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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Tebuconazole

Project No.: 0-0405
TOX Chem No.: 463P

FROM: Ray Landolt
Review Section I
Toxicology Branch II - Herbicide, Fungicide, and Antimicrobial Support
Health Effects Division (H7509C)

TO: Susan T. Lewis, PM 21
Fungicide-Herbicide Branch
Registration Division (H7505C)

THRU: Mike Ioannou, Section Head
Review Section I
Toxicology Branch II - Herbicide, Fungicide, and Antimicrobial Support
Health Effects Division (H7509C)

and

Marcia van Gemert, Branch Chief
Toxicology Branch II - Herbicide, Fungicide, and Antimicrobial Support
Health Effects Division (H7509C)

Registrant: Mobay Corporation, Letter of November 3, 1989

Action Requested:

1. The registrant has submitted additional data and comment in response to the deficiencies noted in the Toxicology Review (DER 007200) of May 23, 1989.

2. To register the technical formulation (93%) for use in the manufacture of fungicides (EPA No 3125-GIG).

Recommendation: Register the technical formulation for manufacturing use only.

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1. Mobay response to data deficiencies cited in Toxicology Review (DER 007200).

   a. Acute dermal toxicity (81-2)
   Mobay Report No 94395, MRID No. 40700917 and 412908-01.

   This study was found deficient for the lack of the initial individual body weights and the dermal area exposed.

   Tebuconazole (97.1%) powder was applied as a paste (moistened with physiological saline) to a 6 cm x 6 cm area of dorsal surface of five female rats weighing between 195-200 g and five male rats weighing between 204-210 g.

   Conclusion:

   This acute dermal toxicity study may be upgraded from Supplementary to Guideline (corrected one-liner attached).

   b. Dermal Sensitization (81-6)
   Mobay Report No 95695, MRID No. 407009-28 and 412908-02. The following deficiency was cited for this study accompanied by registrant's response.

      i. Further information was requested regarding the application of a 25% concentration of the test material.

      The technical material was described as a lumpy powder. The use of a 25% concentration "was the highest possible concentration which was still homogenous and stable. Higher concentrations resulted in inconsistent pasty lumps because the compound is so insoluble."

   Conclusion:

   The limitations for testing higher concentrations based on the physical characteristics of the test material is reasonable justification for the dose selected.

   With consideration given to the omission of a positive control (stain sensitivity was verified) this study may be upgraded from Supplementary to Minimum.

c. Mobay Corporation:

"We recognize that a MTD was not obtained in our mouse oncogenicity study (Mobay Report No. 96709, EPA MRID No. 40700941). In order to approximate a MTD in this study, dosing at a level greater than 180 ppm is underway. These data will be submitted to the Agency when available."

d. Mobay Corporation:

"A rat metabolism study (EPA Guideline No. 85-1) was requested. Mobay Report Nos. 97438 and 97439 have previously been submitted to the Agency to fulfill this data requirement and are on file under EPA MRID Nos. 40995911 and 40995912."

A general metabolism and dermal penetration studies are currently under review.

2. Registration of the technical formulation (93%) for manufacturing use only.

a. The acute toxicity studies conducted on this formulation support the category of toxicity and precautionary labeling recommended on this label.

b. The directions for use on this label propose that Folicur Technical fungicide is intended for formulation into end-use products for:

Terrestrial Food Crop:
Grain and edible seed crops: wheat, barley and peanut
Small fruits: grapes
Grasses grown for seed

Terrestrial Nonfood Crop:
Grasses grown for seed

Terrestrial Nonfood Crop or Domestic Outdoor:
Lawn and turfgrasses - ornamental

Domestic Outdoor:
Yards, lawn, turf

c. Applications for food uses are pending (9F3724, 9H5575, 9G3814 and 9F3818).