following conclusions:

- (1a) Because of the poor resolution of method No. AG-359 used to determine propiconazole residues in animal commodities, all the residue data of animal commodities generated from this method are considered invalid. Accordingly, the petitioner should be advised to submit adequate residue data in support of the proposed tolerances for residues of propiconazole in/on animal commodities. If the petitioner has reserved samples which can be proved to be adequate by storage stability data, analyses of the reserved samples with adequate methodology will be acceptable.
- (1b) The above requirement does not effect tolerances as requested in PP#4F3007 (pecan) and PP#4F3026 (banana) because no animal commodities are involved in these petitions.
- (2) For method No. AG-356, however, the resolution of the GCMS analyses is reasonably adequate. Therefore, all the residue data of plant commodities generated from method AG-356 are considered valid.
- (3) All future residue data should be generated with adequate methodology.

Currently, the petitioner submitted two improved methods No. AG-454A and No. AG-517 which were submitted for method trial on 3/11/87 per an expedite request by E. F. Tinsworth (3/4/87).

NOTE TO PM: A deferral to TOX was made in connection with PP#4F3074 (memo of A. Smith, 12/31/86 and in RCB's memo of 3/13/87 by S. Malak) as to their concern regarding the toxicological significance of residues containing the triazole moiety. This question needs to be resolved so that an assessment can be made as to the need for additional metabolism studies and analytical methodologies specific for the triazole moieties contributed by propiconazole.

cc: RF, Circu, SF (propiconazole or Tilt® or CAG-64250), S. Malak, W.T.Chin, James Akerman, Anne Barton, PP#4F3007, PP#4F3026, PP#4F3074, TOX, PM#21 and PMSD/ISB.

RDI: P.V.Errico(3/17/87): R.D.Schmitt(3/17/87)
TS-769: RCB: CM#2: RM812:557-4352:S. Malak(3/18/87):W.T.Chin,wc(3/18/87)