Data Evaluation Report on the Acute Oral Toxicity of AMPA to Avian Species, *Colinus virginianus*

PMRA Submission Number {.....} EPA MRID Number 43334709

Data Requirement:	PMRA Data Code	{.....}
	EPA DP Barcode	Not Provided
	OECD Data Point	{.....}
	EPA MRID	43334709
	EPA Guideline	OPPTS 850.2100 (71-1a)

Test material: Aminomethyl Phosphonic Acid (Glyphosate Degradate) **Purity:** 87.8%

Common name: AMPA

Chemical name: IUPAC: Not Reported
CAS name: Not Reported
CAS No. Not Reported
Synonyms: None Reported

Primary Reviewer: John Marton **Signature:**
Staff Scientist, Cambridge Environmental Inc. **Date:** 1/11/07

Secondary Reviewer: Teri S. Myers **Signature:**
Senior Scientist, Cambridge Environmental Inc. **Date:** 2/12/07

Primary Reviewer: Stephen Carey **Date:** 7/18/07
EPA Biologist, OPP, EFED, ERBIII

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

Reference/Submission No.: {.....}

Company Code	{.....}	[For PMRA]
Active Code	{.....}	[For PMRA]
Use Site Category:	{.....}	[For PMRA]
EPA PC Code	417300 (Parent Compound) & 207800 (Degradate Compound)	

Date Evaluation Completed: July 18 2007

CITATION: Campbell, S., J. Grimes, G.J. Smith and S.P. Lynn. 1991. An Acute Oral Toxicity Study with the Northern Bobwhite. Unpublished study performed by Wildlife International Ltd., Easton, MD. Laboratory project number 139-277. Study sponsored by Monsanto Agricultural Company, St. Louis, Missouri. Study completed October 28, 1991.

DISCLAIMER: This document provides guidance for EPA and PMRA reviewers on how to complete a data evaluation record after reviewing a scientific study concerning the acute oral toxicity of a pesticide to avian species. It is not intended to prescribe conditions to any external party for conducting this study nor to establish absolute criteria regarding the assessment of whether the study is scientifically sound and whether the study satisfies any applicable data requirements. Reviewers are expected to review and to determine for each study, on a case-by-case basis, whether it is scientifically sound and provides sufficient information to satisfy applicable data requirements. Studies that fail to meet any of the conditions may be accepted, if appropriate; similarly, studies that meet all of the conditions may be rejected, if appropriate. In sum, the reviewer is to take into account the totality of factors related to the test methodology and results in determining the acceptability of the study.

EXECUTIVE SUMMARY:

The acute oral toxicity of AMPA (Glyphosate Degradate) to 18 week-old Northern Bobwhite Quail (*Colinus virginianus*) was assessed over 14 days. AMPA was administered to the birds by oral intubation at nominal doses of 0 (negative control), 256, 427, 711, 1185 and 1976 mg ai/kg bw. The 14 day-acute oral LD_{50} was >1976 mg ai/kg bw. The 14 day NOAEC of AMPA to the bobwhite quail, based on sub-lethal effects was 1185 mg ai/kg bw. According to the US EPA classification, AMPA (Glyphosate Degradate) would be classified as practically non-toxic to bobwhite quail on an acute oral basis at a dosage up to and including 1976 mg ai/kg bw.

No mortalities were observed in the control or any of the treatment levels during the definitive toxicity test.

No apparent effects were observed on weight gain or on estimated feed consumption. The total change in body weight ranged from 8 to 12 g in males and 8 to 15 g in females. Estimated feed consumption ranged from 16 to 26 g/bird/day for males and from 16 to 24 g/bird/day for females.

Within an hour of dosing, birds in the highest treatment group were observed with lower limb weakness, a ruffled appearance and reduced reaction to external stimuli (sound and movement). These effects persisted throughout Day 1. All birds appeared normal and healthy by the morning of Day 2.

One male at the 711 mg ai/kg bw treatment level was noted to have foot lesions; however, these were attributed to penwear on Days 13 and 14. The study authors' NOAEL and LOAEL values, based on sub-lethal effects, were 1350 and 2250 mg/kg bw, respectively; however, after correction for the purity by the reviewer, these values were 1185 and 1976 mg ai/kg bw, respectively.

This toxicity study is classified as scientifically sound and does satisfy the guideline requirement for avian acute oral toxicity study with Northern bobwhite quail.

Results Synopsis

Test Organism Size/Age(Mean Weight): 18 Weeks Old; 164-220 g

Mortality

LD_{50}: >1976 mg ai/kg bw	95% C.I.: N/A
Probit slope: N/A	95% C.I.: N/A
NOAEL: 1976 mg ai/kg bw	

Sublethal Effects

LOAEC: 1976 mg ai/kg bw
NOAEC: 1185 mg ai/kg bw

Endpoint(s) Affected: Clinical Signs of Toxicity

I. MATERIALS AND METHODS:

GUIDELINE FOLLOWED: This study was conducted following guidelines outlined in section 71-1 of the Environmental Protection Agency Registration Guidelines, *Pesticide Assessment Guidelines, FIFRA Subdivision E, Hazard Evaluation; Wildlife and Aquatic Organisms*. The following deviation from OPPTS 850.2100 was noted:

Samples of the dosing solutions were not collected for confirmation of the test concentration, homogeneity or stability.

This deviation did not impact the acceptability of the study.

COMPLIANCE: Signed and dated No Data Confidentiality, GLP and Quality Assurance statements were provided. This study was conducted in compliance with GLP standards as published by the U.S. EPA in 40 CFR, Part 160; OECD, ISBN 92-84-12367-9; and Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Bureau with the following exception: samples of the dosing solutions were not collected for confirmation of the test concentration, homogeneity or stability.

A. MATERIALS:

1. Test Material Aminomethyl Phosphonic Acid (Glyphosate Degradate)

Description: White Powder

Lot No./Batch No. : PIT-9008-2407T

Purity: 87.8%

Stability of compound under test conditions: Stability was not determined

Storage conditions of test chemicals: Stored at room temperature

Physicochemical properties of AMPA.

Parameter	Values	Comments
Water solubility at 20EC	Not Reported	
Vapor pressure	Not Reported	
UV absorption	Not Reported	
pKa	Not Reported	
Kow	Not Reported	

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

2. Test Organism:

Species (common and scientific names): Northern bobwhite quail (*Colinus virginianus*)

Age at study initiation: 18 Weeks Old

Weight at study initiation (mean and range): 184 (164-220) g

Source: Fritts Quail Farm, Phillipsburg, New Jersey

(EPA recommends using either bobwhite quail or mallard duck. Birds should be at least 16 weeks old at test initiation and should be uniform in size and weight as well as phenotypically indistinguishable from wild birds).

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding study: A range-finding study was not reported.

b. Definitive study

Table 1: Experimental Parameters

Parameter	Details	Remarks *Criteria*
Acclimation Period: Conditions: (same as test or not) Feeding: Health: (any mortality observed)	 16 Days Same as test Game bird ration formulated to Wildlife International Ltd.'s specifications Not reported; however, birds exhibiting abnormal behavior or physical injury were not used in the definitive test.	 *The recommended acclimation period is a minimum of 15 days. OECD recommends a minimum of 7 days.*
Pen size and construction materials	Battery floors were 78 x 51 cm with a slope to that ceiling height ranged from 20-25 cm. External walls, ceilings and floors were constructed of galvanized wire while side walls were constructed of galvanized sheeting.	*Pen size and construction should conform to good husbandry practices and should not create crowding stress. OECD recommends that pens be suitable for the captive rearing of that species.*
Test duration	14 Days	*Recommended test duration is one day for dosing and at least 14 days observation.*

Parameter	Details	Remarks *Criteria*
Dose preparation [Indicate method of confirmation of dose]	The test substance was dispersed in corn oil. Confirmation of dose was not conducted	
Mode of dose administration	Oral intubation	*Gavage or gelatin capsule is recommended*
Dose levels nominal: measured:	0 (negative control), 256, 427, 711, 1185 and 1976 mg ai/kg bw Not Determined	Nominal doses were corrected for the purity of the test material by the reviewer. *Dose levels should be a minimum of 5 treatment levels unless LD_{50} is demonstrated to be greater than 2000 mg ai/kg*
Solvent/vehicle, if used type: amount/bw:	Corn Oil 50 mL	*The test material should be administered without a vehicle if possible. Maximum vehicle should not exceed 0.1 to 1.0% of body weight.*
Number of birds per groups/treatment for negative control: for solvent/vehicle control: for treated:	N/A 10 (5 males and 5 females) 10 (5 males and 5 females)	*Recommended number of birds in a treatment group is 10 and 10 birds for each control and vehicle group.*
No. of feed withholding days before dosing	15 Hours	*Food should be withheld for at least 15 hours prior to dosing.*
Test conditions Temperature: Relative humidity: Photoperiod:	21±1°C 41±15% 8L:16D	*The recommended photoperiod is 10 hours of light and 14 hours of dark.*
Reference chemical, if used name: concentrations tested:	N/A N/A	A reference chemical was not used.

2. Observations:

Table 2: Observations

Criteria	Details	Remarks *Criteria*
Parameters measured (mortality/individual body weight at test initiation and termination/ mean feed consumption/ others)	Mortality, average weight and estimated food consumption	*Body weight should be measured at test initiation, on day 14 and at the end of the test if the test is extended beyond 14 days. Mortality should not be more than 10% in controls.* *Feed consumption should be measured as average daily food consumption.*
Indicate if the test material was regurgitated	No regurgitation was reported.	*Regurgitation is an indication that the dose was rejected. If this problem persists, the test should be repeated.*
Groups on which necropsies were performed	No necropsies were conducted.	*Gross necropsies should be performed with inspections of the GI tract, liver, kidneys, heart, and spleen.*
Observation intervals	Body weights were measured individually at test initiation and by group on Days 3, 7 and 14. Feed consumption was an estimate due to the unavoidable wastage of the birds.	
Were raw data included?	Yes	

II. RESULTS AND DISCUSSION:

A. MORTALITY:

No mortality occurred in the control or any of the treatment groups during the 14 day exposure period. The NOAEC and LC_{50} values, based on the study author's results, were 2250 and >2250 mg/kg bw, respectively. Correcting these values for the purity of the test material (87.8%) yielded NOAEC and LC_{50} values of 1976 and >1976 mg ai/kg bw, respectively.

Table 3: Effect of AMPA on Mortality of *Colinus virginianus*

Treatment (mg ai/kg bw)		No. of Birds	Cumulative Mortality				
			Day 1	Day 2	Day 3	Day 4	Day 14
Vehicle Control		10	0	0	0	0	0
256		10	0	0	0	0	0
427		10	0	0	0	0	0
711		10	0	0	0	0	0
1185		10	0	0	0	0	0
1976		10	0	0	0	0	0
NOAEL		1976 mg ai/kg bw					
LD_{50}		>1976 mg ai/kg bw					
Reference chemical	mortality	N/A	N/A	N/A	N/A	N/A	N/A
	LD_{50}	N/A					
	NOAEL	N/A					

N/A- Not Applicable

B. SUBLETHAL TOXICITY ENDPOINTS:

No apparent effects were observed on weight gain or on estimated feed consumption. The total change in body weight ranged from 8 to 12 g in males and 8 to 15 g in females. Estimated feed consumption ranged from 16 to 26 g/bird/day for males and from 16 to 24 g/bird/day for females.

Within an hour of dosing, birds in the highest treatment group were observed with lower limb weakness, a ruffled appearance and reduced reaction to external stimuli (sound and movement). These effects persisted throughout Day 1. All birds appeared normal and healthy by the morning of Day 2.

One male at the 711 mg ai/kg bw treatment level was noted to have foot lesions; however, these were attributed to penwear on Days 13 and 14. The study authors' NOAEL and LOAEL values, based on sub-lethal effects, were 1350 and 2250 mg/kg bw, respectively; however, after correction for the purity by the reviewer, these values were 1185 and 1976 mg ai/kg bw, respectively.

Table 4: Sub-lethal Effect of AMPA on *Colinus virginianus*

Treatment (mg ai/kg bw)		Observation					
		Body Weight (g)			Food Consumption (g/bird/day)		
		Day 0	Day 7	Day 14	Days 0-3	Days 4-7	Days 8-14
Vehicle Control		M-188 F-181	M-197 F-189	M-200 F-192	M-23 F-18	M-25 F-21	M-22 F-21
256		M-181 F-184	M-188 F-192	M-192 F-197	M-23 F-16	M-26 F-21	M-24 F-19
427		M-187 F-181	M-194 F-190	M-200 F-196	M-16 F-17	M-19 F-22	M-21 F-24
711		M-195 F-173	M-204 F-177	M-203 F-183	M-25 F-16	M-23 F-20	M-24 F-22
1185		M-187 F-182	M-191 F-185	M-195 F-190	M-16 F-16	M-23 F-18	M-24 F-18
1976		M-180 F-188	M-187 F-193	M-191 F-201	M-18 F-19	M-20 F-22	M-20 F-19
NOAEL		1976 mg ai/kg bw					
EC_{50}		>1976 mg ai/kg bw					
Reference chemical	effect	N/A	N/A	N/A	N/A	N/A	N/A
	NOAEL	N/A					
	LD_{50}	N/A					

N/A- Not Applicable

C. REPORTED STATISTICS:

All toxicity values were determined by visual inspection of the data.

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method(s): There was no mortality in this study and symptoms of intoxication were only observed at the highest treatment level, so all toxicity values were visually determined and were based on nominal doses corrected for the purity of the test material.

Mortality

LD_{50}: >1976 mg ai/kg bw 95% C.I.: N/A
Probit slope: N/A 95% C.I.: N/A

NOAEL: 1976 mg ai/kg bw

Sublethal Effects
LOAEC: 1976 mg ai/kg bw
NOAEC: 1185 mg ai/kg bw

E. STUDY DEFICIENCIES:

There were no study deficiencies.

F. REVIEWER'S COMMENTS:

After correcting the study authors' toxicity values for the purity of the test material, they were identical to those of the reviewer.

The in-life portion of the definitive toxicity test was conducted from October 19 to November 2, 1990.

G. CONCLUSIONS:

This study is scientifically sound and is thus acceptable. The mortality NOAEC and LD_{50} values were 1976 and >1976 mg ai/kg bw, respectively. The sublethal NOAEC and LOAEC values were 1185 and 1976 mg ai/kg bw, respectively, based on limb weakness, ruffled appearance and reduced reaction to external stimuli observed at the highest dose tested.

Mortality
LD_{50}: >1976 mg ai/kg bw 95% C.I.: N/A
Probit slope: N/A 95% C.I.: N/A
NOAEL: 1976 mg ai/kg bw

Sublethal Effects
LOAEC: 1976 mg ai/kg bw
NOAEC: 1185 mg ai/kg bw

Endpoint(s) Affected: Clinical Signs of Toxicity

III. REFERENCES:

Environmental Protection Agency. 1982. Pesticide Assessment Guidelines, FIFRA Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms, Subsection 71-1. Office of Pesticide Programs. Washington, DC. 86 pp.

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