DATA EVALUATION REPORT

1. Chemical: Mycoleptodiscus terrestris

2. Test Material: Technical

3. Study/Action Type: An Avian Oral Pathogenicity and Toxicity Study, Species: Mallard Duck (Anus platyrhynchos) (154A-16)

4. Study Identification: An Avian Oral Pathogenicity and Toxicity Study, By J. Grimes, K. A. Hoxter and M. Jaber. Prepared By Wildlife International LTD, March 1990. Project No. 270-101. Submitted By EcoScience Laboratories, Inc. Amherst, MA. EPA Acc. No. 418335-06.

5. Reviewed By: David C. Bays
Microbiologist
EFED/EEB

Signature: David C Bays
Date: 7/10/91

Les W. Touart
Head, Section 1
EFED/EEB

Signature: LWT
Date: 7.16.91

6. Conclusions:

The study is scientifically sound and demonstrated an LD_{50} > 2,500 mg/kg. This indicates that Mycoleptodiscus terrestris is practically nontoxic to birds. The study fulfills EPA Guideline requirements for an avian oral pathogenicity/toxicity test.

7. Recommendations: N/A

8. Background:

This study was submitted to support the request for the registration of Mycoleptodiscus terrestris.

10. Materials and Methods:

A. Test Organisms: Healthy day old mallard ducklings, phenotypically indistinguishable from wild birds, were purchased from Whistling Wings, Box 1, 113 Washington St., Hanover, IL 61041 and acclimated until they were 21 days old. The mallards were distributed into 12 treatment groups of 5 birds each, without regard for the sex of the bird. The average body weights of the test birds at the beginning of the study ranged from 422±37 to 470±18 grams depending on treatment group. Water and feed, a game bird ration formulated by Wildlife International Ltd, were provided ad libitum during the acclimation and testing periods.

B. Dosage Form: The test substance, a brown solid, was suspended in distilled water at 25% (w/v) to obtain a dosable solution. The suspension was prepared daily and given to the birds at a dose of 1.0% of body weight. The test substance was administered directly into the crop or proventriculus using a stainless steel cannula. Each treated bird received a dose of 2500 mg/kg of body weight once each day for 5 days.

C. Referenced Protocol: The total concentration of the test substance given to each bird was 12,500 mg/kg of body weight. The attenuated controls consisted of a brown solid. The same rate that was used for the test material (2500 mg/kg per day for five days) was used for the attenuated samples. The sterile filtrate control, an amber liquid, was administered to the birds at 1.0% of body weight for five days. The negative control consisted of distilled water administered to the birds at 1.0% of body weight for five days.

All birds were acclimated in brooding pens (61x91x26 cm high), and then assigned to testing pens (75x90x45 cm high) by random draw and housed indoors. Average ambient room temperature for the study was 22±1C with an average relative humidity of 80±7%. The photoperiod (monitored by a time clock) was 16 hours of light per day during acclimation and throughout the study. The light was provided by Chroma 50 fluorescent lights (5000 Kelvin) which closely approximated noon-day sunlight (4870 Kelvin). The birds received approximately 12 footcandles of illumination. Housing and husbandry practices were based upon the "Guide for the Care and Use of Laboratory Animals", NIH Publication No. 85-23, 1985.

All birds were observed daily during acclimation and any exhibiting abnormal behavior or physical injury were not used. After test initiation and continuing until

termination, all birds were observed at least twice daily with all mortality, signs of toxicity or abnormal behavior being recorded. Body weights of the test birds were recorded individually prior to dosing and on days 0, 1, 2, 3, 4, 11, 18, 25 and 30. Average estimated feed consumption was measured for days 0-4, 4-11, 11-18, 18-25 and 25-30.

D. Statistical Analysis: After study completion, one-way analysis of variance was used to determine if significant differences in body weight of test birds existed between treatment groups at each weighing interval.

12. Reported Results:

Dosage	Replicate	Number Dead/Number Exposed (At 30 Days After Dosing)
Negative control	NC1	0/5
	NC2	0/5
Attenuated control	AC1	0/5
	AC2	0/5
Sterile filtrate	SFC1	0/5
	SFC2	0/5
2500 mg/kg	T1	0/5
	T2	0/5
	T3	0/5
	T4	0/5
	T5	0/5
	T6	0/5

LD_{50} > 2,500 mg/kg

No mortalities occurred in any of the control groups (negative, attenuated and sterile filtrate) or among the treated birds (2500 mg/kg per day for five days). All birds were normal in appearance and behavior throughout the test period. There were no apparent effects on body weight or feed consumption between the control and the treated groups.

All birds were euthanized using carbon dioxide at the termination of the study and then subjected to gross necroscopy. The results were not found to be remarkable except for one bird in a control group which had hyperemia throughout the lower intestinal tract, one bird in the attenuated control group which had small (0.5 mm), discrete, free floating yellow globules in the abdominal mesentery, one bird in the sterile filtrate control group which had a small (1.0 mm), free floating abscess in the abdominal cavity, and in the treatment group, 4 birds were feather-picked, 2 were found no have

a retained yolk sac, 2 had hyperemia in the intestinal tract and one had a small (0.5 mm), discreet, free floating yellow globules in the abdominal mesentery.

Although not considered treatment related a sample was collected from each bird and submitted to EcoScience Laboratories, Inc. for further testing. IIT Institute, Chicago, IL, analyzed the tissue samples and found that none of the samples had fungi or material which could be identified as Mycoleptodiscus terrestris. Also, no fungal colonies were observed in any of the tissue samples tested when plated on Martin's agar.

3. Study Author's Conclusions/Quality Assurance Measures:

LD_{50} > 2,500 mg/kg

"This study was conducted so as to conform with Good Laboratory Practices as published by the U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160, with the following exceptions: Samples of the test solutions were not taken for confirmation of test dosage concentrations." Signed by study director, Kimberly Hoxter.

14. Reviewer's Discussion and Interpretation of the Study:

A. Test Procedures: The procedures used follow those recommended by EPA in the 1989 Pesticide Testing Guidelines for Microbial and Biochemical Pest Control Agents, Subdivision M.

B. Statistical Analysis: None was needed since there were no mortalities.

C. Discussion/Results: An LD_{50} > 2,500 mg/kg indicates Mycoleptodiscus terrestris is practically non-toxic, on an acute basis, to birds.

D. Adequacy of the Study:

1. Validation Category: Core

2. Rationale: Meets EPA Guideline requirements

15. Completion of the One-liner: