DATA EVALUATION REPORT (152A-10)

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Study Type:	Acute Oral Toxicity Pathogenicity - mice
MRID No:	418335-02
Caswell No:	584H
Test Material :	Mycoleptodiscus terrestris , mycelia (TGAI)- SN3
Project No:	LO8247 - SN3
Sponsor:	EcoScience Laboratories, Inc., Amherst, MA.
Testing Facility:	IIT Research Institute, Chicago, Ill.
Title of Report:	Acute Oral Toxicity Limit Testing of Mycoleptodiscus terrestris, a Fungal Herbicide.
Authors:	Robert L. Sherwood, Ph.D.
Study Completed:	October, 1990
Conclusion:	A test dose of Mycoleptodiscus terrestris mycelia (TG) at a concentration of 3 x 10^4 CFU/mouse (equivalent to 5400 mg of wet weight/kg) was non-toxic, non-pathogenic and non-infective for mice. A pattern of clearance was established within 7 days after dosing. Note that the test dose was administered based on wet weight; the dry weight was reported to be 18.3% of the wet weight (approximately 988 mg/kg).
Classification:	Acceptable.

I. STUDY DESIGN

Test Material: The microbial pesticide control agent (MPCA) is Mycoleptodiscus terrestris mycelia (Lot No. TOX 002). Two preparations of the dosing material were made; one with viable technical grade mycelia (TG) and the other with killed technical grade mycelia (KTG). The test material was prepared by suspending 250mg wet weight of TG or KTG in 1 ml water. The actual dry weight of the test material is reported to be 18.3% of the wet weight.

Test Animals: CD1 mice were obtained from Charles River Laboratories (Portage, MI). They were assigned to the following experimental groups: 36 mice (18/sex) in each of the naive control (NC), the TG and KTG groups, and 12 mice (6/sex) in the shelf control (SC) group. Six of the mice (3/sex) in each group were maintained as 'extras'. Body weights at the beginning of the study were in the approximate range 19-20g for females, and 23-25 g for males.

Methods: All animals were weighed just prior to the beginning of the study (Day 0). Test animals were then dosed, intragastrically, with 0.5 ml of the appropriate test material (TG or KTG) at a concentration of 5.4g of wet weight/kg (approximately 125 mg wet weight /mouse). The numbers of viable fungi administered were determined by plating samples of the dosing suspension on Martin's Agar plates. Body weights were again recorded on Days 3, 7 and 14 and the animals were observed daily for clinical signs of toxicity. Scheduled sacrifices were performed immediately after dosing, and on Days 3, 7, and 14 at which time gross examinations were done, selected organs (lung, brain, kidney, spleen, liver) were removed and weighed, and tissue samples (lung, blood, brain, kidney, liver, spleen, stomach/intestine, feces) were enumerated for viable test material.

II. RESULTS

The numbers of viable fungal mycelia administered to each mouse in the TG group were reported to be approximately 3×10^4 CFU. About 45.7% of this concentration was recovered from the stomach/intestine immediately after dosing (Day 0). Viable organisms were also found in the liver and feces of TG mice at Day 0 but had cleared from the liver and stomach/intestine by Day 3 and from the feces by Day 7. At Day 7, low levels (24 ± 60 to 185 ± 149 CFU/organ) also were found in the stomach/intestine of NC , KTG and SC animals suggesting probable contamination. No data on microbial clearance were given beyond Day 7 because a pattern of clearance was presumed to have been established by this time.

All mice , except one female KTG mouse which died on Day 2, gained weight over the course of the study. There were no statistically significant differences in body weights or weight gains between any group at the conclusion of the study (14 days). There were also

no significant increases in organ weights.

No clinical signs of toxicity were observed except for the unscheduled death mentioned above. Gross necropsies revealed minor abnormalities: a slightly enlarged spleen in one TG mouse on Day 3 and red, mottled lung in one NC mouse on Day 7.

III. SACB DISCUSSION

When mice were administered the technical grade of Mycoleptodiscus terrestris mycelia (100% mycelia) at a concentration of 125 mg/mouse (equivalent to approximately 3×10^4 CFU fungi/Mouse), there was no evidence of toxicity or pathogenicity or persistence. A pattern of clearance was established by Day 7. It is most likely, in SACB's opinion, that the appearance of small numbers of the Mycoleptodiscus terrestris in organs of dosed animals resulted from contamination within the animal facilities or through handling since the fungus also was detected in non-treated and KTG animals.