

Experiment Number: 20605 - 99
Test Type: SPECIAL STUDY
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Gum Guggul Extract
CAS Number: GUMGUGGULEXT

Date Report Requested: 05/13/2019
Time Report Requested: 15:00:28
First Dose M/F: 07/23/09 / 07/24/09
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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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF GUM GUGGUL EXTRACT

MALE RATS

Organ

Heart

FEMALE RATS

Organ

Liver

Morphology

Cardiomyopathy

Morphology

Fibrosis

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

DOSE	Males				
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	1000 mg/kg
Adrenal Cortex Hypertrophy					
LESION RATES					
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	4/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	40%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
FIRST INCIDENCE	28 (T)	---	---	---	28 (T)
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	P=0.148
POLY 1.5	(e)	(e)	(e)	(e)	P=0.148
POLY 6	(e)	(e)	(e)	(e)	P=0.148
COCH-ARM / FISHERS	P=0.123	(e)	(e)	(e)	P=0.152
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.058

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

DOSE	Males				
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	1000 mg/kg
Adrenal Cortex					
Vacuolization Cytoplasmic					
LESION RATES					
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	28 (T)
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.176	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.066

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

DOSE	Males				
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	1000 mg/kg
Blood Vessel Infiltration Cellular Mononuclear Cell					
LESION RATES					
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
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)

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

DOSE	Males				
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	1000 mg/kg
Epididymis Degeneration					
LESION RATES					
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	28 (T)	---	---	---	---
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.399N	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.158N

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First Dose M/F: 07/23/09 / 07/24/09

Lab: BAT

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

DOSE	Males				
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	1000 mg/kg
Heart					
Cardiomyopathy					
LESION RATES					
OVERALL (a)	1/10 (10%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	1/1.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	100%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	28 (T)	---	28 (T)	---	---
STATISTICAL TESTS					
POLY 3	(e)	(e)	P=0.146	(e)	P=0.500N
POLY 1.5	(e)	(e)	P=0.146	(e)	P=0.500N
POLY 6	(e)	(e)	P=0.146	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.243N	(e)	P=0.182	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.022*	(e)	P=0.158N

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

DOSE	Males				
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	1000 mg/kg
Kidney					
Developmental Malformation					
LESION RATES					
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	28 (T)
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.399	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.158

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 TERMINAL SACRIFICE AT 4 WEEKS**

DOSE	Males				
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	1000 mg/kg
Kidney					
Nephropathy					
LESION RATES					
OVERALL (a)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	6/10 (60%)
POLY-3 RATE (b)	3/10.00	0/0.00	0/0.00	0/0.00	6/10.00
POLY-3 PERCENT (g)	30%	0%	0%	0%	60%
TERMINAL (d)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	6/10 (60%)
FIRST INCIDENCE	28 (T)	---	---	---	28 (T)
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	P=0.186
POLY 1.5	(e)	(e)	(e)	(e)	P=0.186
POLY 6	(e)	(e)	(e)	(e)	P=0.186
COCH-ARM / FISHERS	P=0.156	(e)	(e)	(e)	P=0.185
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.089

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TERMINAL SACRIFICE AT 4 WEEKS**

DOSE	Males				
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	1000 mg/kg
Liver Fatty Change					
LESION RATES					
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
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)

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

DOSE	Males				
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	1000 mg/kg
Liver Fibrosis					
LESION RATES					
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
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)

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 TERMINAL SACRIFICE AT 4 WEEKS**

DOSE	Males				
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	1000 mg/kg
Skeletal Muscle Degeneration					
LESION RATES					
OVERALL (a)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
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)

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

DOSE	Males				
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	1000 mg/kg
Stomach, Forestomach Mineralization					
LESION RATES					
OVERALL (a)	0/0 (0%)	2/2 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	2/2.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	100%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	2/2 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	28 (T)	---	---	---
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)

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

DOSE	Males				
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	1000 mg/kg
Thymus Hemorrhage					
LESION RATES					
OVERALL (a)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/2 (100%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	0/0.00	0/0.00	2/2.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	100%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/2 (100%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	28 (T)	---
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 4 WEEKS

DOSE	Males				
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	1000 mg/kg
Thymus					
Inflammation Chronic					
LESION RATES					
OVERALL (a)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/2 (50%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	0/0.00	0/0.00	1/2.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	50%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/2 (50%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	28 (T)	---
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=1.000N	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 4 WEEKS**

DOSE	Males				
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	1000 mg/kg
Thyroid Gland Infiltration Cellular Mononuclear Cell					
LESION RATES					
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	28 (T)	---	---	---	---
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.399N	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.158N

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 Route: GAVAGE
 Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Gum Guggul Extract
 CAS Number: GUMGUGGULEXT

Date Report Requested: 05/13/2019
 Time Report Requested: 15:00:28
 First Dose M/F: 07/23/09 / 07/24/09
 Lab: BAT

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

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Adrenal Cortex Hypertrophy						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	4/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	40%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
FIRST INCIDENCE	28 (T)	---	---	---	---	28 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.148
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.148
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.148
COCH-ARM / FISHERS	P=0.098	(e)	(e)	(e)	(e)	P=0.152
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.058

Experiment Number: 20605 - 99
 Test Type: SPECIAL STUDY
 Route: GAVAGE
 Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Gum Guggul Extract
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 Lab: BAT

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

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Adrenal Cortex						
Vacuolization Cytoplasmic						
LESION RATES						
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	10%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	28 (T)	---	---	---	---	28 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.377N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.274N

Experiment Number: 20605 - 99
 Test Type: SPECIAL STUDY
 Route: GAVAGE
 Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Gum Guggul Extract
 CAS Number: GUMGUGGULEXT

Date Report Requested: 05/13/2019
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 First Dose M/F: 07/23/09 / 07/24/09
 Lab: BAT

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

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Blood Vessel Infiltration Cellular Mononuclear Cell						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	28 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158N

Experiment Number: 20605 - 99
 Test Type: SPECIAL STUDY
 Route: GAVAGE
 Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
 TERMINAL SACRIFICE AT 4 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Heart						
Cardiomyopathy						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20605 - 99
Test Type: SPECIAL STUDY
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Gum Guggul Extract
CAS Number: GUMGUGGULEXT

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First Dose M/F: 07/23/09 / 07/24/09
Lab: BAT

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

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Kidney Developmental Malformation						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20605 - 99
 Test Type: SPECIAL STUDY
 Route: GAVAGE
 Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Gum Guggul Extract
 CAS Number: GUMGUGGULEXT

Date Report Requested: 05/13/2019
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 First Dose M/F: 07/23/09 / 07/24/09
 Lab: BAT

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

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Kidney						
Nephropathy						
LESION RATES						
OVERALL (a)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	4/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	40%	0%	0%	0%	0%	10%
TERMINAL (d)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	28 (T)	---	---	---	---	28 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.148N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.148N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.148N
COCH-ARM / FISHERS	P=0.098N	(e)	(e)	(e)	(e)	P=0.152N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.058N

Experiment Number: 20605 - 99
 Test Type: SPECIAL STUDY
 Route: GAVAGE
 Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Gum Guggul Extract
 CAS Number: GUMGUGGULEXT

Date Report Requested: 05/13/2019
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 First Dose M/F: 07/23/09 / 07/24/09
 Lab: BAT

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

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Liver Fatty Change						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/1.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	28 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.288	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158

Experiment Number: 20605 - 99
 Test Type: SPECIAL STUDY
 Route: GAVAGE
 Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Gum Guggul Extract
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Date Report Requested: 05/13/2019
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 First Dose M/F: 07/23/09 / 07/24/09
 Lab: BAT

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

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Liver Fibrosis						
LESION RATES						
OVERALL (a)	0/10 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/1.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	100%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	28 (T)	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	P=0.091	(e)	(e)	(e)	(e)
POLY 1.5	(e)	P=0.091	(e)	(e)	(e)	(e)
POLY 6	(e)	P=0.091	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.366N	P=0.091	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	P<0.001**	(e)	(e)	(e)	(e)

Experiment Number: 20605 - 99
Test Type: SPECIAL STUDY
Route: GAVAGE
Species/Strain: RATS/HSD

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Gum Guggul Extract
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 4 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Skeletal Muscle Degeneration						
LESION RATES						
OVERALL (a)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	1/1.00	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	100%	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	28 (T)	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Stomach, Forestomach Mineralization						
LESION RATES						
OVERALL (a)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20605 - 99
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
 TERMINAL SACRIFICE AT 4 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Thymus Hemorrhage						
LESION RATES						
OVERALL (a)	0/0 (0%)	2/2 (100%)	1/1 (100%)	3/3 (100%)	2/2 (100%)	1/1 (100%)
POLY-3 RATE (b)	0/0.00	2/2.00	1/1.00	3/3.00	2/2.00	1/1.00
POLY-3 PERCENT (g)	0%	100%	100%	100%	100%	100%
TERMINAL (d)	0/0 (0%)	2/2 (100%)	1/1 (100%)	3/3 (100%)	2/2 (100%)	1/1 (100%)
FIRST INCIDENCE	---	28 (T)	28 (T)	28 (T)	28 (T)	28 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Thymus						
Inflammation Chronic						
LESION RATES						
OVERALL (a)	0/0 (0%)	1/2 (50%)	0/1 (0%)	0/3 (0%)	1/2 (50%)	1/1 (100%)
POLY-3 RATE (b)	0/0.00	1/2.00	0/1.00	0/3.00	1/2.00	1/1.00
POLY-3 PERCENT (g)	0%	50%	0%	0%	50%	100%
TERMINAL (d)	0/0 (0%)	1/2 (50%)	0/1 (0%)	0/3 (0%)	1/2 (50%)	1/1 (100%)
FIRST INCIDENCE	---	28 (T)	---	---	28 (T)	28 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.216	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

Experiment Number: 20605 - 99
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
 TERMINAL SACRIFICE AT 4 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Thyroid Gland Infiltration Cellular Mononuclear Cell						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20605 - 99
 Test Type: SPECIAL STUDY
 Route: GAVAGE
 Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
 TERMINAL SACRIFICE AT 4 WEEKS**

DOSE	Females					
	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus						
Hyperplasia Cystic						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	30%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	28 (T)	---	---	---	---	28 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.292
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.292
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.292
COCH-ARM / FISHERS	P=0.201	(e)	(e)	(e)	(e)	P=0.291
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.136

Experiment Number: 20605 - 99

Test Type: SPECIAL STUDY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum Guggul Extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 05/13/2019

Time Report Requested: 15:00:28

First Dose M/F: 07/23/09 / 07/24/09

Lab: BAT

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 ***