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Data Evaluation Report on the Acute Oral Toxicity of AE 0172747 to Avian Species {*Colinus virginianus*}

PMRA Submission Number 2006-2445 EPA MRID Number 468017-29

Data Requirement:	PMRA Data Code	DACO 9.6.2.1
	EPA DP Barcode	D328639
	OECD Data Point	IIA 8.1.1
	EPA MRID	468017-29
	EPA Guideline	850.2100

Test material: Pyrasulfotole Purity: 95.4%
Common name: AE 0317309
Chemical name: IUPAC: (5-hydroxy-1,3-dimethylpyrazol-4-yl)(2-mesyl-4-trifluoromethylphenyl)methanone
CAS name: Not reported
CAS No.: Not reported
Synonyms: Not reported

Primary Reviewer: Rebecca Bryan **Signature:** Rebecca L. Bryan
Staff Scientist, Dynamac Corporation **Date:** 5/18/06

Secondary Reviewer: Teri S. Myers **Signature:** Teri S Myers
Senior Scientist, Cambridge Environmental Inc. **Date:** 5/22/06

Primary Reviewer: Melissa Panger **Date:** 7-7-06
EPA

Secondary Reviewer: J.D. Whall (Officer No. 1268) **Date:** 11/21/06
PMRA J.D. Whall

Secondary Reviewer(s): David McAdam **Date:** 7 Nov 2006
Australian Commonwealth Department of the Environment and Heritage (DEH) D. McAdam

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

Company Code	BCZ
Active Code	PSA
Use Site Category:	13, 14
EPA PC Code	000692

Date Evaluation Completed: 11-27-2006

CITATION: Stoughton, T.L. 2006. Technical AE0317309: An Acute Oral LD_{50} with Northern Bobwhite. Unpublished study performed by Bayer Corporation, Agriculture Division, Research and Development Department, Environmental Research and Toxicology, Stilwell, Kansas. Study No. A9711701/201125. Study sponsored by Bayer CropScience, Research Triangle Park, NC. The final report issued January 11, 2006.

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

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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 Pyrasulfotole to 18-week old Northern bobwhite quail (*Colinus virginianus*) was assessed over 14 days. Pyrasulfotole was administered to the birds via gelatin capsules at nominal concentrations of 125, 250, 500, 1000, and 2000 mg/kg (doses were adjusted for percent active ingredient).

By 14 days, there were no mortalities in the control or treatment groups. No clinical signs of toxicity were observed. No adverse effects on bodyweight or feed consumption were observed. The NOAEL is ≥2000 mg/kg based on all endpoints. The 14-day acute oral toxicity LD_{50} was estimated as >2000 mg/kg, which categorizes Pyrasulfotole as practically nontoxic to Northern bobwhite quail.

This study is classified as **ACCEPTABLE**; it is scientifically sound and does satisfy the guideline requirement for an acute avian oral toxicity study with *Colinus virginianus*.

Results Synopsis

Test Organism Size/Age (Mean Weight): Approximately 18 weeks old, 267-307 g (combined sexes)

LD_{50}: >2000 mg/kg 95% C.I.: N/A
Probit slope: Not determined 95% C.I.: N/A
NOAEL: ≥2000 mg/kg

Endpoint(s) Affected: None

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study protocol was based on procedures outlined in the U.S. EPA Pesticide Assessment Guidelines, Series •71-1. The deviation from the OPPTS Guideline No. 850.2100, Avian acute oral toxicity test included:

No deviations were observed

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. This study was conducted in accordance with the U.S. EPA Good Laboratory Practice Standards (40 CFR Part 160).

A. MATERIALS:

1. Test Material Pyrasulfotole (AE 0317309)

Description: Light brown powder

Lot No./Batch No. : OP 1-4

Purity: 95.4%

Stability of compound under test conditions: The stability of test substance concentrations during the course of the study was not determined.

Storage conditions of test chemicals: Stored at room temperature.

Physicochemical properties of Pyrasulfotole.

Parameter	Value	Comment
Molecular weight	362.3 g/mol	
Water Solubility (g/L) at 20°C	4.2 at pH 4 69.1 at pH 7 49.0 at pH 9	Very soluble
Vapor Pressure/Volatility	2.7×10^{-7} Pa at 20°C 6.8×10^{-7} Pa at 25°C	Non-volatile
UV Absorption	water $\lambda_{max} = 264$ 0.1M HCl $\lambda_{max} = 241$ 0.1M NaOH $\lambda_{max} = 216$	Not likely to undergo photolysis.
Pka	4.2 ± 0.15	
log K_{ow} at 23°C	0.276 at pH 4 -1.362 at pH 7 -1.58 at pH 9	Not likely to bioaccumulate
Stability of compound at room temperature, if provided		No significant degradation over 12 months at ambient temperatures.

Data obtained from pyrasulfatole chemistry review of Submission 2006-2445.

2. Test Organism:

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

Age at study initiation: Approximately 18 weeks old

Weight at study initiation (mean and range): Mean: 286.5 g; range267-307 g (combined sexes)

Source: Barrett's Quail Farm, Houston, Texas

(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: No range-finding study was 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)	 34 days Same as test Teklad Bayer Starter Ration and local tap water were provided, *ad libitum,* except for the 21 hours of fasting prior to testing. No mortality observed during acclimation.	 *The recommended acclimation period is a minimum of 15 days. OECD recommends a minimum of 7 days.*
Pen size and construction materials	Stainless steel cages measuring 36L x 30W x 10H inches.	*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	

Parameter	Details	Remarks
		Criteria
		Recommended test duration is one day for dosing and at least 14 days observation.
Dose preparation [Indicate method of confirmation of dose]	The appropriate dose of test substance (mg) was placed in the gelatin capsules.	
Mode of dose administration	Gelatin capsule	*Gavage or gelatin capsule is recommended*
<u>Dose levels</u> nominal: measured:	 125, 250, 500, 1000, and 2000 mg/kg Not determined.	The dose levels were not measured. *Dose levels should be a minimum of 5 treatment levels unless LD_{50} is demonstrated to be greater than 2000 mg ai/kg*
<u>Solvent/vehicle, if used</u> type: amount/bw:	 N/A	*The test material should be administered without a vehicle if possible. Maximum vehicle should not exceed 0.1 to 1.0% of body weight.*
<u>Number of birds per groups/treatment</u> for negative control: for solvent/vehicle control: for treated:	 10 N/A 10	5 males and 5 females per treatment group. *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	21 hours	*Food should be withheld for at least 15 hours prior to dosing.*
<u>Test conditions</u> Temperature: Relative humidity: Photoperiod:	 22°C 54% 10 hours light/14 hours dark	*The recommended photoperiod is 10 hours of light and 14 hours of dark.*
<u>Reference chemical, if used</u> name: concentrations tested:	 N/A	

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 - Clinical signs of toxicity - Mean feed consumption (g/bird/day) - Mean body weight	*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	All surviving birds.	*Gross necropsies should be performed with inspections of the GI tract, liver, kidneys, heart, and spleen.*
Observation intervals	Mortality and signs of toxicity: Determined three times on Day 0 and daily (1 to 2 times) thereafter. Feed consumption: Determined daily Body Weight: Days -1, 7, and 14	
Were raw data included?	Yes	

II. RESULTS AND DISCUSSION:

A. MORTALITY:

By 14 days, there were no mortalities in the control or treatment groups. The NOAEL based on mortality was ≥2000 mg/kg.

Table 3: Effect of Pyrasulfotole on Mortality of Northern bobwhite quail, *Colinus virginianus*

Treatment (mg/kg)		No. of Birds	Cumulative Mortality		
			day 1	day 7	day 14
Control		10	0	0	0
125		10	0	0	0
250		10	0	0	0
500		10	0	0	0
1000		10	0	0	0
2000		10	0	0	0
NOAEL		≥2000 mg/kg			
LD_{50}		>2000 mg/kg			
Reference chemical	mortality	N/A			
	LD_{50}	N/A			
	NOAEL	N/A			

B. SUBLETHAL TOXICITY ENDPOINTS:

No clinical signs of toxicity were observed. No adverse effects on bodyweight or feed consumption were observed. The NOAEL based on all sublethal endpoints was ≥2000 mg/kg.

No treatment-related findings were observed during necropsy.

Table 4: Sublethal Effect of Pyrasulfotole on Northern bobwhite quail, *Colinus virginianus*

Mean Body Weight (and Change), g						
Treatment (mg/kg)	**Males**			**Females**		
	Day 0	**Day 7**	**Day 14**	**Day 0**	**Day 7**	**Day 14**
Control	289.2	293.0 (3.8)	290.0 (0.8)	287.6	291.4 (3.8)	286.8 (-0.8)
125	287.6	291.2 (3.6)	290.6 (3.0)	286.8	291.2 (4.4)	285.8 (-1.0)
250	287.8	296.8 (9.0)	296.4 (8.6)	284.6	285.8 (1.2)	284.6 (0)
500	286.2	289.2 (3.0)	291.0 (4.8)	284.0	284.2 (0.2)	283.0 (-1.0)
1000	286.6	290.8 (4.2)	293.8 (7.2)	285.0	290.2 (5.2)	288.6 (3.6)
2000	287.2	295.0 (7.8)	294.8 (7.6)	285.6	292.4 (6.8)	292.4 (6.8)
NOAEL	≥2000 mg/kg			≥2000 mg/kg		
EC_{50}	Not determined			Not determined		
Reference chemical	effect: NOEL: LD_{50}:	N/A				

Mean Feed Consumption, g/bird/day			
Treatment (mg/kg)		**Males**	**Females**
		Days 0-14	**Days 0-14**
Control		29.7	23.0
125		29.9	20.3
250		34.6	21.7
500		28.2	17.0
1000		24.6	29.0
2000		23.9	24.7
NOEL		≥2000 mg/kg	≥2000 mg/kg
EC_{50}		Not determined	Not determined
Reference chemical	effect NOEL LD_{50}	N/A	N/A

C. REPORTED STATISTICS:

The LD_{50} could not be calculated because there were no mortalities. The body weight and body weight change data were analyzed using the chi-square test for normality and the Levene's test for homogeneity of variance. The body weight treatment group data were compared to the control using Bonferroni's one-tailed test (α=0.05). The statistical analyses on body weight were conducted using the TOXSTAT version 3.4 computer program. Nominal concentrations were used in all estimations. Feed consumption data were not analyzed statistically.

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: Percent body weight gain was calculated for males and females during the day 0-7 and 7-14 intervals; data were statistically analyzed for the day 0-7 interval only because there were no significant effects during that interval and it could be visually determined that effects did not occur during the later time interval (days 7-14). Analyzed data satisfied the assumptions of normality and homogeneity of variances. The NOAEL values were determined using ANOVA via Toxstat statistical software. Replicate feed consumption data were not provided, so this endpoint was not statistically analyzed; however, percent reduction from control was calculated by the reviewer.

LD_{50}: >2000 mg/kg 95% C.I.: N/A

NOAEL: ≥2000 mg/kg

Probit Slope: Not determined 95% C.I.: N/A

E. STUDY DEFICIENCIES:

There were no study deficiencies.

F. REVIEWERS' COMMENTS:

The reviewers' conclusions were identical to the study author's. The reviewers calculated a 17 and 20% reduction from control in food consumption for males at the 1000 and 2000 mg/kg treatment levels, respectively; however, because no significant effects were detected on body weight gain, the reduced food consumption was not considered to be a toxicological response.

G. CONCLUSIONS:

The study is scientifically sound and is classified as **ACCEPTABLE**. The NOAEL is ≥2000 mg/kg based on all endpoints. The 14-day acute oral toxicity LD_{50} was estimated as >2000 mg/kg, which categorizes pyrasulfotole as practically non-toxic to Northern bobwhite quail on an acute oral basis.

LD_{50}: >2000 mg/kg 95% C.I.: N/A
Probit slope: Not determined 95% C.I.: N/A
NOAEL: ≥2000 mg/kg

Endpoint(s) Affected: None

III. REFERENCES:

Anonymous, Pesticide Assessment Guidelines, FIFRA Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms, subsection 71-1, Environmental Protection Agency, Office of Pesticide Programs, October 1982.

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APPENDIX I. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

% body weight gain (males)
File: 1729mw Transform: NO TRANSFORMATION

ANOVA TABLE

SOURCE	DF	SS	MS	F
Between	5	17.898	3.580	0.557
Within (Error)	24	154.132	6.422	
Total	29	172.030		

Critical F value = 2.62 (0.05,5,24)
Since F < Critical F FAIL TO REJECT Ho:All groups equal

% body weight gain (males)
File: 1729mw Transform: NO TRANSFORMATION

DUNNETTS TEST - TABLE 1 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	T STAT	SIG
1	control	1.418	1.418		
2	125	1.366	1.366	0.032	
3	250	3.142	3.142	-1.076	
4	500	1.052	1.052	0.228	
5	1000	1.462	1.462	-0.027	
6	2000	2.688	2.688	-0.792	

Dunnett table value = 2.36 (1 Tailed Value, P=0.05, df=24,5)

% body weight gain (males)
File: 1729mw Transform: NO TRANSFORMATION

DUNNETTS TEST - TABLE 2 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	NUM OF REPS	Minimum Sig Diff (IN ORIG. UNITS)	% of CONTROL	DIFFERENCE FROM CONTROL
1	control	5			
2	125	5	3.782	266.7	0.052
3	250	5	3.782	266.7	-1.724
4	500	5	3.782	266.7	0.366
5	1000	5	3.782	266.7	-0.044
6	2000	5	3.782	266.7	-1.270

% body weight gain (males)
File: 1729mw Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	control	5	1.418	1.418	1.392
2	125	5	1.366	1.366	1.392
3	250	5	3.142	3.142	1.885
4	500	5	1.052	1.052	1.885
5	1000	5	1.462	1.462	1.885
6	2000	5	2.688	2.688	2.688

% body weight gain (males)
File: 1729mw Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
control	1.392				
125	1.392	0.016		1.71	k= 1, v=24
250	1.885	0.292		1.79	k= 2, v=24
500	1.885	0.292		1.82	k= 3, v=24
1000	1.885	0.292		1.83	k= 4, v=24
2000	2.688	0.792		1.84	k= 5, v=24

s = 2.534
Note: df used for table values are approximate when v > 20.

% body weight gain (females)
File: 1729fw Transform: NO TRANSFORMATION

ANOVA TABLE

SOURCE	DF	SS	MS	F
Between	5	18.423	3.685	1.638
Within (Error)	24	53.992	2.250	
Total	29	72.415		

Critical F value = 2.62 (0.05,5,24)
Since F < Critical F FAIL TO REJECT Ho:All groups equal

% body weight gain (females)
File: 1729fw Transform: NO TRANSFORMATION

DUNNETTS TEST - TABLE 1 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	T STAT	SIG
1	control	1.338	1.338		
2	125	1.544	1.544	-0.217	
3	250	0.404	0.404	0.985	
4	500	0.108	0.108	1.297	
5	1000	1.848	1.848	-0.538	
6	2000	2.352	2.352	-1.069	

Dunnett table value = 2.36 (1 Tailed Value, P=0.05, df=24,5)

% body weight gain (females)
File: 1729fw Transform: NO TRANSFORMATION

DUNNETTS TEST - TABLE 2 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	NUM OF REPS	Minimum Sig Diff (IN ORIG. UNITS)	% of CONTROL	DIFFERENCE FROM CONTROL
1	control	5			
2	125	5	2.239	167.3	-0.206
3	250	5	2.239	167.3	0.934
4	500	5	2.239	167.3	1.230
5	1000	5	2.239	167.3	-0.510
6	2000	5	2.239	167.3	-1.014

% body weight gain (females)
File: 1729fw Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	control	5	1.338	1.338	0.848
2	125	5	1.544	1.544	0.848
3	250	5	0.404	0.404	0.848
4	500	5	0.108	0.108	0.848
5	1000	5	1.848	1.848	1.848
6	2000	5	2.352	2.352	2.352

% body weight gain (females)

File: 1729fw Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
control	0.848				
125	0.848	0.516		1.71	k= 1, v=24
250	0.848	0.516		1.79	k= 2, v=24
500	0.848	0.516		1.82	k= 3, v=24
1000	1.848	0.538		1.83	k= 4, v=24
2000	2.352	1.069		1.84	k= 5, v=24

s = 1.500
Note: df used for table values are approximate when v > 20.

					% body weight gain	
		d0	d7	d14	d 0-7	d 7-14
control	f	292	294	285	0.68	-3.06
	f	276	283	287	2.54	1.41
	f	287	290	278	1.05	-4.14
	f	279	283	280	1.43	-1.06
	f	304	307	304	0.99	-0.98
	m	297	282	276	-5.05	-2.13
	m	270	285	283	5.56	-0.70
	m	294	302	301	2.72	-0.33
	m	278	286	282	2.88	-1.40
	m	307	310	308	0.98	-0.65
125	f	280	285	278	1.79	-2.46
	f	280	282	279	0.71	-1.06
	f	276	283	282	2.54	-0.35
	f	292	296	289	1.37	-2.36
	f	306	310	301	1.31	-2.90
	m	297	304	305	2.36	0.33
	m	283	282	285	-0.35	1.06
	m	281	283	278	0.71	-1.77
	m	270	289	282	7.04	-2.42
	m	307	298	303	-2.93	1.68
250	f	278	278	279	0.00	0.36
	f	283	285	281	0.71	-1.40
	f	293	298	294	1.71	-1.34
	f	277	274	276	-1.08	0.73
	f	292	294	293	0.68	-0.34
	m	283	283	281	0.00	-0.71
	m	285	301	300	5.61	-0.33
	m	300	311	310	3.67	-0.32
	m	301	307	311	1.99	1.30
	m	270	282	280	4.44	-0.71
500	f	288	284	285	-1.39	0.35
	f	272	279	279	2.57	0.00
	f	285	289	284	1.40	-1.73
	f	278	277	276	-0.36	-0.36
	f	297	292	291	-1.68	-0.34
	m	267	267	269	0.00	0.75
	m	302	304	307	0.66	0.99
	m	291	299	301	2.75	0.67
	m	271	276	278	1.85	0.72
	m	300	300	300	0.00	0.00
1000	f	273	280	281	2.56	0.36
	f	288	296	294	2.78	-0.68
	f	285	283	282	-0.70	-0.35
	f	278	288	285	3.60	-1.04
	f	301	304	301	1.00	-0.99
	m	303	308	311	1.65	0.97

	m	292	298	301	2.05	1.01
	m	296	298	303	0.68	1.68
	m	275	281	283	2.18	0.71
	m	267	269	271	0.75	0.74
2000	f	286	300	298	4.90	-0.67
	f	279	280	271	0.36	-3.21
	f	273	273	285	0.00	4.40
	f	302	308	307	1.99	-0.32
	f	288	301	301	4.51	0.00
	m	305	318	319	4.26	0.31
	m	292	300	300	2.74	0.00
	m	268	270	277	0.75	2.59
	m	275	286	278	4.00	-2.80
	m	296	301	300	1.69	-0.33

% body weight gain (females)
6
5
5
5
5
5
5
control
0.68
2.54
1.05
1.43
0.99
125
1.79
0.71
2.54
1.37
1.31
250
0
0.71
1.71
-1.08
0.68
500
-1.39
2.57
1.4
-0.36
-1.68
1000
2.56
2.78
-0.7
3.6
1
2000
4.9
0.36
0
1.99
4.51

% body weight gain (males)
6
5
5
5
5
5
5
control
-5.05
5.56
2.72
2.88
0.98
125
2.36
-0.35
0.71
7.04
-2.93
250
0
5.61
3.67
1.99
4.44
500
0
0.66
2.75
1.85
0
1000
1.65
2.05
0.68
2.18
0.75
2000
4.26
2.74
0.75
4
1.69