

US EPA ARCHIVE DOCUMENT

Data Evaluation Report on the acute toxicity of an SL formulation of Glyphosate (YF11357) to Bluegill sunfish (*Lepomis macrochirus* Rafinesque)

PMRA Submission Number {.....}

EPA MRID Number 45374002

Data Requirement:

PMRA DATA CODE	{.....}
EPA DP Barcode	D275559
OECD Data Point	Mortality
EPA MRID	45374002
EPA Guideline	72-1

Test material: Purity: 28.3%

Common name: Glyphosate formulation (YF11357)

Chemical name: IUPAC: N-(Phosphonomethyl)glycine

CAS name: N-(Phosphonomethyl)glycine

CAS No.: 1071-83-6

Synonyms: YF11357

Primary Reviewer: Dana Worcester, M.S.
Staff Scientist, Dynamac Corporation

Signature: *Dana Worcester*
Date: 10/11/01

QC Reviewer: Teri Myers, Ph.D.
Staff Scientist, Dynamac Corporation

Signature: *Teri Myers*
Date: 10/11/01

Primary Reviewer: Stephen Carey
Biologist, Environmental Protection Agency

Signature: *Stephen Carey*
Date: 02/13/02

Secondary Reviewer(s): Thomas Steeger, p.H.D
Fishery Biologist, Environmental Protection Agency

Signature: *Thomas M. Steeger*
Date: 2/27/02

Company Code {.....} [For PMRA]
Active Code {.....} [For PMRA]
EPA PC Code 417300

Date Evaluation Completed: February 15, 2002

CITATION: Magor, S.E., and N. Shillabeer. 2000. Glyphosate: Acute Toxicity to Bluegill sunfish (*Lepomis macrochirus*) of a SL Formulation. Unpublished study performed by Brixham Environmental Laboratory, Devon, UK. Laboratory Project ID AH0297/A and sponsored by Zeneca Agrochemicals, Berkshire, UK. Sponsor Project ID 43908. Completed August 18, 2000.

US EPA ARCHIVE DOCUMENT



2020474

EXECUTIVE SUMMARY:

In a 96-h acute toxicity study, bluegill sunfish (*Lepomis macrochirus*) were exposed to one limit concentration of YF11357 (an SL formulation of glyphosate) under static conditions. The mean measured concentration of the formulation was 183.7 mg/L. There were no mortalities and no significant symptoms of toxicity. The 96-h LC₅₀ was shown to be >183.7 mg/L (>52 mg a.i./L). The NOEC was 183.7 mg/L. The test concentration was not high enough to produce an effect on the organisms or a precise LC₅₀. Based on these results, YF11357 is categorized as practically non-toxic to bluegill sunfish on an acute toxicity basis.

This study is scientifically valid, but is classified as Supplemental for a formulated product because dechlorinated tap water was used as dilution water and there were several procedural deviations which may have impacted water quality and test substance exposure (EPA-540/9-85-006, 72-1). The guideline is not fulfilled for an acute toxicity test for freshwater fish (EPA-540/9-85-006, 72-1), however, EPA is not requiring this study to be repeated at this time.

Results Synopsis

Test Organism Size (mean Weight or Length): 0.971g (34.3mm)
Test Type (Flowthrough, Static, Static Renewal): Static
LC₅₀: >183.7 mg/L (>52 mg a.i./L) 95% C.I.: NA
NOEC: 183.7 mg/L Probit Slope: NA
Endpoint(s) Affected: None

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study was conducted in accordance with the Standard Evaluation Procedure, Acute Toxicity Test for Freshwater Fish (EPA-540/9-85-006). Data requirements followed OECD Guideline No. 203 (OPP Guideline No. 72-1, 3)

Deviations included the following:

1. Dechlorinated tap water was used. US EPA advises against the use of dechlorinated tap water as dilution water.
2. Control and test vessels were aerated after 72 hours. US EPA prohibits aeration of the test solutions. No explanation was provided for aeration of the test vessels on the final day of the test.
3. Acclimation period (7 days) was shorter than EPA guidelines (14 days).
4. Test organism weight and length at study initiation were not reported.
5. Total organic carbon was not reported
6. Dissolved oxygen dropped to 26% air saturation. USEPA requires dissolved oxygen to be maintained above 60% of air saturation through out the study.

These deviations, together, impacted the acceptability of this study.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Confidentiality statements were provided.

A. MATERIALS:

1. Test Material Glyphosate SL formulation (YF11357)

Description: Brown liquid

Lot No./Batch No. : AH0297

Purity: 28.3%

Stability of Compound

Under Test Conditions: Test concentrations were measured at 0 and 96 hours. Mean recovery of Glyphosate was 102% of nominal.

Storage conditions

of test chemicals: The test substance was stored at room temperature in the dark.

Data Evaluation Report on the acute toxicity of an SL formulation of Glyphosate (YF11357) to Bluegill sunfish (*Lepomis macrochirus Rafinesque*)

PMRA Submission Number {.....}

EPA MRID Number 453740-02

2. Test organism:

Species: Bluegill sunfish (*Lepomis macrochirus*)

Age at test initiation: Not reported

Weight at study initiation: Not reported Mean weight at test conclusion was 0.97 g.

Length at study initiation: Not reported Mean length at test conclusion was 35mm.

Source: Aquatic Research Organisms (Hampton, NH)

B. STUDY DESIGN:

1. Experimental Conditions

a) Range-finding Study

No range finding study was conducted.

b) Definitive Study

Table 1 . Experimental Parameters

Parameter	Details	Remarks
		Criteria
Acclimation: period: conditions: (same as test or not)	7days Same as test	Fish treated of an one hour bath in 0.2 ml/l formalin.
Feeding: Health: (any mortality observed)	Not fed 24-hours prior to test initiation; not fed during exposure 2% mortality observed in batch of fish 2 days prior to test initiation. Last medication was given to fish 4 days prior to test.	<i>EPA requires: minimum 14 days; no feeding during test OECD requires minimum of 12 days.</i>
Duration of the test	96-hour	<i>(EPA/OECD requires: 96 hour)</i>
Test condition static/flow through	Static	<i>(EPA requires: Must provide reproducible supply of toxicant) (EPA requires: Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period</i>
Type of dilution system- for flow through method.	NA	
Renewal rate for static renewal	NA	

Parameter	Details	Remarks
		Criteria
Aeration, if any	After 72 hours because D.O. dropped 60% below saturation.	<i>(EPA requires: no aeration; OECD permits aeration)</i>
<u>Test vessel</u> Material: (glass/stainless steel) Size: Fill volume:	Glass aquaria 91.5 x 30.5 x 46.5 cm; 130 L 90 L	The aquaria and fill volume were substantially greater than required by EPA. <i>EPA requires: Size 19 L (5 gal) or 30 x 60 x 30 cm Fill volume: 15-30 L of solution)</i>
Source of dilution water Quality:	Tap water passed through activated carbon, filtered, dechlorinated with sodium thiosulfate, filtered (25 & 10 µm), and UV-irradiated.	Dechlorinated tap water is prohibited for use as dilution water by US EPA. <i>(EPA 1975; Soft reconstituted water or water from a natural source, not dechlorinated tap water); OECD permits dechlorinated tap water.</i>

US EPA ARCHIVE DOCUMENT

Data Evaluation Report on the acute toxicity of an SL formulation of Glyphosate (YF11357) to Bluegill sunfish (*Lepomis macrochirus Rafinesque*)

PMRA Submission Number {.....}

EPA MRID Number 453740-02

<p>Water parameters:</p> <p>Hardness pH Dissolved oxygen Total Organic carbon Particulate Matter Metals</p> <p>Pesticides Chlorine</p> <p>Temperature</p> <p>{Salinity for marine or estuarine species}</p> <p>Intervals of water quality measurement</p>	<p>45.7 mg/L CaCO₃ 6.78-7.67 ≥26% Not reported Not reported Not reported</p> <p>Not reported <2 µg/L</p> <p>22±1°C</p> <p>NA</p> <p>DO, pH, and hardness were measured daily. Temperature measured hourly</p>	<p>On Day 3, D.O. dropped to 26% and test chambers were aerated to increase the air saturation. No details provided.</p> <p>-----</p> <p>(EPA hardness: 40 - 48 mg as CaCO₃/L; OECD allows 10 -250 mg as CaCO₃/L) (EPA pH: 7.2 - 7.6; 8.0-8.3 for marine-stenohaline fishes, 7.7-8.0 for estuarine-euryhaline fishes, monthly range < 0.8); OECD allows pH 6.0 - 8.5 (EPA Dissolved Oxygen: Static: ≥ 60% during 1st 48 hrs and ≥ 40% during 2nd 48 hrs, flow-through: ≥ 60%); OECD requires at least 80% saturation value. (EPA temperature: estuarine/marine: 22 ± 1 °C OECD requires 21 - 25°C for bluegill and 13 - 17°C for rainbow trout (EPA salinity: 30-34 ‰ (parts per thousand) salinity, weekly range < 6 ‰) (EPA water quality: measured at beginning of test and every 48 hours)</p>
<p>Number of replicates/groups: control: solvent control: treated ones:</p>	<p>1 1 1</p>	<p>-----</p> <p>(EPA/OECD requires: Control & 5 treatment levels; each conc. should be 60% of the next highest conc.; concentrations should be in a geometric series)</p>
<p>Number of organisms per replicate /groups: control: solvent control: treated ones:</p>	<p>30 NA 30</p>	<p>(EPA: ≥ 10/concentration); OECD requires at least 7 fish/concentration</p>

US EPA ARCHIVE DOCUMENT

Data Evaluation Report on the acute toxicity of an SL formulation of Glyphosate (YF11357) to Bluegill sunfish (*Lepomis macrochirus Rafinesque*)

PMRA Submission Number {.....}

EPA MRID Number 453740-02

Biomass loading rate	0.32 g fish/L/day	<i>Static: ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°C; flow-through: ≤ 1 g/L/day; OECD requires maximum of 1 g fish/L for static and semi-static with higher rates accepted for flow-through</i>
Test concentrations: nominal:	180 mg/L (SL formulation) 51 mg a.i. /L N-(phosphonomethyl)glycine	Glyphosate SL formulation contains 28.3% a.i. N-(phosphonomethyl)glycine
measured:	183.7 mg/L (SL formulation) 52 mg a.i. /L N-(phosphonomethyl)glycine	
Solvent (type, percentage, if used)	NA	<i>EPA requires: Not to exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests; OECD requires solvent, exceed 100 mg/L.</i>
Lighting	16:8	<i>(EPA requires: 16 hours light/8 hours dark); OECD requires 12 -16 hours photoperiod.</i>
Feeding	Not fed 24-hour prior to study or during exposure	<i>EPA/OECD requires: No feeding during the study</i>
Recovery of chemical	102%	
Level of Quantitation	0.011 mg/L	
Level of Detection	Not reported	
Positive control {if used, indicate the chemical and concentrations}	NA	
Other parameters, if any	NA	

2. Observations:

US EPA ARCHIVE DOCUMENT

Data Evaluation Report on the acute toxicity of an SL formulation of Glyphosate (YF11357) to Bluegill sunfish (*Lepomis macrochirus* Rafinesque)

PMRA Submission Number {.....}

EPA MRID Number 453740-02

Table 2: Observations

Criteria	Details	Remarks/Criteria
Parameters measured including the sublethal effects/toxicity symptoms	Mortality	
Observation intervals	Mortality was measured at 3, 24, 48, 72 and 96 hours of exposure	----- <i>(EPA/OECD requires: minimally every 24 hours)</i>
Were raw data included?	Yes	
Other observations, if any	NA	

II. RESULTS and DISCUSSION:

A. MORTALITY:

No treatment-related mortality occurred at any concentration tested

Data Evaluation Report on the acute toxicity of an SL formulation of Glyphosate (YF11357) to Bluegill sunfish (*Lepomis macrochirus* Rafinesque)

PMRA Submission Number {.....}

EPA MRID Number 453740-02

Table 3: Effect of Glyphosate SL formulation on mortality of Bluegill (*Lepomis macrochirus*).

Treatment (mg formulation/L) [record measured and nominal conc. used] ¹	No. of fish at start of study	Observation period									
		Hour 3		Day 1		Day 2		Day 3		Day 4	
		No Dead	% mortality	No Dead	% mortality	No Dead	% mortality	No Dead	% mortality	No Dead	% mortality
Control (dilution water only)	30	0	0	0	0	0	0	0	0	0	0
Solvent control	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
180 (183.7 hour)	30	0	0	0	0	0	0	0	0	0	0
NOEC	183.7 mg/L										
LC ₅₀	>183.7 mg/L										
Positive control, if used mortality: LC ₅₀ :	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

¹ Measured value is presented in parentheses.

Data Evaluation Report on the acute toxicity of an SL formulation of Glyphosate (YF11357) to Bluegill sunfish (*Lepomis macrochirus* Rafinesque)

PMRA Submission Number {.....}

EPA MRID Number 453740-02

B. NON-LETHAL TOXICITY ENDPOINTS:

No sublethal effects were observed. The 96-hour EC₅₀ was >183.7 mg/L.

Table 4. Sub-lethal effect of Glyphosate SL formulation on Bluegill (*Lepomis macrochirus*).

Treatment (mg formulation/L) [record measured and nominal conc. used] ¹	Observation period				
	endpoint at Hour 3	endpoint at Day 1	endpoint at Day 2	endpoint at Day 3	endpoint at Day 4
	% affected	% affected	% affected	% affected	% affected
Control (dilution water only)	0	0	0	0	0
Solvent control	NA	NA	NA	NA	NA
180 (183.7)	0	0	0	0	0
NOEC	183.7 mg/L				
LOEC	Not determined				
LC ₅₀	>183.7 mg/L				
Positive control, if used % sublethal effect: EC ₅₀ :	NA	NA	NA	NA	NA

¹ Measured value is presented in parentheses.

C. REPORTED STATISTICS:

Statistics were not conducted

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical verification based on survival data was performed visually due to the fact that no mortality occurred at any either of the control groups or any of the treatment level.

LC₅₀: >183.7 mg/L 95% C.I.: N/A
NOEC: 183.7 mg/L

E. STUDY DEFICIENCIES:

The major deviations from US EPA (EPA-540/9-85-006, 72-1) experimental procedure were the use of dechlorinated dilution water and aeration of the test vessels. As a result, this study is classified as Supplemental for a formulated product.

F. REVIEWER'S COMMENTS:

The reviewer's conclusions agreed with those of the study authors. However, the reviewer's estimates were slightly higher, because they were based on the mean measured concentration, rather than the nominal concentration of YF11357.

The glyphosate formulation contained 28.3% a.i. NOEC and LC₅₀ estimates were based on the formulation concentration, rather than the active ingredient (N-(phosphonomethyl)glycine) concentrations.

The reviewer recommends recording the fish length and weight at test initiation because the fish appeared to be sick prior to the study, and the degree of illness cannot be determined since the author failed to report the weight of the fish prior to the study.

G. CONCLUSIONS:

No mortality or sublethal effects were observed in bluegill (*Lepomis macrochirus*) at the single test concentration of the SL formulation (YF11357), 183.7 mg/L. This study is classified as Supplemental for a formulated product due to major deviations from US EPA protocol, including the use of dechlorinated tap water and aeration of the test vessels. This study does not fulfill EPA guidelines 72-1, however, EPA is not requiring the study to be repeated at this time because it contains useful information. The LC₅₀ was determined to be >183.7 mg/L (>52 mg a.i./L), based on the mean measured concentration. As a result, this SL formulation of Glyphosate is classified as practically non-toxic to bluegill sunfish (*Lepomis macrochirus*) on an acute basis according to the classification system of the U.S. EPA.

LC₅₀: >183.7 mg./L (>52 mg a.i./L) 95% C.I.: N/A
NOEC: 183.7 mg./L

III. REFERENCES:

- U.S. Environmental Protection Agency. 1985. Hazard Evaluation Division. Standard Evaluation Procedure. EPA-540/9-85-006. Acute Toxicity Test for Freshwater Fish.
- OECD. 1992. OECD Guidelines for Testing Chemicals. Method 203. Fish, Acute Toxicity Test.
- Official Journal of the European Communities, L 383 A, Part C.1, Acute Toxicity for Fish. December 29, 1992.