DATA EVALUATION RECORD

1. Chemical: Glyphosate, S# 103601

2. Test Material: 62.4% IPA salt of glyphosate (MON 0139)

3. Study Type: 48-hour LC_{50} - Daphnia magna

4. Study ID: Forbis, A.D.; Boudreau, P. (1981) Acute Toxicity of MON 0139 (Lot LURT 12011) (AB-81-074) to Daphnia magna: Static Acute Bioassay Report No. 27203. (Unpublished study received July 1, 1981, under 524-308; prepared by Analytical Bio-Chemistry Laboratories, Inc., submitted by Monsanto Co., Washington, DC; CDL:070171-J.)

5. Reviewed by: Dennis J. McLane
Wildlife Biologist
EEB/HED
Signature: Dennis McLane
Date: 8-28-85

6. Approved by: Raymond W. Matheny
Section Head
EEB/HED
Signature: Raymond W. Matheny
Date: 8-30-85

7. Conclusion:

This study can be used for hazard assessment purposes. Also ~~However~~, it does ~~not~~ meet the guideline requirements for formulation testing. Using the toxicity categories of Brooks et al. (1973) the acute LC_{50} of 869.3 mg/l would place MON 0139 into the category of practically nontoxic.

8. Recommendation:

N/A

2009155

9. Background:

McLane reviewed the initial submission on August 3, 1981. This validation is due to the Registration Standard for glyphosate.

10. Discussion of Individual Test:

N/A

11. Materials and Methods:

a. Test animals - were Daphnia magna from ABC facilities; first instar less than 24 hours old.

Test system - Twelve (12) 250 ml glass beakers per 200 ml of test solution; static exposure to well water, at 20 °C (± 1.0); 48-hour duration.

b. Dose - Static bioassay using nominal concentrations; no solvent used.

c. Design - Twenty Daphnia per level; 6 levels; 10 Daphnia per beaker (0, 56, 100, 180, 320, 560, and 1000 mg/l).

d. Statistics (Excerpted from the Study):

> Stephan et al. (1978) A computer program for calculating an LC_{50}. U.S. EPA, Duluth, MN, prepublication manuscript, August 1978.

12. Reported Results:

The following table 2 is excerpted from the study.

TABLE 2

The Acute Toxicity of MON 0139

to Daphnia magna

	LC_{50} (mg/l)	
Compound	24 hours	48 hours
MON 0139	> 1,000	930 (800-1200)*

*95% confidence interval (6).

NOTE: The LC_{50} values presented above were the results of a computerized program (6) performing the following statistical tests: binomial, moving

average and probit tests. The results from the moving average or probit tests will be used when there are two or more partial mortalities. If there is not more than one partial mortality, the results from the binomial test will be recorded.

13. Study Author's Conclusions/QA Measures:

In addition to the information under Reported Results the author provided table 3 (see attached).

The following quality assurance statement was dated and signed by the company Quality Assurance Officer.

> Quality Assurance Statement for final report #27203 entitled "Acute Toxicity of MON 0139 to Daphnia magna," for Dr. F. B. Oleson, Monsanto Chemical Company, St. Louis, Missouri.
>
> In accordance with ABC Laboratories' intent that all studies conducted at our facilities are designed and function in conformance with good laboratory practice regulations and the protocols for individual laboratory studies, an inspection of the final report for MON 0139 was conducted and found to be in acceptable form by a member our Quality Assurance Unit. An in progress study inspection was conducted on April 22, 1981. A final inspection to all data and records on April 28, 1981, indicating that the report submitted to you is an accurate reflection of the study as it was conducted by ABC Laboratories.
>
> Should you have any questions relating to the information provided in this statement or the function of our Quality Assurance Unit, please contact me at your convenience.

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

a. Test Procedures: The procedures were in accordance with protocols recommended by the guidelines. There were no major problems in this regard.

b. Statistical Analysis: The statistical presentation is confusing. The formal report (table 3, p. 221) indicates mortality of 5 percent at 560 ppm level and 60 percent mortality at the 1000 ppm level. In the raw data (p. 229) a Stephan's type printout also shows this same mortality with LC_{50} values for the binomial, moving average, and probit methods which are identical to EEB's. However, table 2 (p. 220) of the formal report presents

the 48-hour LC_{50} as 930 ppm with confidence limits of 800 and 1200. The closest that the Stephan method comes to this value is the probit value of 925.5 with confidence limits of 796.5 and 1152.36. To further complicate the matter the raw data reporting mortality (p. 225) indicates 14 and not 12 died after 48 hours at the 1000 ppm level. With this in mind, the EEB computer program was used to calculate the 48-hour LC_{50} values. They were 853.1 for the binomial, 853.1 for the moving average, and 869.3 for the probit. Since this last mortality value indicates lower LC_{50} values and the probit goodness of fit probability is high, only the probit value is acceptable if the study is used in connection with registration.

c. Discussion/Results: With a 48-hour LC_{50} 869.3 ppm - 62.4 percent ai, MON 0139 formulation is practically nontoxic.

d. Adequacy of Study:

1. Classification: Core for 62.4 ai (MON 0139) formulation.

2. Rationale: The study followed the guidelines for formulation testing.

3. Repairability: N/A

15. Completion of One-Liner for Study:

Completed July 15, 1985

16. CBI Appendix:

N/A

DATA EVALUATION

CHEMICAL: Glyphosate

FORMULATION: This formulation contains no surfactant, only the active ingredient, water and related impurities.

CITATION: Forbis, A.D., Boudreau, P., 1981. Acute toxicity of MON 0139 (Lot LURT 12011) (AB-81-074) to Daphnia magna, Analytical Bio Chemistry Laboratories, Inc. Submitted by Monsanto Co. CDL Acc# 070171, Part I for EPA Reg. No. 524-308, Petition Numbers 9F2163, 9H5204 on 7-1-81

REVIEWED BY: Dennis J. McLane
Biologist
EEB/HED

DATE REVIEWED: 8-3-81

TEST TYPE: Forty-eight hour LC_{50} 930 mg/l

REPORTED RESULTS:

TABLE 2
The Acute Toxicity of MON 0139 to Daphnia magna

Compound	LC_{50} (mg/l) 24 hours	48 hours
MON 0139	>1000	930 (800-1200)*

* 95% confidence interval

REVIEWER'S CONCLUSIONS:

This study is scientifically sound and indicates that the compound is practically non-toxic to Daphnia magna.

9. MATERIALS AND METHODS

A. Test Procedures

Six concentrations of the test compound, 1000, 560, 320, 180, 100 and 56 mg/l, with ten daphnids per concentration were selected for definitive bioassay.

B. Statistical Analysis

The statistical values were obtained by employing a computerized LC_{50} program developed by Stephan's EPA.

C. Discussion/Results

The raw data indicated that at the 1000 mg/l level in both replicates the remaining daphnids were sluggish.

10. REVIEWER'S EVALUATION

A. Test Procedure

The test procedure is scientifically sound.

B. Statistical Analysis

The reported statistical values were identical to those produced by the binomial method available to EEB. (see attached computer printout.)

C. Discussion/Results

The testing of a formulation is not covered by the guidelines. However, this study is scientifically sound and sufficient for use in a hazard assessment.

D. Conclusion

Supplemental

NOTE TO REVIEWER: THIS DATA SET DOES NOT MEET
THE CRITERIA ESTABLISHED BY THE COMMITTEE ON
METHODS FOR TOXICITY TESTS WITH AQUATIC ORGANISMS
BECAUSE NO PERCENT DEAD IS GREATER THAN 65 PERCENT.

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
1000	20	12	60	25.17223
560	20	1	5	0.002002716
320	20	0	0	9.536743E-05
180	20	0	0	9.536743E-05
100	20	0	0	9.536743E-05
56	20	0	0	9.536743E-05

THE BINOMIAL TEST SHOWS THAT 560 AND +INFINITY 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 913.4501

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
1	0.2481508	913.4501	788.7526	1206.669

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
18	0.3051245	1	0.9999968

SLOPE = 7.57492
95 PERCENT CONFIDENCE LIMITS = 3.39068 AND 11.75916

LC50 = 925.4894
95 PERCENT CONFIDENCE LIMITS = 796.5503 AND 1152.361

LC10 = 629.0901
95 PERCENT CONFIDENCE LIMITS = 407.3493 AND 741.7844