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. 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 Review Section I, Toxicology Branch I Health Effects Division (H7509C) and Karl Baetcke, Ph.D, Chief Toxicology Branch I Health Effects Division (H7509C)

The Pivotal Toxicology studies for Oxyfluorfen are presented below:

Rat oral LD₅₀ > 5.0 gm/kg (technical) maternal NOEL = 10 mg/kg; Developmental NOEL = 10 mg/kg; maternal and developmental LEL = 30 mg/kg (fused sternebrae)

Rabbit teratology

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); 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.