

**Experiment Number:** 56348-02  
**Test Type:** 90-DAY  
**Route:** DOSED FEED  
**Species/Strain:** Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

**Test Compound:** Citral  
**CAS Number:** 5392-40-5

**Date Report Requested:** 10/22/2014  
**Time Report Requested:** 05:32:24  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**C Number:** C56348A  
**Lock Date:** 01/02/1996  
**Cage Range:** All  
**Date Range:** All  
**Reasons For Removal:** All  
**Removal Date Range:** All  
**Treatment Groups:** All  
**Study Gender:** Both  
**PWG Approval Date** NONE

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**Lab:** BAT

**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF CITRAL**

**MALE MOUSE**

**Organ**

Thymus

**FEMALE MOUSE**

**Organ**

Ovary: Corpus Luteum

**Morphology**

Atrophy

**Morphology**

Atrophy

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 2 WEEKS**

DOSE	MALE				
	VEHICLE CONTROL	3900	7800	15600	31300
<b>Liver</b>					
<b>Vacuolization Cytoplasmic</b>					
<b>LESION RATES</b>					
OVERALL(a)	0/20 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/20.00	0/0.00	0/0.00	0/0.00	0/6.01
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/20 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 56348-02  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 2 WEEKS**

DOSE	MALE				
	VEHICLE CONTROL	3900	7800	15600	31300
<b>Stomach, Forestomach</b>					
<b>Hyperkeratosis</b>					
<b>LESION RATES</b>					
OVERALL(a)	0/20 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/20.00	0/0.00	0/0.00	0/10.00	0/6.01
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/20 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 56348-02  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 2 WEEKS**

DOSE	MALE				
	VEHICLE CONTROL	3900	7800	15600	31300
<b>Stomach, Forestomach: Epithelium</b>					
<b>Hyperplasia</b>					
<b>LESION RATES</b>					
OVERALL(a)	0/20 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/20.00	0/0.00	0/0.00	0/10.00	0/6.01
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/20 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 56348-02  
 Test Type: 90-DAY  
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 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 2 WEEKS**

DOSE	MALE				
	VEHICLE CONTROL	3900	7800	15600	31300
<b>Thymus</b>					
<b>Atrophy</b>					
<b>LESION RATES</b>					
OVERALL(a)	0/20 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/8 (25%)
POLY-3 RATE (b)	0/20.00	0/0.00	0/0.00	0/0.00	2/8.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	25%
TERMINAL (d)	0/20 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	10
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	(e)	P=0.053
POLY 1.5	(e)	(e)	(e)	(e)	P=0.053
POLY 6	(e)	(e)	(e)	(e)	P=0.053
COCH-ARM / FISHERS	P=0.028*	(e)	(e)	(e)	P=0.074
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.019*
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

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 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Citral  
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 Time Report Requested: 05:32:24  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE				
	VEHICLE CONTROL	3900	7800	15600	31300
<b>Liver</b>					
<b>Vacuolization Cytoplasmic</b>					
<b>LESION RATES</b>					
OVERALL(a)	0/20 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/20.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%
TERMINAL (d)	0/20 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	(e)	P=0.359
POLY 1.5	(e)	(e)	(e)	(e)	P=0.359
POLY 6	(e)	(e)	(e)	(e)	P=0.359
COCH-ARM / FISHERS	P=0.185	(e)	(e)	(e)	P=0.333
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.107
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 56348-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Citral  
 CAS Number: 5392-40-5

Date Report Requested: 10/22/2014  
 Time Report Requested: 05:32:24  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE				
	VEHICLE CONTROL	3900	7800	15600	31300
<b>Ovary: Corpus Luteum Atrophy</b>					
<b>LESION RATES</b>					
OVERALL(a)	0/20 (0%)	0/0 (0%)	0/10 (0%)	7/10 (70%)	10/10 (100%)
POLY-3 RATE (b)	0/20.00	0/0.00	0/10.00	7/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	70%	100%
TERMINAL (d)	0/20 (0%)	0/0 (0%)	0/10 (0%)	7/10 (70%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	93(T)	93(T)
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	P=0.000**	P=NA
POLY 1.5	(e)	(e)	(e)	P=0.000**	P=NA
POLY 6	(e)	(e)	(e)	P=0.000**	P=NA
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	P=0.000**	P=0.000**
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.000**	P=0.000**
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE				
	VEHICLE CONTROL	3900	7800	15600	31300
<b>Stomach, Forestomach</b>					
<b>Hyperkeratosis</b>					
<b>LESION RATES</b>					
OVERALL(a)	0/20 (0%)	0/0 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/20.00	0/0.00	0/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	0%
TERMINAL (d)	0/20 (0%)	0/0 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	93(T)	---
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	P=0.359	(e)
POLY 1.5	(e)	(e)	(e)	P=0.359	(e)
POLY 6	(e)	(e)	(e)	P=0.359	(e)
COCH-ARM / FISHERS	P=0.608	(e)	(e)	P=0.333	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.107	(e)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE				
	VEHICLE CONTROL	3900	7800	15600	31300
<b>Stomach, Forestomach: Epithelium</b>					
<b>Hyperplasia</b>					
<b>LESION RATES</b>					
OVERALL(a)	0/20 (0%)	0/0 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/20.00	0/0.00	0/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	0%
TERMINAL (d)	0/20 (0%)	0/0 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	93(T)	---
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	P=0.359	(e)
POLY 1.5	(e)	(e)	(e)	P=0.359	(e)
POLY 6	(e)	(e)	(e)	P=0.359	(e)
COCH-ARM / FISHERS	P=0.608	(e)	(e)	P=0.333	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.107	(e)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 56348-02  
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 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE				
	VEHICLE CONTROL	3900	7800	15600	31300
Thymus					
Atrophy					
<b>LESION RATES</b>					
OVERALL(a)	0/20 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/20.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/20 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

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**LEGEND**

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) Number of tumor-bearing animals/Poly-3 number
  - (d) Observed incidence at terminal kill.
  - (e) Value of statistic cannot be computed.
  - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
  - (g) Poly-3 adjusted lifetime tumor incidence.
  - (n) No statistics are calculated if all dose groups have fewer than two tumors.
  - (I) Interim sacrifice
  - (T) Terminal sacrifice
  - # Tumor rates based on numbers of animals necropsied.
  - \* To the right of any statistical result, indicates significance at ( $P \leq 0.05$ ).
  - \*\* To the right of any statistical result, indicates significance at ( $P \leq 0.01$ ).
  - N Indicates a negative trend for all tests
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

**\*\* END OF REPORT \*\***