

7 Day
46 hours

Data Evaluation Report on the acute toxicity of Mesosulfuron-methyl metabolite (AE F147447) to aquatic vascular plants *Lemna gibba*

PMRA Submission #: {.....}

EPA MRID#: 45386313

Data Requirement: PMRA Data Code: {.....}
EPA DP Barcode: D284719
OECD Data Point: {.....}
EPA MRID: 45386313
EPA Guideline: 123-2

Test material: AEF147447 Purity: 93.1%
Common name: Mesosulfuron-methyl metabolite
Chemical name: IUPAC:6-methanesulfonamidomethyl-1,2-benzisothiazol-3(2H)-one 1,1-dioxide
CAS name: Not reported
CAS No.: Not reported
Synonyms: Not reported

Primary Reviewer: Rebecca Bryan
Staff Scientist, Dynamac Corporation

Signature: *Rebecca Bryan*
Date: 9/26/03

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

Signature: *Teri Myers*
Date: 9/26/03

Primary Reviewer: *Leo LaSoda*
Tim Bargar
{EPA/OECD/PMRA}

Date: *10/09/04*
{.....} *Leo LaSoda*

Secondary Reviewer(s): {.....}
{EPA/OECD/PMRA}

Date: {.....}

Company Code {.....} [For PMRA]
Active Code {.....} [For PMRA]
EPA PC Code 122009

Date Evaluation Completed: {dd-mmm-yyyy}

CITATION: Sowig, P. and Weller, O. 2000. Duckweed (*Lemna gibba* G3) Growth Inhibition Test, AE F147447, substance, pure, (Metabolite of AE F130060). Unpublished study performed by Aventis CropScience GmbH, Frankfurt, Germany. Laboratory Study Identification No. CE00/057. Study submitted by Aventis CropScience, Research Triangle Park, NC. Experimental start date July 28, 2000 and experimental termination date August 4, 2000. The final report issued September 29, 2000.

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EXECUTIVE SUMMARY:

In a 7-day acute toxicity study, freshwater floating aquatic vascular plants Duckweed, *Lemna gibba* G3, were exposed to Mesosulfuron-methyl metabolite (AEF147447) at mean measured concentrations of 9.1, 16.3, 28.9, 50.2, and 90.9 mg/L under static-renewal conditions. Nominal concentrations were 10, 18, 32, 56, and 100 mg/L. Mean percent inhibition was -2, 0, -1, 1, and 0.4% in the 9.1, 16.3, 28.9, 50.2, and 90.9 mg/L treatment groups, respectively. By day 7, the mean dry weights were 25.9, 27.7, 26.9, 26.9, 27.4, and 25.5 mg in the 9.1, 16.3, 28.9, 50.2, and 90.9 mg/L treatment groups, respectively. No treatment groups were significantly different from the dilution water control based on mean frond number, frond number growth rate, or biomass. No signs of intoxication were observed in the control or treatment groups. The NOEC was 90.9 mg/L, the highest concentration tested. The EC₅₀ was estimated as >90.9 mg/L.

This toxicity study is scientifically sound and satisfies the U.S. EPA Guideline Subdivision J, §123-2 for an aquatic vascular plant study with *Lemna gibba*. As a result, this study is classified as Core.

Results Synopsis

Test Organism: *Lemna gibba* G3

Test Type: Static-renewal

Number of fronds:

NOEC: 90.9 mg/L

EC₀₅: >90.9 mg/L 95% C.I.: N/A

EC₅₀: >90.9 mg/L 95% C.I.: N/A

Slope: N/A

Dry Weight:

NOEC: 90.9 mg/L

EC₀₅: >90.9 mg/L 95% C.I.: N/A

EC₅₀: >90.9 mg/L 95% C.I.: N/A

Slope: N/A

Growth Rate:

NOEC: 90.9 mg/L

EC₀₅: >90.9 mg/L 95% C.I.: N/A

EC₅₀: >90.9 mg/L 95% C.I.: N/A

Slope: N/A

Endpoint(s) Affected: None

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I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The test was based on the following guidelines: OECD Guideline no. 201, US-EPA Subdivision J, §123-2, and American Society for Testing and Materials Guide E 1415-91. The following deviations from U.S. EPA Guideline 123-2 are noted:

1. The pretest health of the test organism was not reported.
2. The number of plants tested (4 plants) was less than the 5 plants that is recommended; therefore, there were 12 fronds per replicate, instead of the 15 fronds per replicate that is recommended.
3. The storage conditions of the test chemical, carbon source of the growth medium, and some dilution water characteristics were not reported.

These deviations did not affect the acceptability or the validity of the study.

COMPLIANCE: Signed and dated GLP, Quality Assurance and No Data Confidentiality statements were provided.

A. MATERIALS:

1. Test Material Mesosulfuron-methyl metabolite (AE F147447)

Description: Light yellow powder

Lot No./Batch No. : AE F147447 00 1C93 0001

Purity: 93.1%

Stability of Compound

Under Test Conditions: Measured concentrations (days 0, 3, and 5) for new test solutions ranged from 91.6 to 103.9 % of nominal concentrations and measured concentrations (days 3, 5, and 7) of old test concentrations ranged from 93.2 to 101.1% of nominal concentrations, showing that the test material was stable under test conditions. OECD requirements were not reported.

(OECD requires water solubility, stability in water and light, pKa, Pow, vapor pressure of test compound)

Storage conditions of test chemicals: Not reported.

2. Test organism:

Name: Duckweed, *Lemna gibba* EPA requires a vascular species: *Lemna gibba*.

Strain, if provided: G3

Source: Plant Hormone Laboratory, USDA, Beltsville, MD

Age of inoculum: 6 weeks

Method of cultivation: 20X AAP culture medium

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B. STUDY DESIGN:

a) Range-finding Study: No range-finding study was reported.

b) Definitive Study

Table 1 . Experimental Parameters

Parameter	Details	Remarks
		Criteria
Acclimation period: culturing media and conditions: (same as test or not) health: (any toxicity observed)	Approximately 6 weeks 20X AAP medium; same as test. Not reported.	
Test system static/static renewal/ renewal rate for static renewal:	Static-renewal	<i>EPA expects the test concentrations to be renewed every 3 to 4 days (one renewal for the 7 day test, 3-4 renewals for the 14 day test).</i>
Incubation facility	Environmental chamber-water bath	
Duration of the test	7 days	<i>EPA requires a duration of 14 days. Seven day studies will be accepted for review by the Agency.</i>
Test vessel material: (glass/polystyrene) size: fill volume:	Glass Erlenmeyer-flasks 300 mL 150 mL	
Details of growth medium name: pH at test initiation: pH at test termination: Chelator used: Carbon source:	20X AAP medium 7.5-7.6 9.0 Na ₂ EDTA•2H ₂ O NaHCO ₃	<i>EPA recommend the following culture media: Modified hoagland's E+ or 20X-AAP.</i>
If non-standard nutrient medium was used, detailed composition provided (Yes/No)	Not applicable	

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Parameter	Details	Remarks
		Criteria
Dilution water source/type: pH: water pretreatment (if any): Total Organic Carbon: particulate matter: metals: pesticides: chlorine:	Reagent grade water 7.5±0.1 Deionized water which is additionally filtered by an ultrafiltration, ion exchange and a charcoal unit. Not reported Not reported Not reported Not reported Not reported	EPA recommends a pH of ~5.0. A solution pH of 7.5 is acceptable if type 20X-AAP nutrient media is used.
Indicate how the test material is added to the medium (added directly or used stock solution)	Stock solution	
Aeration or agitation	Not reported	
Sediment used (for rooted aquatic vascular plants) origin: textural classification (% sand, silt and clay): organic carbon (%): geographic location:	Not applicable	
Number of replicates control: solvent control: treatments:	3 N/A 3	
Number of plants/replicate	4 plants per replicate	The number of plants tested (4 plants) were less than the required 5 plants. EPA requires 5 plants.
Number of fronds/plant	12 fronds per replicate at test initiation	There were probably three fronds per plant. EPA requires 3 fronds per plant.

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Parameter	Details	Remarks
		Criteria
Test concentrations nominal: measured:	10, 18, 32, 56, and 100 mg/L 9.1, 16.3, 28.9, 50.2, and 91.0 mg/L	Mean measured concentrations were reviewer-calculated from mean fresh water and mean aged water values. <i>EPA requires at least 5 test concentrations with a dose range of 2X or 3X progression.</i>
Solvent (type, percentage, if used)	N/A	
Method and interval of analytical verification	HPLC; new test solutions at 0, 3, and 5 days and old test solutions at 3, 5 and 7 days.	
Test conditions temperature: photoperiod: light intensity and quality:	23.5-24.5°C continuous light 102-108 $\mu\text{E}\cdot\text{m}^{-2}\cdot\text{s}^{-1}$, white fluorescent lighting	<i>EPA temperature: 25°C EPA photoperiod: continuous EPA light: 5.0 Klux ($\pm 15\%$)</i>
Reference chemical (if used) name: concentrations:	None	
Other parameters, if any	None	

2. Observations:

Table 2: Observation parameters

Parameters	Details	Remarks/Criteria
Parameters measured (eg: number of fronds, plant dry weight or other toxicity symptoms)	Number of fronds, dry weights, growth rates, and toxicity symptoms.	
Measurement technique for frond number and other end points	Direct counts	
Observation intervals	3, 5, and 7 days.	
Other observations, if any	None	

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Indicate whether there was exponential growth in the control	Yes, average frond number at day 7 was 13x greater than average frond number at day 0.	
Were raw data included?	Replicate data provided	

II. RESULTS and DISCUSSION:

A. INHIBITORY EFFECTS:

Mean percent inhibition was -2, 0, -1, 1, and 0.4% in the 9.1, 16.3, 28.9, 50.2, and 90.9 mg/L treatment groups, respectively. By day 7, the mean dry weights were 25.9, 27.7, 26.9, 26.9, 27.4, and 25.5 mg in the 9.1, 16.3, 28.9, 50.2, and 90.9 mg/L treatment groups, respectively. No treatment groups were significantly different from the dilution water control based on mean frond number, frond number growth rate, or biomass.

The mean doubling times were 1.88, 1.86, 1.88, 1.87, 1.89, and 1.88 days in the 9.1, 16.3, 28.9, 50.2, and 90.9 mg/L treatment groups, respectively. The mean increase in biomass was 24.1, 25.9, 25.1, 25.1, 25.6, and 23.7 in the 9.1, 16.3, 28.9, 50.2, and 90.9 mg/L treatment groups, respectively.

No signs of intoxication were observed in the control or treatment groups.

Table 3: Effect of Mesosulfuron-methyl metabolite (AEF147447) on frond number of Duckweed, *Lemna gibba*

Treatment ¹ (estimated measured and nominal concentration) mg/L	Initial frond number/test solution	Mean frond number at ²				Mean Growth Rate at Day 7	Mean Dry Weight of Fronds (biomass) (mg) ²
		3 days	5 days	7 days	% inhibition at 7 days ³		
Negative control (dilution water)	12	39	89	159	---	0.369	25.9
9.1 (10)	12	38	94	163	-2	0.372	27.7
16.3 (18)	12	38	90	159	0	0.369	26.9
28.9 (32)	12	37	88	161	-1	0.371	26.9
50.2 (56)	12	37	94	157	1	0.367	27.4
90.9 (100)	12	39	86	158	0.4	0.368	25.5
Reference chemical (if used)	Not applicable						

¹ Mean measured concentrations of Mesosulfuron-methyl metabolite were reviewer-calculated. Nominal concentrations are in parentheses.

² Mean frond number and dry weights were reviewer-calculated from replicate data.

³ % inhibition was determined by comparing the treatment groups to the dilution water control.

* Significantly different from dilution water control.

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Table 4: Statistical endpoint values.

Statistical Endpoint ^a	frond No.	growth rate	dry weight (biomass)
NOEC or EC ₀₅ (mg/L)	100	100	100
LOEC (mg/L)	>100	>100	>100
IC ₅₀ or EC ₅₀ (mg/L) (95% C.I.)	>100	>100	>100
other (IC ₂₅ /EC ₂₅)	Not reported	Not reported	Not reported
Reference chemical NOAEC IC ₅₀ /EC ₅₀	Not applicable	Not applicable	Not reported

^a Statistical data based on nominal test concentrations.

B. REPORTED STATISTICS: The formulas used for growth rates, doubling time, and mean percent inhibitions are reported on pages 18 and 19. The NOEC was verified using Analysis of Variance, General Linear Models with DUNCAN's Multiple Range Test Procedures (SAS 1989). The EC₅₀ values were determined using binomial probability.

Biomass:

NOEC: 90.9 mg/L
 EC₅₀: >90.9 mg/L 95% C.I.: N/A
 Slope: N/A

Growth Rate:

NOEC: 90.9 mg/L
 EC₅₀: >90.9 mg/L 95% C.I.: N/A
 Slope: N/A

Endpoint(s) Affected: None

C. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: No statistical analysis was conducted. It could be visually determined that AE F147447 did not affect duckweed growth. Reductions in growth parameters in this study did not exceed 5%, so the NOEC, EC₀₅, and EC₅₀ values could be visually determined.

Number of fronds:

NOEC: 90.9 mg/L
 EC₀₅: >90.9 mg/L 95% C.I.: N/A
 EC₅₀: >90.9 mg/L 95% C.I.: N/A
 Slope: N/A

Dry Weight:



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Slope: N/A

Growth Rate:

NOEC: 90.9 mg/L
EC₀₅: >90.9 mg/L 95% C.I.: N/A
EC₅₀: >90.9 mg/L 95% C.I.: N/A
Slope: N/A

Endpoint(s) Affected: None

D. STUDY DEFICIENCIES:

The deviations, including the reduced replicate size, were not considered to have impacted the study results, so they did not affect the acceptability or validity of the study.

E. REVIEWER'S COMMENTS:

The reviewer's conclusions were identical to the study authors'. There was no effect of AE F147447 on growth of *Lemna gibba*.

F. CONCLUSIONS: This toxicity study is scientifically sound and satisfies the U.S. EPA Guideline Subdivision J, §123-2 for an aquatic vascular plant study with *Lemna gibba*. As a result, this study is classified as Core.

Number of fronds:

NOEC: 90.9 mg/L
EC₀₅: >90.9 mg/L 95% C.I.: N/A
EC₅₀: >90.9 mg/L 95% C.I.: N/A
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EC₀₅: >90.9 mg/L 95% C.I.: N/A
EC₅₀: >90.9 mg/L 95% C.I.: N/A
Slope: N/A

Endpoint(s) Affected: None

III. REFERENCES:

- Organization of Economic Co-operation and Development. Draft OECD Guideline for Testing of Chemicals Guideline: *Lemna*. Growth Inhibition Test, April 1997.
- U.S. Environmental Protection Agency (EPA). 1982 Pesticide Assessment Guidelines. Subdivision J, Hazard Evaluation: Nontarget Plants: Tier 2 of nontarget area testing; §123-2 Growth and reproduction of aquatic plants.
- U.S. Environmental Protection Agency (EPA). April 1996, Ecological Effects Test Guidelines: OPPTS 850.4400 Aquatic Plant Toxicity Test Using *Lemna* spp., Tiers I and II; EPA 712-C-96-156, Public Draft.
- ASTM (1991). Standard Guide for Conducting Static Toxicity Test With *Lemna gibba* G3. American Society for Testing and Materials. E 1415-91
- U.S. Environmental Protection Agency (EPA). 1983. Toxic Substances Control; Good Laboratory Practice Standards; Final Rule (40 CFR Part 792) Fed. Reg., Vol. 48, No. 230, Nov. 23, 1983, pp. 53922-53944.
- SAS Institute Inc., 1989-1996. Release 6.12 TS Level 0060 SAS Institute Inc., Cary, North Carolina 27511.

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