

Experiment Number: 20605 - 98
Test Type: SPECIAL STUDY
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum Guggul Extract
CAS Number: GUMGUGGULEXT

Date Report Requested: 05/13/2019
Time Report Requested: 15:00:27
First Dose M/F: 07/31/09 / 07/30/09
Lab: BAT

NTP Study Number: C20605
Lock Date: Not Entered.
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 3.0.2.3_002
PWG Approval Date: NONE

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 4 WEEKS**

DOSE	Males		
	0 mg/kg	31 mg/kg	250 mg/kg
Kidney			
Hydronephrosis			
LESION RATES			
OVERALL (a)	1/5 (20%)	0/0 (0%)	0/5 (0%)
POLY-3 RATE (b)	1/5.00	0/0.00	0/5.00
POLY-3 PERCENT (g)	20%	0%	0%
TERMINAL (d)	1/5 (20%)	0/0 (0%)	0/5 (0%)
FIRST INCIDENCE	28 (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=0.448N	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.158N

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TERMINAL SACRIFICE AT 4 WEEKS**

DOSE	Males		
	0 mg/kg	31 mg/kg	250 mg/kg
Kidney			
Nephropathy			
LESION RATES			
OVERALL (a)	0/5 (0%)	0/0 (0%)	1/5 (20%)
POLY-3 RATE (b)	0/5.00	0/0.00	1/5.00
POLY-3 PERCENT (g)	0%	0%	20%
TERMINAL (d)	0/5 (0%)	0/0 (0%)	1/5 (20%)
FIRST INCIDENCE	---	---	28 (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=0.448	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	P=0.158

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TERMINAL SACRIFICE AT 4 WEEKS**

DOSE	Males		
	0 mg/kg	31 mg/kg	250 mg/kg
<hr/>			
Liver			
Clear Cell Focus			
<hr/>			
LESION RATES			
OVERALL (a)	0/5 (0%)	0/0 (0%)	1/5 (20%)
POLY-3 RATE (b)	0/5.00	0/0.00	1/5.00
POLY-3 PERCENT (g)	0%	0%	20%
TERMINAL (d)	0/5 (0%)	0/0 (0%)	1/5 (20%)
FIRST INCIDENCE	---	---	28 (T)
<hr/>			
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=0.448	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	P=0.158

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TERMINAL SACRIFICE AT 4 WEEKS**

DOSE	Males		
	0 mg/kg	31 mg/kg	250 mg/kg
<hr/>			
Liver			
Hematopoietic Cell Proliferation			
<hr/>			
LESION RATES			
OVERALL (a)	0/5 (0%)	0/0 (0%)	0/5 (0%)
POLY-3 RATE (b)	0/5.00	0/0.00	0/5.00
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/5 (0%)	0/0 (0%)	0/5 (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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TERMINAL SACRIFICE AT 4 WEEKS**

DOSE	Males		
	0 mg/kg	31 mg/kg	250 mg/kg
<hr/>			
Liver: Hepatocyte Necrosis			
<hr/>			
LESION RATES			
OVERALL (a)	0/5 (0%)	0/0 (0%)	1/5 (20%)
POLY-3 RATE (b)	0/5.00	0/0.00	1/5.00
POLY-3 PERCENT (g)	0%	0%	20%
TERMINAL (d)	0/5 (0%)	0/0 (0%)	1/5 (20%)
FIRST INCIDENCE	---	---	28 (T)
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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=0.448	(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 4 WEEKS**

Females

DOSE	0 mg/kg	250 mg/kg
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Kidney
Hydronephrosis

LESION RATES

OVERALL (a)	0/5 (0%)	0/5 (0%)
POLY-3 RATE (b)	0/5.00	0/5.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/5 (0%)	0/5 (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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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 4 WEEKS**

Females

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

Kidney
Nephropathy

LESION RATES

OVERALL (a)	0/5 (0%)	0/5 (0%)
POLY-3 RATE (b)	0/5.00	0/5.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/5 (0%)	0/5 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

POLY 3	(n)
POLY 1.5	(n)
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Females

DOSE	0 mg/kg	250 mg/kg
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Liver
Clear Cell Focus

LESION RATES

OVERALL (a)	0/5 (0%)	0/5 (0%)
POLY-3 RATE (b)	0/5.00	0/5.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/5 (0%)	0/5 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
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TERMINAL SACRIFICE AT 4 WEEKS**

Females

DOSE	0 mg/kg	250 mg/kg
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Liver
Hematopoietic Cell Proliferation

LESION RATES

OVERALL (a)	0/5 (0%)	1/5 (20%)
POLY-3 RATE (b)	0/5.00	1/5.00
POLY-3 PERCENT (g)	0%	20%
TERMINAL (d)	0/5 (0%)	1/5 (20%)
FIRST INCIDENCE	---	28 (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 4 WEEKS**

Females

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

Liver: Hepatocyte
Necrosis

LESION RATES

OVERALL (a)	0/5 (0%)	0/5 (0%)
POLY-3 RATE (b)	0/5.00	0/5.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/5 (0%)	0/5 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

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