

Experiment Number: 20605 - 02
Test Type: 14-WEEK
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract
CAS Number: GUMGUGGULEXT

Date Report Requested: 04/20/2012
Time Report Requested: 11:28:04
First Dose M/F: 07/31/09 / 07/30/09
Lab: BAT

F1_M3

NTP Study Number: C20605
Lock Date: 11/04/2010
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.6.0.0_007
PWG Approval Date: NONE

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males		
	0 mg/kg	31 mg/kg	250 mg/kg
Adrenal Cortex			
Vacuolization Cytoplasmic			
LESION RATES			
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---
STATISTICAL TESTS			
POLY 3	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males		
	0 mg/kg	31 mg/kg	250 mg/kg
Kidney			
Nephropathy			
LESION RATES			
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---	---
STATISTICAL TESTS			
POLY 3	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.449N	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.158N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males		
	0 mg/kg	31 mg/kg	250 mg/kg
Kidney: Renal Tubule Regeneration			
LESION RATES			
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---
STATISTICAL TESTS			
POLY 3	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males		
	0 mg/kg	31 mg/kg	250 mg/kg

Liver
Infiltration Cellular Mixed Cell

LESION RATES			
OVERALL (a)	2/10 (20%)	0/0 (0%)	4/10 (40%)
POLY-3 RATE (b)	2/10.00	0/0.00	4/10.00
POLY-3 PERCENT (g)	20%	0%	40%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	4/10 (40%)
FIRST INCIDENCE	92 (T)	---	92 (T)

STATISTICAL TESTS			
POLY 3	(e)	(e)	P=0.318
POLY 1.5	(e)	(e)	P=0.318
POLY 6	(e)	(e)	P=0.318
COCH-ARM / FISHERS	P=0.292	(e)	P=0.314
MAX-ISO-POLY-3	(e)	(e)	P=0.172

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males		
	0 mg/kg	31 mg/kg	250 mg/kg

Liver: Hepatocyte, Centrilobular
Vacuolization Cytoplasmic Diffuse

LESION RATES

OVERALL (a)	0/10 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	92 (T)

STATISTICAL TESTS

POLY 3	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	P=0.500
POLY 6	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.449	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	P=0.158

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Species/Strain: MICE/B6C3F1

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First Dose M/F: 07/31/09 / 07/30/09

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males		
	0 mg/kg	31 mg/kg	250 mg/kg
<hr/>			
Lung			
Infiltration Cellular Histiocyte			
<hr/>			
LESION RATES			
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
STATISTICAL TESTS			
POLY 3	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)

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Species/Strain: MICE/B6C3F1

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Gum guggul extract

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First Dose M/F: 07/31/09 / 07/30/09

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males		
	0 mg/kg	31 mg/kg	250 mg/kg
Stomach, Forestomach Hyperkeratosis Focal			
LESION RATES			
OVERALL (a)	0/10 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	92 (T)
STATISTICAL TESTS			
POLY 3	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	P=0.500
POLY 6	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.449	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	P=0.158

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Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: MICE/B6C3F1

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First Dose M/F: 07/31/09 / 07/30/09

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males		
	0 mg/kg	31 mg/kg	250 mg/kg
Stomach, Forestomach Hyperplasia Focal			
LESION RATES			
OVERALL (a)	0/10 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	92 (T)
STATISTICAL TESTS			
POLY 3	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	P=0.500
POLY 6	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.449	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	P=0.158

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 mg/kg	250 mg/kg
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Adrenal Cortex
Vacuolization Cytoplasmic

LESION RATES

OVERALL (a)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---

STATISTICAL TESTS

POLY 3	P=0.500N
POLY 1.5	P=0.500N
POLY 6	P=0.500N
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.158N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 mg/kg	250 mg/kg
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Kidney
Nephropathy

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

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TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 mg/kg	250 mg/kg
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**Kidney: Renal Tubule
Regeneration**

LESION RATES

OVERALL (a)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	10%
TERMINAL (d)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	92 (T)

STATISTICAL TESTS

POLY 3	P=0.500
POLY 1.5	P=0.500
POLY 6	P=0.500
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.158

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TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 mg/kg	250 mg/kg
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Liver
Infiltration Cellular Mixed Cell

LESION RATES

OVERALL (a)	8/10 (80%)	8/10 (80%)
POLY-3 RATE (b)	8/10.00	8/10.00
POLY-3 PERCENT (g)	80%	80%
TERMINAL (d)	8/10 (80%)	8/10 (80%)
FIRST INCIDENCE	92 (T)	92 (T)

STATISTICAL TESTS

POLY 3	P=0.702
POLY 1.5	P=0.702
POLY 6	P=0.702
COCH-ARM / FISHERS	P=0.709N
MAX-ISO-POLY-3	P=1.000

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TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 mg/kg	250 mg/kg
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Liver: Hepatocyte, Centrilobular
Vacuolization Cytoplasmic Diffuse

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

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TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 mg/kg	250 mg/kg
------	---------	-----------

Lung
Infiltration Cellular Histiocyte

LESION RATES

OVERALL (a)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---

STATISTICAL TESTS

POLY 3	P=0.500N
POLY 1.5	P=0.500N
POLY 6	P=0.500N
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.158N

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TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 mg/kg	250 mg/kg
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Stomach, Forestomach
Hyperkeratosis Focal

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

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TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	0 mg/kg	250 mg/kg
-------------	----------------	------------------

**Stomach, Forestomach
Hyperplasia Focal**

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

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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 ***