DATA EVALUATION REPORT

1. Chemical: Mycostop™ - Streptomyces griseoviridis

2. Test Material: Technical

3. Study/Action Type: An Avian Oral Pathogenicity and Toxicity Study, Species: Bobwhite Quail (Colinus virginianus) 154A-16

4. Study Identification: An Avian Oral Pathogenicity and Toxicity Study, By J. B. Beavers and Gregory J. Smith. Prepared By Wildlife International LTD, October 1990. Project No. 293-102. Submitted By Kemira Oy, Helsinki, Finland. EPA Acc. No. 418211-19.

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

Signature:
Date: 9/8/92

Les Touart
Supervisory Biologist
EFED/EEB

Signature:
Date: 9/11/92

6. Conclusions:

The study is scientifically sound and demonstrated an LD_{50} > 2500 mg/kg. This indicates that Streptomyces griseoviridis is practically nontoxic to quail. 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 Mycostop™ - Streptomyces griseovirdis.

10. Materials and Methods:

A. Test Organisms: Healthy northern bobwhite, phenotypically indistinguishable from wild birds, were obtained from Wildlife International Ltd. Production Flock in Easton, Maryland and acclimated until they were 14 days old. The bobwhite were distributed into 10 test 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 22±1 to 31±4 grams depending on test 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 (tan powder-9.8 x 10^8 cfu/g test material) and attenuated control were prepared fresh daily by suspending the test substance in distilled water at a concentration of 25% (w/v). The attenuated control was deactivated by autoclaving at 121C for 60 minutes. A vehicle negative control, as described in Subdivision M, was used instead of an undosed control. The suspension was given to the birds at a dose of 1.0% (v/w) of body weight (2500 mg/kg of body weight or 2.45 x 10^7 cfu/kg) each day for 5 days. The test substance was administered directly into the crop or proventriculus using a stainless steel cannula.

C. Referenced Protocol: The total concentration of the test substance given to each bird was 1.225 x 10^{10} cfu/kg of body weight. Two groups of 5 birds each were administered distilled water at 1.0% (v/w) to serve as a negative control. The attenuated control consisted of 2 groups of 5 birds each which received oral doses of heat deactivated test substance (Streptomyces griseoviridis) in a 1.0% (v/w) of body weight suspension. The 6 treatment groups each consisted of 5 birds which received a 25% (w/v) suspension of test substance in distilled water at a concentration of 1.0% (v/w) of body weight.

During acclimation and testing, all birds were assigned to breeding pens (72x90x23 cm high) by random draw and housed indoors. Average ambient room temperature for the study was 25.1±1.0C 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 130 lux 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: None was needed due to the lack of mortalities observed in the study.

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	1/5
	T2	0/5
	T3	0/5
	T4	1/5
	T5	0/5
	T6	0/5

LD_{50} > 2500 mg/kg

No mortalities occurred in either of the control groups (negative or attenuated) and 2 occurred among the treated birds (2500 mg/kg or approximately 2.45×10^9 cfu/kg per day for five days). Due to the nature of lesions observed in the necropsy, neither death was considered to be treatment related. All other birds were normal in appearance and behavior throughout the test period, except for one bird in a treatment group which exhibited limping, lethargy and a ruffled appearance. These conditions were not thought to be treatment related. 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 necropsy. The results were not found to be remarkable.

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

LD_{50} > 2500 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 exception: Samples of the test solutions were not taken to determine the homogeneity and stability of test dosage concentrations. Bacteriology on sample of lung 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 B. 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 attributable to the test substance.

C. Discussion/Results: An LD_{50} > 2500 mg/kg indicates Mycostop (Streptomyces griseovirdis) 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