

US EPA ARCHIVE DOCUMENT

9-9-85 (1000000000)

CASE GS

Glyphosate

PM 25

CHEM 103601

Isopropylamine glyphosate (N-phosphon

BRANCH EEB DISC

FORMULATION Technical 83%

FICHE/MASTER ID MCOGLY04 ✓

CITATION: Beavers <sup>and Fink</sup> (1978) Acute oral LD<sub>50</sub> - Bobwhite quail  
 technical glyphosate, final report; Wildlife International, Ltd.,  
 Project No. 139-140; Submitted by Monsanto Company, Acc # 234 395

SUBST. CLASS=

OTHER SUBJECT DESCRIPTORS  
 PRIM:

DIRECT RW TIME = (MH) START-DATE END DATE

REVIEWED BY: Dennis J. McLane  
 TITLE: Wildlife Biologist  
 ORG: EEB/HED  
 LOC/TEL:

SIGNATURE:

*Dennis McLane*

DATE: 9-9-85

APPROVED BY: Raymond W. Matheny  
 TITLE: Head, Section 1  
 ORG: EEB/HED  
 LOC/TEL:

SIGNATURE:

*Raymond W. Matheny*

DATE: 9-9-85

*Jan*

00108204

## DATA EVALUATION RECORD

1. Chemical: Glyphosate
2. Test Material: Technical glyphosate - 83%
3. Study Type: Acute Oral LD<sub>50</sub> - Colinus virginianus
4. Study ID: Beavers, J.B., Fink, R. (1978) Acute Oral LD<sub>50</sub> - Bobwhite Quail Technical Glyphosate Final Report Project No. 139-140 Wildlife International Ltd. Easton, MD 21601. Submitted by Monsanto Company on July 14, 1978, for EPA Registration No. 524-308 under Accession No. 234395.

5. Reviewed by: Dennis J. McLane  
Wildlife Biologist  
EEB/HED

Signature: *Dennis J. McLane*  
Date: 9-9-85

6. Approved by: Raymond W. Matheny  
Supervisory Biologist  
EEB/HED

Signature: *Raymond W. Matheny*  
Date: 9-9-85

7. Conclusion:

This study can be used for hazard assessment purposes. Also, it meets the guideline requirements. Using the toxicity categories of Brooks et al. (1973) the acute LD<sub>50</sub> of > 2000 mg/L would place technical glyphosate into the category of practically nontoxic.

8. Recommendation:

N/A

9. Background:

This study was received on July 14, 1978, by RD and validated by D. Urban on July 18, 1978. The present review was initiated by the Registration Standard for Glyphosate.

10. Discussion of Individual Tests:

N/A

11. Materials and Methods: (excerpted from citation)

At 14 days of age, the birds were randomly assigned to the treatment groups outlined below without regard to sex.

<u>Treatment</u>	<u>Pens</u>	<u>Birds/Pen</u>	<u>Dosage Level (mg/kg)</u>
Control	5	10	Corn oil only
Lab standard	5	10	4.6, 6.8, 10.0, 14.7, 21.5
Experimental	5	10	178, 385, 830, 1785, 3851

The experimental material and dieldrin were dissolved in corn oil and intubated directly into the crop via a stainless steel catheter. Each bird was individually weighed and dosed on the basis of a milligram of material per kilogram of body weight. The control birds received a corresponding volume of corn oil only. The experimental material as received was 83 percent active ingredient but the LD<sub>50</sub>, as reported, is calculated on the basis of 100 percent active ingredient.

Body weight was recorded individually at initiation, and by pen at termination of the study. Food consumption was accurately measured, but is presented as an estimated due to the unavoidable wastage by the birds.

12. Reported Results: (excerpted from citation)

Principal Toxic Effects

Control - There was one death in negative control group five, which occurred on day 5 with the dead bird showing lesions of the feet and legs pathognomonic of toe picking. Toe and nostril picking had first become evident at this level on day 3, and these forms of cannibalism were also responsible for the reduction in body weight gain among surviving birds at this level. All other birds at all other levels were normal in both appearance and behavior throughout the test period.

Experimental Material - There were no mortalities at any dosage level tested. At the 3851 mg/kg dose level the birds showed evidence of a transient lethargy on day 1, and then were symptomatic until the termination of the study. There was a slight reduction in body weight gain at this dose level. The birds at all other dose levels appeared normal throughout the test period. The acute oral LD<sub>50</sub> of Technical Glyphosate in the Bobwhite quail is estimated to be greater than 3851 mg/kg.

13. Study Author's Conclusions/QA Measures:

No specific conclusions or quality assurance measures were mentioned other than those previously addressed.

14. Reviewer's Discussion and Interpretation of the Study:

a. Test Procedures: The following items did not meet the guidelines criteria:

1. The birds were 14 days rather than 16 days old.
2. The observation period should be 14 rather than 8 days.
3. Fasting the birds 15 hours prior to dosage was not provided.
4. The amount of corn oil in the diet in relation to the weight of the bird was not reported.
5. The dosage levels were actually 147.7, 319.6, 688.9, 1481, and 3196 mg/kg active ingredient.

b. Statistical Analysis: No mortality was indicated at the highest level tested, 3196 ppm. Therefore, though the Finney (1971) method was referenced it was needed for this data. Simply indicating the LC<sub>50</sub> is greater than 3196 ppm is adequate.

c. Discussion/Results: The items under Test Procedures are likely to change the LD<sub>50</sub> value. However, the guidelines allow test one level at 2000 mg/kg to be tested. The results from this do not require further testing providing less than half of the birds died at this level. In view of this, further testing is not in keeping with the intent of the guidelines. Though the deviations would be expected to change the LD<sub>50</sub> slightly, the lowering below 2000 mg/kg is certainly not indicated.

d. Adequacy of Study:

1. Classification: Core for the technical glyphosate.
2. Rationale: The practical nontoxic nature <sup>LD<sub>50</sub> ></sup> (2000 mg/kg) of glyphosate is demonstrated by this study.
3. Repairability: N/A

15. Completion of One-Liner for Study:

Completed July 26, 1985.

16. CBI Appendix:

N/A

VALIDATION SHEET

FORMULATION: Roundup

PERCENT A.I.: 83%. Technical Glyphosate

CHEMICAL NAME: N-phosphonomethylglycine

TEST TYPE: Avian Acute Oral LD<sub>50</sub> - Bobwhite Quail

TEST ID NO: ES-C1

CITATION: Accession No. 234395; Prepared by Joann B. Beavers, Wildlife International, Ltd., East Kennedy Street, Easton, Maryland 21601; Dated: February 9, 1978; Project No. 139-140; Title: Acute Oral LD<sub>50</sub> - Bobwhite Quail Technical Glyphosate Final Report; Submitted by: Monsanto Company, St. Louis, Missouri 63166.

VALIDATION CATEGORY: Core

- RESULTS:
- (1) The acute oral LD<sub>50</sub> of technical glyphosate in the Bobwhite quail is estimated to be greater than 3851 mg/kg. There were no mortalities at any level tested. At 3851 mg/kg the birds showed evidence of a transient lethargy on Day 1, and then were asymptomatic until study termination. There was also a slight depression in body weight gain at this level. All other birds at other dose levels appeared normal.
  - (2) Control mortality in one control group (out of 5) was 10%. This one death occurred on Day 5. This death was attributed to toe picking. This form of cannibalism was also responsible for the reduction in body weight gain among survivors in this control group. All other control birds appeared normal.
  - (3) The acute oral LD<sub>50</sub> of technical dieldrin, the positive control, in the Bobwhite quail is 9 mg/kg (8 - 10 mg/kg).
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VALIDATION CATEGORY RATIONALE: This study deviated from accepted standard protocol in two respects:  
(1) the age of the birds tested was 14 days instead of "not less than 16 weeks old...", and  
(2) the post dosing observation period was only 8 days, not the "minimum of 14 days..." This protocol, however, has been and is currently accepted by this Section (see EPA Memo from J. Akerman dated 3/13/78 - Validation of Avian Acute Oral LD<sub>50</sub> Studies). This protocol is being re-reviewed by the Agency.

CATEGORY REPAIRABILITY/RATIONALE: N/A

VALIDATOR: D. J. Urban

DATE: 7/18/78

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