

Experiment Number: 20605 - 01
Test Type: 14-WEEK
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract
CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012
Time Report Requested: 13:56:16
First Dose M/F: 07/23/09 / 07/24/09
Lab: BAT

F1_Rev.1_HSD

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: 05/11/2012

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF GUM GUGGUL EXTRACT

MALE RATS

Organ

Brain: Cerebrum

Kidney

Lymph Node, Mandibular

FEMALE RATS

Organ

Lung: Pleura

Spleen

Thymus

Thymus: Mediastinum

Thyroid Gland

Morphology

Hydrocephalus

Nephropathy

Hyperplasia Lymphoid

Morphology

Inflammation

Hyperplasia Lymphoid

Atrophy Diffuse

Inflammation

Cyst

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Males | | | | | |
|--------------------------|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Adrenal Cortex | | | | | | |
| Hypertrophy Focal | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%) | 1/10 (10%) |
| POLY-3 RATE (b) | 1/10.00 | 0/10.00 | 0/10.00 | 0/10.00 | 0/10.00 | 1/10.00 |
| POLY-3 PERCENT (g) | 10% | 0% | 0% | 0% | 0% | 10% |
| TERMINAL (d) | 1/10 (10%) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%) | 1/10 (10%) |
| FIRST INCIDENCE | 92 (T) | --- | --- | --- | --- | 92 (T) |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | P=0.415 | P=0.500N | P=0.500N | P=0.500N | P=0.500N | P=0.760 |
| POLY 1.5 | P=0.415 | P=0.500N | P=0.500N | P=0.500N | P=0.500N | P=0.760 |
| POLY 6 | P=0.415 | P=0.500N | P=0.500N | P=0.500N | P=0.500N | P=0.760 |
| COCH-ARM / FISHERS | P=0.414 | P=0.500N | P=0.500N | P=0.500N | P=0.500N | P=0.763N |
| MAX-ISO-POLY-3 | P=0.300 | P=0.158N | P=0.158N | P=0.158N | P=0.158N | P=1.000 |

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

| DOSE | Males | | | | | |
|--|-----------|------------|-----------|------------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Adrenal Cortex | | | | | | |
| Vacuolization Cytoplasmic Diffuse | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%) | 1/10 (10%) | 0/10 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/10.00 | 0/10.00 | 0/10.00 | 1/10.00 | 0/10.00 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 10% | 0% | 0% |
| TERMINAL (d) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%) | 1/10 (10%) | 0/10 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | --- | --- | --- | 92 (T) | --- | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | P=0.697N | (e) | (e) | P=0.500 | (e) | (e) |
| POLY 1.5 | P=0.697N | (e) | (e) | P=0.500 | (e) | (e) |
| POLY 6 | P=0.697N | (e) | (e) | P=0.500 | (e) | (e) |
| COCH-ARM / FISHERS | P=0.699N | (e) | (e) | P=0.500 | (e) | (e) |
| MAX-ISO-POLY-3 | P=0.516 | (e) | (e) | P=0.158 | (e) | (e) |

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

| DOSE | Males | | | | | |
|------------------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Bone Marrow Hyperplasia | | | | | | |
| 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) |

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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 14 WEEKS**

| DOSE | Males | | | | | |
|--------------------------|-----------|------------|-----------|-----------|------------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Brain: Cerebrum | | | | | | |
| Hydrocephalus | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 1/1 (100%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 1/1.00 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 100% | 0% |
| TERMINAL (d) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 1/1 (100%) | 0/10 (0%) |
| FIRST INCIDENCE | --- | --- | --- | --- | 92 (T) | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | (e) | (e) | P=0.091 | (e) |
| POLY 1.5 | (e) | (e) | (e) | (e) | P=0.091 | (e) |
| POLY 6 | (e) | (e) | (e) | (e) | P=0.091 | (e) |
| COCH-ARM / FISHERS | P=0.700 | (e) | (e) | (e) | P=0.091 | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | P<0.001** | (e) |

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Lab: BAT

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

| DOSE | Males | | | | | |
|--------------------------|------------|------------|-----------|-----------|-----------|------------|
| | 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) | 4/10 (40%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 2/10 (20%) |
| POLY-3 RATE (b) | 4/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 2/10.00 |
| POLY-3 PERCENT (g) | 40% | 0% | 0% | 0% | 0% | 20% |
| TERMINAL (d) | 4/10 (40%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 2/10 (20%) |
| FIRST INCIDENCE | 92 (T) | --- | --- | --- | --- | 92 (T) |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.318N |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.318N |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.318N |
| COCH-ARM / FISHERS | P=0.232N | (e) | (e) | (e) | (e) | P=0.314N |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | P=0.171N |

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Lab: BAT

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

| DOSE | Males | | | | | |
|---|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Heart: Epicardium Inflammation | | | | | | |
| 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) |

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Lab: BAT

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

| DOSE | Males | | | | | |
|-------------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Intestine Large, Colon | | | | | | |
| Parasite Metazoan | | | | | | |
| 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) |

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

| DOSE | Males | | | | | |
|--------------------------|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Kidney Infarct | | | | | | |
| 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 | 92 (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 |

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Lab: BAT

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

| DOSE | Males | | | | | |
|---------------------------|------------|------------|-----------|-----------|-----------|--------------|
| | 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) | 6/10 (60%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 10/10 (100%) |
| POLY-3 RATE (b) | 6/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 10/10.00 |
| POLY-3 PERCENT (g) | 60% | 0% | 0% | 0% | 0% | 100% |
| TERMINAL (d) | 6/10 (60%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 10/10 (100%) |
| FIRST INCIDENCE | 92 (T) | --- | --- | --- | --- | 92 (T) |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.033* |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.033* |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.033* |
| COCH-ARM / FISHERS | P=0.025* | (e) | (e) | (e) | (e) | P=0.043* |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | P=0.007** |

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Lab: BAT

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

| DOSE | Males | | | | | |
|----------------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Kidney: Renal Tubule Cyst | | | | | | |
| 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) |

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Males | | | | | |
|--------------------------|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Liver | | | | | | |
| Clear Cell Focus | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 2/10 (20%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) | 1/10 (10%) |
| POLY-3 RATE (b) | 2/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/10.00 | 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%) | 0/10 (0%) | 1/10 (10%) |
| FIRST INCIDENCE | 92 (T) | --- | --- | --- | --- | 92 (T) |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | (e) | (e) | P=0.227N | P=0.500N |
| POLY 1.5 | (e) | (e) | (e) | (e) | P=0.227N | P=0.500N |
| POLY 6 | (e) | (e) | (e) | (e) | P=0.227N | P=0.500N |
| COCH-ARM / FISHERS | P=0.355N | (e) | (e) | (e) | P=0.237N | P=0.500N |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | P=0.067N | P=0.274N |

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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 14 WEEKS**

| DOSE | Males | | | | | |
|---|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Liver | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) | 1/10 (10%) |
| POLY-3 RATE (b) | 0/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/10.00 | 1/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 10% |
| TERMINAL (d) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) | 1/10 (10%) |
| FIRST INCIDENCE | --- | --- | --- | --- | --- | 92 (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=0.267 | (e) | (e) | (e) | (e) | P=0.500 |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | P=0.158 |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|-----------------------------------|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Liver | | | | | | |
| Hepatodiaphragmatic Nodule | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 1/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/10.00 | 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%) | 0/10 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 92 (T) | --- | --- | --- | --- | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | (e) | (e) | P=0.500N | P=0.500N |
| POLY 1.5 | (e) | (e) | (e) | (e) | P=0.500N | P=0.500N |
| POLY 6 | (e) | (e) | (e) | (e) | P=0.500N | P=0.500N |
| COCH-ARM / FISHERS | P=0.267N | (e) | (e) | (e) | P=0.500N | P=0.500N |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | P=0.158N | P=0.158N |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|---|------------|------------|-----------|-----------|------------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Liver | | | | | | |
| Infiltration Cellular Mixed Cell | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 8/10 (80%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 9/10 (90%) | 8/10 (80%) |
| POLY-3 RATE (b) | 8/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 9/10.00 | 8/10.00 |
| POLY-3 PERCENT (g) | 80% | 0% | 0% | 0% | 90% | 80% |
| TERMINAL (d) | 8/10 (80%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 9/10 (90%) | 8/10 (80%) |
| FIRST INCIDENCE | 92 (T) | --- | --- | --- | 92 (T) | 92 (T) |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | (e) | (e) | P=0.500 | P=0.702 |
| POLY 1.5 | (e) | (e) | (e) | (e) | P=0.500 | P=0.702 |
| POLY 6 | (e) | (e) | (e) | (e) | P=0.500 | P=0.702 |
| COCH-ARM / FISHERS | P=0.618 | (e) | (e) | (e) | P=0.500 | P=0.709N |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | P=0.274 | P=1.000 |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|----------------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Liver | | | | | | |
| Vacuolization Cytoplasmic | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/10.00 | 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%) | 0/10 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Males | | | | | |
|--|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Liver: Centrilobular Necrosis Acute | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) | 1/10 (10%) |
| POLY-3 RATE (b) | 0/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/10.00 | 1/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 10% |
| TERMINAL (d) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) | 1/10 (10%) |
| FIRST INCIDENCE | --- | --- | --- | --- | --- | 92 (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=0.267 | (e) | (e) | (e) | (e) | P=0.500 |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | P=0.158 |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|----------------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Liver: Hepatocyte Atrophy | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/10.00 | 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%) | 0/10 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|--|-----------|------------|-----------|-----------|------------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Liver: Hepatocyte Hypertrophy Diffuse | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 1/10 (10%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 1/10.00 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 10% | 0% |
| TERMINAL (d) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 1/10 (10%) | 0/10 (0%) |
| FIRST INCIDENCE | --- | --- | --- | --- | 92 (T) | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | (e) | (e) | P=0.500 | (e) |
| POLY 1.5 | (e) | (e) | (e) | (e) | P=0.500 | (e) |
| POLY 6 | (e) | (e) | (e) | (e) | P=0.500 | (e) |
| COCH-ARM / FISHERS | P=0.733 | (e) | (e) | (e) | P=0.500 | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | P=0.158 | (e) |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|---------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lung | | | | | | |
| Congestion Diffuse | | | | | | |
| 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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|-----------------------------|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lung | | | | | | |
| Inflammation Chronic | | | | | | |
| 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 | 92 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|---------------------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lung: Mediastinum Inflammation | | | | | | |
| 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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|----------------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lung: Pleura Inflammation | | | | | | |
| 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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|---------------------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lymph Node, Mandibular Atrophy | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/10.00 | 0/0.00 | 0/1.00 | 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%) | 0/1 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Males | | | | | |
|--|-----------|------------|------------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lymph Node, Mandibular Hyperplasia Lymphoid | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 1/1 (100%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/10.00 | 0/0.00 | 1/1.00 | 0/0.00 | 0/0.00 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 100% | 0% | 0% | 0% |
| TERMINAL (d) | 0/10 (0%) | 0/0 (0%) | 1/1 (100%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | --- | --- | 92 (T) | --- | --- | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.091 | (e) | (e) | (e) |
| POLY 1.5 | (e) | (e) | P=0.091 | (e) | (e) | (e) |
| POLY 6 | (e) | (e) | P=0.091 | (e) | (e) | (e) |
| COCH-ARM / FISHERS | P=0.412N | (e) | P=0.091 | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | P<0.001** | (e) | (e) | (e) |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|---------------------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lymph Node, Mesenteric Atrophy | | | | | | |
| 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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|--|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lymph Node, Mesenteric Hyperplasia Lymphoid | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (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 | 0/0.00 | 1/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 10% |
| TERMINAL (d) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 1/10 (10%) |
| FIRST INCIDENCE | --- | --- | --- | --- | --- | 92 (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=0.304 | (e) | (e) | (e) | (e) | P=0.500 |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | P=0.158 |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|--------------------------------------|----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lymph Node: Renal Hyperplasia | | | | | | |
| 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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|---------------------------------------|----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lymph Node: Renal Pigmentation | | | | | | |
| 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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Males | | | | | |
|---------------------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Pituitary Gland: Pars Distalis | | | | | | |
| Hypertrophy Diffuse | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (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 | 0/0.00 | 1/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 10% |
| TERMINAL (d) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 1/10 (10%) |
| FIRST INCIDENCE | --- | --- | --- | --- | --- | 92 (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=0.304 | (e) | (e) | (e) | (e) | P=0.500 |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | P=0.158 |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|---|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Preputial Gland Inflammation Chronic | | | | | | |
| 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 | 92 (T) | --- | --- | --- | --- | 92 (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=0.135 |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|--------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Spleen Atrophy | | | | | | |
| 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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|---|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Spleen | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (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 | 0/0.00 | 1/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 10% |
| TERMINAL (d) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 1/10 (10%) |
| FIRST INCIDENCE | --- | --- | --- | --- | --- | 92 (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=0.304 | (e) | (e) | (e) | (e) | P=0.500 |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | P=0.158 |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|--------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Spleen | | | | | | |
| Hyperplasia Lymphoid | | | | | | |
| 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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|--------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| <hr/> | | | | | | |
| Thymus | | | | | | |
| Atrophy Diffuse | | | | | | |
| <hr/> | | | | | | |
| 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 | --- | --- | --- | --- | --- | --- |
| <hr/> | | | | | | |
| 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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Males | | | | | |
|------------------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Thymus Pigmentation Hemosiderin | | | | | | |
| 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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Males | | | | | |
|---|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Thymus: Mediastinum Inflammation | | | | | | |
| 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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Males | | | | | |
|---------------------------|------------|------------|------------|------------|------------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Thyroid Gland Cyst | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 1/10 (10%) | 2/10 (20%) | 2/10 (20%) | 3/10 (30%) | 2/10 (20%) |
| POLY-3 RATE (b) | 1/10.00 | 1/10.00 | 2/10.00 | 2/10.00 | 3/10.00 | 2/10.00 |
| POLY-3 PERCENT (g) | 10% | 10% | 20% | 20% | 30% | 20% |
| TERMINAL (d) | 1/10 (10%) | 1/10 (10%) | 2/10 (20%) | 2/10 (20%) | 3/10 (30%) | 2/10 (20%) |
| FIRST INCIDENCE | 92 (T) | 92 (T) | 92 (T) | 92 (T) | 92 (T) | 92 (T) |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | P=0.316 | P=0.760 | P=0.500 | P=0.500 | P=0.292 | P=0.500 |
| POLY 1.5 | P=0.316 | P=0.760 | P=0.500 | P=0.500 | P=0.292 | P=0.500 |
| POLY 6 | P=0.316 | P=0.760 | P=0.500 | P=0.500 | P=0.292 | P=0.500 |
| COCH-ARM / FISHERS | P=0.310 | P=0.763N | P=0.500 | P=0.500 | P=0.291 | P=0.500 |
| MAX-ISO-POLY-3 | P=0.371 | P=1.000 | P=0.274 | P=0.274 | P=0.135 | P=0.274 |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 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 Focal | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 1/10 (10%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 1/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 10% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 1/10 (10%) |
| FIRST INCIDENCE | --- | --- | --- | --- | --- | 92 (T) |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.517 |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.512 |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.520 |
| COCH-ARM / FISHERS | P=0.286 | (e) | (e) | (e) | (e) | P=0.500 |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | P=0.179 |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 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 Diffuse | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Females | | | | | |
|--------------------------------|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Bone Marrow Hyperplasia | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 1/10.00 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 10% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 52 | --- | --- | --- | --- | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.938N | (e) | P=0.938N | P=0.500N |
| POLY 1.5 | (e) | (e) | P=0.932N | (e) | P=0.931N | P=0.500N |
| POLY 6 | (e) | (e) | P=0.942N | (e) | P=0.942N | P=0.500N |
| COCH-ARM / FISHERS | P=0.311N | (e) | P=0.909N | (e) | P=0.909N | P=0.500N |
| MAX-ISO-POLY-3 | (e) | (e) | P=0.477N | (e) | P=0.476N | P=0.158N |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|--------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Brain: Cerebrum | | | | | | |
| Hydrocephalus | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|--|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Clitoral Gland Inflammation Chronic | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 3/10 (30%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 1/10 (10%) |
| POLY-3 RATE (b) | 3/9.18 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 1/10.00 |
| POLY-3 PERCENT (g) | 32.7% | 0% | 0% | 0% | 0% | 10% |
| TERMINAL (d) | 3/9 (33%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 1/10 (10%) |
| FIRST INCIDENCE | 92 (T) | --- | --- | --- | --- | 92 (T) |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.823N | (e) | P=0.821N | P=0.258N |
| POLY 1.5 | (e) | (e) | P=0.782N | (e) | P=0.780N | P=0.268N |
| POLY 6 | (e) | (e) | P=0.849N | (e) | P=0.848N | P=0.252N |
| COCH-ARM / FISHERS | P=0.218N | (e) | P=0.727N | (e) | P=0.727N | P=0.291N |
| MAX-ISO-POLY-3 | (e) | (e) | P=0.453N | (e) | P=0.451N | P=0.123N |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 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%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Females | | | | | |
|---------------------------------------|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Heart: Epicardium Inflammation | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 1/10.00 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 10% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 52 | --- | --- | --- | --- | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.938N | (e) | P=0.938N | P=0.500N |
| POLY 1.5 | (e) | (e) | P=0.932N | (e) | P=0.931N | P=0.500N |
| POLY 6 | (e) | (e) | P=0.942N | (e) | P=0.942N | P=0.500N |
| COCH-ARM / FISHERS | P=0.311N | (e) | P=0.909N | (e) | P=0.909N | P=0.500N |
| MAX-ISO-POLY-3 | (e) | (e) | P=0.477N | (e) | P=0.476N | P=0.158N |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|---|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Intestine Large, Colon Parasite Metazoan | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 1/9.18 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 10.9% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 1/9 (11%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 92 (T) | --- | --- | --- | --- | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.939N | (e) | P=0.939N | P=0.483N |
| POLY 1.5 | (e) | (e) | P=0.932N | (e) | P=0.931N | P=0.488N |
| POLY 6 | (e) | (e) | P=0.943N | (e) | P=0.943N | P=0.480N |
| COCH-ARM / FISHERS | P=0.311N | (e) | P=0.909N | (e) | P=0.909N | P=0.500N |
| MAX-ISO-POLY-3 | (e) | (e) | P=0.476N | (e) | P=0.474N | P=0.157N |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|--------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Kidney Infarct | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 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) | 2/10 (20%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 3/10 (30%) |
| POLY-3 RATE (b) | 2/9.18 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 3/10.00 |
| POLY-3 PERCENT (g) | 21.8% | 0% | 0% | 0% | 0% | 30% |
| TERMINAL (d) | 2/9 (22%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 3/10 (30%) |
| FIRST INCIDENCE | 92 (T) | --- | --- | --- | --- | 92 (T) |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.866N | (e) | P=0.865N | P=0.542 |
| POLY 1.5 | (e) | (e) | P=0.843N | (e) | P=0.841N | P=0.529 |
| POLY 6 | (e) | (e) | P=0.881N | (e) | P=0.881N | P=0.550 |
| COCH-ARM / FISHERS | P=0.362 | (e) | P=0.818N | (e) | P=0.818N | P=0.500 |
| MAX-ISO-POLY-3 | (e) | (e) | P=0.464N | (e) | P=0.463N | P=0.351 |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|----------------------------------|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Kidney: Renal Tubule Cyst | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 1/9.18 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 10.9% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 1/9 (11%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 92 (T) | --- | --- | --- | --- | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.939N | (e) | P=0.939N | P=0.483N |
| POLY 1.5 | (e) | (e) | P=0.932N | (e) | P=0.931N | P=0.488N |
| POLY 6 | (e) | (e) | P=0.943N | (e) | P=0.943N | P=0.480N |
| COCH-ARM / FISHERS | P=0.311N | (e) | P=0.909N | (e) | P=0.909N | P=0.500N |
| MAX-ISO-POLY-3 | (e) | (e) | P=0.476N | (e) | P=0.474N | P=0.157N |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|--------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Liver | | | | | | |
| Clear Cell Focus | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/10.00 | 0/9.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) | 0/9 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|---|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Liver | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/10.00 | 0/9.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) | 0/9 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Females | | | | | |
|----------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Liver | | | | | | |
| Hepatodiaphragmatic Nodule | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/10.00 | 0/9.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) | 0/9 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Females | | | | | |
|---|------------|------------|-----------|------------|------------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Liver | | | | | | |
| Infiltration Cellular Mixed Cell | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 8/10 (80%) | 0/0 (0%) | 0/1 (0%) | 9/10 (90%) | 8/10 (80%) | 6/10 (60%) |
| POLY-3 RATE (b) | 8/9.18 | 0/0.00 | 0/0.23 | 9/10.00 | 8/9.24 | 6/10.00 |
| POLY-3 PERCENT (g) | 87.1% | 0% | 0% | 90% | 86.6% | 60% |
| TERMINAL (d) | 8/9 (89%) | 0/0 (0%) | 0/0 (0%) | 9/10 (90%) | 8/9 (89%) | 6/10 (60%) |
| FIRST INCIDENCE | 92 (T) | --- | --- | 92 (T) | 92 (T) | 92 (T) |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.837N | P=0.695 | P=0.746N | P=0.204N |
| POLY 1.5 | (e) | (e) | P=0.638N | P=0.635 | P=0.732N | P=0.236N |
| POLY 6 | (e) | (e) | P=0.927N | P=0.730 | P=0.757N | P=0.187N |
| COCH-ARM / FISHERS | P=0.207N | (e) | P=0.273N | P=0.500 | P=0.709N | P=0.314N |
| MAX-ISO-POLY-3 | (e) | (e) | P=0.330N | P=0.424 | P=0.484N | P=0.098N |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Females | | | | | |
|----------------------------------|-----------|------------|-----------|-----------|------------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Liver | | | | | | |
| Vacuolization Cytoplasmic | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) | 1/10 (10%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/10.00 | 1/9.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 10.8% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) | 1/9 (11%) | 0/10 (0%) |
| FIRST INCIDENCE | --- | --- | --- | --- | 92 (T) | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | (e) | (e) | P=0.501 | (e) |
| POLY 1.5 | (e) | (e) | (e) | (e) | P=0.501 | (e) |
| POLY 6 | (e) | (e) | (e) | (e) | P=0.501 | (e) |
| COCH-ARM / FISHERS | P=0.689 | (e) | (e) | (e) | P=0.500 | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | P=0.159 | (e) |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|--|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Liver: Centrilobular Necrosis Acute | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/10.00 | 0/9.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) | 0/9 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|----------------------------------|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Liver: Hepatocyte Atrophy | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 1/10.00 | 0/0.00 | 0/0.23 | 0/10.00 | 0/9.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 10% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) | 0/9 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 52 | --- | --- | --- | --- | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.938N | P=0.500N | P=0.516N | P=0.500N |
| POLY 1.5 | (e) | (e) | P=0.932N | P=0.500N | P=0.510N | P=0.500N |
| POLY 6 | (e) | (e) | P=0.942N | P=0.500N | P=0.520N | P=0.500N |
| COCH-ARM / FISHERS | P=0.311N | (e) | P=0.909N | P=0.500N | P=0.500N | P=0.500N |
| MAX-ISO-POLY-3 | (e) | (e) | P=0.477N | P=0.158N | P=0.178N | P=0.158N |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|--|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Liver: Hepatocyte Hypertrophy Diffuse | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/10.00 | 0/9.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) | 0/9 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Females | | | | | |
|---------------------------|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lung | | | | | | |
| Congestion Diffuse | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 1/10.00 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 10% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 52 | --- | --- | --- | --- | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.938N | (e) | P=0.938N | P=0.500N |
| POLY 1.5 | (e) | (e) | P=0.932N | (e) | P=0.931N | P=0.500N |
| POLY 6 | (e) | (e) | P=0.942N | (e) | P=0.942N | P=0.500N |
| COCH-ARM / FISHERS | P=0.311N | (e) | P=0.909N | (e) | P=0.909N | P=0.500N |
| MAX-ISO-POLY-3 | (e) | (e) | P=0.477N | (e) | P=0.476N | P=0.158N |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|-----------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lung | | | | | | |
| Inflammation Chronic | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Females | | | | | |
|---------------------------------------|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lung: Mediastinum Inflammation | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 1/10.00 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 10% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 52 | --- | --- | --- | --- | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.938N | (e) | P=0.938N | P=0.500N |
| POLY 1.5 | (e) | (e) | P=0.932N | (e) | P=0.931N | P=0.500N |
| POLY 6 | (e) | (e) | P=0.942N | (e) | P=0.942N | P=0.500N |
| COCH-ARM / FISHERS | P=0.311N | (e) | P=0.909N | (e) | P=0.909N | P=0.500N |
| MAX-ISO-POLY-3 | (e) | (e) | P=0.477N | (e) | P=0.476N | P=0.158N |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Females | | | | | |
|----------------------------------|------------|------------|------------|-----------|------------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lung: Pleura Inflammation | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 0/0 (0%) | 1/1 (100%) | 0/0 (0%) | 1/1 (100%) | 0/10 (0%) |
| POLY-3 RATE (b) | 1/10.00 | 0/0.00 | 1/1.00 | 0/0.00 | 1/1.00 | 0/10.00 |
| POLY-3 PERCENT (g) | 10% | 0% | 100% | 0% | 100% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 52 | --- | 56 | --- | 57 | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.146 | (e) | P=0.146 | P=0.500N |
| POLY 1.5 | (e) | (e) | P=0.146 | (e) | P=0.146 | P=0.500N |
| POLY 6 | (e) | (e) | P=0.146 | (e) | P=0.146 | P=0.500N |
| COCH-ARM / FISHERS | P=0.230N | (e) | P=0.182 | (e) | P=0.182 | P=0.500N |
| MAX-ISO-POLY-3 | (e) | (e) | P=0.022* | (e) | P=0.022* | P=0.158N |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|---------------------------------------|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lymph Node, Mandibular Atrophy | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 1/10.00 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 10% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 52 | --- | --- | --- | --- | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.938N | (e) | P=0.938N | P=0.500N |
| POLY 1.5 | (e) | (e) | P=0.932N | (e) | P=0.931N | P=0.500N |
| POLY 6 | (e) | (e) | P=0.942N | (e) | P=0.942N | P=0.500N |
| COCH-ARM / FISHERS | P=0.311N | (e) | P=0.909N | (e) | P=0.909N | P=0.500N |
| MAX-ISO-POLY-3 | (e) | (e) | P=0.477N | (e) | P=0.476N | P=0.158N |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|--|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lymph Node, Mandibular Hyperplasia Lymphoid | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Females | | | | | |
|---------------------------------------|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lymph Node, Mesenteric Atrophy | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 1/10.00 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 10% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 52 | --- | --- | --- | --- | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.938N | (e) | P=0.938N | P=0.500N |
| POLY 1.5 | (e) | (e) | P=0.932N | (e) | P=0.931N | P=0.500N |
| POLY 6 | (e) | (e) | P=0.942N | (e) | P=0.942N | P=0.500N |
| COCH-ARM / FISHERS | P=0.311N | (e) | P=0.909N | (e) | P=0.909N | P=0.500N |
| MAX-ISO-POLY-3 | (e) | (e) | P=0.477N | (e) | P=0.476N | P=0.158N |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|--|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lymph Node, Mesenteric Hyperplasia Lymphoid | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|--------------------------------------|----------|------------|------------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lymph Node: Renal Hyperplasia | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/0 (0%) | 0/0 (0%) | 1/1 (100%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) |
| POLY-3 RATE (b) | 0/0.00 | 0/0.00 | 1/1.00 | 0/0.00 | 0/0.00 | 0/0.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 100% | 0% | 0% | 0% |
| TERMINAL (d) | 0/0 (0%) | 0/0 (0%) | 1/1 (100%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) |
| FIRST INCIDENCE | --- | --- | 92 (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) |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|---------------------------------------|----------|------------|------------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Lymph Node: Renal Pigmentation | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/0 (0%) | 0/0 (0%) | 1/1 (100%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) |
| POLY-3 RATE (b) | 0/0.00 | 0/0.00 | 1/1.00 | 0/0.00 | 0/0.00 | 0/0.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 100% | 0% | 0% | 0% |
| TERMINAL (d) | 0/0 (0%) | 0/0 (0%) | 1/1 (100%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) |
| FIRST INCIDENCE | --- | --- | 92 (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) |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|---|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Pituitary Gland: Pars Distalis Hypertrophy Diffuse | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|--------------------------|------------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Spleen Atrophy | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 1/10.00 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 10% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 52 | --- | --- | --- | --- | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.938N | (e) | P=0.938N | P=0.500N |
| POLY 1.5 | (e) | (e) | P=0.932N | (e) | P=0.931N | P=0.500N |
| POLY 6 | (e) | (e) | P=0.942N | (e) | P=0.942N | P=0.500N |
| COCH-ARM / FISHERS | P=0.311N | (e) | P=0.909N | (e) | P=0.909N | P=0.500N |
| MAX-ISO-POLY-3 | (e) | (e) | P=0.477N | (e) | P=0.476N | P=0.158N |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|---|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Spleen | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (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 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|--------------------------|-----------|------------|------------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Spleen | | | | | | |
| Hyperplasia Lymphoid | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 1/1 (100%) | 0/0 (0%) | 0/1 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 1/1.00 | 0/0.00 | 0/0.24 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 100% | 0% | 0% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | --- | --- | 56 | --- | --- | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P<0.001** | (e) | (e) | (e) |
| POLY 1.5 | (e) | (e) | P<0.001** | (e) | (e) | (e) |
| POLY 6 | (e) | (e) | P<0.001** | (e) | (e) | (e) |
| COCH-ARM / FISHERS | P=0.410N | (e) | P=0.091 | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | P<0.001** | (e) | (e) | (e) |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

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

| DOSE | Females | | | | | |
|---------------------------|------------|------------|------------|-----------|------------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Thymus | | | | | | |
| Atrophy Diffuse | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 0/0 (0%) | 1/1 (100%) | 0/0 (0%) | 1/1 (100%) | 0/10 (0%) |
| POLY-3 RATE (b) | 1/10.00 | 0/0.00 | 1/1.00 | 0/0.00 | 1/1.00 | 0/10.00 |
| POLY-3 PERCENT (g) | 10% | 0% | 100% | 0% | 100% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 52 | --- | 56 | --- | 57 | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.146 | (e) | P=0.146 | P=0.500N |
| POLY 1.5 | (e) | (e) | P=0.146 | (e) | P=0.146 | P=0.500N |
| POLY 6 | (e) | (e) | P=0.146 | (e) | P=0.146 | P=0.500N |
| COCH-ARM / FISHERS | P=0.230N | (e) | P=0.182 | (e) | P=0.182 | P=0.500N |
| MAX-ISO-POLY-3 | (e) | (e) | P=0.022* | (e) | P=0.022* | P=0.158N |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:16

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Females | | | | | |
|------------------------------------|-----------|------------|-----------|-----------|-----------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Thymus Pigmentation Hemosiderin | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 0/1 (0%) | 1/10 (10%) |
| POLY-3 RATE (b) | 0/9.18 | 0/0.00 | 0/0.23 | 0/0.00 | 0/0.24 | 1/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 10% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 1/10 (10%) |
| FIRST INCIDENCE | --- | --- | --- | --- | --- | 92 (T) |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.517 |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.512 |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.520 |
| COCH-ARM / FISHERS | P=0.286 | (e) | (e) | (e) | (e) | P=0.500 |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | P=0.179 |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 14 WEEKS

| DOSE | Females | | | | | |
|---|------------|------------|-----------|-----------|------------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Thymus: Mediastinum Inflammation | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 0/0 (0%) | 0/1 (0%) | 0/0 (0%) | 1/1 (100%) | 0/10 (0%) |
| POLY-3 RATE (b) | 1/10.00 | 0/0.00 | 0/0.23 | 0/0.00 | 1/1.00 | 0/10.00 |
| POLY-3 PERCENT (g) | 10% | 0% | 0% | 0% | 100% | 0% |
| TERMINAL (d) | 0/9 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 52 | --- | --- | --- | 57 | --- |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | (e) | (e) | P=0.938N | (e) | P=0.146 | P=0.500N |
| POLY 1.5 | (e) | (e) | P=0.932N | (e) | P=0.146 | P=0.500N |
| POLY 6 | (e) | (e) | P=0.942N | (e) | P=0.146 | P=0.500N |
| COCH-ARM / FISHERS | P=0.370N | (e) | P=0.909N | (e) | P=0.182 | P=0.500N |
| MAX-ISO-POLY-3 | (e) | (e) | P=0.477N | (e) | P=0.022* | P=0.158N |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

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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 14 WEEKS**

| DOSE | Females | | | | | |
|---------------------------|------------|------------|------------|------------|------------|------------|
| | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
| Thyroid Gland Cyst | | | | | | |
| LESION RATES | | | | | | |
| OVERALL (a) | 1/10 (10%) | 4/10 (40%) | 2/10 (20%) | 3/10 (30%) | 2/10 (20%) | 5/10 (50%) |
| POLY-3 RATE (b) | 1/9.18 | 4/10.00 | 2/9.23 | 3/10.00 | 2/9.24 | 5/10.00 |
| POLY-3 PERCENT (g) | 10.9% | 40% | 21.7% | 30% | 21.7% | 50% |
| TERMINAL (d) | 1/9 (11%) | 4/10 (40%) | 2/9 (22%) | 3/10 (30%) | 2/9 (22%) | 5/10 (50%) |
| FIRST INCIDENCE | 92 (T) | 92 (T) | 92 (T) | 92 (T) | 92 (T) | 92 (T) |
| STATISTICAL TESTS | | | | | | |
| POLY 3 | P=0.122 | P=0.176 | P=0.502 | P=0.325 | P=0.502 | P=0.079 |
| POLY 1.5 | P=0.116 | P=0.166 | P=0.502 | P=0.314 | P=0.502 | P=0.073 |
| POLY 6 | P=0.126 | P=0.182 | P=0.501 | P=0.331 | P=0.501 | P=0.084 |
| COCH-ARM / FISHERS | P=0.104 | P=0.152 | P=0.500 | P=0.291 | P=0.500 | P=0.070 |
| MAX-ISO-POLY-3 | P=0.038* | P=0.080 | P=0.274 | P=0.168 | P=0.275 | P=0.032* |

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

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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 ***