

DATA EVALUATION RECORD

1. Chemical: Zinc Oxide
2. Test Material: 100% (technical a.i.) a white powder
3. Study Type: Acute Oral LD₅₀

Species Tested: Bobwhite Quail

4. Study ID: Beavers, J. B. (1985) Acute Oral Toxicity Study with Bobwhite (Colinus virginianus); Project No. 139-225; Prepared by Wildlife International LTD for Monsanto Company, 800 N. Lindberg Blvd, St. Louis, MO 63167; ACC # 260702.

5. Reviewed By:

Curtis E. Laird
Fishery Biologist
EEB/HED

Signature: Curtis E. Laird

Date: 2-14-86

6. Approved By:

Norman J. Cook
Supervisory Biologist
EEB/HED

Signature: Norman J. Cook

Date: 2-14-86

7. Conclusions:

The study indicates Zinc Oxide is slightly toxic to bobwhite quail with an LD₅₀ of 606 mg/kg. This study does fulfill the requirements in support of registration for an avian LD₅₀ study.

8. Recommendations: N/A

9. Background: Submission of data to support the proposed registration of industrial uses.

10. Discussion of Individual Test: N/A

11. Materials and Methods

A. Test Animals: Were bobwhite quail (Colinus virginianus) from Sand Prairie Quail Farm, Maquoketa, IA; 23 weeks old.

B. Test System: Constructed of galvanized wire and sheet (78 X 51 cm floor space and 20-25 cm ceiling space); temperature was 70+4°F and humidity was 81%.

- C. Dose: Acute oral using nominal dosage concentrations; Corn oil was used as a solvent.
- D. Design: Ten birds (5 male and 5 female) per dosage level, five dosage levels plus one controls (0, 292, 484, 810, 1350, 2250 mg/kg).
- E. Statistics: Stephens program.

12. Reported Results: The study authors found the acute oral LD₅₀ value to be 607 mg/kg for Zinc Oxide 100% a.i. The no-effect levels was 292 mg/kg.

13. Study Author's Conclusions:

The acute oral LD₅₀ was > 607 mg/kg. The study was examined for conformance with the Good Laboratory Practices Program. The final report was determined to be an accurate reflection of the data obtained. The dates of all audits and the dates that the results of those audits were reported to the Study Director/Laboratory Management were finalized on August 6, 1985.

14. Reviewer's Discussion and Interpretation of the Study

A. Test Procedures:

The test procedure complied with the recommended EPA protocol of Oct., 1982 (Part 158).

B. Statistical Analysis: Probit method shows the Acute Oral LD₅₀ to be 606 mg/kg with 95% confidence limits of 431 to 809 mg/kg.

C. Discussion/Results:

With an acute oral LD₅₀ of 606 mg/kg, Zinc Oxide, a representative 100% a.i., is slightly toxic to bobwhite quail.

D. Adequacy of Study: Core

15. Completion of One-Liner: Yes

16. CBI Appendix: N/A

Laird zinc oxide acute oral Ld50 for bobwhite quail 100% a.i.

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
2250	10	9	90	1.074219
1350	10	9	90	1.074219
810	10	9	90	1.074219
484	10	4	40	37.69531
292	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 292 AND 810 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 531.6197

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	.1662211	566.254	428.0774	719.6011

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H
4	.2219642	1

ODNESS OF FIT PROBABILITY
 .236542E-02

SLOPE = 3.650386
 95 PERCENT CONFIDENCE LIMITS = 1.930577 AND 5.370196

LC50 = 606.3425
 95 PERCENT CONFIDENCE LIMITS = 431.6441 AND 809.9402

LC10 = 272.1506
 95 PERCENT CONFIDENCE LIMITS = 113.4357 AND 393.1

DATA EVALUATION RECORD

1. Chemical: Zinc Oxide
2. Test Material: > 99% (technical a.i.) a white powder
3. Study Type: Eight-day Dietary LC₅₀

Species Tested: Bobwhite Quail

4. Study ID: Beavers, J. B. (1985) Zinc Oxide Dietary LC₅₀ Study with Bobwhite Quail Final Report; Project No. 139-224; Prepared by Wildlife International LTD for Monsanto Company, 800 N. Lindberg Blvd, St. Louis, MO 63167; ACC # 260702.
5. Reviewed By:

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7. Conclusions:

The study indicates Zinc Oxide is practically nontoxic to the bobwhite quail with an LC₅₀ > 5000 ppm. This study does not fulfill the requirements in support of registration for an avian study.

8. Recommendations: N/A

9. Background: Submission of data to support the proposed registration of industrial uses.

10. Discussion of Individual Test: N/A

11. Materials and Methods

A. Test Animals: Were bobwhite quail (Colinus virginianus) from Sand Prairie Farm, Maquoketa, IA; 11 days old at the initiation of the study.

B. Test System: Birds were housed in thermostatically brooding pens (72 X 90 cm floor space, ceiling height ~ 23 cm), dietary exposure; Eight-day duration.

- C. Dose: Dietary exposure using nominal concentration; solvent was white corn oil (2% by weight of diet).
- D. Design: Ten birds per dosage level, one dosage levels plus five controls.
- E. Statistics: No statistics were performed due to lack of mortality.

12. Reported Results: The Eight-day dietary LC₅₀ was > 5000 ppm. The no-effect level was 5000 ppm based on mortality and clinical effects.

13. Study Author's Conclusions:

The eight-day dietary LC₅₀ was > 5000 ppm. This study was examined for conformance with the Good Laboratory Practices as published by the USEPA, Office of Pesticide Program. The final report was determined to be an accurate reflection of the data obtained. The dates of all audits and the dates that the results of those audits were reported to the Study Director/Laboratory Management were finalized on August 6, 1985.

14. Reviewer's Discussion and Interpretation of the Study

A. Test Procedures:

The test procedure complied with the recommended EPA protocol of Oct., 1982 (Part 158).

B. Statistical Analysis:

No statistics were performed due to lack of mortality.

C. Discussion/Results:

The eight-day dietary LC₅₀ was > 5000 ppm. A representative 99% a.i., of Zinc Oxide, a whit powder, is practically non-toxic to bobwhite quail.

D. Adequacy of Study: Core

15. Completion of One-Liner: Yes

16. CBI Appendix: N/A

DATA EVALUATION RECORD

1. Chemical: Zinc Oxide
2. Test Material: 99.0% (technical a.i.) a white powder
3. Study Type: 96-hr LC₅₀

Species Tested: Rainbow Trout

4. Study ID: McAllister, W. A. (1985) Acute Toxicity of Zinc Oxide to Rainbow Trout (Salmo gairdneri); Report No. 33228; Prepared by ABC Laboratories, Inc., for Monsanto Company, 800 N. Lindberg Blvd, St. Louis, MO 63167. ACC. NO. 260702

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7. Conclusions:

The study appears to indicate Zinc Oxide is moderately toxic to rainbow trout with an LC₅₀ of 1.1 ppm. This study does not fulfill the requirements in support of registration for a coldwater fish because there was a white precipitate on the bottom of all test chambers with and increased amount of precipitate as the concentration increased.

8. Recommendations:

EEB recommends using a suitable solvent to get the test material into solutions. If a suitable solvent can not be obtained, then the test solution should be chemically analyzed in order to determine the concentration of exposure to cold-water fish.

9. Background: Submission of data to support the proposed registration of industrial uses.
10. Discussion of Individual Test: N/A
11. Materials and Methods
 - A. Test Animals: Were rainbow trout (Salmo gairdneri) from Trout Lodge in McMillin, Washington; Mean Weight = 0.78 g; No age given.
 - B. Test System: Five gallon glass/15 liters of test solution; static exposure to test solution at 12°C; 96-hr duration.
 - C. Dose: Static bioassay using nominal concentration; No solvent used.
 - D. Design: Ten fish per dosage level, nine dosage levels plus control (0, .12, .25, 0.5, 1, 2, 4, 8, 16, and 32 ppm).
 - E. Statistics: Stephan et al 1978 computer program for calculating LC₅₀; "binomial" method used for this data set.
12. Reported Results: The 96-hr LC₅₀ with 95% confidence limits of 1.1 (0.53-2.0)mg/l.
13. Study Author's Conclusions:

The 96-hr LC₅₀ with 95% confidence limits was 1.1 (0.53-2.0) mg/l. The study was conducted following the intent of the Good Laboratory Practice Regulations. The final report was reviewed by Analytical Bio-Chemistry Laboratories Quality Assurance Unit. All original raw data were provide to Monsanto Company, with a copy retained at Analytical Bio-Chemistry Laboratories.
14. Reviewer's Discussion and Interpretation of the Study
 - A. Test Procedures:

The test procedure complied with the recommended EPA protocol of Oct., 1982 (Part 158), except there was a

white precipitation on the bottom of each test chamber.

B. Statistical Analysis: Binominal

C. Discussion/Results:

The reported LC₅₀ value was 1.1 (0.53-2.0) mg/l. The raw data sheet under the chemical and physical properties section shows the solubility of Zinc Oxide in water to be ~ 1.6 ppm. The abnormal effects of mortality, surfacing, less of equilibrium dark discoloration and quiescence were observed.

D. Adequacy of Study: Supplemental

15. Completion of One-Liner: Yes

16. CBI Appendix: N/A

LAIRD ZINC OXIDE 96-HOUR LC50 FOR RAINBOW TROUT 99% A.I.

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
32	10	10	100	.0976563
16	10	8	80	5.46875
8	10	9	90	1.07422
4	10	8	80	5.46875
2	10	9	90	1.07422
1	10	7	70	17.1875
.5	10	3	30	17.1875
.25	10	0	0	.0976563
.12	10	0	0	.0976563

THE BINOMIAL TEST SHOWS THAT .25 AND 32 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .707107

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
7	.219036	1.11108	.526287	2.04878

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
5	.376036	2.15437	.0349805

SINCE THE PROBABILITY IS LESS THAN 0.05, RESULTS CALCULATED USING THE PROBIT METHOD PROBABLY SHOULD NOT BE USED.

SLOPE = 1.5502
 95 PERCENT CONFIDENCE LIMITS = .599591 AND 2.50082

LC50 = 1.12014
 95 PERCENT CONFIDENCE LIMITS = .337366 AND 3.05273

LC10 = .169834
 95 PERCENT CONFIDENCE LIMITS = 4.99611E-03 AND .487768

DATA EVALUATION RECORD

1. Chemical: Zinc Oxide
2. Test Material: 99.0% (technical a.i.) a white powder
3. Study Type: 96-hr LC₅₀

Species Tested: Bluegill Sunfish

4. Study ID: McAllister, W. A. (1985) Acute Toxicity of Zinc Oxide to Bluegill sunfish (Lepomis macrochirus); Report No. 33227; Prepared by Analytical Bio-Chemistry Laboratories, Inc., for Monsanto Company, 800 N. Lindberg Blvd, St. Louis, MO 63167. ACC. No. 260702

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7. Conclusions:

The study appears to indicate Zinc Oxide is practically non-toxic to the bluegill sunfish with an LC₅₀ > 320 ppm. However, this study does not fulfill the requirements in support of registration because all test solution had increased cloudiness and white precipitate on the bottom of the test chambers as the concentration increased.

8. Recommendations:

EEB recommends using a suitable solvent to get the test material into solutions. If a suitable solvent can not be obtained, then the test solution should be chemically analyzed in order to determine the concentration of exposure to fish.

9. Background: Submission of data to support the proposed registration of industrial uses.

10. Discussion of Individual Test: N/A

11. Materials and Methods
 - A. Test Animals: Were bluegill (Lepomis macrochirus) obtained from Osage Catfisheries in Osage Beach, MO; Mean Weight = 0.38 g; Mean Length = 24 mm.

 - B. Test System: Five gallon glass/15 liters of test solution; static exposure to test solution at 22°C; 96-hr duration.

 - C. Dose: Static bioassay using nominal concentration; No solvent used.

 - D. Design: Ten fish per dosage level, six dosage levels plus control (0, 10, 20, 40, 80, 160, and 320 ppm).

 - E. Statistics: No statistics were performed due to lack of mortality.

12. Reported Results: The 96-hr LC₅₀ was > 320 ppm.

13. Study Author's Conclusions:

The 96-hr LC₅₀ was > 320 ppm. The study was conducted following the intent of the Good Laboratory Practice Regulations, the final report was reviewed by Analytical Bio-Chemistry Laboratories Quality Assurance Unit. All original raw data were provide to Monsanto Company, with a copy retained at Analytical Bio-Chemistry Laboratories.

14. Reviewer's Discussion and Interpretation of the Study
 - A. Test Procedures:

The test procedure complied with the recommended EPA protocol of Oct., 1982 (Part 158), except there was cloudiness and white precipitation in all test levels.

B. Statistical Analysis:

No statistics were performed due to lack of mortality.

C. Discussion/Results:

Zinc Oxide solubility in water is 1.6 ppm. The 96-hr LC₅₀ value was > 320 ppm. A white powder, a representative 99% a.i., of Zinc Oxide appears to be practically nontoxic to the bluegill sunfish.

D. Adequacy of Study: Supplemental

15. Completion of One-Liner: Yes

16. CBI Appendix: N/A

DATA EVALUATION RECORD

1. Chemical: Zinc Oxide
2. Test Material: 99.0% (technical a.i.) a white powder
3. Study Type: 48-hr LC₅₀

Species Tested: Daphnia magna

4. Study ID: Forbis, A. D. (1985) Acute Toxicity of Zinc Oxide to Daphnia magna; Report No. 33229; Prepared by Analytical Bio-Chemistry Laboratories, Inc., for Monsanto Company, 800 N. Lindberg Blvd, St. Louis, MO 63167. ACC # 260702.

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7. Conclusions:

This study appears to indicate Zinc Oxide is practically non-toxic to Daphnia magna with an LC₅₀ > 1000 ppm. However, this study does not fulfill the requirements in support of registration for an aquatic invertebrate study because a white precipitate was observed in all test solutions.

8. Recommendations:

EEB recommends using a suitable solvent to get the test material into solutions. If a suitable solvent can not be obtained, then the test solution should be chemically analyzed at the beginning and termination of the study in order to determine the exposure concentration to aquatic invertebrate.

9. Background: Submission of data to support the proposed registration of industrial uses.

10. Discussion of Individual Test: N/A

11. Materials and Methods

A. Test Animals: Were Daphnia magna from laboratory stock; Age = <24 hours old at the initiation of study.

B. Test System: Ten 250 ml glass beakers/200 ml of test solution; static exposure, at 20±2°C; 48-hr duration.

C. Dose: Static bioassay using nominal concentration; No solvent used.

D. Design: 20 daphnid per dosage level, five dosage levels plus control (0, 100, 180, 320, 560, and 1000 ppm).

E. Statistics: Stephens et al.

12. Reported Results: The 48-hr LC₅₀ value was > 1000 mg/l and the no effect level observed for Zinc Oxide was 1000 mg/l after 48-hrs.

13. Study Author's Conclusions:

The 48-hr LC₅₀ = > 1000 mg/l. The study was conducted following Good Laboratory Practice Regulations and the final report was reviewed by Analytical Bio-Chemistry Laboratories Quality Assurance Unit. All original raw data were provide to Monsanto Company, with a copy retained at Analytical Bio-Chemistry Laboratories.

14. Reviewer's Discussion and Interpretation of the Study

A. Test Procedures:

The test procedure complied with the recommended EPA protocol of Oct., 1982 (Part 158), except some of the material was not in solution.

B. Statistical Analysis:

No statistics were performed due to lack of mortality.

14
13
14

C. Discussion/Results:

The reported LC₅₀ value was > 1000 ppm. The raw data sheet under chemical and physical properties section shows the solubility of Zinc Oxide in water to be 1.6 ppm.

D. Adequacy of Study: Supplemental

15. Completion of One-Liner: Yes

16. CBI Appendix: N/A