

DATA EVALUATION RECORD

1. Chemical: Prometon Technical 98.5%
2. Test Material:
2,4-bis[isopropylamino]-6-methoxy-s-triazine
3. Study Type: Bobwhite single-dose oral LD50
4. Study ID: MRID # 416091-24
Campbell, Susan (1990) Prometon: An acute oral toxicity study with the northern bobwhite. An unpublished study prepared by Wildlife International Ltd., 305 Commerce Drive, Easton, MD 21601.
5. Reviewed by: Cynthia Moulton
Biologist
EEB/EFED
Cynthia A. Moulton
2.27.91
6. Approved by: Norman Cook
Head Section II
EEB/EFED
Norman J. Cook
2.28.91
7. Conclusion: The study was scientifically sound and completes the guideline requirements for a single dose oral LD₅₀ study with the bobwhite quail. The LD₅₀ was > 2264 mg a.i./kg. However, a no observed effect level (NOEL) could not be ascertained due to the toxic symptoms seen at all dose levels; the lowest dose tested was 294 mg a.i./kg. The toxic symptoms seen may impair the ability of birds exposed to Prometon to find food, care for young, or escape predation.
8. Recommendations:
9. Background: An acute oral LD₅₀ study is required to support reregistration of Prometon. Review of this study is part of phase IV, response of data submission, of the reregistration process.
10. Discussion of Individual Tests: N/A
11. Materials and Methods:
 - a. Test Animals - 26 week old Bobwhite quail (*Colinus virginianus*) were acclimated for 16 days prior to test initiation. All birds were pen reared, phenotypically indistinguishable from wild birds and were received from Fritts Quail Farm, Phillipsburg, NJ.

b. Test System - The quail were maintained on a diet of Wildlife International, Ltd. gamebird ration and water ad libitum during acclimation and the test, then fasted for a minimum of 15 hours prior to dosing. Birds were housed indoors with artificial light 8 hours/day. Ambient temperature averaged 26 C and the average relative humidity was 71%.

c. Dosing - The appropriate aliquot of test substance was dispersed in corn oil as to provide for constant volume to body weight dosage for all birds. Nominal dosages used were 294, 489, 815, 1358, and 2264 milligrams a.i. Prometon per kilogram of body weight.

d. Design - Birds were randomly grouped 5 per pen with sexes separate. One pen of each sex was assigned to each dosage group. Individual body weights were measured at initiation of the test and by group on days 3, 7, and 14 of the test. Average feed consumption was estimated per group for days 0-3, 4-7, and 8-14.

e. Statistics - "The pattern of mortality in this study did not facilitate the calculation of a LD₅₀ value using the computer program of C.E. Stephan...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 any of the dosages tested. Signs of toxicity occurred at all dose levels between 20 minutes and 2 hours of dosing. The following is a brief chart derived from the information given in the study write up, indicating toxic symptoms in each dosage group:

GROUP	TOXIC SIGNS	DURATION
294	ruffled appearance lethargy	day 0 - day 5
489	s/a and reduced reaction to external stimuli	day 0 - day 4
815	s/a and loss of coordination, lower limb weakness, depression, and wing droop.	day 0 - day 4
1358	s/a plus rapid respiration	day 0 - day 4
2264	s/a	day 0 - day 6

In addition, a dose responsive loss in body weight was seen in all but the 294 dosage group, from day 0 - 3, however, by study termination, feed consumption values were equal to or greater than the control level.

13. Study Authors Conclusion:

"In conclusion, the acute oral LD₅₀ value for northern bobwhite exposed to Prometon as a single oral dosage was greater than 2264 mg a.i./kg, the highest dosage tested. The no observed effect dosage was less than 294 mg a.i./kg due to signs of toxicosis at this, the lowest dosage tested."

Reviewers Discussion and Interpretation of the Study:

a. Test Procedures - The following discrepancies were noted:

- body weights were taken individually on day 0 and by group on day 3,7, and 14; the guidelines require individual body weights be taken on day 0 and day 14.

- a photoperiod of 8 hours light and 16 hours dark was used and a 10/14 photoperiod is recommended in the guidelines.

b. Statistical Analysis - Statistics were not performed on the data.

c. Discussion/ Results - Based on these data, it appears that the LD50 for Prometon 98.5% for the bobwhite is >2264 mg a.i./kg. Toxic symptoms occurred at all dosage levels therefore a NOEL was not obtained.

d. Adequacy of Study

1) Classification: core

2) Rationale: The discrepancies mentioned in section 14 a. did not detract from the scientific validity of the study.

3) Repairability: n/a

15. Completion of One-Liner:

TABLE 2

AVERAGE BODY WEIGHT AND ESTIMATED FEED CONSUMPTION OF BOBWHITE
GAVAGED WITH PROMETON

Dosage	Average Body Weight in Grams						Total Change	Estimated Feed Consumption					
	mg a.i./kg	Sex	Day 0	Change	Day 3	Change		Day 7	Change	Day 14	Change	Days 0-3	Days 4-7
Control	M		181	7	188	5	193	2	195	14	43	28	23
	F		178	3	181	8	189	-7	182	4	42	35	21
294	M		185	12	197	-9	188	-8	180	-5	25	37	23
	F		179	3	182	7	189	4	193	14	27	26	25
489	M		175	-3	172	9	181	5	186	11	24	30	21
	F		176	-6	170	7	177	8	185	9	22	31	23
815	M		184	-6	178	12	190	4	194	10	21	32	22
	F		182	-13	169	12	181	-3	178	-4	23	37	26
1358	M		187	-14	173	6	179	8	187	0	15	29	23
	F		175	-18	157	15	172	8	180	5	21	37	23
2264	M		181	-18	163	4	167	17	184	3	15	36	20
	F		180	-20	160	7	167	12	179	-1	10	32	22

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