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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Risk Assessment of Human Consumption of Oxyfluorfen Contaminated Home Garden Vegetables; Oxyfluorfen Contamination of Orthomite Insecticidal Soap (EPA Reg. No. 239-2564)

Caswell No.: 188AAA

FROM: William Dykstra, Ph.D. William Dykstra 7/3/91
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TO: Phil Hutton, PM# 17/Joanne Miller, PM# 23
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and
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THRU: Roger Gardner, Section Head Roger Gardner 7/3/91
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The Pivotal Toxicology studies for Oxyfluorfen are presented below:

Rat oral LD_{50}	> 5.0 gm/kg (technical)
Rabbit teratology	maternal NOEL = 10 mg/kg; Developmental NOEL = 10 mg/kg; maternal and developmental LEL = 30 mg/kg (fused sternebrae)
Rat teratology	Maternal NOEL = 100 mg/kg Developmental NOEL = 100 mg/kg; Maternal and Developmental LEL = 1000 mg/kg

3-generation rat reproduction study	NOEL = 10 ppm, LEL = 100 ppm (deceased pup body weight and viability indices)
20-month mouse feeding/oncogenicity study	oncogenic potential: positive for liver tumors in males Q_1^* = 0.128 $(mg/kg/day)^{-1}$; NOEL = 2.0 ppm; LEL = 20 ppm (liver effects)
2-year chronic toxicity/oncogenicity rat study	oncogenic potential: no MTD; NOEL = 40 ppm, LEL = 800 ppm (liver effects)
2-year dog feeding study	NOEL = 100 ppm; LEL = 600 ppm (liver effects)

Positive mutagenicity studies: Ames, mouse lymphoma
Negative mutagenicity studies: Ames, in vivo cytogenetic, UDS

Case I = Acute Toxicity Risks 20 kg Child

If, by chance, a 20 kg child consumed 1.0 kg (2.2 lbs) of contaminated vegetables at a residue level of 2.0 ppm, the child would be exposed to 0.1 mg oxyfluorfen per kg body weight. Compared to the Rat oral LD_{50}, which was greater than 5000 mg/kg BW, the child would be below the level of toxicity by a factor of 50,000 for acute effects.

Therefore, TB-I concludes that there are no overt acute toxicity health risks from consumption of Oxyfluorfen contaminated vegetables.

Case II - Pregnant Woman

If a 60 kg pregnant woman consumed 1.5 kg of contaminated vegetables at 2.0 ppm level of oxyfluorfen, the woman would be exposed to 0.05 mg/kg BW of oxyfluorfen. Compared to the NOEL for developmental toxicity in rabbits of 10.0 mg/kg/day, the woman would have a margin of exposure (MOE) of 200.

The remainder of the toxicological risk assessment requested by Registration Division is contained in the DRES analysis which will be completed later today.