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

5-14-82

MAY 14 1982

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Henry Jacoby (21)
Registration Division (TS-767)
and
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

SUBJECT: Metalaxyl; Ridomil 2E; EPA Reg.#100-607; 100-EUP-TR; PP#1G2532, 1H5314; Metalaxyl in/on various crops; Recalculation of the ADI CASWELL#375AA

Recommendation:

The recalculated ADI is 0.025 mg/kg/day.

Review:

1) Toxicity Data considered in Setting the ADI

°Acute Oral LD_{50} in Rats: 669 mg/kg; Category III.

°Acute Dermal LD_{50} in Rabbits: Greater than 6000 mg/kg; Category III.

°Acute Dermal LD_{50} in Rats: 3170 mg/kg; Category III.

°Skin Irritation in Rabbits: Draize Index = 0.1/8, mild skin irritant ; Category IV.

°Primary Eye Irritation in Rabbits: Corneal involvement, completely clearly in 3 days; Category II.

°Skin Sensitization in Guinea Pigs: Negative

°3-Month Dietary Study In Rats: NOEL = 250 ppm

°90-Day Dietary Study in Dogs: NOEL = 250 ppm

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°Teratology Study in Rats: Not teratogenic at doses up to 120 mg/kg..

°Salmonella/Mammalian Microsome Mutagenicity Study: Not mutagenic.

°Mouse Dominant Lethal Mutagenic Study: Not mutagenic.

°21-Day Subacute Dermal in Rabbits: NOEL = 1000 mg/kg/day

°Rabbit Teratology: Negative at 20 mg/kg

°3-Generation Rat Reproduction: NOEL = 1250 ppm

°6-Month Oral Dog: NOEL = 250 ppm

°2-Year Chronic/Oncogenic Rat Feeding Study: NOEL = 50 ppm; oncogenic potential: negative

2) Calculation of the ADI

The ADI is based on the NOEL of 50 ppm (2.5 mg/kg/day) in the 2-year rat feeding study. This is the most sensitive species for which chronic toxicity data are available. A 100 fold safety factor was used to calculate the ADI.

$$\text{ADI} = 2.5 \text{ mg/kg/day} \times \frac{1}{100}$$

$$\text{ADI} = 0.025 \text{ mg/kg/day}$$

The MPI for a 60 kg person is 1.5 mg/day.

3) The current action utilizes 8.24% of the ADI.

Attachment

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Toxicology Branch
Hazard Evaluation Division (TS-769)

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