TDMS DATA EVALUATION RECORD PAGE 1 OF

CASE GS Glyphosate PM 25

CHEM 103601 Isopropylamine glyphosate (N-phosphon

BRANCH EEB DISC

FORMULATION 31% & MON0818

FICHE/MASTER ID MCOGLY03

CITATION: Forbis, (Boudreau & Schofield) (1982) Dynamic 48-hour acute toxicity of Roundup to Gammarus pseudolimnaeus, Project No: 28747, Study No: AB-82-035, Accession No. 249159

SUBST. CLASS=

OTHER SUBJECT DESCRIPTORS
PRIM:

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

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

SIGNATURE: Dennis J 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

Supp 1

DATA EVALUATION RECORD

1. Chemical: Glyphosate

2. Test Material: Roundup formulation 31.01% glyphosate (41.83% IPA salt of glyphosate)

3. Study Type: Forty-eight hour Gammarus pseudolimnaeus LC_{50}

4. Study ID: Forbis, A.D., Boudreau, P., Schofield, M., (1982) Dynamic 48-Hour Acute Toxicity of Roundup to Gammarus pseudolimnaeus, Project No. 28747 Study No. AB-82-035 Analytical Bio-Chemistry Laboratories. Submitted by Monsanto Agricultural Products Co., St. Louis, Missouri, for EPA Registration No. 524-308 on December 27, 1982, Accession No. 249159.

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. However, it does not meet the guideline requirements. Using the toxicity categories of Brooks et al. (1973) the acute LC_{50} of 42 mg/L would place Roundup into the category of slightly toxic.

8. Recommendation:

N/A

9. Background:

This study was first received by RD on December 27, 1982, and reviewed by W. Faatz of EEB on March 4, 1983. The present review was initiated by the Registration Standard for the chemical, glyphosate.

10. Discussion of Individual Tests:

N/A

11. Materials and Methods: (excerpted from the citation)

a. Test Gammarids: The test lot of Gammarus were collected from a wild population, moved to the laboratory and held in a controlled temperature area on a 16-hour daylight photoperiod at the same temperature used for testing (17 ± 2 °C). During the holding period, they were maintained in an aquarium with a substrate of deciduous leaves and gravel. The gammarids were fed a standard Tetra-Min® fish food. Late juvenile to mature adults (at least 6th instar) were chosen for exposure to the toxicant and were not fed during the test. The taxonomic keys were used to identify the gammarids as Gammarus pseudolimnaeus.

b. Test System: A proportional diluter system described by Mount and Brungs was used for the intermittent introduction of Roundup® and diluent water into the test aquaria. The test was conducted in 1-liter glass beakers with notched over-flows to provide 900 ml of test solution per beaker. The test chambers were placed in a water bath with temperature maintained at 17 °C ± 2 °C with the use of a thermostatically controlled submersible heating element. Each test concentration was replicated four times by means of a flow splitting device incorporated into the diluter system. Aerated well water was delivered to the test chambers at a minimum rate of 12 ml/minute/chamber, an amount which replaced the 900 ml test volume 19.2 times per day.

c. Test Compound: The Roundup® standard was received on February 24, 1982, in good condition. The sample upon receipt was observed to be a yellow liquid and was refrigerated at 4°C. The stock solution was prepared in deionized water on a weight/volume basis (mg/l).

d. Test Procedure - Biological: The test was initiated on April 2, 1982, by random assignment of 5 Gammarus pseudolimnaeus to each of the liter test aquaria after test solutions had been flowing through the aquaria for 24 hours. The gammarids were exposed to the following nominal concentrations of Roundup®: 100 mg/L, 47 mg/L, 20 mg/L, 11 mg/L, and 5.4 mg/L. The gammarids were observed for mortality and abnormal behavior initially and once ever 24 hours for the 48-hour test period. Immobile individuals were removed at each observation. A computerized LC_{50} program developed by Stephan et al. (8) was used to calculate the EC_{50} values and their 95 percent confidence limits.

e. Test Procedure - Chemical and Physical: Water quality parameters of temperature, dissolved oxygen, pH and ammonia were measured throughout the test and were within acceptable limits.

12. Reported Results: (excerpted from the citation)

Nominal Concentration mg/L	Measured Concentration mg/L	Immobility 24-hr	48-hr
0	0	0	0
5.4	4.4	0	0
11.0	9.1	0	2(10%)
20.0	20.0	0	4(20%)
47.0	39.0	0	9(45%)
100.0	110.0	1(5%)	17(85%)

13. Study Author's Conclusions/QA Measures:

(excerpted from citation)

Based on the measured exposure concentrations [glyphosate] and the resulting "immobilities", the 24- and 48-hour EC_{50} values for the dynamic exposure of Gammarus pseudolimnaeus to ROUNDUP formulation were > 110 and 42 mg per liter of water, respectively. The 48-hour no-effect-level in this study was 4.4 mg/L.

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 for Roundup was conducted and found to be in an acceptable form by a member of our Quality Assurance Unit. An inspection of the daily mortality rate of the test organisms prior to the initiation of the study indicated they were in good health and should not bias the observed mortality in the study. A final inspection of all data and records on April 23, 1982, indicated that the report submitted to you is an accurate reflection of the study as it was conducted by ABC Laboratories.

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

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

1. The gammarids were described as late juvenile to mature adults > 6th instar; the guidelines requires < 2nd instar gammarids.

2. The dosage levels are not 60 percent apart or consistently separated. (5.4/11 mg/L = 45%, 11/20 mg/L = 55%, 20/47 mg/L = 42%,47/100 mg/1 = 47%).

b. Statistical Analysis: The methods and calculations of the LC_{50} are in keeping with the guidelines. The LC_{50} from the nominal concentrations and the estimated Roundup by glyphosate measurements were very similar, LC_{50} = 42 mg/L versus 44.3 mg/L respectively. The statistical analysis meets the guidelines requirements.

c. Discussion/Results: The use of older gammarids than < 2nd instar is critical and would be expected to change the animals resistance to the toxic effects to any chemical. Based on this, the study does not adequately meet the guideline requirements.

d. Adequacy of Study:

1. Classification: Supplemental for formulation of Roundup.

2. Rationale: The gammerids were > 6th instar rather than the required < 2nd instar.

3. Repairability: Only a study with the correct age invertebrate will be sufficient.

15. Completion of One-Liner for Study:

Completed July 25, 1985.

16. CBI Appendix:

N/A

MC0064763

DATA EVALUATION RECORD

1. Chemical: Glyphosate; Roundup

2. Formulation: Formulated Product 31% active ingredient
   Surfactant [redacted]

3. Citation

   Dynamic 48-Hour Acute Toxicity of Roundup to Grammarus pseudolimnaeus.

   Conducted by: Analytical Biochemistry
   Laboratories, Inc.
   Columbia, MO 65205
   Project No: 28747
   Study No: AB-82-035
   Report Date: April 27, 1982
   Study Director: Allan D. Forbis

   Accession Number 249159

4. Reviewed by: Wayne C. Faatz, Ph.D.

5. Date Reviewed: July 1983

6. Test Type: Aquatic Invertebrate

   Species: Grammarus pseudolimnaeus

Reported Results

Nominal Concentration mg/l	Measured Concentration mg/l	Immobility 24-hr	Immobility 48-hr
0	0	0	0
5.4	4.4	0	0
11.0	9.1	0	2(10%)
20.0	20.0	0	4(20%)
47.0	39.0	0	9(45%)
100.0	110.0	1(5%)	17(85%)

EC_{50}	C.I.	HRS
>110	-	24
42	31-62	48

The 48 hour no effect level is 4.4 mg/l.

Reviewers Conclusions

The test is scientifically sound and allows comparisons be made between the technical and formulated material based on active ingredient. By comparing the technical and formulated material an assessment on the toxicity of the surfactant can be made.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Material/Methods

The follow description of the material/methods was taken directly from the report.

I. Test Gammarids

The test lot of Gammarus were collected from a wild population, moved to the laboratory and held in a controlled temperature area on a 16-hour daylight photoperiod at the same temperature used for testing (17 ±2°C). During the holding period, they were maintained in an aquarium with a substrate of deciduous leaves and gravel. The gammarids were fed a standard Tetra-Min® fish food. Late juvenile to mature adults (at least 6th instar) were chosen for exposure to the toxicant and were not fed during the test. The taxonomic keys were used to identify the gammarids as Gammarus pseudolimnaeus.

II. Test System

A proportional diluter system described by Mount and Brungs was used for the intermittent introduction of Roundup® and diluent water into the test aquaria. The test was conducted in 1-liter glass beakers with notched over-flows to provide 900 ml of test solution per beaker. The test chambers were placed in a water bath with temperature maintained at 17°C ± 2°C with the use of a thermostatically controlled submersible heating element. Each test concentration was replicated four times by means of a flow splitting device incorporated into the diluter system. Aerated well water was delivered to the test chambers at a minimum rate of 12 ml/minute/chamber, an amount which replaced the 900 ml test volume 19.2 times per day.

III. Test Compound

The Roundup® standard was received on February 24, 1982, in good condition. The sample upon receipt was observed to be a yellow liquid and was refrigerated at 4°C. The stock solution was prepared in deionized water on a weight/volume basis (mg/l).

IV. Test Procedure - Biological

The test was initiated on April 2, 1982, by random assignment of 5 Gammarus pseudolimnaeus to each of the liter test aquaria after test solutions had been flowing through the aquaria for 24 hours. The gammarids were exposed to the following nominal concentrations of Roundup®: 100 mg/l, 47 mg/l, 20 mg/l, 11 mg/l and 5.4 mg/l. The gammarids were observed for mortality and abnormal behavior initially and once ever 24 hours for the 48-hour test period. Immobile individuals were removed at each observation. A computerized LC_{50} program developed by Stephan et al. (8) was used to calculate the EC_{50} values and their 95% confidence limits.

V. Test Procedure - Chemical and Physical

Water quality parameters of temperature, dissolved oxygen, pH and ammonia were measured throughout the test and were within acceptable limits.

Reviewers Evaluation

Test Procedure

The test procedure is appropriate.

Statistical Analysis

The data was analysed by EEB using a One way Analysis of Variance. The test results are essentially the same as those submitted by the registrant.

Discussion/Results

The calculated LC_{50} is supported by the data.

Conclusion

1. Category: Supplemental

2. Rationale: There is no specific requirement for a test with the formulated product. This test allows a comparison between the technical and formulated product because the surfactant is known to be toxic to aquatics.

3. Repairability: None

MCOGL403

ROUNDUP FORMULATED WITH SURFACTANT
AQUATIC INVERTEBRATE GRAMMARUS

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
110	20	17	85	0.1288414
39	20	9	45	41.19015
20	20	4	20	0.5908966
9.1	20	2	10	0.02012253
4.4	20	0	0	

[New Message-of-the-Day available]
9.536743E-05

THE BINOMIAL TEST SHOWS THAT 20 AND 110 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 43.96019

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
2	0.2084193	43.71594	30.09886	64.22929

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
4	0.1224789	1	0.8226711

SLOPE = 2.335601
95 PERCENT CONFIDENCE LIMITS = 1.518211 AND 3.152991

LC50 = 41.92301
95 PERCENT CONFIDENCE LIMITS = 30.71292 AND 62.06019

LC10 = 11.98658
95 PERCENT CONFIDENCE LIMITS = 6.311342 AND 17.40642

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June 6-4-92

MCOGLY03

ROUNDUP FORMULATED WITH SURFACTANT
AQUATIC INVERTEBRATE GRAMMARUS

estimated Roundup concentrations from measured levels of glyphosate

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
110	20	17	85	0.1288414
39	20	9	45	41.19015
20	20	4	20	0.5908966
9.1	20	2	10	0.02012253
4.4	20	0	0	

[New Message-of-the-Day available]
9.536743E-05

THE BINOMIAL TEST SHOWS THAT 20 AND 110 CAN BE
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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 43.96019

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
2	0.2084193	43.71594	30.09886	64.22929

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
4	0.1224789	1	0.8226711

SLOPE = 2.335601
95 PERCENT CONFIDENCE LIMITS = 1.518211 AND 3.152991

LC50 = 41.92301
95 PERCENT CONFIDENCE LIMITS = 30.71292 AND 62.06019

LC10 = 11.98658
95 PERCENT CONFIDENCE LIMITS = 6.311342 AND 17.40642

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MCLANE ROUNDUP GAMMERIDS LC50 Nominal Concentrations

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
100	20	17	85	.128841
47	20	9	45	41.1901
20	20	4	20	.590897
11	20	2	10	.0201225
5.4	20	0	0	9.53674E-05

THE BINOMIAL TEST SHOWS THAT 20 AND 100 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 51.2811

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	.142525	44.6579	32.5761	69.1623

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABIL
3	.119903	1	.733866

SLOPE = 2.50166
95 PERCENT CONFIDENCE LIMITS = 1.63541 AND 3.36791

LC50 = 44.2807
95 PERCENT CONFIDENCE LIMITS = 33.1307 AND 63.4101

LC10 = 13.7579
95 PERCENT CONFIDENCE LIMITS = 7.55531 AND 19.5202

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