DATA EVALUATION REPORT

1. Chemical: Mycostop™ Streptomyces griseovirdis

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. B. Beavers and G. J. Smith Prepared By Wildlife International LTD, March 1990. Project No. 293-103. Submitted By Kemira Oy, Helsinki, Finland, EPA Acc. No. 418211-20.

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

Signature:
Date: 9/15/92

Les W. Touart
Head, Section 1
EFED/EEB

Signature:
Date: 9/15/92

6. Conclusions:

The study is scientifically sound and demonstrated an LD_{50} > 2,500 mg/kg. This indicates that Streptomyces griseovirdis is practically nontoxic to aquatic 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 Streptomyces griseovirdis.

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 14 days old. The mallards were distributed into 10 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 241±35 to 275±18 grams depending on treatment group. Water, from the town of Easton, 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 tan powder ($9.8x10^8$ cfu/g test material), 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 ($2.45x10^9$ cfu/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 ($1.225x10^8$ cfu/kg) of body weight. The attenuated controls consisted of heat deactivated Mycostop™ in a 1.0% (v/w of body weight) solution at the same rate that was used for the test material (2500 mg/kg per day 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 25.1±1C with an average relative humidity of 69±11%. 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
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 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 2 male birds in the control groups which had single plaques in their air sacs. In the treatment group, one male bird was small, with reduced muscle mass and feather loss on the rump. Two males and one female were found to have plaques on there air sacs, and a second female had plaques on and in the lungs and a somewhat pale spleen.

Although not considered treatment related samples were collected from each affected bird, if possible, and submitted to the Maryland Department of Agriculture Animal Health Laboratory in Salisbury Maryland for further testing. The tissue samples were analyzed and found to be negative for the

presence of this organism.

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 to determine the homogeneity and stability of test dosage concentrations. Bacteriology on samples of tissue collected during terminal necropsy was performed by Maryland Department of Agriculture Animal Health Laboratory, which was not a GLP facility." Signed by study director, Joann Beavers.

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 Streptomyces griseovirdis is practically non-toxic, on an acute basis, to mallards.

D. Adequacy of the Study:

1. Validation Category: Core

2. Rationale: Meets EPA Guideline requirements

15. Completion of the One-liner: