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FSA

file PP#7G0516

Mr. William Stokes
Petitions Control Branch

October 6, 1966

George E. Whitmore
Division of Toxicological Evaluation
Petitions Review Branch

Temporary tolerance request - Deconil-2787, 0.1 ppm in or on potatoes.

PESTICIDE PETITION NO. 7G-0516

Diamond Alkali Company
Cleveland, Ohio 44115
(AF 25-202)

Six month progress report of the two year Deconil dog feeding study:

Young adult beagles, four of each sex on diet levels of 0, 0.15, 1.5, and 3%.

Observations for effects include:

1. Appearance.
2. Pharmacologic or toxic effects.
3. Weekly weights.
4. Food consumption, measured weekly.
5. Behavior.
6. Clinical studies--initially, at 21 and 45 days, and at 6 months.

   a. Hematology: Erythocyte counts, total and differential leucocyte counts, coagulation time, hematocrit, hemoblobin, and sedimentation rats.

   b. Biochemical tests: Bromosulfathaline liver function tests, blood urea nitrogen, and serum transaminase determination.

   c. Urine analysis: Appearance, pH, specific gravity, sugar, acetone, protein, bilirubin, occult blood and sediment examination.

Results: Differences were not found between compound fed dogs and non-compound fed dogs.

Thirteen week progress report of a 2-year Deconil rat feeding study:

Cesarean derived Charles River strain albino rats were fed 0, 0.15, 1.5 and 2.0% Deconil diets. Thirty-five of each sex were fed compound; 70 of each sex were maintained as controls.

Observations for effects:

1. Weekly body weights.

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2. Mortality.
3. Appearance.
4. Pharmacologic or toxic signs.
5. Weekly food and compound consumption.
6. Hematology initially, at 30 days and at 3 months: Five animals of each sex were examined for erthrocyte numbers, total and differential leucocyte numbers, coagulation time, hematocrit, and hemoglobin.
7. Urine examination initially, at 30 days, and at 3 months. Pooled urine samples from the same rat groups used as a source of blood for hematology were examined for appearance, pH, specific gravity, sugar, acetone, protein, bilirubin, occult blood and sediment.
8. Necropsy of 5 rats of each sex in each group at 13 weeks: Examination for gross organ and tissue changes. Suitably prepared specimens of important organ and tissues were obtained from the high diet and control group rats and examined microscopically. Additional specimens were obtained from the brain, heart, liver, spleen, kidney, testes, caecum from the other diet groups and examined microscopically.

Results: Effects in the 0.15 group were confined to questionable increased kidney to body weight ratios. Effects in the 1.5 and 2% diet groups included slight histologic alterations in the thyroid, kidney and stomach. Lessened weight gains were recorded for the 1.5 and 2.0% groups. Increased kidney to body weight ratios were recorded for the 1.5 and 2.0% groups.

Summary of Toxicity Data:

Six month progress report of a 2 year dog study-diet levels of 0, 0.15, 1.5, and 3% without effects.

Thirteen week progress report of a 2 year rat feeding study: Diet levels of 0, 0.15, 1.5 and 2%. Sacrifice of 5 of each sex in each group at 13 weeks. Significant effects confined to slight histologic alterations in the thyroid, kidney, and stomach, in the 1.5 and 2% groups.

CONCLUSION:

The petition data support the safety of the requested temporary tolerance for 0.1 ppm of Daconil on potatoes.

INIT:HBlumenthal

cc: DIE
LIB (Dr. Jacobson)
FSA
PP No. 7G-0516

GEWhitmore:dps 10-6-66