7-3-91

Cheryl Long
215-967-8471

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

FAX
215-967-8956

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
Review Section I, Toxicology Branch I
Health Effects Division (H7509C)

TO: Phil Hutton, PM# 17/Joanne Miller, PM# 23
Registration Division (H7505C)
and
Chemistry Branch II
Health Effects Division (H7509C)

THRU: Roger Gardner, Section Head Roger Gardner 7/3/91
Review Section I, Toxicology Branch I
Health Effects Division (H7509C)

and

Karl Baetcke, Ph.D, Chief Karl D. Baetcke 7/3/91
Toxicology Branch I
Health Effects Division (H7509C)

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.