Accession Number 406386-20

DATA EVALUATION RECORD

1. CHEMICAL: MON 7200/MON 15151.

2. TEST MATERIAL: MON 7200/MON 15151; 91.5% purity; a yellowish, crystalline solid.

3. STUDY TYPE: Avian Single-Dose Oral LD50 Test. Species Tested: (Colinus virginianus).

4. CITATION: Grimes, J. and Jaber, M. 1987. MON 7200: An Acute Oral Toxicity Study with the Bobwhite. Prepared by Wildlife International Ltd., Easton, Maryland. Submitted by Monsanto Company, St. Louis, Missouri. Study Number 139-235/WL-87-87. Accession Number 406386-20.

5. REVIEWED BY:

Prapimpan Kosalwat, Ph.D.
Staff Toxicologist
KBN Engineering and
Applied Sciences, Inc.

Signature: P. Kosalwat
Date: 7/26/88

6. APPROVED BY:

James R. Newman, Ph.D.
Project Manager/
Principal Scientist
KBN Engineering and
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Signature: James R Newman
Date: 7/26/88

for Henry T. Craven
Supervisor, EEB/HED
USEPA

Signature: Richard m Lee
Date: 9/6/88

7. CONCLUSIONS: This study is scientifically sound and meets the guideline requirements for an avian single-dose oral LD50 test. With an LD50 value of greater than 2250 mg a.i./kg, MON 7200 is considered practically non-toxic to Bobwhite quail (Colinus virginianus).

8. RECOMMENDATIONS: N/A.

9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

A. Test Animals: All Bobwhite (Colinus virginianus) were 27 weeks of age, ranged in weight from 166 grams to 217 grams and appeared to be in good health at initiation of the study. The birds were obtained from Fritts Quail Farm, New Jersey. The birds were pen-reared and phenotypically indistinguishable from wild birds. All birds were acclimated to the caging and facilities for 3 weeks prior to the initiation of the study. During acclimation, all birds were observed daily. Birds exhibiting abnormal behavior or physical injury were not used.

B. Test System: Test birds were housed indoors by dosage group in batteries of commercial pens. Birds were assigned to pens by random draw. Each pen had floor space that measured approximately 78 x 51 cm. Floors were soloped so that ceiling height ranged from approximately 20 to 25 cm. External walls, ceilings and floors were constructed of galvanized wire, while side walls were constructed of galvanized sheeting. Birds were maintained at ambient room temperature. Average temperature for this study was $24^{o}C \pm 2^{o}C$ (SD) with an average relative humidity of 72%. The photoperiod (maintained by a time clock) was eight hours of light per day during acclimation and throughout the study. The birds received approximately twelve footcandles of illumination.

Throughout acclimation and testing, all test birds were fed a game bird ration (the diet formulation was included in the report). Water from the town of Easton and feed were provided ad libitum during acclimation and during the test. The birds were fasted for a minimum of 15 hours prior to dosing. The birds received no form of antibiotic medication during acclimation or the study.

The test material was dispersed in corn oil. All stock solutions prepared appeared homogenous by visual inspection. The concentration of the test material in the diluent was adjusted to provide a constant volume to body weight dosage for all treatment birds. All dosages

were adjusted to 100% active ingredient. Therefore, all dosages and the LD50 value were reported as milligrams of active ingredient per kilogram of body weight.

C. Dosage: Fourteen-day single-dose oral LD50 test. The nominal dosages were 292, 486, 810, 1350, and 2250 milligrams active ingredient (a.i.) of MON 7200 per kilogram of body weight.

D. Design: Groups of ten Bobwhite, five males and five females, were assigned to each of the five treatment groups and the control group by random draw. The dosages were established based upon known toxicity data. At initiation of the test, a single dose of the test material in diluent was orally intubated directly into the crop or proventriculus of each bird using a stainless steel catheter. Each bird was individually weighed and dosed on the basis of milligrams of test substance per kilogram of body weight. The control birds received a corresponding volume of diluent only. All treatment and control birds received a constant dosage volume of 6 milliliters per kilogram of body weight.

Following test initiation (dosing) until test termination (Day 14), all birds were observed at least twice daily. A record was maintained of all mortality, signs of toxicity, or abnormal behavior. Individual body weights were measured at initiation of the test and by group on Days 3, 7, and 14 of the test. Average estimated feed consumption was determined for each dosage group and the control for Days 0-3, 4-7, and 8-14. Feed consumption was measured accurately, but was presented as an estimate due to the unavoidable wastage by the birds.

E. Statistics: The mortality pattern in the study was not conducive to calculating the LD50 value. Therefore, an estimation of the LD50 value was made by a visual inspection of the mortality data.

12. REPORTED RESULTS: There were no mortalities in the control group and in any of the dosages tested (Table 1, attached). Two birds in the control group displayed a ruffled appearance intermittently from Day 10 to study termination. All other birds in the control and all birds in the 292-mg/kg dosage level were normal in appearance and behavior throughout the test period.

At the 486-, 810-, 1350-, and 2250-mg/kg dosages, one to four birds displayed a ruffled appearance and/or wing droop from Day 0 through the morning of Day 3. At the 810- and 1350-mg/kg dosages, one female also was noted as lethargic on Days 1 and 2. At the 810-mg/kg dosage, one female was noted with a ruffled appearance from Day 13 until study termination. All other birds at these dosages were normal in appearance and behavior for the duration of the study. It was not possible to determine if the clinical signs noted were treatment related. This was due to the intermittent occurrence of signs and the presence of similar clinical signs among the control birds.

When compared to the controls, there was no effect on body weight or feed consumption at any of the dosages tested.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES: The oral LD50 for MON 7200 in Bobwhite quail was considered to be greater than 2250 mg/kg, the highest dose tested. MON 7200 was considered to be practically non-toxic to Bobwhite quail by ingestion in single doses.

The study was conducted so as to conform with Good Laboratory Practices (Federal Register, Volume 48, No. 230, November 29, 1983). The study was examined and the final report was signed by the Quality Assurance Unit of Wildlife International Ltd.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:

A. Test Procedure: The test procedures are in accordance with the SEP guidelines, except gross necropsy was not performed at test termination.

B. Statistical Analysis: Statistical analysis was not needed due to the lack of mortalities in any treatments.

C. Discussion/Results: The LD50 value of MON 7200 for Bobwhite quail, when administered as oral single dose, was greater than 2250 mg a.i./kg. Therefore, MON 7200 is considered practically non-toxic to Bobwhite quails.

D. Adequacy of the Study:

(1) Classification: Core.

(2) Rationale: N/A.

(3) Repairability: N/A.

15. COMPLETION OF ONE-LINER: Yes, July 14, 1988.

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No. _____ Chemical Name MON 7200 Chemical Class _____ Page 1 of _____

Study/Species/Lab/ Succession	Chemical % a.i.	Results	Reviewer/ Date	Validat: Status
14-Day Single Dose Oral LD_{50}		LD50 = mg/kg (95% C.L.) Contr. Mort.(%)=		
Species	_____	Slope= # Animals/Level= Age(Days)= Sex =	_____	_____
Lab		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
14-Day Single Dose Oral LD_{50}		LD50 = >2250 mg/kg.* (95% C.L. N/A) Contr. Mort.(%)= 0 (189 days)		
Species Colinus virginianus	91.5	Slope= N/A # Animals/Level= 10 Age(Days)= 27 weeks Sex = M/F	PK/7-14-88	Core
Lab Wildlife International Ltd.		14-Day Dose Level mg/kg*/(% Mortality) 292(0),486(0),810(0),1350(0),2250(0)		
Acc. 406386-20		Comments: * active ingredient		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L.) Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Age(Days)= Sex =	_____	_____
Lab	_____	8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L.) Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Age(Days)= Sex =	_____	_____
Lab	_____	8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L.) Contr. Mort.(%)= Sol. Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Temperature =	_____	_____
Lab	_____	96-Hour Dose Level ppm /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc		Comments:		
96-Hour LC_{50}		LC50 = ppm (95% C.L.) Con. Mor(%)= Sol. Con. Mor.(%)=		
Species		Slope= # Animals/Level= Temp.=	_____	_____
Lab	_____	96-Hour Dose Level ppm /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
96-Hour LC_{50}		LC50 = ppm (95% C.I.) Con. Mort.(%)= Sol. Con. Mort.(%)=		
Species		Slope= # Animals/Level= Temp.=	_____	_____
Lab	_____	96-Hour Dose Level ppm /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		