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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

CASWELL FILE
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SUBJECT: Propanil - 3',4'-dichloropropionanilide. Section 18 Exemption for Use on Wheat in North Dakota.

FROM: Roland A. Gessert, D.V.M., Toxicology Branch

TO: Mr. Hoyt Jamerson, Special Registrations Section

Under Section 18 of Amended FIFRA, the State of North Dakota requests an emergency exemption from the requirements of registration of the herbicide propanil for use on wheat to control foxtail (Setaria sp.).

Toxicities of propanil are as follows:

ACUTE ORAL TOXICITY, RATS - $LD_{50}$ = 2270 mg/kg.
ACUTE DERMAL TOXICITY, RABBITS - $LD_{50}$ = 7080 mg/kg.
ACUTE INHALATION TOXICITY, RATS - $LC_{50}$ = 18.6 mg/liter
PRIMARY DERMAL IRRITATION, RABBITS - Mild skin irritant
PRIMARY EYE IRRITATION, RABBITS - Moderate to moderately severe eye irritant
SUBACUTE ORAL TOXICITY, RATS - 30 days - no significant toxicity
90 days - no-effect level above 200 ppm

TWO-YEAR DOG FEEDING STUDY (Medical College of Virginia, 1974) ✓

Groups of purebred beagle dogs, 2 of each sex in each group were fed 0, 100, 600, or 4000 ppm compound (1st 4 weeks at 3000 ppm) in diets for two years. Observations for effects included:

1. Weekly body weights
2. Daily food consumption measurements
3. Hematology, initially and at 3-month intervals, including hematocrits, hemoglobin, total & differential leucocyte counts.
4. Urine tests for sugar & protein were done at same intervals as hematology.
5. Liver function tests including bromsulphalein, SGOT, & SAP were done during the 24th month.
6. Necropsy at termination:
   a. Gross examination of tissues & organs for compound-related changes
   b. Heart, liver, spleen, kidney, & testes weighed.
7. Microscopic examination of heart, lung, liver, kidney, spleen, GI tract, urinary bladder, skin, smooth muscle, lymph nodes, bone marrow, brain, pituitary, thyroid, pancreas, adrenals, & gonads.

RESULTS: 4000 ppm group
1. Depressed weight gains ✓ (stated to be related to decreased food intake)
2. Slightly increased SGOT and SAP values. ✓

600 and 100 ppm groups: Effects not revealed by observations.

EPA FORM 1320-6 (REV. 3-76)

TWO YEAR RAT FEEDING STUDY (Medical College of Virginia, 1962)

Groups of Wistar strain albino rats, 25 of each sex in each group, were fed 0, 100, 400, or 1600 ppm compound in diets for two years. Observations for effects included:

1. Weekly body weights
2. Food consumption measured during 3-day periods at the beginning of the 1st, 3rd, 6th, 12th, and 24th months.
3. Hematology, including hematocrits, hemoglobin, total and differential leucocyte counts, done at 3-month intervals.
4. Urine examination for sugar and protein, done at 3-month intervals.
5. Necropsy at termination
   a. Examination of tissues & organs for compound related effects
   b. Heart, liver, spleen, kidney, and gonads weighed.
6. Microscopic examination of heart, liver, lung, spleen, GI tract, kidney, urinary bladder, thyroid, adrenals, pancreas, gonads, pituitary, skeletal muscle, skin, bone marrow, and brain.

RESULTS: 1600 ppm group

1. Depressed body weight gain, lessened food intake; slightly lowered hematocrits and hemoglobin values
2. Increased mortality (males only - after 20 months)

100 and 400 ppm groups: compound-related effect not revealed by observations

THREE-GENERATION RAT REPRODUCTION STUDY (Medical College of Virginia, 1966)

Groups of Wistar strain albino rats, 20 of each sex in each group, were fed 0, 100, 300, or 1000 ppm compound in diets during the production of 3 generations. Each female was bred to a male in her diet group to produce 2 litters in each generation. Records were maintained to provide the gestation, fertility, viability, and lactation indexes. Ten of each sex in each group of the $F_{3b}$ offspring were necropsied and heart, bladder, lung, liver, kidney, spleen, GI tract, bone marrow, skeletal muscle, skin, brain, pituitary, thyroid, adrenals, pancreas, and gonads were examined microscopically.

Compound-related organ and tissue changes were not found in the examined $F_{3b}$ weanlings.

TOXICITY DATA SUMMARY: DEMONSTRATED NO-EFFECT LEVELS:

Dogs, two-years 600 ppm diets ✓
Rats, two-years 400 ppm diets
Three-generation rat reproduction study -- 1000 ppm ✓

Currently propanil is registered for use on rice and the following residue tolerances have been established under 40 CFR 180.274:

| | | | |
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| rice straw | 75 ppm | meat | 0.1 ppm |
| rice grain | 2 ppm | eggs, milk | 0.005 ppm |

Rohm and Haas Company is preparing a tolerance petition and registration application to provide for use of propanil on wheat. I have examined material contained in the pesticide petitions for use of propanil on rice and am satisfied that no hazard will exist in granting this exemption for wheat, unless Chemistry Branch have new data which would refute this conclusion.

Unless Chemistry Branch have new data which would demonstrate propanil to be unsafe on wheat, Toxicology Branch recommends this exemption for use on wheat in North Dakota be granted.

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