

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

Custom Report with Litter-Based Statistics

NTP Study Number: C00058B
Lock Date: 10/02/2018
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.5.0.0_sfh
PWG Approval Date: NONE

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

MALE RATS

Organ

Adrenal Cortex

Adrenal Cortex: Bilateral

Bone Marrow

Eye: Cornea

Liver

Liver: Bile Duct

Lung

Lymph Node: Renal

Nose

Parathyroid Gland

Skin

Skin: Epidermis

Stomach, Forestomach: Epithelium

Thymus

FEMALE RATS

Organ

Adrenal Medulla: Bilateral

Bone Marrow

Brain

Heart

Kidney

Morphology

Hyperplasia Focal

Thrombus

Hyperplasia Focal

Hemorrhage

Inflammation Chronic

Basophilic Focus

Clear Cell Focus

Eosinophilic Focus

Necrosis

Hyperplasia

Inflammation Chronic

Mineral

Thrombus

Ectasia

Foreign Body

Inflammation

Hyperplasia Diffuse

Inflammation Chronic

Ulcer

Hyperplasia

Hyperplasia

Atrophy

Morphology

Hyperplasia Focal

Hemorrhage

Hypercellularity

Gliosis

Cardiomyopathy

Infarct

Inflammation Chronic

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Kidney: Renal Tubule
Liver

Lung

Mammary Gland
Nose
Ovary

Pituitary Gland: Pars Distalis
Spleen
Spleen: White Pulp
Stomach, Forestomach
Thymus
Thyroid Gland: C-Cell
Uterus

Uterus: Endometrium

Nephropathy Chronic Progressive
Polyarteritis Nodosa
Apoptosis
Basophilic Focus
Clear Cell Focus
Degeneration Cystic
Eosinophilic Focus
Infiltration Cellular Histiocyte
Inflammation Granulomatous
Squamous Metaplasia
Thrombus
Hyperplasia
Inflammation Chronic
Atrophy
Cyst
Hyperplasia
Pigment
Atrophy
Mineral
Ectopic Parathyroid Gland
Hyperplasia
Dilation
Hemorrhage
Squamous Metaplasia
Thrombus
Ulcer
Hyperplasia Cystic

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Adrenal Cortex				
Angiectasis				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	0/37.00	0/38.80	1/37.21
POLY-3 PERCENT (g)	0%	0%	0%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	1/16 (6%)
FIRST INCIDENCE	---	---	---	730 (T)
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Adrenal Cortex Degeneration Cystic				
LESION RATES				
OVERALL (a)	5/50 (10%)	4/50 (8%)	5/50 (10%)	4/50 (8%)
LITTERS (b)	4/25 (16%)	4/25 (16%)	5/25 (20%)	4/25 (16%)
POLY-3 RATE (c)	5/39.49	4/37.41	5/39.54	4/37.84
POLY-3 PERCENT (g)	12.7%	10.7%	12.7%	10.6%
TERMINAL (d)	1/15 (7%)	2/15 (13%)	2/21 (10%)	1/16 (6%)
FIRST INCIDENCE	643	637	606	611
STATISTICAL TESTS				
POLY 3	P=0.501N	P=0.534N	P=0.632N	P=0.527N
POLY 1.5	P=0.492N	P=0.517N	P=0.630N	P=0.512N
POLY 6	P=0.513N	P=0.556N	P=0.623N	P=0.546N
RAO-SCOTT	P=0.490N	P=0.513N	P=0.611N	P=0.507N
LITTER C-A/FISHERS	P=0.583N	P=0.649	P=0.500	P=0.649

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Adrenal Cortex				
Extramedullary Hematopoiesis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	0/37.00	0/38.80	0/37.21
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

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TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Adrenal Cortex				
Hyperplasia Focal				
<hr/>				
LESION RATES				
OVERALL (a)	7/50 (14%)	10/50 (20%)	9/50 (18%)	14/50 (28%)
LITTERS (b)	7/25 (28%)	10/25 (40%)	9/25 (36%)	11/25 (44%)
POLY-3 RATE (c)	7/40.04	10/39.65	9/39.00	14/39.37
POLY-3 PERCENT (g)	17.5%	25.2%	23.1%	35.6%
TERMINAL (d)	2/15 (13%)	4/15 (27%)	8/21 (38%)	8/16 (50%)
FIRST INCIDENCE	598	447	679	434
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.051	P=0.282	P=0.366	P=0.052
POLY 1.5	P=0.058	P=0.292	P=0.380	P=0.061
POLY 6	P=0.042*	P=0.271	P=0.359	P=0.042*
RAO-SCOTT	P=0.059	P=0.279	P=0.357	P=0.061
LITTER C-A/FISHERS	P=0.227	P=0.276	P=0.381	P=0.189

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TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Adrenal Cortex				
Hypertrophy Focal				
<hr/>				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	1/38.95	0/37.00	0/38.80	0/37.21
POLY-3 PERCENT (g)	2.6%	0%	0%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	618	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Adrenal Cortex				
Necrosis				
<hr/>				
LESION RATES				
OVERALL (a)	2/50 (4%)	3/50 (6%)	4/50 (8%)	3/50 (6%)
LITTERS (b)	2/25 (8%)	3/25 (12%)	4/25 (16%)	3/25 (12%)
POLY-3 RATE (c)	2/39.23	3/38.06	4/40.47	3/39.11
POLY-3 PERCENT (g)	5.1%	7.9%	9.9%	7.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	631	560	604	442
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.504	P=0.486	P=0.350	P=0.499
POLY 1.5	P=0.507	P=0.493	P=0.344	P=0.502
POLY 6	P=0.499	P=0.481	P=0.369	P=0.494
RAO-SCOTT	P=0.487	P=0.453	P=0.329	P=0.467
LITTER C-A/FISHERS	P=0.500	P=0.500	P=0.334	P=0.500

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Adrenal Cortex Thrombus				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	4/50 (8%)
LITTERS (b)	0/25 (0%)	2/25 (8%)	0/25 (0%)	4/25 (16%)
POLY-3 RATE (c)	0/38.56	2/37.55	0/38.80	4/38.60
POLY-3 PERCENT (g)	0%	5.3%	0%	10.4%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	0/21 (0%)	1/16 (6%)
FIRST INCIDENCE	---	560	---	442
STATISTICAL TESTS				
POLY 3	P=0.032*	P=0.230	(e)	P=0.059
POLY 1.5	P=0.032*	P=0.234	(e)	P=0.060
POLY 6	P=0.031*	P=0.228	(e)	P=0.058
RAO-SCOTT	P=0.065	P=0.281	(e)	P=0.103
LITTER C-A/FISHERS	P=0.032*	P=0.245	(e)	P=0.055

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

**Adrenal Cortex: Bilateral
Degeneration Cystic**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	0/37.00	0/38.80	0/37.21
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Adrenal Cortex: Bilateral Hyperplasia Focal				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	5/50 (10%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	1/25 (4%)	4/25 (16%)
POLY-3 RATE (c)	1/38.88	0/37.00	1/38.80	5/38.50
POLY-3 PERCENT (g)	2.6%	0%	2.6%	13%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	1/21 (5%)	2/16 (13%)
FIRST INCIDENCE	643	---	730 (T)	434
STATISTICAL TESTS				
POLY 3	P=0.006**	P=0.510N	P=0.761	P=0.096
POLY 1.5	P=0.006**	P=0.505N	P=0.761	P=0.100
POLY 6	P=0.006**	P=0.516N	P=0.759N	P=0.092
RAO-SCOTT	P=0.032*	P=0.584N	P=0.762	P=0.180
LITTER C-A/FISHERS	P=0.023*	P=0.500N	P=0.755	P=0.174

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Adrenal Medulla Hyperplasia Focal				
LESION RATES				
OVERALL (a)	14/50 (28%)	11/50 (22%)	16/50 (32%)	19/50 (38%)
LITTERS (b)	13/25 (52%)	9/25 (36%)	13/25 (52%)	16/25 (64%)
POLY-3 RATE (c)	14/40.06	11/38.62	16/41.77	19/40.03
POLY-3 PERCENT (g)	35%	28.5%	38.3%	47.5%
TERMINAL (d)	8/15 (53%)	6/15 (40%)	6/21 (29%)	11/16 (69%)
FIRST INCIDENCE	573	611	547	502
STATISTICAL TESTS				
POLY 3	P=0.067	P=0.351N	P=0.465	P=0.171
POLY 1.5	P=0.073	P=0.337N	P=0.441	P=0.187
POLY 6	P=0.060	P=0.360N	P=0.533	P=0.156
RAO-SCOTT	P=0.070	P=0.337N	P=0.451	P=0.172
LITTER C-A/FISHERS	P=0.089	P=0.197N	P=0.611	P=0.284

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Adrenal Medulla: Bilateral Hyperplasia Focal				
LESION RATES				
OVERALL (a)	5/50 (10%)	2/50 (4%)	3/50 (6%)	4/50 (8%)
LITTERS (b)	4/25 (16%)	2/25 (8%)	3/25 (12%)	4/25 (16%)
POLY-3 RATE (c)	5/38.61	2/37.17	3/39.25	4/37.21
POLY-3 PERCENT (g)	13%	5.4%	7.6%	10.8%
TERMINAL (d)	4/15 (27%)	1/15 (7%)	1/21 (5%)	4/16 (25%)
FIRST INCIDENCE	718	687	664	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.534	P=0.228N	P=0.345N	P=0.524N
POLY 1.5	P=0.540	P=0.223N	P=0.351N	P=0.510N
POLY 6	P=0.526	P=0.233N	P=0.325N	P=0.539N
RAO-SCOTT	P=0.517	P=0.240N	P=0.351N	P=0.510N
LITTER C-A/FISHERS	P=0.437	P=0.334N	P=0.500N	P=0.649

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Blood Vessel				
Mineral				
LESION RATES				
OVERALL (a)	14/32 (44%)	15/33 (45%)	13/32 (41%)	11/33 (33%)
LITTERS (b)	12/21 (57%)	12/23 (52%)	11/22 (50%)	10/23 (43%)
POLY-3 RATE (c)	14/27.34	15/28.80	13/27.45	11/27.46
POLY-3 PERCENT (g)	51.2%	52.1%	47.4%	40.1%
TERMINAL (d)	0/8 (0%)	1/7 (14%)	3/13 (23%)	1/10 (10%)
FIRST INCIDENCE	538	488	402	502
STATISTICAL TESTS				
POLY 3	P=0.202N	P=0.581	P=0.494N	P=0.285N
POLY 1.5	P=0.186N	P=0.577	P=0.482N	P=0.267N
POLY 6	P=0.224N	P=0.580	P=0.505N	P=0.311N
RAO-SCOTT	P=0.210N	P=0.570	P=0.487N	P=0.288N
LITTER C-A/FISHERS	P=0.241N	P=0.489N	P=0.435N	P=0.273N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

**Blood Vessel: Aorta
Dilation**

LESION RATES

OVERALL (a)	0/32 (0%)	2/33 (6%)	1/32 (3%)	1/33 (3%)
LITTERS (b)	0/21 (0%)	2/23 (9%)	1/22 (5%)	1/23 (4%)
POLY-3 RATE (c)	0/23.16	2/24.56	1/23.37	1/24.09
POLY-3 PERCENT (g)	0%	8.1%	4.3%	4.2%
TERMINAL (d)	0/8 (0%)	0/7 (0%)	0/13 (0%)	0/10 (0%)
FIRST INCIDENCE	---	553	664	613

STATISTICAL TESTS

POLY 3	P=0.628	P=0.247	P=0.502	P=0.508
POLY 1.5	P=0.629	P=0.247	P=0.501	P=0.509
POLY 6	P=0.632	P=0.248	P=0.509	P=0.510
RAO-SCOTT	P=0.599	P=0.254	P=0.469	P=0.475
LITTER C-A/FISHERS	P=0.636	P=0.267	P=0.512	P=0.523

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Bone Marrow Hemorrhage				
LESION RATES				
OVERALL (a)	10/50 (20%)	19/50 (38%)	15/50 (30%)	21/50 (42%)
LITTERS (b)	8/25 (32%)	16/25 (64%)	13/25 (52%)	16/25 (64%)
POLY-3 RATE (c)	10/41.15	19/43.46	15/42.59	21/44.25
POLY-3 PERCENT (g)	24.3%	43.7%	35.2%	47.5%
TERMINAL (d)	0/15 (0%)	4/15 (27%)	4/21 (19%)	3/16 (19%)
FIRST INCIDENCE	562	488	402	442
STATISTICAL TESTS				
POLY 3	P=0.062	P=0.044*	P=0.193	P=0.019*
POLY 1.5	P=0.057	P=0.041*	P=0.189	P=0.017*
POLY 6	P=0.071	P=0.053	P=0.210	P=0.023*
RAO-SCOTT	P=0.065	P=0.047*	P=0.189	P=0.022*
LITTER C-A/FISHERS	P=0.090	P=0.023*	P=0.126	P=0.023*

Experiment Number: 00058 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Black Cohosh
 CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
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 First Dose M/F: 07/03/12 / 07/02/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Bone Marrow Hypercellularity				
LESION RATES				
OVERALL (a)	28/50 (56%)	27/50 (54%)	30/50 (60%)	29/50 (58%)
LITTERS (b)	20/25 (80%)	21/25 (84%)	21/25 (84%)	20/25 (80%)
POLY-3 RATE (c)	28/45.62	27/42.67	30/45.17	29/45.64
POLY-3 PERCENT (g)	61.4%	63.3%	66.4%	63.5%
TERMINAL (d)	5/15 (33%)	9/15 (60%)	11/21 (52%)	8/16 (50%)
FIRST INCIDENCE	155	274	435	441
STATISTICAL TESTS				
POLY 3	P=0.497	P=0.515	P=0.386	P=0.501
POLY 1.5	P=0.474	P=0.579	P=0.393	P=0.507
POLY 6	P=0.505	P=0.441	P=0.402	P=0.482
RAO-SCOTT	P=0.495	P=0.508	P=0.388	P=0.497
LITTER C-A/FISHERS	P=0.513N	P=0.500	P=0.500	P=0.637

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Bone Marrow				
Myelofibrosis				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	2/25 (8%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	2/37.88	0/38.80	0/37.21
POLY-3 PERCENT (g)	0%	5.3%	0%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	553	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.376N	P=0.232	(e)	(e)
POLY 1.5	P=0.372N	P=0.235	(e)	(e)
POLY 6	P=0.379N	P=0.231	(e)	(e)
RAO-SCOTT	P=0.452N	P=0.346	(e)	(e)
LITTER C-A/FISHERS	P=0.368N	P=0.245	(e)	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Bone				
Osteopetrosis				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	2/25 (8%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	0/37.00	2/39.05	1/37.44
POLY-3 PERCENT (g)	0%	0%	5.1%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	1/21 (5%)	0/16 (0%)
FIRST INCIDENCE	---	---	664	669
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.344	(e)	P=0.239	P=0.494
POLY 1.5	P=0.348	(e)	P=0.238	P=0.498
POLY 6	P=0.341	(e)	P=0.245	P=0.491
RAO-SCOTT	P=0.386	(e)	P=0.306	P=0.531
LITTER C-A/FISHERS	P=0.349	(e)	P=0.245	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

Brain
Gliosis

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/49 (4%)	1/50 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	2/25 (8%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	0/37.00	2/38.82	1/37.75
POLY-3 PERCENT (g)	0%	0%	5.2%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	1/21 (5%)	0/16 (0%)
FIRST INCIDENCE	---	---	679	564

STATISTICAL TESTS

POLY 3	P=0.349	(e)	P=0.238	P=0.496
POLY 1.5	P=0.351	(e)	P=0.236	P=0.498
POLY 6	P=0.348	(e)	P=0.245	P=0.494
RAO-SCOTT	P=0.392	(e)	P=0.310	P=0.538
LITTER C-A/FISHERS	P=0.349	(e)	P=0.245	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Brain Hemorrhage				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/49 (0%)	0/50 (0%)
LITTERS (b)	1/25 (4%)	2/25 (8%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	1/38.76	2/37.91	0/38.62	0/37.21
POLY-3 PERCENT (g)	2.6%	5.3%	0%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	678	575	---	---
STATISTICAL TESTS				
POLY 3	P=0.215N	P=0.492	P=0.501N	P=0.508N
POLY 1.5	P=0.212N	P=0.496	P=0.502N	P=0.504N
POLY 6	P=0.217N	P=0.490	P=0.496N	P=0.514N
RAO-SCOTT	P=0.268N	P=0.517	P=0.548N	P=0.543N
LITTER C-A/FISHERS	P=0.208N	P=0.500	P=0.500N	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Brain				
Necrosis				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/49 (4%)	2/50 (4%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	2/25 (8%)	2/25 (8%)
POLY-3 RATE (c)	0/38.56	1/37.55	2/39.83	2/37.71
POLY-3 PERCENT (g)	0%	2.7%	5%	5.3%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	559	445	598
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.223	P=0.495	P=0.244	P=0.231
POLY 1.5	P=0.227	P=0.497	P=0.240	P=0.235
POLY 6	P=0.219	P=0.493	P=0.253	P=0.229
RAO-SCOTT	P=0.244	P=0.483	P=0.270	P=0.251
LITTER C-A/FISHERS	P=0.225	P=0.500	P=0.245	P=0.245

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<hr/>				
Epididymis Atrophy				
<hr/>				
LESION RATES				
OVERALL (a)	2/50 (4%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
LITTERS (b)	2/25 (8%)	2/25 (8%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	2/38.71	2/37.62	0/38.80	1/37.28
POLY-3 PERCENT (g)	5.2%	5.3%	0%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	711	637	---	713
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.387N	P=0.685	P=0.236N	P=0.513N
POLY 1.5	P=0.384N	P=0.689	P=0.236N	P=0.506N
POLY 6	P=0.391N	P=0.683	P=0.231N	P=0.522N
RAO-SCOTT	P=0.396N	P=0.661	P=0.260N	P=0.505N
LITTER C-A/FISHERS	P=0.381N	P=0.695	P=0.245N	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Epididymis				
Polyarteritis Nodosa				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	0/37.00	2/38.80	0/37.21
POLY-3 PERCENT (g)	0%	0%	5.2%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	2/21 (10%)	0/16 (0%)
FIRST INCIDENCE	---	---	730 (T)	---
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.705N	(e)	P=0.238	(e)
POLY 1.5	P=0.700N	(e)	P=0.238	(e)
POLY 6	P=0.709N	(e)	P=0.243	(e)
RAO-SCOTT	P=0.704N	(e)	P=0.356	(e)
LITTER C-A/FISHERS	P=0.698N	(e)	P=0.245	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Eye: Cornea				
Inflammation Acute				
<hr/>				
LESION RATES				
OVERALL (a)	5/50 (10%)	5/50 (10%)	2/50 (4%)	4/50 (8%)
LITTERS (b)	4/25 (16%)	5/25 (20%)	2/25 (8%)	3/25 (12%)
POLY-3 RATE (c)	5/39.50	5/38.76	2/39.34	4/38.38
POLY-3 PERCENT (g)	12.7%	12.9%	5.1%	10.4%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	621	553	618	598
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.449N	P=0.620	P=0.215N	P=0.518N
POLY 1.5	P=0.442N	P=0.626	P=0.215N	P=0.507N
POLY 6	P=0.455N	P=0.617	P=0.208N	P=0.528N
RAO-SCOTT	P=0.460N	P=0.610	P=0.253N	P=0.520N
LITTER C-A/FISHERS	P=0.351N	P=0.500	P=0.334N	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<hr/>				
Eye: Cornea				
Inflammation Chronic				
<hr/>				
LESION RATES				
OVERALL (a)	3/50 (6%)	8/50 (16%)	11/50 (22%)	6/50 (12%)
LITTERS (b)	3/25 (12%)	7/25 (28%)	11/25 (44%)	5/25 (20%)
POLY-3 RATE (c)	3/38.71	8/37.50	11/39.74	6/38.13
POLY-3 PERCENT (g)	7.8%	21.3%	27.7%	15.7%
TERMINAL (d)	1/15 (7%)	5/15 (33%)	8/21 (38%)	2/16 (13%)
FIRST INCIDENCE	704	666	604	569
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.470	P=0.083	P=0.019*	P=0.230
POLY 1.5	P=0.478	P=0.091	P=0.019*	P=0.238
POLY 6	P=0.466	P=0.076	P=0.021*	P=0.225
RAO-SCOTT	P=0.465	P=0.088	P=0.025*	P=0.225
LITTER C-A/FISHERS	P=0.566	P=0.145	P=0.013*	P=0.351

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<hr/>				
Eye: Retina Degeneration				
<hr/>				
LESION RATES				
OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
LITTERS (b)	3/25 (12%)	0/25 (0%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	3/38.74	0/37.00	1/38.80	0/37.21
POLY-3 PERCENT (g)	7.7%	0%	2.6%	0%
TERMINAL (d)	1/15 (7%)	0/15 (0%)	1/21 (5%)	0/16 (0%)
FIRST INCIDENCE	704	---	730 (T)	---
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.155N	P=0.126N	P=0.303N	P=0.125N
POLY 1.5	P=0.156N	P=0.122N	P=0.304N	P=0.121N
POLY 6	P=0.153N	P=0.129N	P=0.296N	P=0.129N
RAO-SCOTT	P=0.210N	P=0.179N	P=0.348N	P=0.178N
LITTER C-A/FISHERS	P=0.158N	P=0.117N	P=0.305N	P=0.117N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<hr/>				
Harderian Gland Atrophy				
<hr/>				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	2/25 (8%)	1/25 (4%)
POLY-3 RATE (c)	1/38.92	0/37.00	2/39.20	1/37.21
POLY-3 PERCENT (g)	2.6%	0%	5.1%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	1/21 (5%)	1/16 (6%)
FIRST INCIDENCE	631	---	616	730 (T)
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.544	P=0.510N	P=0.503	P=0.751
POLY 1.5	P=0.549	P=0.505N	P=0.502	P=0.757
POLY 6	P=0.538	P=0.516N	P=0.511	P=0.745
RAO-SCOTT	P=0.526	P=0.485N	P=0.494	P=0.718
LITTER C-A/FISHERS	P=0.552	P=0.500N	P=0.500	P=0.755

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<hr/>				
Heart				
Cardiomyopathy				
<hr/>				
LESION RATES				
OVERALL (a)	37/50 (74%)	40/50 (80%)	40/50 (80%)	37/50 (74%)
LITTERS (b)	23/25 (92%)	23/25 (92%)	24/25 (96%)	23/25 (92%)
POLY-3 RATE (c)	37/45.60	40/48.90	40/48.78	37/46.56
POLY-3 PERCENT (g)	81.2%	81.8%	82%	79.5%
TERMINAL (d)	12/15 (80%)	10/15 (67%)	14/21 (67%)	11/16 (69%)
FIRST INCIDENCE	538	274	402	434
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.448N	P=0.576	P=0.566	P=0.525N
POLY 1.5	P=0.410N	P=0.493	P=0.484	P=0.524N
POLY 6	P=0.511N	P=0.565N	P=0.568N	P=0.545N
RAO-SCOTT	P=0.450N	P=0.570	P=0.561	P=0.520N
LITTER C-A/FISHERS	P=0.622N	P=0.695	P=0.500	P=0.695

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Heart				
Mineral				
LESION RATES				
OVERALL (a)	4/50 (8%)	8/50 (16%)	1/50 (2%)	3/50 (6%)
LITTERS (b)	4/25 (16%)	8/25 (32%)	1/25 (4%)	3/25 (12%)
POLY-3 RATE (c)	4/39.55	8/40.79	1/39.20	3/38.72
POLY-3 PERCENT (g)	10.1%	19.6%	2.6%	7.8%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	562	488	618	554
STATISTICAL TESTS				
POLY 3	P=0.201N	P=0.187	P=0.179N	P=0.512N
POLY 1.5	P=0.197N	P=0.183	P=0.179N	P=0.504N
POLY 6	P=0.205N	P=0.200	P=0.174N	P=0.518N
RAO-SCOTT	P=0.215N	P=0.194	P=0.180N	P=0.492N
LITTER C-A/FISHERS	P=0.188N	P=0.160	P=0.174N	P=0.500N

Experiment Number: 00058 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Black Cohosh
 CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
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 First Dose M/F: 07/03/12 / 07/02/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Heart				
Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	2/25 (8%)	1/25 (4%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	2/38.56	1/37.00	0/38.80	0/37.21
POLY-3 PERCENT (g)	5.2%	2.7%	0%	0%
TERMINAL (d)	2/15 (13%)	1/15 (7%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.168N	P=0.514N	P=0.235N	P=0.244N
POLY 1.5	P=0.168N	P=0.507N	P=0.236N	P=0.240N
POLY 6	P=0.168N	P=0.522N	P=0.229N	P=0.248N
RAO-SCOTT	P=0.228N	P=0.533N	P=0.304N	P=0.308N
LITTER C-A/FISHERS	P=0.167N	P=0.500N	P=0.245N	P=0.245N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

Heart: Atrium
Thrombus

LESION RATES

OVERALL (a)	2/50 (4%)	1/50 (2%)	4/50 (8%)	3/50 (6%)
LITTERS (b)	2/25 (8%)	1/25 (4%)	4/25 (16%)	3/25 (12%)
POLY-3 RATE (c)	2/38.84	1/37.46	4/39.91	3/38.91
POLY-3 PERCENT (g)	5.2%	2.7%	10%	7.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	676	596	589	449

STATISTICAL TESTS

POLY 3	P=0.344	P=0.513N	P=0.348	P=0.501
POLY 1.5	P=0.342	P=0.506N	P=0.343	P=0.503
POLY 6	P=0.347	P=0.519N	P=0.366	P=0.500
RAO-SCOTT	P=0.339	P=0.484N	P=0.343	P=0.482
LITTER C-A/FISHERS	P=0.329	P=0.500N	P=0.334	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

Heart: Perivascular
Infiltration Cellular Lymphocyte

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	1/37.24	2/39.23	0/37.21
POLY-3 PERCENT (g)	0%	2.7%	5.1%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	1/21 (5%)	0/16 (0%)
FIRST INCIDENCE	---	666	606	---

STATISTICAL TESTS

POLY 3	P=0.526N	P=0.493	P=0.240	(e)
POLY 1.5	P=0.520N	P=0.496	P=0.239	(e)
POLY 6	P=0.534N	P=0.490	P=0.247	(e)
RAO-SCOTT	P=0.533N	P=0.531	P=0.309	(e)
LITTER C-A/FISHERS	P=0.515N	P=0.500	P=0.245	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Intestine Large, Cecum Erosion				
LESION RATES				
OVERALL (a)	3/50 (6%)	4/49 (8%)	0/50 (0%)	2/49 (4%)
LITTERS (b)	3/25 (12%)	3/25 (12%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (c)	3/39.15	4/37.94	0/38.80	2/36.94
POLY-3 PERCENT (g)	7.7%	10.5%	0%	5.4%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/15 (0%)
FIRST INCIDENCE	631	560	---	613
STATISTICAL TESTS				
POLY 3	P=0.347N	P=0.483	P=0.119N	P=0.527N
POLY 1.5	P=0.342N	P=0.486	P=0.119N	P=0.517N
POLY 6	P=0.353N	P=0.485	P=0.117N	P=0.538N
RAO-SCOTT	P=0.386N	P=0.504	P=0.184N	P=0.541N
LITTER C-A/FISHERS	P=0.413N	P=0.666	P=0.117N	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Intestine Large, Cecum Inflammation Chronic				
LESION RATES				
OVERALL (a)	3/50 (6%)	3/49 (6%)	0/50 (0%)	4/49 (8%)
LITTERS (b)	3/25 (12%)	3/25 (12%)	0/25 (0%)	4/25 (16%)
POLY-3 RATE (c)	3/39.33	3/37.27	0/38.80	4/38.17
POLY-3 PERCENT (g)	7.6%	8.1%	0%	10.5%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/15 (0%)
FIRST INCIDENCE	631	618	---	502
STATISTICAL TESTS				
POLY 3	P=0.368	P=0.639	P=0.120N	P=0.484
POLY 1.5	P=0.370	P=0.645	P=0.119N	P=0.489
POLY 6	P=0.366	P=0.634	P=0.118N	P=0.479
RAO-SCOTT	P=0.374	P=0.617	P=0.136N	P=0.476
LITTER C-A/FISHERS	P=0.372	P=0.666	P=0.117N	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Intestine Large, Cecum Mineral				
LESION RATES				
OVERALL (a)	3/50 (6%)	4/49 (8%)	1/50 (2%)	5/49 (10%)
LITTERS (b)	3/25 (12%)	3/25 (12%)	1/25 (4%)	5/25 (20%)
POLY-3 RATE (c)	3/39.01	4/37.71	1/39.62	5/38.59
POLY-3 PERCENT (g)	7.7%	10.6%	2.5%	13%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/15 (0%)
FIRST INCIDENCE	672	611	413	502
STATISTICAL TESTS				
POLY 3	P=0.288	P=0.481	P=0.299N	P=0.348
POLY 1.5	P=0.289	P=0.485	P=0.301N	P=0.349
POLY 6	P=0.289	P=0.484	P=0.291N	P=0.351
RAO-SCOTT	P=0.315	P=0.483	P=0.323N	P=0.367
LITTER C-A/FISHERS	P=0.215	P=0.666	P=0.305N	P=0.351

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Intestine Large, Cecum Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	3/50 (6%)	8/49 (16%)	1/50 (2%)	4/49 (8%)
LITTERS (b)	3/25 (12%)	7/25 (28%)	1/25 (4%)	4/25 (16%)
POLY-3 RATE (c)	3/39.06	8/38.60	1/39.23	4/37.91
POLY-3 PERCENT (g)	7.7%	20.7%	2.6%	10.6%
TERMINAL (d)	1/15 (7%)	2/15 (13%)	0/21 (0%)	0/15 (0%)
FIRST INCIDENCE	646	559	606	554
STATISTICAL TESTS				
POLY 3	P=0.441N	P=0.090	P=0.302N	P=0.484
POLY 1.5	P=0.437N	P=0.091	P=0.304N	P=0.488
POLY 6	P=0.442N	P=0.092	P=0.295N	P=0.483
RAO-SCOTT	P=0.448N	P=0.117	P=0.317N	P=0.481
LITTER C-A/FISHERS	P=0.498N	P=0.145	P=0.305N	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Intestine Large, Cecum Ulcer				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/49 (2%)	0/50 (0%)	1/49 (2%)
LITTERS (b)	2/25 (8%)	1/25 (4%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	2/38.82	1/36.54	0/38.80	1/36.77
POLY-3 PERCENT (g)	5.2%	2.7%	0%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/15 (0%)
FIRST INCIDENCE	672	644	---	554
STATISTICAL TESTS				
POLY 3	P=0.504N	P=0.521N	P=0.236N	P=0.519N
POLY 1.5	P=0.504N	P=0.514N	P=0.237N	P=0.512N
POLY 6	P=0.506N	P=0.527N	P=0.232N	P=0.527N
RAO-SCOTT	P=0.497N	P=0.505N	P=0.249N	P=0.504N
LITTER C-A/FISHERS	P=0.500N	P=0.500N	P=0.245N	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Intestine Large, Colon Parasite Metazoan				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
LITTERS (b)	1/25 (4%)	2/25 (8%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	1/38.84	2/37.08	1/39.44	1/37.21
POLY-3 PERCENT (g)	2.6%	5.4%	2.5%	2.7%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	0/21 (0%)	1/16 (6%)
FIRST INCIDENCE	654	711	521	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.546N	P=0.484	P=0.758N	P=0.752
POLY 1.5	P=0.539N	P=0.492	P=0.759N	P=0.757
POLY 6	P=0.554N	P=0.475	P=0.753N	P=0.746
RAO-SCOTT	P=0.521N	P=0.457	P=0.723N	P=0.711
LITTER C-A/FISHERS	P=0.535N	P=0.500	P=0.755	P=0.755

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Intestine Large, Colon Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	3/50 (6%)
LITTERS (b)	1/25 (4%)	2/25 (8%)	2/25 (8%)	3/25 (12%)
POLY-3 RATE (c)	1/38.56	2/37.00	2/39.47	3/38.38
POLY-3 PERCENT (g)	2.6%	5.4%	5.1%	7.8%
TERMINAL (d)	1/15 (7%)	2/15 (13%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	595	598
STATISTICAL TESTS				
POLY 3	P=0.271	P=0.486	P=0.508	P=0.302
POLY 1.5	P=0.272	P=0.493	P=0.504	P=0.305
POLY 6	P=0.274	P=0.478	P=0.522	P=0.303
RAO-SCOTT	P=0.265	P=0.448	P=0.476	P=0.284
LITTER C-A/FISHERS	P=0.264	P=0.500	P=0.500	P=0.305

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

Intestine Large, Colon: Lymphoid Tissue
Hyperplasia

LESION RATES

OVERALL (a)	1/50 (2%)	4/50 (8%)	2/50 (4%)	0/50 (0%)
LITTERS (b)	1/25 (4%)	3/25 (12%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (c)	1/38.56	4/37.00	2/38.80	0/37.21
POLY-3 PERCENT (g)	2.6%	10.8%	5.2%	0%
TERMINAL (d)	1/15 (7%)	4/15 (27%)	2/21 (10%)	0/16 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	730 (T)	---

STATISTICAL TESTS

POLY 3	P=0.143N	P=0.164	P=0.502	P=0.507N
POLY 1.5	P=0.139N	P=0.171	P=0.501	P=0.503N
POLY 6	P=0.148N	P=0.156	P=0.511	P=0.511N
RAO-SCOTT	P=0.208N	P=0.241	P=0.544	P=0.569N
LITTER C-A/FISHERS	P=0.179N	P=0.305	P=0.500	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Intestine Large, Rectum Parasite Metazoan				
LESION RATES				
OVERALL (a)	0/50 (0%)	3/50 (6%)	1/50 (2%)	2/50 (4%)
LITTERS (b)	0/25 (0%)	3/25 (12%)	1/25 (4%)	2/25 (8%)
POLY-3 RATE (c)	0/38.56	3/37.17	1/38.80	2/37.21
POLY-3 PERCENT (g)	0%	8.1%	2.6%	5.4%
TERMINAL (d)	0/15 (0%)	2/15 (13%)	1/21 (5%)	2/16 (13%)
FIRST INCIDENCE	---	687	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.420	P=0.111	P=0.501	P=0.228
POLY 1.5	P=0.429	P=0.115	P=0.501	P=0.233
POLY 6	P=0.410	P=0.107	P=0.506	P=0.223
RAO-SCOTT	P=0.433	P=0.143	P=0.504	P=0.255
LITTER C-A/FISHERS	P=0.436	P=0.117	P=0.500	P=0.245

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

Intestine Large, Rectum
Polyarteritis Nodosa

LESION RATES

OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
LITTERS (b)	2/25 (8%)	2/25 (8%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	2/38.56	2/37.07	1/39.22	0/37.21
POLY-3 PERCENT (g)	5.2%	5.4%	2.6%	0%
TERMINAL (d)	2/15 (13%)	1/15 (7%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	730 (T)	713	609	---

STATISTICAL TESTS

POLY 3	P=0.145N	P=0.681	P=0.494N	P=0.244N
POLY 1.5	P=0.143N	P=0.687	P=0.497N	P=0.240N
POLY 6	P=0.147N	P=0.676	P=0.483N	P=0.248N
RAO-SCOTT	P=0.169N	P=0.657	P=0.494N	P=0.264N
LITTER C-A/FISHERS	P=0.138N	P=0.695	P=0.500N	P=0.245N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Intestine Small, Duodenum Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	3/49 (6%)	1/49 (2%)
LITTERS (b)	2/25 (8%)	0/25 (0%)	3/25 (12%)	1/25 (4%)
POLY-3 RATE (c)	2/38.61	0/37.00	3/39.58	1/36.98
POLY-3 PERCENT (g)	5.2%	0%	7.6%	2.7%
TERMINAL (d)	1/15 (7%)	0/15 (0%)	0/21 (0%)	1/16 (6%)
FIRST INCIDENCE	718	---	604	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.583N	P=0.246N	P=0.511	P=0.515N
POLY 1.5	P=0.582N	P=0.242N	P=0.503	P=0.510N
POLY 6	P=0.586N	P=0.250N	P=0.532	P=0.522N
RAO-SCOTT	P=0.576N	P=0.267N	P=0.513	P=0.510N
LITTER C-A/FISHERS	P=0.579N	P=0.245N	P=0.500	P=0.500N

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Intestine Small, Jejunum Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
LITTERS (b)	2/25 (8%)	1/25 (4%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	2/38.56	1/37.55	0/38.80	1/37.53
POLY-3 PERCENT (g)	5.2%	2.7%	0%	2.7%
TERMINAL (d)	2/15 (13%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	730 (T)	559	---	643
STATISTICAL TESTS				
POLY 3	P=0.501N	P=0.509N	P=0.235N	P=0.510N
POLY 1.5	P=0.500N	P=0.505N	P=0.236N	P=0.504N
POLY 6	P=0.502N	P=0.513N	P=0.229N	P=0.514N
RAO-SCOTT	P=0.494N	P=0.497N	P=0.251N	P=0.497N
LITTER C-A/FISHERS	P=0.500N	P=0.500N	P=0.245N	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Islets, Pancreatic Hyperplasia				
LESION RATES				
OVERALL (a)	2/50 (4%)	3/50 (6%)	1/50 (2%)	3/50 (6%)
LITTERS (b)	2/25 (8%)	3/25 (12%)	1/25 (4%)	2/25 (8%)
POLY-3 RATE (c)	2/38.83	3/37.56	1/38.80	3/37.56
POLY-3 PERCENT (g)	5.2%	8%	2.6%	8%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	1/21 (5%)	2/16 (13%)
FIRST INCIDENCE	672	653	730 (T)	633
STATISTICAL TESTS				
POLY 3	P=0.463	P=0.485	P=0.500N	P=0.485
POLY 1.5	P=0.470	P=0.492	P=0.500N	P=0.494
POLY 6	P=0.454	P=0.479	P=0.495N	P=0.475
RAO-SCOTT	P=0.472	P=0.494	P=0.513N	P=0.494
LITTER C-A/FISHERS	P=0.538N	P=0.500	P=0.500N	P=0.695

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

Kidney
Calculus Micro Observation Only

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	1/25 (4%)	2/25 (8%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	1/38.95	2/37.31	0/38.80	0/37.21
POLY-3 PERCENT (g)	2.6%	5.4%	0%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	618	669	---	---

STATISTICAL TESTS

POLY 3	P=0.215N	P=0.485	P=0.501N	P=0.509N
POLY 1.5	P=0.212N	P=0.492	P=0.500N	P=0.504N
POLY 6	P=0.219N	P=0.478	P=0.498N	P=0.515N
RAO-SCOTT	P=0.271N	P=0.513	P=0.551N	P=0.550N
LITTER C-A/FISHERS	P=0.208N	P=0.500	P=0.500N	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Kidney Hyperplasia Oncocytic				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	2/25 (8%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	2/38.65	0/37.00	0/38.80	0/37.21
POLY-3 PERCENT (g)	5.2%	0%	0%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	718	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.235N	P=0.246N	P=0.235N	P=0.245N
POLY 1.5	P=0.238N	P=0.242N	P=0.236N	P=0.240N
POLY 6	P=0.231N	P=0.251N	P=0.230N	P=0.250N
RAO-SCOTT	P=0.337N	P=0.350N	P=0.347N	P=0.350N
LITTER C-A/FISHERS	P=0.241N	P=0.245N	P=0.245N	P=0.245N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Kidney Infarct				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	1/38.88	0/37.00	0/38.80	1/37.53
POLY-3 PERCENT (g)	2.6%	0%	0%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	643	---	---	643
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Kidney				
Inflammation Chronic				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	0/37.00	0/38.80	1/37.28
POLY-3 PERCENT (g)	0%	0%	0%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	---	---	713
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Kidney				
Nephropathy Chronic Progressive				
LESION RATES				
OVERALL (a)	50/50 (100%)	50/50 (100%)	50/50 (100%)	50/50 (100%)
LITTERS (b)	25/25 (100%)	25/25 (100%)	25/25 (100%)	25/25 (100%)
POLY-3 RATE (c)	50/50.00	50/50.00	50/50.00	50/50.00
POLY-3 PERCENT (g)	100%	100%	100%	100%
TERMINAL (d)	15/15 (100%)	15/15 (100%)	21/21 (100%)	16/16 (100%)
FIRST INCIDENCE	155	274	402	434
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
RAO-SCOTT	(e)	(e)	(e)	(e)
LITTER C-A/FISHERS	(e)	(e)	(e)	(e)

Experiment Number: 00058 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Black Cohosh
 CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
 Time Report Requested: 09:53:31
 First Dose M/F: 07/03/12 / 07/02/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Kidney				
Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	1/25 (4%)	2/25 (8%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	1/38.56	2/37.79	0/38.80	0/37.21
POLY-3 PERCENT (g)	2.6%	5.3%	0%	0%
TERMINAL (d)	1/15 (7%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	730 (T)	559	---	---
STATISTICAL TESTS				
POLY 3	P=0.213N	P=0.493	P=0.499N	P=0.507N
POLY 1.5	P=0.211N	P=0.496	P=0.499N	P=0.503N
POLY 6	P=0.215N	P=0.492	P=0.494N	P=0.511N
RAO-SCOTT	P=0.274N	P=0.522	P=0.552N	P=0.550N
LITTER C-A/FISHERS	P=0.208N	P=0.500	P=0.500N	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Kidney: Pelvis Dilation				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	1/39.45	0/37.00	0/38.80	0/37.21
POLY-3 PERCENT (g)	2.5%	0%	0%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	354	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Kidney: Pelvis				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
LITTERS (b)	2/25 (8%)	2/25 (8%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	2/39.15	2/37.31	1/38.80	0/37.21
POLY-3 PERCENT (g)	5.1%	5.4%	2.6%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	1/21 (5%)	0/16 (0%)
FIRST INCIDENCE	618	669	730 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.147N	P=0.678	P=0.503N	P=0.248N
POLY 1.5	P=0.144N	P=0.685	P=0.501N	P=0.242N
POLY 6	P=0.150N	P=0.669	P=0.500N	P=0.256N
RAO-SCOTT	P=0.170N	P=0.655	P=0.502N	P=0.268N
LITTER C-A/FISHERS	P=0.138N	P=0.695	P=0.500N	P=0.245N

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Kidney: Renal Tubule Accumulation, Hyaline Droplet				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
LITTERS (b)	2/25 (8%)	0/25 (0%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (c)	2/39.22	0/37.00	0/38.80	2/37.88
POLY-3 PERCENT (g)	5.1%	0%	0%	5.3%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	623	---	---	633
STATISTICAL TESTS				
POLY 3	P=0.386	P=0.250N	P=0.239N	P=0.683
POLY 1.5	P=0.384	P=0.243N	P=0.238N	P=0.689
POLY 6	P=0.389	P=0.257N	P=0.236N	P=0.676
RAO-SCOTT	P=0.413	P=0.312N	P=0.309N	P=0.673
LITTER C-A/FISHERS	P=0.380	P=0.245N	P=0.245N	P=0.695

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Kidney: Renal Tubule Apoptosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	0/37.00	0/38.80	0/37.21
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Kidney: Renal Tubule Cyst				
LESION RATES				
OVERALL (a)	4/50 (8%)	5/50 (10%)	4/50 (8%)	6/50 (12%)
LITTERS (b)	4/25 (16%)	5/25 (20%)	4/25 (16%)	6/25 (24%)
POLY-3 RATE (c)	4/39.32	5/38.49	4/39.26	6/38.87
POLY-3 PERCENT (g)	10.2%	13%	10.2%	15.4%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	3/21 (14%)	1/16 (6%)
FIRST INCIDENCE	621	560	595	434
STATISTICAL TESTS				
POLY 3	P=0.329	P=0.486	P=0.644	P=0.360
POLY 1.5	P=0.335	P=0.493	P=0.644N	P=0.368
POLY 6	P=0.323	P=0.483	P=0.640N	P=0.353
RAO-SCOTT	P=0.316	P=0.457	P=0.615	P=0.336
LITTER C-A/FISHERS	P=0.325	P=0.500	P=0.649	P=0.363

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<hr/>				
Liver				
Angiectasis				
<hr/>				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	1/38.56	0/37.00	0/38.80	0/37.21
POLY-3 PERCENT (g)	2.6%	0%	0%	0%
TERMINAL (d)	1/15 (7%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	730 (T)	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Liver				
Basophilic Focus				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	4/50 (8%)
LITTERS (b)	0/25 (0%)	2/25 (8%)	1/25 (4%)	4/25 (16%)
POLY-3 RATE (c)	0/38.56	2/37.47	1/39.00	4/38.07
POLY-3 PERCENT (g)	0%	5.3%	2.6%	10.5%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	2/16 (13%)
FIRST INCIDENCE	---	666	679	598
STATISTICAL TESTS				
POLY 3	P=0.044*	P=0.230	P=0.502	P=0.057
POLY 1.5	P=0.046*	P=0.233	P=0.501	P=0.059
POLY 6	P=0.043*	P=0.228	P=0.508	P=0.056
RAO-SCOTT	P=0.067	P=0.251	P=0.498	P=0.083
LITTER C-A/FISHERS	P=0.044*	P=0.245	P=0.500	P=0.055

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Liver				
Clear Cell Focus				
LESION RATES				
OVERALL (a)	19/50 (38%)	13/50 (26%)	24/50 (48%)	17/50 (34%)
LITTERS (b)	19/25 (76%)	11/25 (44%)	18/25 (72%)	11/25 (44%)
POLY-3 RATE (c)	19/39.72	13/37.96	24/39.91	17/38.40
POLY-3 PERCENT (g)	47.8%	34.3%	60.1%	44.3%
TERMINAL (d)	13/15 (87%)	10/15 (67%)	19/21 (91%)	14/16 (88%)
FIRST INCIDENCE	621	475	606	586
STATISTICAL TESTS				
POLY 3	P=0.505	P=0.150N	P=0.173	P=0.463N
POLY 1.5	P=0.523	P=0.143N	P=0.191	P=0.434N
POLY 6	P=0.482	P=0.160N	P=0.169	P=0.503N
RAO-SCOTT	P=0.492	P=0.163N	P=0.192	P=0.453N
LITTER C-A/FISHERS	P=0.079N	P=0.021N*	P=0.500N	P=0.021N*

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Liver				
Degeneration Cystic				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	2/25 (8%)	1/25 (4%)
POLY-3 RATE (c)	0/38.56	0/37.00	2/38.95	1/37.44
POLY-3 PERCENT (g)	0%	0%	5.1%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	1/21 (5%)	0/16 (0%)
FIRST INCIDENCE	---	---	694	669
STATISTICAL TESTS				
POLY 3	P=0.344	(e)	P=0.239	P=0.494
POLY 1.5	P=0.348	(e)	P=0.238	P=0.498
POLY 6	P=0.341	(e)	P=0.244	P=0.491
RAO-SCOTT	P=0.388	(e)	P=0.308	P=0.535
LITTER C-A/FISHERS	P=0.349	(e)	P=0.245	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Liver				
Eosinophilic Focus				
LESION RATES				
OVERALL (a)	5/50 (10%)	7/50 (14%)	2/50 (4%)	1/50 (2%)
LITTERS (b)	5/25 (20%)	7/25 (28%)	2/25 (8%)	1/25 (4%)
POLY-3 RATE (c)	5/39.40	7/37.17	2/39.58	1/37.21
POLY-3 PERCENT (g)	12.7%	18.8%	5.1%	2.7%
TERMINAL (d)	2/15 (13%)	6/15 (40%)	0/21 (0%)	1/16 (6%)
FIRST INCIDENCE	599	687	618	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.034N*	P=0.335	P=0.212N	P=0.112N
POLY 1.5	P=0.032N*	P=0.357	P=0.214N	P=0.106N
POLY 6	P=0.036N*	P=0.307	P=0.201N	P=0.121N
RAO-SCOTT	P=0.038N*	P=0.326	P=0.209N	P=0.113N
LITTER C-A/FISHERS	P=0.027N*	P=0.371	P=0.209N	P=0.095N

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Liver				
Extramedullary Hematopoiesis				
LESION RATES				
OVERALL (a)	0/50 (0%)	3/50 (6%)	1/50 (2%)	3/50 (6%)
LITTERS (b)	0/25 (0%)	3/25 (12%)	1/25 (4%)	3/25 (12%)
POLY-3 RATE (c)	0/38.56	3/38.51	1/38.88	3/38.71
POLY-3 PERCENT (g)	0%	7.8%	2.6%	7.8%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	274	711	520
STATISTICAL TESTS				
POLY 3	P=0.216	P=0.117	P=0.502	P=0.118
POLY 1.5	P=0.218	P=0.119	P=0.501	P=0.119
POLY 6	P=0.217	P=0.116	P=0.507	P=0.118
RAO-SCOTT	P=0.253	P=0.158	P=0.514	P=0.159
LITTER C-A/FISHERS	P=0.213	P=0.117	P=0.500	P=0.117

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<hr/>				
Liver				
Hepatodiaphragmatic Nodule				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	3/50 (6%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	2/25 (8%)	2/25 (8%)
POLY-3 RATE (c)	0/38.56	1/37.00	2/39.28	3/37.28
POLY-3 PERCENT (g)	0%	2.7%	5.1%	8.1%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	0/21 (0%)	2/16 (13%)
FIRST INCIDENCE	---	730 (T)	616	713
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.081	P=0.492	P=0.241	P=0.111
POLY 1.5	P=0.084	P=0.496	P=0.239	P=0.115
POLY 6	P=0.077	P=0.488	P=0.248	P=0.107
RAO-SCOTT	P=0.150	P=0.564	P=0.343	P=0.200
LITTER C-A/FISHERS	P=0.225	P=0.500	P=0.245	P=0.245

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<hr/>				
Liver				
Mixed Cell Focus				
<hr/>				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
LITTERS (b)	2/25 (8%)	1/25 (4%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (c)	2/39.09	1/37.00	0/38.80	2/37.40
POLY-3 PERCENT (g)	5.1%	2.7%	0%	5.4%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	0/21 (0%)	1/16 (6%)
FIRST INCIDENCE	599	730 (T)	---	682
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.509	P=0.519N	P=0.238N	P=0.679
POLY 1.5	P=0.511	P=0.510N	P=0.238N	P=0.687
POLY 6	P=0.506	P=0.531N	P=0.235N	P=0.670
RAO-SCOTT	P=0.496	P=0.510N	P=0.262N	P=0.656
LITTER C-A/FISHERS	P=0.512	P=0.500N	P=0.245N	P=0.695

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Liver Necrosis				
LESION RATES				
OVERALL (a)	8/50 (16%)	3/50 (6%)	4/50 (8%)	2/50 (4%)
LITTERS (b)	8/25 (32%)	3/25 (12%)	4/25 (16%)	2/25 (8%)
POLY-3 RATE (c)	8/40.31	3/37.81	4/40.00	2/37.78
POLY-3 PERCENT (g)	19.8%	7.9%	10%	5.3%
TERMINAL (d)	1/15 (7%)	0/15 (0%)	1/21 (5%)	0/16 (0%)
FIRST INCIDENCE	538	617	547	633
STATISTICAL TESTS				
POLY 3	P=0.084N	P=0.115N	P=0.176N	P=0.053N
POLY 1.5	P=0.082N	P=0.107N	P=0.176N	P=0.049N*
POLY 6	P=0.086N	P=0.124N	P=0.167N	P=0.059N
RAO-SCOTT	P=0.092N	P=0.117N	P=0.177N	P=0.058N
LITTER C-A/FISHERS	P=0.073N	P=0.085N	P=0.160N	P=0.037N*

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Liver Pigment				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	0/37.00	0/38.80	0/37.21
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Liver				
Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
LITTERS (b)	2/25 (8%)	0/25 (0%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	2/39.11	0/37.00	0/38.80	1/37.56
POLY-3 PERCENT (g)	5.1%	0%	0%	2.7%
TERMINAL (d)	1/15 (7%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	562	---	---	633
STATISTICAL TESTS				
POLY 3	P=0.643N	P=0.249N	P=0.238N	P=0.514N
POLY 1.5	P=0.646N	P=0.243N	P=0.238N	P=0.506N
POLY 6	P=0.640N	P=0.255N	P=0.234N	P=0.522N
RAO-SCOTT	P=0.645N	P=0.310N	P=0.306N	P=0.535N
LITTER C-A/FISHERS	P=0.651N	P=0.245N	P=0.245N	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<hr/>				
Liver: Bile Duct Cyst				
<hr/>				
LESION RATES				
OVERALL (a)	4/50 (8%)	4/50 (8%)	1/50 (2%)	1/50 (2%)
LITTERS (b)	4/25 (16%)	4/25 (16%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	4/38.83	4/37.81	1/38.80	1/37.21
POLY-3 PERCENT (g)	10.3%	10.6%	2.6%	2.7%
TERMINAL (d)	1/15 (7%)	1/15 (7%)	1/21 (5%)	1/16 (6%)
FIRST INCIDENCE	693	637	730 (T)	730 (T)
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.106N	P=0.631	P=0.177N	P=0.189N
POLY 1.5	P=0.104N	P=0.636	P=0.178N	P=0.183N
POLY 6	P=0.110N	P=0.629	P=0.170N	P=0.197N
RAO-SCOTT	P=0.126N	P=0.610	P=0.195N	P=0.205N
LITTER C-A/FISHERS	P=0.097N	P=0.649	P=0.174N	P=0.174N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<hr/>				
Liver: Bile Duct Dilation				
<hr/>				
LESION RATES				
OVERALL (a)	3/50 (6%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
LITTERS (b)	3/25 (12%)	1/25 (4%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	3/38.71	1/37.28	1/38.80	0/37.21
POLY-3 PERCENT (g)	7.8%	2.7%	2.6%	0%
TERMINAL (d)	1/15 (7%)	0/15 (0%)	1/21 (5%)	0/16 (0%)
FIRST INCIDENCE	711	654	730 (T)	---
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.116N	P=0.318N	P=0.303N	P=0.124N
POLY 1.5	P=0.116N	P=0.312N	P=0.304N	P=0.121N
POLY 6	P=0.117N	P=0.323N	P=0.295N	P=0.128N
RAO-SCOTT	P=0.147N	P=0.336N	P=0.326N	P=0.156N
LITTER C-A/FISHERS	P=0.114N	P=0.305N	P=0.305N	P=0.117N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Liver: Bile Duct Hyperplasia				
LESION RATES				
OVERALL (a)	27/50 (54%)	19/50 (38%)	25/50 (50%)	18/50 (36%)
LITTERS (b)	19/25 (76%)	15/25 (60%)	19/25 (76%)	12/25 (48%)
POLY-3 RATE (c)	27/42.46	19/39.94	25/42.91	18/40.67
POLY-3 PERCENT (g)	63.6%	47.6%	58.3%	44.3%
TERMINAL (d)	10/15 (67%)	9/15 (60%)	14/21 (67%)	6/16 (38%)
FIRST INCIDENCE	481	575	521	442
STATISTICAL TESTS				
POLY 3	P=0.095N	P=0.093N	P=0.383N	P=0.049N*
POLY 1.5	P=0.096N	P=0.083N	P=0.397N	P=0.047N*
POLY 6	P=0.096N	P=0.107N	P=0.339N	P=0.054N
RAO-SCOTT	P=0.117N	P=0.113N	P=0.388N	P=0.067N
LITTER C-A/FISHERS	P=0.046N*	P=0.182N	P=0.629	P=0.040N*

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<hr/>				
Lung Hemorrhage				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	2/25 (8%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	2/37.74	0/38.80	0/37.21
POLY-3 PERCENT (g)	0%	5.3%	0%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	596	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.376N	P=0.231	(e)	(e)
POLY 1.5	P=0.372N	P=0.234	(e)	(e)
POLY 6	P=0.379N	P=0.230	(e)	(e)
RAO-SCOTT	P=0.459N	P=0.354	(e)	(e)
LITTER C-A/FISHERS	P=0.368N	P=0.245	(e)	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Lung				
Infiltration Cellular Histiocyte				
<hr/>				
LESION RATES				
OVERALL (a)	21/50 (42%)	19/50 (38%)	29/50 (58%)	26/50 (52%)
LITTERS (b)	16/25 (64%)	15/25 (60%)	21/25 (84%)	20/25 (80%)
POLY-3 RATE (c)	21/42.40	19/42.89	29/43.81	26/43.41
POLY-3 PERCENT (g)	49.5%	44.3%	66.2%	59.9%
TERMINAL (d)	7/15 (47%)	6/15 (40%)	12/21 (57%)	10/16 (63%)
FIRST INCIDENCE	481	274	435	434
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.114	P=0.391N	P=0.077	P=0.216
POLY 1.5	P=0.119	P=0.389N	P=0.077	P=0.222
POLY 6	P=0.114	P=0.401N	P=0.097	P=0.214
RAO-SCOTT	P=0.122	P=0.382N	P=0.084	P=0.219
LITTER C-A/FISHERS	P=0.088	P=0.500N	P=0.098	P=0.173

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Lung Inflammation Acute				
LESION RATES				
OVERALL (a)	3/50 (6%)	4/50 (8%)	1/50 (2%)	1/50 (2%)
LITTERS (b)	3/25 (12%)	4/25 (16%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	3/38.83	4/38.14	1/38.88	1/37.98
POLY-3 PERCENT (g)	7.7%	10.5%	2.6%	2.6%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	693	559	711	449
STATISTICAL TESTS				
POLY 3	P=0.157N	P=0.490	P=0.304N	P=0.312N
POLY 1.5	P=0.155N	P=0.495	P=0.304N	P=0.307N
POLY 6	P=0.160N	P=0.489	P=0.296N	P=0.318N
RAO-SCOTT	P=0.176N	P=0.482	P=0.312N	P=0.318N
LITTER C-A/FISHERS	P=0.149N	P=0.500	P=0.305N	P=0.305N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Lung Inflammation Chronic				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	4/50 (8%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	1/25 (4%)	4/25 (16%)
POLY-3 RATE (c)	0/38.56	0/37.00	1/38.80	4/37.23
POLY-3 PERCENT (g)	0%	0%	2.6%	10.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	1/21 (5%)	3/16 (19%)
FIRST INCIDENCE	---	---	730 (T)	725
STATISTICAL TESTS				
POLY 3	P=0.004**	(e)	P=0.501	P=0.054
POLY 1.5	P=0.004**	(e)	P=0.501	P=0.058
POLY 6	P=0.004**	(e)	P=0.506	P=0.051
RAO-SCOTT	P=0.017*	(e)	P=0.547	P=0.105
LITTER C-A/FISHERS	P=0.005**	(e)	P=0.500	P=0.055

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Lung				
Inflammation Granulomatous				
<hr/>				
LESION RATES				
OVERALL (a)	10/50 (20%)	9/50 (18%)	13/50 (26%)	9/50 (18%)
LITTERS (b)	8/25 (32%)	8/25 (32%)	11/25 (44%)	9/25 (36%)
POLY-3 RATE (c)	10/40.78	9/38.77	13/40.35	9/40.00
POLY-3 PERCENT (g)	24.5%	23.2%	32.2%	22.5%
TERMINAL (d)	4/15 (27%)	4/15 (27%)	8/21 (38%)	2/16 (13%)
FIRST INCIDENCE	481	488	558	442
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.474N	P=0.551N	P=0.298	P=0.519N
POLY 1.5	P=0.471N	P=0.526N	P=0.306	P=0.506N
POLY 6	P=0.474N	P=0.578N	P=0.308	P=0.530N
RAO-SCOTT	P=0.468N	P=0.534N	P=0.297	P=0.506N
LITTER C-A/FISHERS	P=0.450	P=0.619	P=0.280	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Lung Mineral				
LESION RATES				
OVERALL (a)	6/50 (12%)	11/50 (22%)	1/50 (2%)	5/50 (10%)
LITTERS (b)	6/25 (24%)	9/25 (36%)	1/25 (4%)	5/25 (20%)
POLY-3 RATE (c)	6/40.72	11/41.63	1/39.64	5/38.98
POLY-3 PERCENT (g)	14.7%	26.4%	2.5%	12.8%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	538	488	402	554
STATISTICAL TESTS				
POLY 3	P=0.212N	P=0.147	P=0.058N	P=0.531N
POLY 1.5	P=0.203N	P=0.145	P=0.057N	P=0.514N
POLY 6	P=0.222N	P=0.155	P=0.059N	P=0.549N
RAO-SCOTT	P=0.250N	P=0.178	P=0.083N	P=0.527N
LITTER C-A/FISHERS	P=0.273N	P=0.269	P=0.049N*	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Lung				
Squamous Metaplasia				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	1/37.55	0/38.80	0/37.21
POLY-3 PERCENT (g)	0%	2.7%	0%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	560	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Black Cohosh
 CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
 Time Report Requested: 09:53:31
 First Dose M/F: 07/03/12 / 07/02/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Lung Thrombus				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (c)	0/38.56	0/37.00	0/38.80	2/38.38
POLY-3 PERCENT (g)	0%	0%	0%	5.2%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	---	---	520
STATISTICAL TESTS				
POLY 3	P=0.041*	(e)	(e)	P=0.235
POLY 1.5	P=0.041*	(e)	(e)	P=0.237
POLY 6	P=0.041*	(e)	(e)	P=0.234
RAO-SCOTT	P=0.121	(e)	(e)	P=0.355
LITTER C-A/FISHERS	P=0.041*	(e)	(e)	P=0.245

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Lung: Alveolar Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/50 (2%)	2/50 (4%)	2/50 (4%)
LITTERS (b)	2/25 (8%)	1/25 (4%)	2/25 (8%)	2/25 (8%)
POLY-3 RATE (c)	2/38.75	1/37.19	2/38.95	2/37.26
POLY-3 PERCENT (g)	5.2%	2.7%	5.1%	5.4%
TERMINAL (d)	1/15 (7%)	0/15 (0%)	1/21 (5%)	1/16 (6%)
FIRST INCIDENCE	680	680	693	718
STATISTICAL TESTS				
POLY 3	P=0.521	P=0.514N	P=0.693N	P=0.681
POLY 1.5	P=0.527	P=0.507N	P=0.693N	P=0.688
POLY 6	P=0.513	P=0.521N	P=0.686N	P=0.673
RAO-SCOTT	P=0.495	P=0.476N	P=0.660N	P=0.644
LITTER C-A/FISHERS	P=0.530	P=0.500N	P=0.695	P=0.695

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

Lymph Node, Mandibular
Ectasia

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	0/37.00	2/39.49	0/37.21
POLY-3 PERCENT (g)	0%	0%	5.1%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	1/21 (5%)	0/16 (0%)
FIRST INCIDENCE	---	---	498	---

STATISTICAL TESTS

POLY 3	P=0.704N	(e)	P=0.242	(e)
POLY 1.5	P=0.700N	(e)	P=0.240	(e)
POLY 6	P=0.709N	(e)	P=0.249	(e)
RAO-SCOTT	P=0.700N	(e)	P=0.350	(e)
LITTER C-A/FISHERS	P=0.698N	(e)	P=0.245	(e)

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Lymph Node, Mandibular Infiltration Cellular Plasma Cell				
LESION RATES				
OVERALL (a)	2/50 (4%)	2/50 (4%)	0/50 (0%)	2/50 (4%)
LITTERS (b)	2/25 (8%)	2/25 (8%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (c)	2/38.95	2/37.28	0/38.80	2/37.28
POLY-3 PERCENT (g)	5.1%	5.4%	0%	5.4%
TERMINAL (d)	1/15 (7%)	1/15 (7%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	618	654	---	718
STATISTICAL TESTS				
POLY 3	P=0.610	P=0.679	P=0.237N	P=0.679
POLY 1.5	P=0.615	P=0.686	P=0.237N	P=0.687
POLY 6	P=0.604	P=0.673	P=0.233N	P=0.670
RAO-SCOTT	P=0.590	P=0.654	P=0.256N	P=0.654
LITTER C-A/FISHERS	P=0.620	P=0.695	P=0.245N	P=0.695

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Lymph Node, Mandibular Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	2/25 (8%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	2/37.94	0/38.80	0/37.21
POLY-3 PERCENT (g)	0%	5.3%	0%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	559	---	---
STATISTICAL TESTS				
POLY 3	P=0.376N	P=0.233	(e)	(e)
POLY 1.5	P=0.372N	P=0.235	(e)	(e)
POLY 6	P=0.378N	P=0.232	(e)	(e)
RAO-SCOTT	P=0.460N	P=0.357	(e)	(e)
LITTER C-A/FISHERS	P=0.368N	P=0.245	(e)	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

Lymph Node: Renal
Ectasia

LESION RATES

OVERALL (a)	0/5 (0%)	0/4 (0%)	0/3 (0%)	2/4 (50%)
LITTERS (b)	0/5 (0%)	0/3 (0%)	0/3 (0%)	2/4 (50%)
POLY-3 RATE (c)	0/4.36	0/2.76	0/3.00	2/3.75
POLY-3 PERCENT (g)	0%	0%	0%	53.3%
TERMINAL (d)	0/0 (0%)	0/1 (0%)	0/3 (0%)	1/1 (100%)
FIRST INCIDENCE	---	---	---	564

STATISTICAL TESTS

POLY 3	P=0.020*	(e)	(e)	P=0.147
POLY 1.5	P=0.018*	(e)	(e)	P=0.143
POLY 6	P=0.023*	(e)	(e)	P=0.154
RAO-SCOTT	P=0.089	(e)	(e)	P=0.266
LITTER C-A/FISHERS	P=0.037*	(e)	(e)	P=0.167

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Mammary Gland				
Galactocele				
<hr/>				
LESION RATES				
OVERALL (a)	1/48 (2%)	0/48 (0%)	0/49 (0%)	0/48 (0%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	1/37.14	0/35.77	0/37.80	0/35.69
POLY-3 PERCENT (g)	2.7%	0%	0%	0%
TERMINAL (d)	0/14 (0%)	0/14 (0%)	0/20 (0%)	0/15 (0%)
FIRST INCIDENCE	577	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Mammary Gland Hyperplasia				
LESION RATES				
OVERALL (a)	1/48 (2%)	1/48 (2%)	1/49 (2%)	0/48 (0%)
LITTERS (b)	1/25 (4%)	1/25 (4%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	1/36.69	1/36.11	1/38.59	0/35.69
POLY-3 PERCENT (g)	2.7%	2.8%	2.6%	0%
TERMINAL (d)	0/14 (0%)	0/14 (0%)	0/20 (0%)	0/15 (0%)
FIRST INCIDENCE	718	637	435	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Nose				
Foreign Body				
LESION RATES				
OVERALL (a)	6/50 (12%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
LITTERS (b)	6/25 (24%)	1/25 (4%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	6/39.62	1/37.00	1/38.80	0/37.21
POLY-3 PERCENT (g)	15.1%	2.7%	2.6%	0%
TERMINAL (d)	2/15 (13%)	1/15 (7%)	1/21 (5%)	0/16 (0%)
FIRST INCIDENCE	573	730 (T)	730 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.022N*	P=0.065N	P=0.057N	P=0.018N*
POLY 1.5	P=0.022N*	P=0.061N	P=0.057N	P=0.016N*
POLY 6	P=0.021N*	P=0.071N	P=0.055N	P=0.020N*
RAO-SCOTT	P=0.044N*	P=0.094N	P=0.086N	P=0.035N*
LITTER C-A/FISHERS	P=0.024N*	P=0.049N*	P=0.049N*	P=0.011N*

Experiment Number: 00058 - 03

Test Type: CHRONIC

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Nose Inflammation				
LESION RATES				
OVERALL (a)	5/50 (10%)	6/50 (12%)	0/50 (0%)	3/50 (6%)
LITTERS (b)	5/25 (20%)	5/25 (20%)	0/25 (0%)	3/25 (12%)
POLY-3 RATE (c)	5/39.58	6/39.57	0/38.80	3/38.41
POLY-3 PERCENT (g)	12.6%	15.2%	0%	7.8%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	616	475	---	564
STATISTICAL TESTS				
POLY 3	P=0.224N	P=0.500	P=0.031N*	P=0.371N
POLY 1.5	P=0.221N	P=0.502	P=0.031N*	P=0.362N
POLY 6	P=0.228N	P=0.500	P=0.030N*	P=0.381N
RAO-SCOTT	P=0.259N	P=0.503	P=0.055N	P=0.388N
LITTER C-A/FISHERS	P=0.265N	P=0.637	P=0.025N*	P=0.351N

Experiment Number: 00058 - 03

Test Type: CHRONIC

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Nose				
Inflammation Acute				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
LITTERS (b)	2/25 (8%)	0/25 (0%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (c)	2/38.56	0/37.00	2/38.95	0/37.21
POLY-3 PERCENT (g)	5.2%	0%	5.1%	0%
TERMINAL (d)	2/15 (13%)	0/15 (0%)	1/21 (5%)	0/16 (0%)
FIRST INCIDENCE	730 (T)	---	693	---
STATISTICAL TESTS				
POLY 3	P=0.287N	P=0.246N	P=0.691N	P=0.244N
POLY 1.5	P=0.286N	P=0.242N	P=0.692N	P=0.240N
POLY 6	P=0.288N	P=0.250N	P=0.682N	P=0.248N
RAO-SCOTT	P=0.338N	P=0.309N	P=0.682N	P=0.308N
LITTER C-A/FISHERS	P=0.285N	P=0.245N	P=0.695	P=0.245N

Experiment Number: 00058 - 03

Test Type: CHRONIC

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Nose				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	6/50 (12%)	4/50 (8%)	5/50 (10%)	4/50 (8%)
LITTERS (b)	5/25 (20%)	4/25 (16%)	4/25 (16%)	3/25 (12%)
POLY-3 RATE (c)	6/39.53	4/37.45	5/39.08	4/37.55
POLY-3 PERCENT (g)	15.2%	10.7%	12.8%	10.7%
TERMINAL (d)	4/15 (27%)	2/15 (13%)	3/21 (14%)	2/16 (13%)
FIRST INCIDENCE	573	630	679	643
STATISTICAL TESTS				
POLY 3	P=0.416N	P=0.402N	P=0.508N	P=0.400N
POLY 1.5	P=0.407N	P=0.387N	P=0.504N	P=0.384N
POLY 6	P=0.428N	P=0.418N	P=0.499N	P=0.419N
RAO-SCOTT	P=0.428N	P=0.413N	P=0.509N	P=0.412N
LITTER C-A/FISHERS	P=0.320N	P=0.500N	P=0.500N	P=0.351N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

**Nose: Nasolacrimal Duct
Inflammation Chronic**

LESION RATES

OVERALL (a)	10/50 (20%)	8/50 (16%)	6/50 (12%)	10/50 (20%)
LITTERS (b)	9/25 (36%)	8/25 (32%)	6/25 (24%)	9/25 (36%)
POLY-3 RATE (c)	10/39.84	8/38.43	6/40.62	10/39.41
POLY-3 PERCENT (g)	25.1%	20.8%	14.8%	25.4%
TERMINAL (d)	4/15 (27%)	3/15 (20%)	3/21 (14%)	4/16 (25%)
FIRST INCIDENCE	599	488	402	442

STATISTICAL TESTS

POLY 3	P=0.447	P=0.427N	P=0.186N	P=0.592
POLY 1.5	P=0.451	P=0.411N	P=0.193N	P=0.600
POLY 6	P=0.446	P=0.446N	P=0.170N	P=0.587
RAO-SCOTT	P=0.437	P=0.411N	P=0.183N	P=0.572
LITTER C-A/FISHERS	P=0.500	P=0.500N	P=0.269N	P=0.616

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

Nose: Respiratory Epithelium
Hyperplasia

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
LITTERS (b)	1/25 (4%)	1/25 (4%)	1/25 (4%)	2/25 (8%)
POLY-3 RATE (c)	1/38.56	1/37.31	1/38.80	2/37.42
POLY-3 PERCENT (g)	2.6%	2.7%	2.6%	5.3%
TERMINAL (d)	1/15 (7%)	0/15 (0%)	1/21 (5%)	1/16 (6%)
FIRST INCIDENCE	730 (T)	644	730 (T)	674

STATISTICAL TESTS

POLY 3	P=0.354	P=0.754	P=0.760N	P=0.490
POLY 1.5	P=0.359	P=0.757	P=0.760N	P=0.496
POLY 6	P=0.350	P=0.752	P=0.755N	P=0.484
RAO-SCOTT	P=0.344	P=0.713	P=0.723N	P=0.463
LITTER C-A/FISHERS	P=0.358	P=0.755	P=0.755	P=0.500

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Pancreas				
Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	6/50 (12%)	6/50 (12%)	7/50 (14%)	10/50 (20%)
LITTERS (b)	5/25 (20%)	6/25 (24%)	7/25 (28%)	7/25 (28%)
POLY-3 RATE (c)	6/40.19	6/37.62	7/39.64	10/39.37
POLY-3 PERCENT (g)	14.9%	16%	17.7%	25.4%
TERMINAL (d)	1/15 (7%)	4/15 (27%)	3/21 (14%)	3/16 (19%)
FIRST INCIDENCE	598	559	606	598
STATISTICAL TESTS				
POLY 3	P=0.123	P=0.575	P=0.489	P=0.185
POLY 1.5	P=0.126	P=0.598	P=0.495	P=0.197
POLY 6	P=0.122	P=0.543	P=0.494	P=0.175
RAO-SCOTT	P=0.151	P=0.564	P=0.490	P=0.213
LITTER C-A/FISHERS	P=0.352	P=0.500	P=0.371	P=0.371

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

Pancreas: Acinus
Atrophy

LESION RATES

OVERALL (a)	5/50 (10%)	4/50 (8%)	1/50 (2%)	4/50 (8%)
LITTERS (b)	5/25 (20%)	3/25 (12%)	1/25 (4%)	4/25 (16%)
POLY-3 RATE (c)	5/38.99	4/37.08	1/39.24	4/37.58
POLY-3 PERCENT (g)	12.8%	10.8%	2.6%	10.6%
TERMINAL (d)	3/15 (20%)	3/15 (20%)	0/21 (0%)	2/16 (13%)
FIRST INCIDENCE	624	711	604	632

STATISTICAL TESTS

POLY 3	P=0.521N	P=0.532N	P=0.097N	P=0.523N
POLY 1.5	P=0.516N	P=0.516N	P=0.099N	P=0.510N
POLY 6	P=0.527N	P=0.551N	P=0.091N	P=0.538N
RAO-SCOTT	P=0.517N	P=0.522N	P=0.124N	P=0.515N
LITTER C-A/FISHERS	P=0.593N	P=0.351N	P=0.095N	P=0.500N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

Pancreas: Acinus
Hyperplasia

LESION RATES

OVERALL (a)	9/50 (18%)	9/50 (18%)	8/50 (16%)	6/50 (12%)
LITTERS (b)	6/25 (24%)	8/25 (32%)	8/25 (32%)	6/25 (24%)
POLY-3 RATE (c)	9/39.51	9/38.54	8/40.62	6/39.08
POLY-3 PERCENT (g)	22.8%	23.4%	19.7%	15.4%
TERMINAL (d)	4/15 (27%)	4/15 (27%)	5/21 (24%)	2/16 (13%)
FIRST INCIDENCE	599	488	413	442

STATISTICAL TESTS

POLY 3	P=0.213N	P=0.584	P=0.474N	P=0.289N
POLY 1.5	P=0.212N	P=0.594	P=0.483N	P=0.284N
POLY 6	P=0.215N	P=0.575	P=0.450N	P=0.295N
RAO-SCOTT	P=0.234N	P=0.570	P=0.474N	P=0.305N
LITTER C-A/FISHERS	P=0.447N	P=0.377	P=0.377	P=0.629

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Parathyroid Gland Hyperplasia Diffuse				
LESION RATES				
OVERALL (a)	13/49 (27%)	24/47 (51%)	16/44 (36%)	14/39 (36%)
LITTERS (b)	11/25 (44%)	16/25 (64%)	13/25 (52%)	12/24 (50%)
POLY-3 RATE (c)	13/40.99	24/43.47	16/38.12	14/34.02
POLY-3 PERCENT (g)	31.7%	55.2%	42%	41.2%
TERMINAL (d)	0/15 (0%)	2/15 (13%)	1/15 (7%)	3/12 (25%)
FIRST INCIDENCE	599	488	413	442
STATISTICAL TESTS				
POLY 3	P=0.515N	P=0.021*	P=0.234	P=0.268
POLY 1.5	P=0.510N	P=0.016*	P=0.225	P=0.264
POLY 6	P=0.538N	P=0.033*	P=0.263	P=0.268
RAO-SCOTT	P=0.535N	P=0.034*	P=0.251	P=0.284
LITTER C-A/FISHERS	P=0.494N	P=0.128	P=0.389	P=0.447

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Peripheral Nerve: Axon, Trigeminal Degeneration				
LESION RATES				
OVERALL (a)	0/0 (0%)	0/1 (0%)	1/1 (100%)	2/2 (100%)
LITTERS (b)	0/0 (0%)	0/1 (0%)	1/1 (100%)	2/2 (100%)
POLY-3 RATE (c)	0/0.00	0/0.60	1/1.00	2/2.00
POLY-3 PERCENT (g)	0%	0%	100%	100%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	711	669
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
RAO-SCOTT	(e)	(e)	(e)	(e)
LITTER C-A/FISHERS	(e)	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Pituitary Gland: Pars Distalis Hyperplasia				
LESION RATES				
OVERALL (a)	20/50 (40%)	15/50 (30%)	15/50 (30%)	15/50 (30%)
LITTERS (b)	15/25 (60%)	10/25 (40%)	13/25 (52%)	13/25 (52%)
POLY-3 RATE (c)	20/43.63	15/38.90	15/39.99	15/39.67
POLY-3 PERCENT (g)	45.8%	38.6%	37.5%	37.8%
TERMINAL (d)	4/15 (27%)	7/15 (47%)	9/21 (43%)	7/16 (44%)
FIRST INCIDENCE	538	575	609	554
STATISTICAL TESTS				
POLY 3	P=0.331N	P=0.324N	P=0.287N	P=0.297N
POLY 1.5	P=0.301N	P=0.260N	P=0.242N	P=0.243N
POLY 6	P=0.381N	P=0.422N	P=0.341N	P=0.382N
RAO-SCOTT	P=0.350N	P=0.333N	P=0.299N	P=0.309N
LITTER C-A/FISHERS	P=0.556	P=0.129N	P=0.388N	P=0.388N

Experiment Number: 00058 - 03

Test Type: CHRONIC

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Prostate Hyperplasia				
LESION RATES				
OVERALL (a)	2/50 (4%)	3/50 (6%)	2/50 (4%)	3/50 (6%)
LITTERS (b)	2/25 (8%)	3/25 (12%)	2/25 (8%)	3/25 (12%)
POLY-3 RATE (c)	2/38.56	3/37.10	2/39.26	3/37.21
POLY-3 PERCENT (g)	5.2%	8.1%	5.1%	8.1%
TERMINAL (d)	2/15 (13%)	2/15 (13%)	1/21 (5%)	3/16 (19%)
FIRST INCIDENCE	730 (T)	706	595	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.470	P=0.482	P=0.689N	P=0.484
POLY 1.5	P=0.478	P=0.491	P=0.691N	P=0.493
POLY 6	P=0.461	P=0.474	P=0.678N	P=0.474
RAO-SCOTT	P=0.451	P=0.449	P=0.654N	P=0.451
LITTER C-A/FISHERS	P=0.483	P=0.500	P=0.695	P=0.500

Experiment Number: 00058 - 03

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Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Prostate Inflammation Chronic				
LESION RATES				
OVERALL (a)	9/50 (18%)	7/50 (14%)	9/50 (18%)	6/50 (12%)
LITTERS (b)	7/25 (28%)	6/25 (24%)	9/25 (36%)	5/25 (20%)
POLY-3 RATE (c)	9/39.97	7/37.78	9/39.67	6/37.99
POLY-3 PERCENT (g)	22.5%	18.5%	22.7%	15.8%
TERMINAL (d)	2/15 (13%)	1/15 (7%)	4/21 (19%)	3/16 (19%)
FIRST INCIDENCE	618	669	616	614
STATISTICAL TESTS				
POLY 3	P=0.312N	P=0.438N	P=0.599	P=0.319N
POLY 1.5	P=0.300N	P=0.416N	P=0.602	P=0.301N
POLY 6	P=0.331N	P=0.467N	P=0.608N	P=0.346N
RAO-SCOTT	P=0.316N	P=0.430N	P=0.583	P=0.319N
LITTER C-A/FISHERS	P=0.334N	P=0.500N	P=0.381	P=0.371N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Prostate				
Polyarteritis Nodosa				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	0/37.00	2/38.80	0/37.21
POLY-3 PERCENT (g)	0%	0%	5.2%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	2/21 (10%)	0/16 (0%)
FIRST INCIDENCE	---	---	730 (T)	---
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.705N	(e)	P=0.238	(e)
POLY 1.5	P=0.700N	(e)	P=0.238	(e)
POLY 6	P=0.709N	(e)	P=0.243	(e)
RAO-SCOTT	P=0.705N	(e)	P=0.360	(e)
LITTER C-A/FISHERS	P=0.698N	(e)	P=0.245	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Seminal Vesicle Inflammation Chronic				
LESION RATES				
OVERALL (a)	3/50 (6%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
LITTERS (b)	2/25 (8%)	2/25 (8%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	3/38.95	2/37.31	1/38.80	1/37.23
POLY-3 PERCENT (g)	7.7%	5.4%	2.6%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	1/21 (5%)	0/16 (0%)
FIRST INCIDENCE	678	669	730 (T)	725
STATISTICAL TESTS				
POLY 3	P=0.268N	P=0.520N	P=0.305N	P=0.320N
POLY 1.5	P=0.265N	P=0.510N	P=0.305N	P=0.312N
POLY 6	P=0.273N	P=0.530N	P=0.300N	P=0.331N
RAO-SCOTT	P=0.316N	P=0.534N	P=0.359N	P=0.368N
LITTER C-A/FISHERS	P=0.380N	P=0.695	P=0.500N	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Seminal Vesicle				
Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	0/37.00	2/39.00	0/37.21
POLY-3 PERCENT (g)	0%	0%	5.1%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	1/21 (5%)	0/16 (0%)
FIRST INCIDENCE	---	---	679	---
STATISTICAL TESTS				
POLY 3	P=0.704N	(e)	P=0.239	(e)
POLY 1.5	P=0.700N	(e)	P=0.238	(e)
POLY 6	P=0.709N	(e)	P=0.245	(e)
RAO-SCOTT	P=0.703N	(e)	P=0.355	(e)
LITTER C-A/FISHERS	P=0.698N	(e)	P=0.245	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Skin				
Cyst Epithelial Inclusion				
<hr/>				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
LITTERS (b)	1/25 (4%)	2/25 (8%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	1/38.88	2/37.35	1/39.26	1/37.46
POLY-3 PERCENT (g)	2.6%	5.4%	2.6%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	643	654	595	663
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.544N	P=0.486	P=0.759N	P=0.753
POLY 1.5	P=0.539N	P=0.493	P=0.760N	P=0.757
POLY 6	P=0.551N	P=0.480	P=0.754N	P=0.749
RAO-SCOTT	P=0.519N	P=0.458	P=0.723N	P=0.712
LITTER C-A/FISHERS	P=0.535N	P=0.500	P=0.755	P=0.755

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Skin				
Inflammation Chronic				
<hr/>				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	6/50 (12%)
LITTERS (b)	1/25 (4%)	1/25 (4%)	1/25 (4%)	5/25 (20%)
POLY-3 RATE (c)	1/38.76	1/37.07	1/38.80	6/38.00
POLY-3 PERCENT (g)	2.6%	2.7%	2.6%	15.8%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	1/21 (5%)	1/16 (6%)
FIRST INCIDENCE	678	713	730 (T)	614
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.005**	P=0.751	P=0.761N	P=0.050*
POLY 1.5	P=0.005**	P=0.756	P=0.761N	P=0.053
POLY 6	P=0.005**	P=0.747	P=0.758N	P=0.047*
RAO-SCOTT	P=0.022*	P=0.740	P=0.753N	P=0.105
LITTER C-A/FISHERS	P=0.017*	P=0.755	P=0.755	P=0.095

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Skin				
Ulcer				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	5/50 (10%)
LITTERS (b)	1/25 (4%)	1/25 (4%)	1/25 (4%)	4/25 (16%)
POLY-3 RATE (c)	1/38.76	1/37.07	1/38.80	5/38.16
POLY-3 PERCENT (g)	2.6%	2.7%	2.6%	13.1%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	1/21 (5%)	1/16 (6%)
FIRST INCIDENCE	678	713	730 (T)	442
STATISTICAL TESTS				
POLY 3	P=0.018*	P=0.751	P=0.761N	P=0.095
POLY 1.5	P=0.019*	P=0.756	P=0.761N	P=0.099
POLY 6	P=0.017*	P=0.747	P=0.758N	P=0.090
RAO-SCOTT	P=0.050*	P=0.740	P=0.753N	P=0.161
LITTER C-A/FISHERS	P=0.055	P=0.755	P=0.755	P=0.174

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Skin: Epidermis Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	3/50 (6%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (c)	0/38.56	0/37.00	0/38.80	3/38.01
POLY-3 PERCENT (g)	0%	0%	0%	7.9%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	1/16 (6%)
FIRST INCIDENCE	---	---	---	442
STATISTICAL TESTS				
POLY 3	P=0.008**	(e)	(e)	P=0.115
POLY 1.5	P=0.008**	(e)	(e)	P=0.118
POLY 6	P=0.008**	(e)	(e)	P=0.112
RAO-SCOTT	P=0.095	(e)	(e)	P=0.316
LITTER C-A/FISHERS	P=0.041*	(e)	(e)	P=0.245

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Spleen				
Extramedullary Hematopoiesis				
LESION RATES				
OVERALL (a)	41/50 (82%)	41/50 (82%)	42/49 (86%)	39/50 (78%)
LITTERS (b)	25/25 (100%)	24/25 (96%)	25/25 (100%)	23/25 (92%)
POLY-3 RATE (c)	41/47.13	41/45.46	42/45.21	39/45.75
POLY-3 PERCENT (g)	87%	90.2%	92.9%	85.3%
TERMINAL (d)	15/15 (100%)	15/15 (100%)	21/21 (100%)	16/16 (100%)
FIRST INCIDENCE	155	274	435	434
STATISTICAL TESTS				
POLY 3	P=0.333N	P=0.426	P=0.242	P=0.526N
POLY 1.5	P=0.325N	P=0.516	P=0.300	P=0.465N
POLY 6	P=0.366N	P=0.284	P=0.205	P=0.632N
RAO-SCOTT	P=0.356N	P=0.435	P=0.277	P=0.519N
LITTER C-A/FISHERS	P=0.149N	P=0.500N	P=1.000	P=0.245N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Spleen Pigment				
LESION RATES				
OVERALL (a)	38/50 (76%)	39/50 (78%)	43/49 (88%)	40/50 (80%)
LITTERS (b)	25/25 (100%)	25/25 (100%)	25/25 (100%)	24/25 (96%)
POLY-3 RATE (c)	38/46.80	39/46.78	43/47.10	40/46.80
POLY-3 PERCENT (g)	81.2%	83.4%	91.3%	85.5%
TERMINAL (d)	14/15 (93%)	13/15 (87%)	20/21 (95%)	14/16 (88%)
FIRST INCIDENCE	155	433	402	434
STATISTICAL TESTS				
POLY 3	P=0.370	P=0.498	P=0.103	P=0.381
POLY 1.5	P=0.376	P=0.481	P=0.102	P=0.378
POLY 6	P=0.404	P=0.546	P=0.113	P=0.428
RAO-SCOTT	P=0.377	P=0.491	P=0.128	P=0.384
LITTER C-A/FISHERS	P=0.213N	P=1.000	P=1.000	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Spleen: White Pulp Atrophy				
LESION RATES				
OVERALL (a)	17/50 (34%)	19/50 (38%)	13/49 (27%)	17/50 (34%)
LITTERS (b)	15/25 (60%)	16/25 (64%)	12/25 (48%)	14/25 (56%)
POLY-3 RATE (c)	17/44.65	19/44.72	13/43.71	17/44.86
POLY-3 PERCENT (g)	38.1%	42.5%	29.7%	37.9%
TERMINAL (d)	0/15 (0%)	1/15 (7%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	354	274	402	441
STATISTICAL TESTS				
POLY 3	P=0.478N	P=0.416	P=0.272N	P=0.580N
POLY 1.5	P=0.475N	P=0.420	P=0.272N	P=0.575N
POLY 6	P=0.485N	P=0.424	P=0.259N	P=0.585N
RAO-SCOTT	P=0.474N	P=0.410	P=0.269N	P=0.571N
LITTER C-A/FISHERS	P=0.399N	P=0.500	P=0.285N	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Stomach, Forestomach Inflammation Acute				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	1/37.28	2/39.97	0/37.21
POLY-3 PERCENT (g)	0%	2.7%	5%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	654	445	---
STATISTICAL TESTS				
POLY 3	P=0.526N	P=0.493	P=0.245	(e)
POLY 1.5	P=0.520N	P=0.496	P=0.242	(e)
POLY 6	P=0.534N	P=0.491	P=0.253	(e)
RAO-SCOTT	P=0.534N	P=0.531	P=0.315	(e)
LITTER C-A/FISHERS	P=0.515N	P=0.500	P=0.245	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Stomach, Forestomach Inflammation Chronic				
LESION RATES				
OVERALL (a)	2/50 (4%)	2/50 (4%)	4/50 (8%)	3/50 (6%)
LITTERS (b)	2/25 (8%)	2/25 (8%)	3/25 (12%)	3/25 (12%)
POLY-3 RATE (c)	2/38.99	2/37.36	4/39.24	3/37.58
POLY-3 PERCENT (g)	5.1%	5.4%	10.2%	8%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	1/16 (6%)
FIRST INCIDENCE	621	637	694	632
STATISTICAL TESTS				
POLY 3	P=0.405	P=0.680	P=0.339	P=0.483
POLY 1.5	P=0.414	P=0.686	P=0.338	P=0.493
POLY 6	P=0.395	P=0.673	P=0.350	P=0.473
RAO-SCOTT	P=0.414	P=0.658	P=0.358	P=0.483
LITTER C-A/FISHERS	P=0.404	P=0.695	P=0.500	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Stomach, Forestomach Mineral				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
LITTERS (b)	1/25 (4%)	2/25 (8%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	1/38.92	2/38.08	1/39.58	0/37.21
POLY-3 PERCENT (g)	2.6%	5.3%	2.5%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	631	553	445	---
STATISTICAL TESTS				
POLY 3	P=0.241N	P=0.492	P=0.758N	P=0.509N
POLY 1.5	P=0.236N	P=0.496	P=0.758N	P=0.504N
POLY 6	P=0.247N	P=0.490	P=0.753N	P=0.515N
RAO-SCOTT	P=0.252N	P=0.485	P=0.731N	P=0.489N
LITTER C-A/FISHERS	P=0.229N	P=0.500	P=0.755	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Stomach, Forestomach Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
LITTERS (b)	1/25 (4%)	1/25 (4%)	2/25 (8%)	1/25 (4%)
POLY-3 RATE (c)	1/38.56	1/37.00	2/39.22	1/37.21
POLY-3 PERCENT (g)	2.6%	2.7%	5.1%	2.7%
TERMINAL (d)	1/15 (7%)	1/15 (7%)	1/21 (5%)	1/16 (6%)
FIRST INCIDENCE	730 (T)	730 (T)	609	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.647N	P=0.752	P=0.506	P=0.754
POLY 1.5	P=0.642N	P=0.756	P=0.503	P=0.758
POLY 6	P=0.647	P=0.748	P=0.517	P=0.749
RAO-SCOTT	P=0.618N	P=0.708	P=0.478	P=0.710
LITTER C-A/FISHERS	P=0.642N	P=0.755	P=0.500	P=0.755

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Stomach, Forestomach Ulcer				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	3/50 (6%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (c)	0/38.56	1/37.34	3/39.77	0/37.21
POLY-3 PERCENT (g)	0%	2.7%	7.5%	0%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	---	637	606	---
STATISTICAL TESTS				
POLY 3	P=0.514N	P=0.494	P=0.123	(e)
POLY 1.5	P=0.505N	P=0.497	P=0.121	(e)
POLY 6	P=0.523N	P=0.491	P=0.131	(e)
RAO-SCOTT	P=0.561N	P=0.629	P=0.272	(e)
LITTER C-A/FISHERS	P=0.515N	P=0.500	P=0.245	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

Stomach, Forestomach: Epithelium
Hyperplasia

LESION RATES

OVERALL (a)	1/50 (2%)	6/50 (12%)	5/50 (10%)	7/50 (14%)
LITTERS (b)	1/25 (4%)	5/25 (20%)	5/25 (20%)	7/25 (28%)
POLY-3 RATE (c)	1/38.61	6/38.37	5/40.05	7/38.56
POLY-3 PERCENT (g)	2.6%	15.6%	12.5%	18.2%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	3/16 (19%)
FIRST INCIDENCE	718	575	435	449

STATISTICAL TESTS

POLY 3	P=0.088	P=0.052	P=0.108	P=0.028*
POLY 1.5	P=0.092	P=0.054	P=0.105	P=0.029*
POLY 6	P=0.084	P=0.052	P=0.117	P=0.026*
RAO-SCOTT	P=0.106	P=0.067	P=0.124	P=0.040*
LITTER C-A/FISHERS	P=0.056	P=0.095	P=0.095	P=0.024*

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Stomach, Glandular Mineral				
LESION RATES				
OVERALL (a)	15/50 (30%)	16/50 (32%)	10/50 (20%)	10/50 (20%)
LITTERS (b)	12/25 (48%)	13/25 (52%)	8/25 (32%)	9/25 (36%)
POLY-3 RATE (c)	15/43.13	16/42.49	10/43.34	10/40.27
POLY-3 PERCENT (g)	34.8%	37.7%	23.1%	24.8%
TERMINAL (d)	0/15 (0%)	2/15 (13%)	0/21 (0%)	1/16 (6%)
FIRST INCIDENCE	538	488	402	502
STATISTICAL TESTS				
POLY 3	P=0.133N	P=0.479	P=0.165N	P=0.223N
POLY 1.5	P=0.117N	P=0.491	P=0.166N	P=0.197N
POLY 6	P=0.159N	P=0.469	P=0.161N	P=0.262N
RAO-SCOTT	P=0.153N	P=0.480	P=0.185N	P=0.239N
LITTER C-A/FISHERS	P=0.181N	P=0.500	P=0.193N	P=0.284N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

Testis
Polyarteritis Nodosa

LESION RATES

OVERALL (a)	24/50 (48%)	25/50 (50%)	24/50 (48%)	23/50 (46%)
LITTERS (b)	20/25 (80%)	18/25 (72%)	19/25 (76%)	16/25 (64%)
POLY-3 RATE (c)	24/43.23	25/42.44	24/42.93	23/42.46
POLY-3 PERCENT (g)	55.5%	58.9%	55.9%	54.2%
TERMINAL (d)	6/15 (40%)	8/15 (53%)	10/21 (48%)	7/16 (44%)
FIRST INCIDENCE	562	475	413	442

STATISTICAL TESTS

POLY 3	P=0.434N	P=0.459	P=0.574	P=0.538N
POLY 1.5	P=0.417N	P=0.484	P=0.583	P=0.510N
POLY 6	P=0.452N	P=0.429	P=0.582	P=0.568N
RAO-SCOTT	P=0.432N	P=0.453	P=0.562	P=0.528N
LITTER C-A/FISHERS	P=0.164N	P=0.371N	P=0.500N	P=0.173N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Testis: Bilateral, Germinal Epithelium Degeneration				
LESION RATES				
OVERALL (a)	14/50 (28%)	21/50 (42%)	19/50 (38%)	10/50 (20%)
LITTERS (b)	11/25 (44%)	16/25 (64%)	14/25 (56%)	9/25 (36%)
POLY-3 RATE (c)	14/41.56	21/43.34	19/42.44	10/39.91
POLY-3 PERCENT (g)	33.7%	48.5%	44.8%	25.1%
TERMINAL (d)	2/15 (13%)	3/15 (20%)	5/21 (24%)	2/16 (13%)
FIRST INCIDENCE	562	553	413	520
STATISTICAL TESTS				
POLY 3	P=0.065N	P=0.116	P=0.202	P=0.267N
POLY 1.5	P=0.055N	P=0.108	P=0.201	P=0.251N
POLY 6	P=0.084N	P=0.143	P=0.224	P=0.287N
RAO-SCOTT	P=0.085N	P=0.142	P=0.225	P=0.284N
LITTER C-A/FISHERS	P=0.117N	P=0.128	P=0.286	P=0.387N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Testis: Germinal Epithelium Degeneration				
LESION RATES				
OVERALL (a)	26/50 (52%)	26/50 (52%)	25/50 (50%)	26/50 (52%)
LITTERS (b)	19/25 (76%)	19/25 (76%)	18/25 (72%)	18/25 (72%)
POLY-3 RATE (c)	26/43.33	26/44.31	25/44.14	26/43.65
POLY-3 PERCENT (g)	60%	58.7%	56.6%	59.6%
TERMINAL (d)	7/15 (47%)	6/15 (40%)	8/21 (38%)	7/16 (44%)
FIRST INCIDENCE	562	475	402	449
STATISTICAL TESTS				
POLY 3	P=0.543	P=0.538N	P=0.458N	P=0.573N
POLY 1.5	P=0.546N	P=0.554N	P=0.466N	P=0.563N
POLY 6	P=0.518	P=0.501N	P=0.434N	P=0.585N
RAO-SCOTT	P=0.539	P=0.533N	P=0.460N	P=0.564N
LITTER C-A/FISHERS	P=0.434N	P=0.629	P=0.500N	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Testis: Interstitial Cell Hyperplasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	1/50 (2%)
LITTERS (b)	1/25 (4%)	2/25 (8%)	2/25 (8%)	1/25 (4%)
POLY-3 RATE (c)	1/38.66	2/37.00	2/39.01	1/37.21
POLY-3 PERCENT (g)	2.6%	5.4%	5.1%	2.7%
TERMINAL (d)	0/15 (0%)	2/15 (13%)	1/21 (5%)	1/16 (6%)
FIRST INCIDENCE	704	730 (T)	677	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.533N	P=0.485	P=0.503	P=0.753
POLY 1.5	P=0.526N	P=0.492	P=0.502	P=0.757
POLY 6	P=0.541N	P=0.476	P=0.512	P=0.748
RAO-SCOTT	P=0.508N	P=0.456	P=0.478	P=0.711
LITTER C-A/FISHERS	P=0.522N	P=0.500	P=0.500	P=0.755

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Thymus Atrophy				
LESION RATES				
OVERALL (a)	43/46 (93%)	41/48 (85%)	44/46 (96%)	40/49 (82%)
LITTERS (b)	25/25 (100%)	23/25 (92%)	25/25 (100%)	23/25 (92%)
POLY-3 RATE (c)	43/44.63	41/46.65	44/45.60	40/48.54
POLY-3 PERCENT (g)	96.3%	87.9%	96.5%	82.4%
TERMINAL (d)	13/14 (93%)	12/15 (80%)	18/19 (95%)	9/16 (56%)
FIRST INCIDENCE	354	274	402	434
STATISTICAL TESTS				
POLY 3	P=0.026N*	P=0.118N	P=0.714	P=0.029N*
POLY 1.5	P=0.037N*	P=0.112N	P=0.683	P=0.034N*
POLY 6	P=0.017N*	P=0.143N	P=0.734	P=0.026N*
RAO-SCOTT	P=0.081N	P=0.229N	P=0.744	P=0.090N
LITTER C-A/FISHERS	P=0.285N	P=0.245N	P=1.000	P=0.245N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Thymus Ectopic Parathyroid Gland				
LESION RATES				
OVERALL (a)	2/46 (4%)	1/48 (2%)	2/46 (4%)	0/49 (0%)
LITTERS (b)	2/25 (8%)	1/25 (4%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (c)	2/36.10	1/35.59	2/35.58	0/36.43
POLY-3 PERCENT (g)	5.5%	2.8%	5.6%	0%
TERMINAL (d)	0/14 (0%)	0/15 (0%)	1/19 (5%)	0/16 (0%)
FIRST INCIDENCE	599	680	621	---
STATISTICAL TESTS				
POLY 3	P=0.206N	P=0.505N	P=0.690	P=0.234N
POLY 1.5	P=0.203N	P=0.495N	P=0.692	P=0.228N
POLY 6	P=0.211N	P=0.516N	P=0.694	P=0.242N
RAO-SCOTT	P=0.226N	P=0.496N	P=0.669	P=0.252N
LITTER C-A/FISHERS	P=0.208N	P=0.500N	P=0.695	P=0.245N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
<hr/>				
Thymus Polyarteritis Nodosa				
<hr/>				
LESION RATES				
OVERALL (a)	2/46 (4%)	1/48 (2%)	1/46 (2%)	0/49 (0%)
LITTERS (b)	2/25 (8%)	1/25 (4%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	2/36.15	1/35.40	1/35.66	0/36.43
POLY-3 PERCENT (g)	5.5%	2.8%	2.8%	0%
TERMINAL (d)	0/14 (0%)	1/15 (7%)	0/19 (0%)	0/16 (0%)
FIRST INCIDENCE	616	730 (T)	595	---
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.188N	P=0.507N	P=0.505N	P=0.234N
POLY 1.5	P=0.187N	P=0.496N	P=0.502N	P=0.228N
POLY 6	P=0.190N	P=0.522N	P=0.503N	P=0.243N
RAO-SCOTT	P=0.211N	P=0.498N	P=0.501N	P=0.252N
LITTER C-A/FISHERS	P=0.191N	P=0.500N	P=0.500N	P=0.245N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male

Thyroid Gland: C-Cell
Hyperplasia

LESION RATES				
OVERALL (a)	9/50 (18%)	10/50 (20%)	9/50 (18%)	6/50 (12%)
LITTERS (b)	7/25 (28%)	8/25 (32%)	9/25 (36%)	6/25 (24%)
POLY-3 RATE (c)	9/39.90	10/38.75	9/39.70	6/38.55
POLY-3 PERCENT (g)	22.6%	25.8%	22.7%	15.6%
TERMINAL (d)	3/15 (20%)	4/15 (27%)	5/21 (24%)	2/16 (13%)
FIRST INCIDENCE	618	559	592	620

STATISTICAL TESTS				
POLY 3	P=0.193N	P=0.470	P=0.602	P=0.307N
POLY 1.5	P=0.187N	P=0.485	P=0.603	P=0.295N
POLY 6	P=0.200N	P=0.458	P=0.602N	P=0.318N
RAO-SCOTT	P=0.211N	P=0.467	P=0.588	P=0.317N
LITTER C-A/FISHERS	P=0.365N	P=0.500	P=0.381	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Tooth: Dentine Degeneration				
LESION RATES				
OVERALL (a)	0/0 (0%)	2/3 (67%)	0/0 (0%)	0/0 (0%)
LITTERS (b)	0/0 (0%)	2/2 (100%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (c)	0/0.00	2/2.44	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	82.2%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	637	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
RAO-SCOTT	(e)	(e)	(e)	(e)
LITTER C-A/FISHERS	(e)	(e)	(e)	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Urinary Bladder Inflammation Chronic				
LESION RATES				
OVERALL (a)	4/50 (8%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
LITTERS (b)	4/25 (16%)	2/25 (8%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	4/39.87	2/37.28	0/38.80	1/37.23
POLY-3 PERCENT (g)	10%	5.4%	0%	2.7%
TERMINAL (d)	0/15 (0%)	0/15 (0%)	0/21 (0%)	0/16 (0%)
FIRST INCIDENCE	577	676	---	725
STATISTICAL TESTS				
POLY 3	P=0.167N	P=0.367N	P=0.063N	P=0.198N
POLY 1.5	P=0.166N	P=0.353N	P=0.061N	P=0.188N
POLY 6	P=0.168N	P=0.386N	P=0.062N	P=0.213N
RAO-SCOTT	P=0.201N	P=0.379N	P=0.090N	P=0.224N
LITTER C-A/FISHERS	P=0.163N	P=0.334N	P=0.055N	P=0.174N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

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P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Adrenal Cortex				
Angiectasis				
<hr/>				
LESION RATES				
OVERALL (a)	5/50 (10%)	2/50 (4%)	3/50 (6%)	3/48 (6%)
LITTERS (b)	5/25 (20%)	2/25 (8%)	2/25 (8%)	3/25 (12%)
POLY-3 RATE (c)	5/41.89	2/39.18	3/42.83	3/34.39
POLY-3 PERCENT (g)	11.9%	5.1%	7%	8.7%
TERMINAL (d)	4/28 (14%)	2/24 (8%)	3/29 (10%)	3/20 (15%)
FIRST INCIDENCE	715	729 (T)	729 (T)	729 (T)
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.543N	P=0.242N	P=0.343N	P=0.468N
POLY 1.5	P=0.522N	P=0.235N	P=0.350N	P=0.434N
POLY 6	P=0.573N	P=0.249N	P=0.336N	P=0.517N
RAO-SCOTT	P=0.547N	P=0.259N	P=0.359N	P=0.460N
LITTER C-A/FISHERS	P=0.469N	P=0.209N	P=0.209N	P=0.351N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Adrenal Cortex Degeneration Cystic				
LESION RATES				
OVERALL (a)	8/50 (16%)	14/50 (28%)	10/50 (20%)	7/48 (15%)
LITTERS (b)	7/25 (28%)	11/25 (44%)	8/25 (32%)	6/25 (24%)
POLY-3 RATE (c)	8/42.39	14/41.57	10/43.31	7/36.32
POLY-3 PERCENT (g)	18.9%	33.7%	23.1%	19.3%
TERMINAL (d)	5/28 (18%)	8/24 (33%)	8/29 (28%)	2/20 (10%)
FIRST INCIDENCE	655	332	608	551
STATISTICAL TESTS				
POLY 3	P=0.315N	P=0.094	P=0.415	P=0.596
POLY 1.5	P=0.281N	P=0.099	P=0.407	P=0.597N
POLY 6	P=0.360N	P=0.088	P=0.422	P=0.555
RAO-SCOTT	P=0.318N	P=0.118	P=0.424	P=0.583
LITTER C-A/FISHERS	P=0.226N	P=0.189	P=0.500	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female

Adrenal Cortex
Extramedullary Hematopoiesis

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	2/25 (8%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	2/40.41	0/42.83	0/34.39
POLY-3 PERCENT (g)	0%	5%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	482	---	---

STATISTICAL TESTS

POLY 3	P=0.398N	P=0.229	(e)	(e)
POLY 1.5	P=0.392N	P=0.231	(e)	(e)
POLY 6	P=0.403N	P=0.229	(e)	(e)
RAO-SCOTT	P=0.468N	P=0.366	(e)	(e)
LITTER C-A/FISHERS	P=0.368N	P=0.245	(e)	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Adrenal Cortex				
Hyperplasia Focal				
<hr/>				
LESION RATES				
OVERALL (a)	3/50 (6%)	2/50 (4%)	4/50 (8%)	5/48 (10%)
LITTERS (b)	3/25 (12%)	2/25 (8%)	4/25 (16%)	5/25 (20%)
POLY-3 RATE (c)	3/42.51	2/39.26	4/42.96	5/35.74
POLY-3 PERCENT (g)	7.1%	5.1%	9.3%	14%
TERMINAL (d)	2/28 (7%)	0/24 (0%)	3/29 (10%)	2/20 (10%)
FIRST INCIDENCE	499	712	697	551
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.140	P=0.536N	P=0.506	P=0.264
POLY 1.5	P=0.155	P=0.525N	P=0.502	P=0.288
POLY 6	P=0.123	P=0.546N	P=0.510	P=0.235
RAO-SCOTT	P=0.135	P=0.516N	P=0.496	P=0.256
LITTER C-A/FISHERS	P=0.191	P=0.500N	P=0.500	P=0.351

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Adrenal Cortex				
Hypertrophy Focal				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/48 (0%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (c)	1/41.83	0/39.18	2/42.84	0/34.39
POLY-3 PERCENT (g)	2.4%	0%	4.7%	0%
TERMINAL (d)	1/28 (4%)	0/24 (0%)	1/29 (3%)	0/20 (0%)
FIRST INCIDENCE	729 (T)	---	726	---
STATISTICAL TESTS				
POLY 3	P=0.505N	P=0.513N	P=0.508	P=0.539N
POLY 1.5	P=0.489N	P=0.509N	P=0.504	P=0.527N
POLY 6	P=0.529N	P=0.516N	P=0.513	P=0.555N
RAO-SCOTT	P=0.502N	P=0.557N	P=0.545	P=0.559N
LITTER C-A/FISHERS	P=0.455N	P=0.500N	P=0.500	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Adrenal Cortex Necrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	2/48 (4%)
LITTERS (b)	0/25 (0%)	2/25 (8%)	1/25 (4%)	2/25 (8%)
POLY-3 RATE (c)	0/41.83	2/39.90	1/42.89	2/35.24
POLY-3 PERCENT (g)	0%	5%	2.3%	5.7%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	512	715	540
STATISTICAL TESTS				
POLY 3	P=0.259	P=0.226	P=0.505	P=0.200
POLY 1.5	P=0.275	P=0.229	P=0.503	P=0.210
POLY 6	P=0.240	P=0.225	P=0.508	P=0.188
RAO-SCOTT	P=0.286	P=0.274	P=0.546	P=0.238
LITTER C-A/FISHERS	P=0.315	P=0.245	P=0.500	P=0.245

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Adrenal Cortex Thrombus				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)	1/48 (2%)
LITTERS (b)	2/25 (8%)	1/25 (4%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	2/41.83	1/39.18	1/42.83	1/34.39
POLY-3 PERCENT (g)	4.8%	2.6%	2.3%	2.9%
TERMINAL (d)	2/28 (7%)	1/24 (4%)	1/29 (3%)	1/20 (5%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.532N	P=0.523N	P=0.492N	P=0.568N
POLY 1.5	P=0.521N	P=0.516N	P=0.496N	P=0.547N
POLY 6	P=0.545N	P=0.529N	P=0.487N	P=0.595N
RAO-SCOTT	P=0.517N	P=0.501N	P=0.481N	P=0.534N
LITTER C-A/FISHERS	P=0.488N	P=0.500N	P=0.500N	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Adrenal Cortex: Bilateral Degeneration Cystic				
LESION RATES				
OVERALL (a)	2/50 (4%)	3/50 (6%)	1/50 (2%)	0/48 (0%)
LITTERS (b)	2/25 (8%)	3/25 (12%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	2/41.89	3/39.18	1/42.89	0/34.39
POLY-3 PERCENT (g)	4.8%	7.7%	2.3%	0%
TERMINAL (d)	1/28 (4%)	3/24 (13%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	715	729 (T)	715	---
STATISTICAL TESTS				
POLY 3	P=0.131N	P=0.469	P=0.492N	P=0.283N
POLY 1.5	P=0.123N	P=0.479	P=0.496N	P=0.269N
POLY 6	P=0.142N	P=0.461	P=0.487N	P=0.303N
RAO-SCOTT	P=0.150N	P=0.479	P=0.511N	P=0.302N
LITTER C-A/FISHERS	P=0.101N	P=0.500	P=0.500N	P=0.245N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female

Adrenal Cortex: Bilateral
Hyperplasia Focal

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/48 (2%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	1/41.83	0/39.18	0/42.83	1/34.73
POLY-3 PERCENT (g)	2.4%	0%	0%	2.9%
TERMINAL (d)	1/28 (4%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	729 (T)	---	---	635

STATISTICAL TESTS

POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Adrenal Medulla Hyperplasia Focal				
LESION RATES				
OVERALL (a)	5/50 (10%)	7/50 (14%)	12/50 (24%)	8/48 (17%)
LITTERS (b)	5/25 (20%)	7/25 (28%)	9/25 (36%)	8/25 (32%)
POLY-3 RATE (c)	5/41.83	7/40.14	12/44.10	8/35.57
POLY-3 PERCENT (g)	12%	17.4%	27.2%	22.5%
TERMINAL (d)	5/28 (18%)	4/24 (17%)	6/29 (21%)	4/20 (20%)
FIRST INCIDENCE	729 (T)	615	608	586
STATISTICAL TESTS				
POLY 3	P=0.186	P=0.348	P=0.063	P=0.175
POLY 1.5	P=0.222	P=0.354	P=0.058	P=0.200
POLY 6	P=0.147	P=0.349	P=0.072	P=0.147
RAO-SCOTT	P=0.212	P=0.359	P=0.086	P=0.193
LITTER C-A/FISHERS	P=0.291	P=0.371	P=0.173	P=0.260

Experiment Number: 00058 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Black Cohosh
 CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
 Time Report Requested: 09:53:31
 First Dose M/F: 07/03/12 / 07/02/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Adrenal Medulla: Bilateral Hyperplasia Focal				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	3/48 (6%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	3/25 (12%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	3/34.87
POLY-3 PERCENT (g)	0%	0%	0%	8.6%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	2/20 (10%)
FIRST INCIDENCE	---	---	---	586
STATISTICAL TESTS				
POLY 3	P=0.006**	(e)	(e)	P=0.088
POLY 1.5	P=0.006**	(e)	(e)	P=0.097
POLY 6	P=0.005**	(e)	(e)	P=0.079
RAO-SCOTT	P=0.037*	(e)	(e)	P=0.209
LITTER C-A/FISHERS	P=0.008**	(e)	(e)	P=0.117

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Blood Vessel				
Mineral				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/48 (0%)	2/48 (4%)	1/43 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	2/25 (8%)	1/25 (4%)
POLY-3 RATE (c)	0/40.83	0/37.18	2/41.13	1/30.19
POLY-3 PERCENT (g)	0%	0%	4.9%	3.3%
TERMINAL (d)	0/27 (0%)	0/22 (0%)	1/28 (4%)	1/17 (6%)
FIRST INCIDENCE	---	---	704	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.254	(e)	P=0.238	P=0.440
POLY 1.5	P=0.278	(e)	P=0.236	P=0.453
POLY 6	P=0.221	(e)	P=0.242	P=0.423
RAO-SCOTT	P=0.318	(e)	P=0.335	P=0.492
LITTER C-A/FISHERS	P=0.349	(e)	P=0.245	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Blood Vessel: Aorta Dilation				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/48 (0%)	0/48 (0%)	0/43 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/40.83	0/37.18	0/41.03	0/30.19
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/27 (0%)	0/22 (0%)	0/28 (0%)	0/17 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Bone Marrow Hemorrhage				
LESION RATES				
OVERALL (a)	10/50 (20%)	0/50 (0%)	0/50 (0%)	9/50 (18%)
LITTERS (b)	8/25 (32%)	0/25 (0%)	0/25 (0%)	9/25 (36%)
POLY-3 RATE (c)	10/42.67	0/39.18	0/42.83	9/39.36
POLY-3 PERCENT (g)	23.4%	0%	0%	22.9%
TERMINAL (d)	6/28 (21%)	0/24 (0%)	0/29 (0%)	2/20 (10%)
FIRST INCIDENCE	556	---	---	475
STATISTICAL TESTS				
POLY 3	P=0.114	P<0.001N**	P<0.001N**	P=0.580N
POLY 1.5	P=0.115	P<0.001N**	P<0.001N**	P=0.553N
POLY 6	P=0.112	P<0.001N**	P<0.001N**	P=0.592
RAO-SCOTT	P=0.142	P=0.007N**	P=0.005N**	P=0.578N
LITTER C-A/FISHERS	P=0.039*	P=0.002N**	P=0.002N**	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Bone Marrow Hypercellularity				
LESION RATES				
OVERALL (a)	31/50 (62%)	31/50 (62%)	34/50 (68%)	42/50 (84%)
LITTERS (b)	19/25 (76%)	22/25 (88%)	22/25 (88%)	24/25 (96%)
POLY-3 RATE (c)	31/48.66	31/47.80	34/48.26	42/48.67
POLY-3 PERCENT (g)	63.7%	64.9%	70.5%	86.3%
TERMINAL (d)	12/28 (43%)	10/24 (42%)	19/29 (66%)	14/20 (70%)
FIRST INCIDENCE	499	302	360	430
STATISTICAL TESTS				
POLY 3	P=0.003**	P=0.538	P=0.310	P=0.008**
POLY 1.5	P=0.003**	P=0.551	P=0.326	P=0.007**
POLY 6	P=0.004**	P=0.523	P=0.279	P=0.009**
RAO-SCOTT	P=0.008**	P=0.545	P=0.334	P=0.016*
LITTER C-A/FISHERS	P=0.061	P=0.232	P=0.232	P=0.049*

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Bone Marrow Myelofibrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/35.85
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Bone				
Osteopetrosis				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/35.85
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Brain				
Gliososis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	2/36.47
POLY-3 PERCENT (g)	0%	0%	0%	5.5%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	637
STATISTICAL TESTS				
POLY 3	P=0.036*	(e)	(e)	P=0.207
POLY 1.5	P=0.037*	(e)	(e)	P=0.218
POLY 6	P=0.033*	(e)	(e)	P=0.194
RAO-SCOTT	P=0.113	(e)	(e)	P=0.352
LITTER C-A/FISHERS	P=0.041*	(e)	(e)	P=0.245

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Brain Hemorrhage				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/35.85
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Brain Necrosis				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	1/42.45	0/39.18	0/42.83	0/35.85
POLY-3 PERCENT (g)	2.4%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	530	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Eye: Cornea				
Inflammation Acute				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	1/36.22
POLY-3 PERCENT (g)	0%	0%	0%	2.8%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	625
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Eye: Cornea				
Inflammation Chronic				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/35.85
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Eye: Retina Degeneration				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/35.85
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Harderian Gland Atrophy				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/35.85
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Heart				
Cardiomyopathy				
LESION RATES				
OVERALL (a)	4/50 (8%)	9/50 (18%)	13/50 (26%)	9/48 (19%)
LITTERS (b)	4/25 (16%)	8/25 (32%)	12/25 (48%)	7/25 (28%)
POLY-3 RATE (c)	4/43.02	9/40.91	13/45.36	9/36.60
POLY-3 PERCENT (g)	9.3%	22%	28.7%	24.6%
TERMINAL (d)	1/28 (4%)	5/24 (21%)	5/29 (17%)	4/20 (20%)
FIRST INCIDENCE	521	512	538	532
STATISTICAL TESTS				
POLY 3	P=0.129	P=0.094	P=0.018*	P=0.060
POLY 1.5	P=0.159	P=0.099	P=0.016*	P=0.073
POLY 6	P=0.097	P=0.090	P=0.022*	P=0.047*
RAO-SCOTT	P=0.155	P=0.112	P=0.030*	P=0.075
LITTER C-A/FISHERS	P=0.421	P=0.160	P=0.016*	P=0.248

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Heart				
Mineral				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/34.57
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Heart				
Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/48 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	1/34.57
POLY-3 PERCENT (g)	0%	0%	0%	2.9%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	1/20 (5%)
FIRST INCIDENCE	---	---	---	729 (T)
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female

Heart: Atrium
Thrombus

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	1/39.39	0/42.83	0/34.57
POLY-3 PERCENT (g)	0%	2.5%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	672	---	---

STATISTICAL TESTS

POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female

Heart: Perivascular
Infiltration Cellular Lymphocyte

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/34.57
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Intestine Large, Cecum Erosion				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/49 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	1/35.61
POLY-3 PERCENT (g)	0%	0%	0%	2.8%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	600
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Intestine Large, Cecum Inflammation Chronic				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/35.17
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Intestine Large, Cecum Mineral				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/35.17
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Intestine Large, Cecum Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/49 (2%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	1/39.18	1/42.83	1/35.17
POLY-3 PERCENT (g)	0%	2.6%	2.3%	2.8%
TERMINAL (d)	0/28 (0%)	1/24 (4%)	1/29 (3%)	1/20 (5%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Intestine Large, Cecum Ulcer				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/35.17
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Intestine Large, Colon				
Parasite Metazoan				
<hr/>				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
LITTERS (b)	1/25 (4%)	1/25 (4%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	1/42.45	1/39.62	1/42.89	1/35.85
POLY-3 PERCENT (g)	2.4%	2.5%	2.3%	2.8%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	1/20 (5%)
FIRST INCIDENCE	530	600	715	729 (T)
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female

Intestine Large, Colon
Polyarteritis Nodosa

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	1/39.18	1/42.83	0/35.85
POLY-3 PERCENT (g)	0%	2.6%	2.3%	0%
TERMINAL (d)	0/28 (0%)	1/24 (4%)	1/29 (3%)	0/20 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---

STATISTICAL TESTS

POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Intestine Large, Colon: Lymphoid Tissue Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	2/42.83	0/35.85
POLY-3 PERCENT (g)	0%	0%	4.7%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	2/29 (7%)	0/20 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.702	(e)	P=0.242	(e)
POLY 1.5	P=0.723N	(e)	P=0.240	(e)
POLY 6	P=0.662	(e)	P=0.245	(e)
RAO-SCOTT	P=0.713N	(e)	P=0.374	(e)
LITTER C-A/FISHERS	P=0.698N	(e)	P=0.245	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Intestine Large, Rectum Parasite Metazoan				
LESION RATES				
OVERALL (a)	1/50 (2%)	4/50 (8%)	3/50 (6%)	3/50 (6%)
LITTERS (b)	1/25 (4%)	4/25 (16%)	3/25 (12%)	3/25 (12%)
POLY-3 RATE (c)	1/41.83	4/39.90	3/42.89	3/36.37
POLY-3 PERCENT (g)	2.4%	10%	7%	8.3%
TERMINAL (d)	1/28 (4%)	2/24 (8%)	2/29 (7%)	2/20 (10%)
FIRST INCIDENCE	729 (T)	482	715	571
STATISTICAL TESTS				
POLY 3	P=0.380	P=0.163	P=0.314	P=0.256
POLY 1.5	P=0.410	P=0.168	P=0.310	P=0.274
POLY 6	P=0.341	P=0.160	P=0.318	P=0.233
RAO-SCOTT	P=0.378	P=0.167	P=0.312	P=0.244
LITTER C-A/FISHERS	P=0.459	P=0.174	P=0.305	P=0.305

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Intestine Large, Rectum Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	3/50 (6%)
LITTERS (b)	0/25 (0%)	2/25 (8%)	2/25 (8%)	3/25 (12%)
POLY-3 RATE (c)	0/41.83	2/39.18	2/43.03	3/35.85
POLY-3 PERCENT (g)	0%	5.1%	4.7%	8.4%
TERMINAL (d)	0/28 (0%)	2/24 (8%)	1/29 (3%)	3/20 (15%)
FIRST INCIDENCE	---	729 (T)	676	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.115	P=0.222	P=0.243	P=0.093
POLY 1.5	P=0.130	P=0.227	P=0.240	P=0.102
POLY 6	P=0.097	P=0.218	P=0.247	P=0.081
RAO-SCOTT	P=0.136	P=0.250	P=0.281	P=0.116
LITTER C-A/FISHERS	P=0.151	P=0.245	P=0.245	P=0.117

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Intestine Small, Duodenum				
Polyarteritis Nodosa				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	1/42.83	0/35.85
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	1/29 (3%)	0/20 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Intestine Small, Jejunum				
Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	1/35.85
POLY-3 PERCENT (g)	0%	0%	0%	2.8%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	1/20 (5%)
FIRST INCIDENCE	---	---	---	729 (T)
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Islets, Pancreatic Hyperplasia				
LESION RATES				
OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)	1/49 (2%)
LITTERS (b)	2/25 (8%)	2/25 (8%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	2/42.02	2/39.86	1/42.83	1/35.88
POLY-3 PERCENT (g)	4.8%	5%	2.3%	2.8%
TERMINAL (d)	1/28 (4%)	1/24 (4%)	1/29 (3%)	0/20 (0%)
FIRST INCIDENCE	681	499	729 (T)	629
STATISTICAL TESTS				
POLY 3	P=0.423N	P=0.675	P=0.493N	P=0.555N
POLY 1.5	P=0.411N	P=0.680	P=0.496N	P=0.537N
POLY 6	P=0.439N	P=0.671	P=0.491N	P=0.579N
RAO-SCOTT	P=0.412N	P=0.654	P=0.485N	P=0.526N
LITTER C-A/FISHERS	P=0.380N	P=0.695	P=0.500N	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Kidney				
Calculus Micro Observation Only				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/34.89
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Kidney Hyperplasia Oncocytic				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/34.89
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Kidney Infarct				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/49 (4%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	2/35.50
POLY-3 PERCENT (g)	0%	0%	0%	5.6%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	1/20 (5%)
FIRST INCIDENCE	---	---	---	532
STATISTICAL TESTS				
POLY 3	P=0.034*	(e)	(e)	P=0.202
POLY 1.5	P=0.036*	(e)	(e)	P=0.213
POLY 6	P=0.031*	(e)	(e)	P=0.187
RAO-SCOTT	P=0.106	(e)	(e)	P=0.341
LITTER C-A/FISHERS	P=0.041*	(e)	(e)	P=0.245

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Kidney Inflammation Chronic				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/49 (4%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	2/36.00
POLY-3 PERCENT (g)	0%	0%	0%	5.6%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	532
STATISTICAL TESTS				
POLY 3	P=0.034*	(e)	(e)	P=0.205
POLY 1.5	P=0.036*	(e)	(e)	P=0.215
POLY 6	P=0.032*	(e)	(e)	P=0.192
RAO-SCOTT	P=0.107	(e)	(e)	P=0.343
LITTER C-A/FISHERS	P=0.041*	(e)	(e)	P=0.245

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Kidney				
Nephropathy Chronic Progressive				
LESION RATES				
OVERALL (a)	43/50 (86%)	40/50 (80%)	45/50 (90%)	47/49 (96%)
LITTERS (b)	25/25 (100%)	23/25 (92%)	25/25 (100%)	25/25 (100%)
POLY-3 RATE (c)	43/45.82	40/46.67	45/49.61	47/47.52
POLY-3 PERCENT (g)	93.9%	85.7%	90.7%	98.9%
TERMINAL (d)	28/28 (100%)	23/24 (96%)	26/29 (90%)	20/20 (100%)
FIRST INCIDENCE	536	302	360	430
STATISTICAL TESTS				
POLY 3	P=0.033*	P=0.127N	P=0.415N	P=0.128
POLY 1.5	P=0.017*	P=0.196N	P=0.626N	P=0.064
POLY 6	P=0.082	P=0.070N	P=0.180N	P=0.528
RAO-SCOTT	P=0.085	P=0.210N	P=0.456N	P=0.274
LITTER C-A/FISHERS	P=0.368	P=0.245N	P=1.000	P=1.000

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Kidney				
Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/49 (4%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	2/35.18
POLY-3 PERCENT (g)	0%	0%	0%	5.7%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	1/20 (5%)
FIRST INCIDENCE	---	---	---	650
STATISTICAL TESTS				
POLY 3	P=0.033*	(e)	(e)	P=0.200
POLY 1.5	P=0.035*	(e)	(e)	P=0.212
POLY 6	P=0.031*	(e)	(e)	P=0.185
RAO-SCOTT	P=0.108	(e)	(e)	P=0.345
LITTER C-A/FISHERS	P=0.041*	(e)	(e)	P=0.245

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Kidney: Pelvis Dilation				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	1/49 (2%)
LITTERS (b)	1/25 (4%)	2/25 (8%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	1/41.87	2/39.72	0/42.83	1/34.89
POLY-3 PERCENT (g)	2.4%	5%	0%	2.9%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	1/20 (5%)
FIRST INCIDENCE	719	588	---	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.584N	P=0.482	P=0.495N	P=0.719
POLY 1.5	P=0.576N	P=0.486	P=0.498N	P=0.734
POLY 6	P=0.592N	P=0.479	P=0.493N	P=0.697
RAO-SCOTT	P=0.579N	P=0.492	P=0.524N	P=0.693
LITTER C-A/FISHERS	P=0.552N	P=0.500	P=0.500N	P=0.755

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Kidney: Pelvis				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/49 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	1/35.57
POLY-3 PERCENT (g)	0%	0%	0%	2.8%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	501
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Kidney: Renal Tubule Accumulation, Hyaline Droplet				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/49 (2%)
LITTERS (b)	2/25 (8%)	0/25 (0%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	2/42.94	0/39.18	0/42.83	1/35.28
POLY-3 PERCENT (g)	4.7%	0%	0%	2.8%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	499	---	---	617
STATISTICAL TESTS				
POLY 3	P=0.650N	P=0.258N	P=0.237N	P=0.568N
POLY 1.5	P=0.653N	P=0.251N	P=0.238N	P=0.545N
POLY 6	P=0.646N	P=0.265N	P=0.238N	P=0.598N
RAO-SCOTT	P=0.673N	P=0.338N	P=0.331N	P=0.584N
LITTER C-A/FISHERS	P=0.651N	P=0.245N	P=0.245N	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Kidney: Renal Tubule Apoptosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	4/49 (8%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	4/25 (16%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	4/37.30
POLY-3 PERCENT (g)	0%	0%	0%	10.7%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	475
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	(e)	P=0.046*
POLY 1.5	P<0.001**	(e)	(e)	P=0.050*
POLY 6	P<0.001**	(e)	(e)	P=0.041*
RAO-SCOTT	P=0.012*	(e)	(e)	P=0.125
LITTER C-A/FISHERS	P=0.002**	(e)	(e)	P=0.055

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female

Kidney: Renal Tubule Cyst

LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/49 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	1/43.09	0/34.89
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	658	---

STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Liver Angiectasis				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/50 (2%)	2/50 (4%)	3/48 (6%)
LITTERS (b)	2/25 (8%)	1/25 (4%)	2/25 (8%)	3/25 (12%)
POLY-3 RATE (c)	2/42.51	1/39.18	2/42.83	3/34.57
POLY-3 PERCENT (g)	4.7%	2.6%	4.7%	8.7%
TERMINAL (d)	1/28 (4%)	1/24 (4%)	2/29 (7%)	3/20 (15%)
FIRST INCIDENCE	499	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.235	P=0.528N	P=0.692N	P=0.406
POLY 1.5	P=0.253	P=0.519N	P=0.693N	P=0.435
POLY 6	P=0.209	P=0.537N	P=0.690N	P=0.368
RAO-SCOTT	P=0.224	P=0.513N	P=0.678N	P=0.393
LITTER C-A/FISHERS	P=0.296	P=0.500N	P=0.695	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<hr/>				
Liver				
Basophilic Focus				
<hr/>				
LESION RATES				
OVERALL (a)	4/50 (8%)	3/50 (6%)	2/50 (4%)	0/48 (0%)
LITTERS (b)	4/25 (16%)	3/25 (12%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (c)	4/42.52	3/39.18	2/42.83	0/34.57
POLY-3 PERCENT (g)	9.4%	7.7%	4.7%	0%
TERMINAL (d)	1/28 (4%)	3/24 (13%)	2/29 (7%)	0/20 (0%)
FIRST INCIDENCE	597	729 (T)	729 (T)	---
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.063N	P=0.545N	P=0.333N	P=0.090N
POLY 1.5	P=0.057N	P=0.530N	P=0.335N	P=0.080N
POLY 6	P=0.072N	P=0.561N	P=0.333N	P=0.108N
RAO-SCOTT	P=0.071N	P=0.536N	P=0.347N	P=0.102N
LITTER C-A/FISHERS	P=0.042N*	P=0.500N	P=0.334N	P=0.055N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Liver				
Clear Cell Focus				
LESION RATES				
OVERALL (a)	15/50 (30%)	6/50 (12%)	8/50 (16%)	4/48 (8%)
LITTERS (b)	11/25 (44%)	5/25 (20%)	7/25 (28%)	4/25 (16%)
POLY-3 RATE (c)	15/42.22	6/39.19	8/43.73	4/34.57
POLY-3 PERCENT (g)	35.5%	15.3%	18.3%	11.6%
TERMINAL (d)	14/28 (50%)	5/24 (21%)	6/29 (21%)	4/20 (20%)
FIRST INCIDENCE	618	726	488	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.034N*	P=0.030N*	P=0.055N	P=0.013N*
POLY 1.5	P=0.028N*	P=0.028N*	P=0.064N	P=0.009N**
POLY 6	P=0.043N*	P=0.031N*	P=0.047N*	P=0.021N*
RAO-SCOTT	P=0.057N	P=0.053N	P=0.086N	P=0.028N*
LITTER C-A/FISHERS	P=0.074N	P=0.064N	P=0.189N	P=0.031N*

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Liver				
Degeneration Cystic				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/48 (4%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	2/34.57
POLY-3 PERCENT (g)	0%	0%	0%	5.8%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	2/20 (10%)
FIRST INCIDENCE	---	---	---	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.032*	(e)	(e)	P=0.196
POLY 1.5	P=0.034*	(e)	(e)	P=0.208
POLY 6	P=0.030*	(e)	(e)	P=0.181
RAO-SCOTT	P=0.103	(e)	(e)	P=0.337
LITTER C-A/FISHERS	P=0.041*	(e)	(e)	P=0.245

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Liver				
Eosinophilic Focus				
LESION RATES				
OVERALL (a)	10/50 (20%)	5/50 (10%)	10/50 (20%)	13/48 (27%)
LITTERS (b)	9/25 (36%)	5/25 (20%)	8/25 (32%)	11/25 (44%)
POLY-3 RATE (c)	10/43.00	5/40.17	10/44.18	13/35.91
POLY-3 PERCENT (g)	23.3%	12.5%	22.6%	36.2%
TERMINAL (d)	6/28 (21%)	3/24 (13%)	6/29 (21%)	10/20 (50%)
FIRST INCIDENCE	521	302	538	551
STATISTICAL TESTS				
POLY 3	P=0.035*	P=0.158N	P=0.574N	P=0.152
POLY 1.5	P=0.046*	P=0.148N	P=0.585N	P=0.196
POLY 6	P=0.023*	P=0.170N	P=0.560N	P=0.103
RAO-SCOTT	P=0.039*	P=0.173N	P=0.569N	P=0.167
LITTER C-A/FISHERS	P=0.137	P=0.173N	P=0.500N	P=0.387

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<hr/>				
Liver				
Extramedullary Hematopoiesis				
<hr/>				
LESION RATES				
OVERALL (a)	3/50 (6%)	5/50 (10%)	8/50 (16%)	5/48 (10%)
LITTERS (b)	3/25 (12%)	5/25 (20%)	7/25 (28%)	5/25 (20%)
POLY-3 RATE (c)	3/43.59	5/40.37	8/43.50	5/36.62
POLY-3 PERCENT (g)	6.9%	12.4%	18.4%	13.7%
TERMINAL (d)	0/28 (0%)	1/24 (4%)	5/29 (17%)	0/20 (0%)
FIRST INCIDENCE	499	386	538	478
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.299	P=0.314	P=0.096	P=0.264
POLY 1.5	P=0.334	P=0.328	P=0.097	P=0.289
POLY 6	P=0.255	P=0.301	P=0.094	P=0.234
RAO-SCOTT	P=0.317	P=0.318	P=0.111	P=0.266
LITTER C-A/FISHERS	P=0.415	P=0.351	P=0.145	P=0.351

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<hr/>				
Liver				
Hepatodiaphragmatic Nodule				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/48 (2%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	2/39.38	0/42.83	1/34.77
POLY-3 PERCENT (g)	0%	5.1%	0%	2.9%
TERMINAL (d)	0/28 (0%)	1/24 (4%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	675	---	675
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.569	P=0.223	(e)	P=0.463
POLY 1.5	P=0.585	P=0.227	(e)	P=0.474
POLY 6	P=0.550	P=0.221	(e)	P=0.449
RAO-SCOTT	P=0.637	P=0.451	(e)	P=0.664
LITTER C-A/FISHERS	P=0.463	P=0.500	(e)	P=0.500

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<hr/>				
Liver				
Mixed Cell Focus				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	1/39.18	0/42.83	0/34.57
POLY-3 PERCENT (g)	0%	2.6%	0%	0%
TERMINAL (d)	0/28 (0%)	1/24 (4%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	729 (T)	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Liver Necrosis				
LESION RATES				
OVERALL (a)	4/50 (8%)	10/50 (20%)	3/50 (6%)	9/48 (19%)
LITTERS (b)	4/25 (16%)	8/25 (32%)	3/25 (12%)	9/25 (36%)
POLY-3 RATE (c)	4/43.29	10/42.70	3/43.81	9/38.15
POLY-3 PERCENT (g)	9.2%	23.4%	6.9%	23.6%
TERMINAL (d)	0/28 (0%)	1/24 (4%)	1/29 (3%)	0/20 (0%)
FIRST INCIDENCE	504	482	360	475
STATISTICAL TESTS				
POLY 3	P=0.154	P=0.066	P=0.493N	P=0.070
POLY 1.5	P=0.169	P=0.066	P=0.495N	P=0.079
POLY 6	P=0.139	P=0.069	P=0.495N	P=0.060
RAO-SCOTT	P=0.173	P=0.091	P=0.503N	P=0.093
LITTER C-A/FISHERS	P=0.131	P=0.160	P=0.500N	P=0.098

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<hr/>				
Liver Pigment				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	3/50 (6%)	0/50 (0%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	3/25 (12%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	3/39.31	0/42.83	0/34.57
POLY-3 PERCENT (g)	0%	7.6%	0%	0%
TERMINAL (d)	0/28 (0%)	1/24 (4%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	712	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.291N	P=0.107	(e)	(e)
POLY 1.5	P=0.281N	P=0.111	(e)	(e)
POLY 6	P=0.302N	P=0.105	(e)	(e)
RAO-SCOTT	P=0.356N	P=0.210	(e)	(e)
LITTER C-A/FISHERS	P=0.253N	P=0.117	(e)	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<hr/>				
Liver				
Polyarteritis Nodosa				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/34.57
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<hr/>				
Liver: Bile Duct Cyst				
<hr/>				
LESION RATES				
OVERALL (a)	4/50 (8%)	7/50 (14%)	10/50 (20%)	8/48 (17%)
LITTERS (b)	4/25 (16%)	7/25 (28%)	9/25 (36%)	7/25 (28%)
POLY-3 RATE (c)	4/42.28	7/39.18	10/44.29	8/35.86
POLY-3 PERCENT (g)	9.5%	17.9%	22.6%	22.3%
TERMINAL (d)	3/28 (11%)	7/24 (29%)	4/29 (14%)	6/20 (30%)
FIRST INCIDENCE	597	729 (T)	643	478
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.141	P=0.216	P=0.084	P=0.103
POLY 1.5	P=0.169	P=0.230	P=0.078	P=0.122
POLY 6	P=0.106	P=0.201	P=0.094	P=0.079
RAO-SCOTT	P=0.155	P=0.221	P=0.097	P=0.111
LITTER C-A/FISHERS	P=0.345	P=0.248	P=0.098	P=0.248

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female

Liver: Bile Duct
Dilation

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	3/50 (6%)	1/48 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	3/25 (12%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	0/39.18	3/42.83	1/34.57
POLY-3 PERCENT (g)	0%	0%	7%	2.9%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	3/29 (10%)	1/20 (5%)
FIRST INCIDENCE	---	---	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.299	(e)	P=0.122	P=0.462
POLY 1.5	P=0.326	(e)	P=0.121	P=0.473
POLY 6	P=0.260	(e)	P=0.124	P=0.446
RAO-SCOTT	P=0.359	(e)	P=0.198	P=0.506
LITTER C-A/FISHERS	P=0.380	(e)	P=0.117	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<hr/>				
Liver: Bile Duct Hyperplasia				
<hr/>				
LESION RATES				
OVERALL (a)	11/50 (22%)	14/50 (28%)	14/50 (28%)	9/48 (19%)
LITTERS (b)	9/25 (36%)	11/25 (44%)	12/25 (48%)	8/25 (32%)
POLY-3 RATE (c)	11/42.87	14/40.32	14/44.46	9/36.44
POLY-3 PERCENT (g)	25.7%	34.7%	31.5%	24.7%
TERMINAL (d)	7/28 (25%)	9/24 (38%)	10/29 (35%)	4/20 (20%)
FIRST INCIDENCE	556	614	538	478
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.373N	P=0.251	P=0.356	P=0.564N
POLY 1.5	P=0.329N	P=0.272	P=0.341	P=0.519N
POLY 6	P=0.439N	P=0.236	P=0.374	P=0.584
RAO-SCOTT	P=0.357N	P=0.255	P=0.358	P=0.548N
LITTER C-A/FISHERS	P=0.319N	P=0.387	P=0.284	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Lung Hemorrhage				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/34.57
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Lung				
Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	39/50 (78%)	38/50 (76%)	45/50 (90%)	46/48 (96%)
LITTERS (b)	22/25 (88%)	22/25 (88%)	24/25 (96%)	25/25 (100%)
POLY-3 RATE (c)	39/48.31	38/46.24	45/49.69	46/46.61
POLY-3 PERCENT (g)	80.7%	82.2%	90.6%	98.7%
TERMINAL (d)	21/28 (75%)	22/24 (92%)	25/29 (86%)	20/20 (100%)
FIRST INCIDENCE	499	332	360	430
STATISTICAL TESTS				
POLY 3	P=0.002**	P=0.534	P=0.128	P=0.003**
POLY 1.5	P<0.001**	P=0.591	P=0.108	P=0.003**
POLY 6	P=0.002**	P=0.464	P=0.153	P=0.003**
RAO-SCOTT	P=0.012*	P=0.559	P=0.205	P=0.023*
LITTER C-A/FISHERS	P=0.061	P=0.666	P=0.305	P=0.117

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Lung Inflammation Acute				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	2/48 (4%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (c)	1/41.83	0/39.18	0/42.83	2/35.54
POLY-3 PERCENT (g)	2.4%	0%	0%	5.6%
TERMINAL (d)	1/28 (4%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	729 (T)	---	---	478
STATISTICAL TESTS				
POLY 3	P=0.169	P=0.513N	P=0.495N	P=0.443
POLY 1.5	P=0.173	P=0.509N	P=0.498N	P=0.459
POLY 6	P=0.163	P=0.516N	P=0.493N	P=0.422
RAO-SCOTT	P=0.224	P=0.590N	P=0.594N	P=0.493
LITTER C-A/FISHERS	P=0.187	P=0.500N	P=0.500N	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Lung				
Inflammation Chronic				
<hr/>				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	4/50 (8%)	1/48 (2%)
LITTERS (b)	1/25 (4%)	1/25 (4%)	4/25 (16%)	1/25 (4%)
POLY-3 RATE (c)	1/41.83	1/39.18	4/42.83	1/35.07
POLY-3 PERCENT (g)	2.4%	2.6%	9.3%	2.9%
TERMINAL (d)	1/28 (4%)	1/24 (4%)	4/29 (14%)	0/20 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	578
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.573	P=0.746	P=0.185	P=0.720
POLY 1.5	P=0.600	P=0.750	P=0.182	P=0.732
POLY 6	P=0.531	P=0.743	P=0.188	P=0.704
RAO-SCOTT	P=0.579	P=0.728	P=0.220	P=0.696
LITTER C-A/FISHERS	P=0.602N	P=0.755	P=0.174	P=0.755

Experiment Number: 00058 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Black Cohosh
 CAS Number: 84776-26-1

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 First Dose M/F: 07/03/12 / 07/02/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Lung				
Inflammation Granulomatous				
LESION RATES				
OVERALL (a)	7/50 (14%)	6/50 (12%)	16/50 (32%)	10/48 (21%)
LITTERS (b)	7/25 (28%)	6/25 (24%)	13/25 (52%)	8/25 (32%)
POLY-3 RATE (c)	7/42.82	6/40.28	16/43.99	10/35.97
POLY-3 PERCENT (g)	16.4%	14.9%	36.4%	27.8%
TERMINAL (d)	5/28 (18%)	3/24 (13%)	11/29 (38%)	6/20 (30%)
FIRST INCIDENCE	536	614	638	571
STATISTICAL TESTS				
POLY 3	P=0.098	P=0.548N	P=0.027*	P=0.168
POLY 1.5	P=0.129	P=0.535N	P=0.027*	P=0.201
POLY 6	P=0.065	P=0.555N	P=0.029*	P=0.130
RAO-SCOTT	P=0.125	P=0.542N	P=0.044*	P=0.186
LITTER C-A/FISHERS	P=0.411	P=0.500N	P=0.074	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Lung				
Mineral				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/48 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/34.57
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Lung				
Squamous Metaplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	4/48 (8%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	0/25 (0%)	4/25 (16%)
POLY-3 RATE (c)	0/41.83	1/39.18	0/42.83	4/35.55
POLY-3 PERCENT (g)	0%	2.6%	0%	11.3%
TERMINAL (d)	0/28 (0%)	1/24 (4%)	0/29 (0%)	1/20 (5%)
FIRST INCIDENCE	---	729 (T)	---	629
STATISTICAL TESTS				
POLY 3	P=0.007**	P=0.487	(e)	P=0.041*
POLY 1.5	P=0.007**	P=0.491	(e)	P=0.046*
POLY 6	P=0.006**	P=0.484	(e)	P=0.036*
RAO-SCOTT	P=0.025*	P=0.573	(e)	P=0.100
LITTER C-A/FISHERS	P=0.010**	P=0.500	(e)	P=0.055

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<hr/>				
Lung Thrombus				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/48 (4%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	2/35.59
POLY-3 PERCENT (g)	0%	0%	0%	5.6%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	509
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.033*	(e)	(e)	P=0.202
POLY 1.5	P=0.035*	(e)	(e)	P=0.211
POLY 6	P=0.031*	(e)	(e)	P=0.190
RAO-SCOTT	P=0.103	(e)	(e)	P=0.337
LITTER C-A/FISHERS	P=0.041*	(e)	(e)	P=0.245

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Lung: Alveolar Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	4/50 (8%)	2/50 (4%)	1/50 (2%)	1/48 (2%)
LITTERS (b)	4/25 (16%)	2/25 (8%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	4/42.86	2/40.03	1/43.14	1/34.77
POLY-3 PERCENT (g)	9.3%	5%	2.3%	2.9%
TERMINAL (d)	1/28 (4%)	1/24 (4%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	597	386	644	675
STATISTICAL TESTS				
POLY 3	P=0.212N	P=0.369N	P=0.176N	P=0.248N
POLY 1.5	P=0.203N	P=0.358N	P=0.177N	P=0.225N
POLY 6	P=0.224N	P=0.382N	P=0.175N	P=0.283N
RAO-SCOTT	P=0.226N	P=0.370N	P=0.193N	P=0.248N
LITTER C-A/FISHERS	P=0.172N	P=0.334N	P=0.174N	P=0.174N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Lymph Node, Mandibular Ectasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/34.89
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Lymph Node, Mandibular Infiltration Cellular Plasma Cell				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/49 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	2/43.25	0/34.89
POLY-3 PERCENT (g)	0%	0%	4.6%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	1/29 (3%)	0/20 (0%)
FIRST INCIDENCE	---	---	608	---
STATISTICAL TESTS				
POLY 3	P=0.695	(e)	P=0.244	(e)
POLY 1.5	P=0.722	(e)	P=0.241	(e)
POLY 6	P=0.651	(e)	P=0.249	(e)
RAO-SCOTT	P=0.715N	(e)	P=0.371	(e)
LITTER C-A/FISHERS	P=0.698N	(e)	P=0.245	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Lymph Node, Mandibular Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/34.89
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Lymph Node: Renal Ectasia				
LESION RATES				
OVERALL (a)	0/0 (0%)	0/6 (0%)	0/0 (0%)	0/3 (0%)
LITTERS (b)	0/0 (0%)	0/5 (0%)	0/0 (0%)	0/2 (0%)
POLY-3 RATE (c)	0/0.00	0/4.36	0/0.00	0/1.58
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Mammary Gland Galactocele				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	4/50 (8%)	2/49 (4%)
LITTERS (b)	2/25 (8%)	0/25 (0%)	4/25 (16%)	2/25 (8%)
POLY-3 RATE (c)	2/41.97	0/39.18	4/43.26	2/36.06
POLY-3 PERCENT (g)	4.8%	0%	9.3%	5.6%
TERMINAL (d)	1/28 (4%)	0/24 (0%)	3/29 (10%)	1/20 (5%)
FIRST INCIDENCE	693	---	605	675
STATISTICAL TESTS				
POLY 3	P=0.384	P=0.252N	P=0.351	P=0.639
POLY 1.5	P=0.413	P=0.248N	P=0.344	P=0.660
POLY 6	P=0.344	P=0.257N	P=0.358	P=0.608
RAO-SCOTT	P=0.384	P=0.260N	P=0.362	P=0.615
LITTER C-A/FISHERS	P=0.450	P=0.245N	P=0.334	P=0.695

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Mammary Gland Hyperplasia				
LESION RATES				
OVERALL (a)	13/50 (26%)	8/50 (16%)	4/50 (8%)	2/49 (4%)
LITTERS (b)	11/25 (44%)	8/25 (32%)	3/25 (12%)	2/25 (8%)
POLY-3 RATE (c)	13/43.27	8/39.58	4/42.83	2/36.10
POLY-3 PERCENT (g)	30.1%	20.2%	9.3%	5.5%
TERMINAL (d)	8/28 (29%)	7/24 (29%)	4/29 (14%)	1/20 (5%)
FIRST INCIDENCE	504	615	729 (T)	661
STATISTICAL TESTS				
POLY 3	P=0.004N**	P=0.217N	P=0.014N*	P=0.005N**
POLY 1.5	P=0.003N**	P=0.198N	P=0.014N*	P=0.003N**
POLY 6	P=0.005N**	P=0.239N	P=0.013N*	P=0.009N**
RAO-SCOTT	P=0.007N**	P=0.229N	P=0.022N*	P=0.009N**
LITTER C-A/FISHERS	P=0.004N**	P=0.280N	P=0.013N*	P=0.004N**

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<hr/>				
Nose				
Foreign Body				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	2/25 (8%)	2/25 (8%)
POLY-3 RATE (c)	0/41.83	0/39.18	2/43.43	2/36.58
POLY-3 PERCENT (g)	0%	0%	4.6%	5.5%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	1/29 (3%)	0/20 (0%)
FIRST INCIDENCE	---	---	538	586
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.097	(e)	P=0.245	P=0.208
POLY 1.5	P=0.106	(e)	P=0.242	P=0.219
POLY 6	P=0.085	(e)	P=0.250	P=0.195
RAO-SCOTT	P=0.151	(e)	P=0.342	P=0.283
LITTER C-A/FISHERS	P=0.119	(e)	P=0.245	P=0.245

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Nose Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
LITTERS (b)	0/25 (0%)	2/25 (8%)	1/25 (4%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	2/39.70	1/42.83	1/36.10
POLY-3 PERCENT (g)	0%	5%	2.3%	2.8%
TERMINAL (d)	0/28 (0%)	1/24 (4%)	1/29 (3%)	0/20 (0%)
FIRST INCIDENCE	---	570	729 (T)	661
STATISTICAL TESTS				
POLY 3	P=0.561	P=0.225	P=0.505	P=0.471
POLY 1.5	P=0.583	P=0.228	P=0.502	P=0.482
POLY 6	P=0.532	P=0.223	P=0.507	P=0.456
RAO-SCOTT	P=0.560	P=0.260	P=0.532	P=0.467
LITTER C-A/FISHERS	P=0.620	P=0.245	P=0.500	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Nose				
Inflammation Acute				
<hr/>				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	3/50 (6%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	2/25 (8%)	3/25 (12%)
POLY-3 RATE (c)	1/42.50	0/39.18	2/43.63	3/35.89
POLY-3 PERCENT (g)	2.4%	0%	4.6%	8.4%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	2/20 (10%)
FIRST INCIDENCE	504	---	538	719
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.080	P=0.516N	P=0.509	P=0.247
POLY 1.5	P=0.089	P=0.511N	P=0.505	P=0.269
POLY 6	P=0.068	P=0.521N	P=0.515	P=0.219
RAO-SCOTT	P=0.100	P=0.539N	P=0.535	P=0.276
LITTER C-A/FISHERS	P=0.101	P=0.500N	P=0.500	P=0.305

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Nose				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	4/50 (8%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	1/25 (4%)	4/25 (16%)
POLY-3 RATE (c)	1/41.83	0/39.18	1/42.83	4/36.96
POLY-3 PERCENT (g)	2.4%	0%	2.3%	10.8%
TERMINAL (d)	1/28 (4%)	0/24 (0%)	1/29 (3%)	1/20 (5%)
FIRST INCIDENCE	729 (T)	---	729 (T)	571
STATISTICAL TESTS				
POLY 3	P=0.019*	P=0.513N	P=0.756N	P=0.142
POLY 1.5	P=0.021*	P=0.509N	P=0.758N	P=0.155
POLY 6	P=0.017*	P=0.516N	P=0.753N	P=0.127
RAO-SCOTT	P=0.037*	P=0.555N	P=0.759N	P=0.192
LITTER C-A/FISHERS	P=0.023*	P=0.500N	P=0.755	P=0.174

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Nose: Nasolacrimal Duct Inflammation Chronic				
LESION RATES				
OVERALL (a)	4/50 (8%)	0/50 (0%)	2/50 (4%)	5/50 (10%)
LITTERS (b)	4/25 (16%)	0/25 (0%)	2/25 (8%)	4/25 (16%)
POLY-3 RATE (c)	4/42.93	0/39.18	2/43.09	5/37.90
POLY-3 PERCENT (g)	9.3%	0%	4.6%	13.2%
TERMINAL (d)	2/28 (7%)	0/24 (0%)	1/29 (3%)	1/20 (5%)
FIRST INCIDENCE	504	---	658	540
STATISTICAL TESTS				
POLY 3	P=0.117	P=0.072N	P=0.335N	P=0.422
POLY 1.5	P=0.123	P=0.068N	P=0.337N	P=0.450
POLY 6	P=0.109	P=0.076N	P=0.333N	P=0.386
RAO-SCOTT	P=0.149	P=0.127N	P=0.390N	P=0.451
LITTER C-A/FISHERS	P=0.261	P=0.055N	P=0.334N	P=0.649

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Nose: Respiratory Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	2/25 (8%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	1/39.18	2/43.76	1/36.46
POLY-3 PERCENT (g)	0%	2.6%	4.6%	2.7%
TERMINAL (d)	0/28 (0%)	1/24 (4%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	729 (T)	538	532
STATISTICAL TESTS				
POLY 3	P=0.440	P=0.487	P=0.247	P=0.473
POLY 1.5	P=0.463	P=0.491	P=0.243	P=0.483
POLY 6	P=0.406	P=0.484	P=0.253	P=0.459
RAO-SCOTT	P=0.449	P=0.485	P=0.279	P=0.458
LITTER C-A/FISHERS	P=0.500	P=0.500	P=0.245	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Ovary Atrophy				
LESION RATES				
OVERALL (a)	32/50 (64%)	39/50 (78%)	38/50 (76%)	47/49 (96%)
LITTERS (b)	21/25 (84%)	23/25 (92%)	24/25 (96%)	25/25 (100%)
POLY-3 RATE (c)	32/44.76	39/47.12	38/46.77	47/47.50
POLY-3 PERCENT (g)	71.5%	82.8%	81.3%	99%
TERMINAL (d)	22/28 (79%)	19/24 (79%)	24/29 (83%)	20/20 (100%)
FIRST INCIDENCE	536	302	538	430
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.133	P=0.180	P<0.001**
POLY 1.5	P<0.001**	P=0.106	P=0.152	P<0.001**
POLY 6	P<0.001**	P=0.198	P=0.236	P<0.001**
RAO-SCOTT	P<0.001**	P=0.173	P=0.220	P<0.001**
LITTER C-A/FISHERS	P=0.049*	P=0.334	P=0.174	P=0.055

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Ovary Cyst				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	4/49 (8%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	0/25 (0%)	4/25 (16%)
POLY-3 RATE (c)	1/42.22	0/39.18	0/42.83	4/35.62
POLY-3 PERCENT (g)	2.4%	0%	0%	11.2%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	2/20 (10%)
FIRST INCIDENCE	618	---	---	600
STATISTICAL TESTS				
POLY 3	P=0.010**	P=0.515N	P=0.497N	P=0.130
POLY 1.5	P=0.011*	P=0.510N	P=0.498N	P=0.145
POLY 6	P=0.009**	P=0.520N	P=0.496N	P=0.112
RAO-SCOTT	P=0.026*	P=0.578N	P=0.582N	P=0.193
LITTER C-A/FISHERS	P=0.014*	P=0.500N	P=0.500N	P=0.174

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
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First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Ovary: Bursa Cyst				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	0/49 (0%)
LITTERS (b)	1/25 (4%)	2/25 (8%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (c)	1/41.92	2/39.24	2/43.06	0/34.89
POLY-3 PERCENT (g)	2.4%	5.1%	4.6%	0%
TERMINAL (d)	0/28 (0%)	1/24 (4%)	1/29 (3%)	0/20 (0%)
FIRST INCIDENCE	708	712	668	---
STATISTICAL TESTS				
POLY 3	P=0.300N	P=0.477	P=0.509	P=0.536N
POLY 1.5	P=0.281N	P=0.484	P=0.505	P=0.524N
POLY 6	P=0.327N	P=0.471	P=0.515	P=0.554N
RAO-SCOTT	P=0.293N	P=0.485	P=0.524	P=0.522N
LITTER C-A/FISHERS	P=0.243N	P=0.500	P=0.500	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Ovary: Follicle Cyst				
LESION RATES				
OVERALL (a)	13/50 (26%)	7/50 (14%)	9/50 (18%)	6/49 (12%)
LITTERS (b)	11/25 (44%)	7/25 (28%)	8/25 (32%)	6/25 (24%)
POLY-3 RATE (c)	13/44.98	7/40.15	9/44.38	6/36.12
POLY-3 PERCENT (g)	28.9%	17.4%	20.3%	16.6%
TERMINAL (d)	5/28 (18%)	4/24 (17%)	6/29 (21%)	3/20 (15%)
FIRST INCIDENCE	499	588	538	578
STATISTICAL TESTS				
POLY 3	P=0.200N	P=0.160N	P=0.241N	P=0.150N
POLY 1.5	P=0.167N	P=0.139N	P=0.239N	P=0.112N
POLY 6	P=0.251N	P=0.184N	P=0.246N	P=0.212N
RAO-SCOTT	P=0.213N	P=0.168N	P=0.250N	P=0.154N
LITTER C-A/FISHERS	P=0.166N	P=0.189N	P=0.280N	P=0.116N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Ovary: Periovarian Tissue Cyst				
LESION RATES				
OVERALL (a)	1/50 (2%)	3/50 (6%)	3/50 (6%)	0/49 (0%)
LITTERS (b)	1/25 (4%)	3/25 (12%)	3/25 (12%)	0/25 (0%)
POLY-3 RATE (c)	1/41.83	3/39.82	3/43.16	0/34.89
POLY-3 PERCENT (g)	2.4%	7.5%	7%	0%
TERMINAL (d)	1/28 (4%)	1/24 (4%)	2/29 (7%)	0/20 (0%)
FIRST INCIDENCE	729 (T)	605	638	---
STATISTICAL TESTS				
POLY 3	P=0.257N	P=0.287	P=0.316	P=0.536N
POLY 1.5	P=0.233N	P=0.291	P=0.311	P=0.524N
POLY 6	P=0.291N	P=0.285	P=0.322	P=0.553N
RAO-SCOTT	P=0.252N	P=0.317	P=0.351	P=0.525N
LITTER C-A/FISHERS	P=0.189N	P=0.305	P=0.305	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Pancreas				
Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	3/49 (6%)
LITTERS (b)	1/25 (4%)	2/25 (8%)	1/25 (4%)	3/25 (12%)
POLY-3 RATE (c)	1/41.83	2/39.18	1/42.83	3/35.86
POLY-3 PERCENT (g)	2.4%	5.1%	2.3%	8.4%
TERMINAL (d)	1/28 (4%)	2/24 (8%)	1/29 (3%)	2/20 (10%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	637
STATISTICAL TESTS				
POLY 3	P=0.203	P=0.477	P=0.756N	P=0.251
POLY 1.5	P=0.217	P=0.484	P=0.758N	P=0.268
POLY 6	P=0.186	P=0.471	P=0.753N	P=0.229
RAO-SCOTT	P=0.215	P=0.482	P=0.746N	P=0.269
LITTER C-A/FISHERS	P=0.243	P=0.500	P=0.755	P=0.305

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female

Pancreas: Acinus
Atrophy

LESION RATES

OVERALL (a)	3/50 (6%)	2/50 (4%)	0/50 (0%)	2/49 (4%)
LITTERS (b)	3/25 (12%)	2/25 (8%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (c)	3/41.92	2/39.31	0/42.83	2/36.38
POLY-3 PERCENT (g)	7.2%	5.1%	0%	5.5%
TERMINAL (d)	2/28 (7%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	706	712	---	571

STATISTICAL TESTS

POLY 3	P=0.537N	P=0.529N	P=0.114N	P=0.565N
POLY 1.5	P=0.531N	P=0.521N	P=0.117N	P=0.544N
POLY 6	P=0.545N	P=0.536N	P=0.112N	P=0.591N
RAO-SCOTT	P=0.545N	P=0.526N	P=0.145N	P=0.553N
LITTER C-A/FISHERS	P=0.510N	P=0.500N	P=0.117N	P=0.500N

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Pancreas: Acinus Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/35.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Parathyroid Gland Hyperplasia Diffuse				
LESION RATES				
OVERALL (a)	0/46 (0%)	1/40 (3%)	0/39 (0%)	0/38 (0%)
LITTERS (b)	0/25 (0%)	1/24 (4%)	0/23 (0%)	0/24 (0%)
POLY-3 RATE (c)	0/38.50	1/31.58	0/33.56	0/27.26
POLY-3 PERCENT (g)	0%	3.2%	0%	0%
TERMINAL (d)	0/25 (0%)	0/20 (0%)	0/23 (0%)	0/15 (0%)
FIRST INCIDENCE	---	672	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

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Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female

Peripheral Nerve: Axon, Trigeminal Degeneration

LESION RATES

OVERALL (a)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
LITTERS (b)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (c)	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Pituitary Gland: Pars Distalis Hyperplasia				
LESION RATES				
OVERALL (a)	18/50 (36%)	18/50 (36%)	19/50 (38%)	24/50 (48%)
LITTERS (b)	13/25 (52%)	16/25 (64%)	13/25 (52%)	20/25 (80%)
POLY-3 RATE (c)	18/42.90	18/41.85	19/44.41	24/42.15
POLY-3 PERCENT (g)	42%	43%	42.8%	56.9%
TERMINAL (d)	14/28 (50%)	13/24 (54%)	13/29 (45%)	11/20 (55%)
FIRST INCIDENCE	578	386	608	478
STATISTICAL TESTS				
POLY 3	P=0.072	P=0.550	P=0.556	P=0.113
POLY 1.5	P=0.077	P=0.554	P=0.529	P=0.120
POLY 6	P=0.068	P=0.548	P=0.586N	P=0.108
RAO-SCOTT	P=0.093	P=0.544	P=0.552	P=0.140
LITTER C-A/FISHERS	P=0.037*	P=0.284	P=0.611	P=0.036*

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Skin				
Cyst Epithelial Inclusion				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/35.85
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Skin				
Inflammation Chronic				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	1/42.84	0/35.85
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	726	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Skin				
Ulcer				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/35.85
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Skin: Epidermis				
Hyperplasia				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	0/39.18	0/42.83	0/35.85
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Spleen				
Extramedullary Hematopoiesis				
LESION RATES				
OVERALL (a)	47/50 (94%)	48/50 (96%)	47/50 (94%)	47/49 (96%)
LITTERS (b)	25/25 (100%)	25/25 (100%)	25/25 (100%)	25/25 (100%)
POLY-3 RATE (c)	47/49.26	48/48.69	47/49.09	47/47.88
POLY-3 PERCENT (g)	95.4%	98.6%	95.8%	98.2%
TERMINAL (d)	28/28 (100%)	24/24 (100%)	29/29 (100%)	20/20 (100%)
FIRST INCIDENCE	499	302	360	4
STATISTICAL TESTS				
POLY 3	P=0.438	P=0.354	P=0.676	P=0.412
POLY 1.5	P=0.471	P=0.391	P=0.673	P=0.451
POLY 6	P=0.395	P=0.350	P=0.668	P=0.381
RAO-SCOTT	P=0.454	P=0.382	P=0.661	P=0.433
LITTER C-A/FISHERS	(e)	P=1.000	P=1.000	P=1.000

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Spleen Pigment				
LESION RATES				
OVERALL (a)	35/50 (70%)	34/50 (68%)	37/50 (74%)	21/49 (43%)
LITTERS (b)	22/25 (88%)	23/25 (92%)	23/25 (92%)	16/25 (64%)
POLY-3 RATE (c)	35/44.13	34/43.96	37/46.94	21/37.91
POLY-3 PERCENT (g)	79.3%	77.3%	78.8%	55.4%
TERMINAL (d)	27/28 (96%)	22/24 (92%)	23/29 (79%)	15/20 (75%)
FIRST INCIDENCE	524	332	538	498
STATISTICAL TESTS				
POLY 3	P=0.004N**	P=0.515N	P=0.586N	P=0.009N**
POLY 1.5	P=0.002N**	P=0.539N	P=0.514	P=0.007N**
POLY 6	P=0.010N**	P=0.417N	P=0.395N	P=0.012N*
RAO-SCOTT	P=0.007N**	P=0.507N	P=0.574N	P=0.020N*
LITTER C-A/FISHERS	P=0.004N**	P=0.500	P=0.500	P=0.048N*

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Spleen: White Pulp Atrophy				
LESION RATES				
OVERALL (a)	9/50 (18%)	10/50 (20%)	3/50 (6%)	9/49 (18%)
LITTERS (b)	9/25 (36%)	10/25 (40%)	3/25 (12%)	9/25 (36%)
POLY-3 RATE (c)	9/45.00	10/43.11	3/43.58	9/39.87
POLY-3 PERCENT (g)	20%	23.2%	6.9%	22.6%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	504	332	605	430
STATISTICAL TESTS				
POLY 3	P=0.501	P=0.458	P=0.066N	P=0.491
POLY 1.5	P=0.527	P=0.468	P=0.063N	P=0.525
POLY 6	P=0.460	P=0.457	P=0.069N	P=0.441
RAO-SCOTT	P=0.475	P=0.446	P=0.063N	P=0.475
LITTER C-A/FISHERS	P=0.550N	P=0.500	P=0.048N*	P=0.616

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Stomach, Forestomach Inflammation Acute				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	1/25 (4%)	1/25 (4%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	1/41.83	1/39.39	0/42.83	0/35.85
POLY-3 PERCENT (g)	2.4%	2.5%	0%	0%
TERMINAL (d)	1/28 (4%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	729 (T)	672	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Stomach, Forestomach Inflammation Chronic				
LESION RATES				
OVERALL (a)	3/50 (6%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
LITTERS (b)	3/25 (12%)	0/25 (0%)	2/25 (8%)	2/25 (8%)
POLY-3 RATE (c)	3/42.74	0/39.18	2/43.48	2/36.62
POLY-3 PERCENT (g)	7%	0%	4.6%	5.5%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	606	---	597	600
STATISTICAL TESTS				
POLY 3	P=0.530	P=0.134N	P=0.492N	P=0.570N
POLY 1.5	P=0.546	P=0.129N	P=0.496N	P=0.543N
POLY 6	P=0.507	P=0.141N	P=0.489N	P=0.605N
RAO-SCOTT	P=0.501	P=0.154N	P=0.498N	P=0.554N
LITTER C-A/FISHERS	P=0.570	P=0.117N	P=0.500N	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Stomach, Forestomach Mineral				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	3/50 (6%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	0/25 (0%)	3/25 (12%)
POLY-3 RATE (c)	1/42.06	0/39.18	0/42.83	3/36.77
POLY-3 PERCENT (g)	2.4%	0%	0%	8.2%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	670	---	---	600
STATISTICAL TESTS				
POLY 3	P=0.048*	P=0.514N	P=0.496N	P=0.258
POLY 1.5	P=0.050*	P=0.510N	P=0.498N	P=0.275
POLY 6	P=0.045*	P=0.519N	P=0.495N	P=0.237
RAO-SCOTT	P=0.081	P=0.575N	P=0.579N	P=0.318
LITTER C-A/FISHERS	P=0.053	P=0.500N	P=0.500N	P=0.305

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Stomach, Forestomach Polyarteritis Nodosa				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	1/25 (4%)	2/25 (8%)
POLY-3 RATE (c)	0/41.83	1/39.18	1/43.03	2/36.18
POLY-3 PERCENT (g)	0%	2.6%	2.3%	5.5%
TERMINAL (d)	0/28 (0%)	1/24 (4%)	0/29 (0%)	1/20 (5%)
FIRST INCIDENCE	---	729 (T)	676	637
STATISTICAL TESTS				
POLY 3	P=0.161	P=0.487	P=0.506	P=0.206
POLY 1.5	P=0.174	P=0.491	P=0.503	P=0.217
POLY 6	P=0.146	P=0.484	P=0.509	P=0.191
RAO-SCOTT	P=0.187	P=0.509	P=0.544	P=0.238
LITTER C-A/FISHERS	P=0.191	P=0.500	P=0.500	P=0.245

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<hr/>				
Stomach, Forestomach Ulcer				
<hr/>				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
LITTERS (b)	1/25 (4%)	1/25 (4%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	1/42.22	1/39.39	0/42.83	1/36.29
POLY-3 PERCENT (g)	2.4%	2.5%	0%	2.8%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	618	672	---	600
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Stomach, Forestomach: Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	3/50 (6%)	2/50 (4%)	1/50 (2%)	4/50 (8%)
LITTERS (b)	3/25 (12%)	2/25 (8%)	1/25 (4%)	4/25 (16%)
POLY-3 RATE (c)	3/42.31	2/39.39	1/43.03	4/36.29
POLY-3 PERCENT (g)	7.1%	5.1%	2.3%	11%
TERMINAL (d)	1/28 (4%)	1/24 (4%)	0/29 (0%)	2/20 (10%)
FIRST INCIDENCE	618	672	676	637
STATISTICAL TESTS				
POLY 3	P=0.261	P=0.533N	P=0.299N	P=0.416
POLY 1.5	P=0.277	P=0.523N	P=0.302N	P=0.448
POLY 6	P=0.240	P=0.542N	P=0.296N	P=0.374
RAO-SCOTT	P=0.247	P=0.523N	P=0.314N	P=0.410
LITTER C-A/FISHERS	P=0.299	P=0.500N	P=0.305N	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Stomach, Glandular Mineral				
LESION RATES				
OVERALL (a)	2/50 (4%)	4/50 (8%)	5/50 (10%)	2/50 (4%)
LITTERS (b)	2/25 (8%)	3/25 (12%)	5/25 (20%)	2/25 (8%)
POLY-3 RATE (c)	2/42.06	4/39.86	5/42.83	2/36.48
POLY-3 PERCENT (g)	4.8%	10%	11.7%	5.5%
TERMINAL (d)	1/28 (4%)	3/24 (13%)	5/29 (17%)	0/20 (0%)
FIRST INCIDENCE	670	499	729 (T)	570
STATISTICAL TESTS				
POLY 3	P=0.511N	P=0.312	P=0.222	P=0.642
POLY 1.5	P=0.478N	P=0.319	P=0.220	P=0.662
POLY 6	P=0.557N	P=0.305	P=0.224	P=0.614
RAO-SCOTT	P=0.490N	P=0.337	P=0.258	P=0.626
LITTER C-A/FISHERS	P=0.500N	P=0.500	P=0.209	P=0.695

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Thymus Atrophy				
LESION RATES				
OVERALL (a)	46/49 (94%)	44/49 (90%)	43/48 (90%)	45/48 (94%)
LITTERS (b)	24/25 (96%)	24/25 (96%)	25/25 (100%)	25/25 (100%)
POLY-3 RATE (c)	46/49.00	44/47.42	43/47.30	45/46.41
POLY-3 PERCENT (g)	93.9%	92.8%	90.9%	97%
TERMINAL (d)	25/28 (89%)	20/23 (87%)	24/28 (86%)	20/20 (100%)
FIRST INCIDENCE	499	302	360	430
STATISTICAL TESTS				
POLY 3	P=0.280	P=0.579N	P=0.434N	P=0.407
POLY 1.5	P=0.298	P=0.507N	P=0.400N	P=0.458
POLY 6	P=0.241	P=0.626N	P=0.464N	P=0.335
RAO-SCOTT	P=0.301	P=0.588N	P=0.454N	P=0.432
LITTER C-A/FISHERS	P=0.302	P=0.755	P=0.500	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Thymus				
Ectopic Parathyroid Gland				
<hr/>				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/49 (0%)	0/48 (0%)	2/48 (4%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (c)	0/41.26	0/38.18	0/40.89	2/34.57
POLY-3 PERCENT (g)	0%	0%	0%	5.8%
TERMINAL (d)	0/28 (0%)	0/23 (0%)	0/28 (0%)	2/20 (10%)
FIRST INCIDENCE	---	---	---	729 (T)
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.034*	(e)	(e)	P=0.199
POLY 1.5	P=0.036*	(e)	(e)	P=0.212
POLY 6	P=0.031*	(e)	(e)	P=0.183
RAO-SCOTT	P=0.098	(e)	(e)	P=0.328
LITTER C-A/FISHERS	P=0.041*	(e)	(e)	P=0.245

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<hr/>				
Thymus				
Polyarteritis Nodosa				
<hr/>				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/49 (0%)	0/48 (0%)	1/48 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	0/25 (0%)	1/25 (4%)
POLY-3 RATE (c)	0/41.26	0/38.18	0/40.89	1/34.57
POLY-3 PERCENT (g)	0%	0%	0%	2.9%
TERMINAL (d)	0/28 (0%)	0/23 (0%)	0/28 (0%)	1/20 (5%)
FIRST INCIDENCE	---	---	---	729 (T)
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Thyroid Gland: C-Cell Hyperplasia				
LESION RATES				
OVERALL (a)	14/50 (28%)	6/49 (12%)	10/50 (20%)	6/49 (12%)
LITTERS (b)	12/25 (48%)	5/25 (20%)	10/25 (40%)	5/25 (20%)
POLY-3 RATE (c)	14/43.39	6/38.38	10/45.73	6/37.51
POLY-3 PERCENT (g)	32.3%	15.6%	21.9%	16%
TERMINAL (d)	10/28 (36%)	5/23 (22%)	3/29 (10%)	0/20 (0%)
FIRST INCIDENCE	521	675	488	570
STATISTICAL TESTS				
POLY 3	P=0.140N	P=0.065N	P=0.191N	P=0.073N
POLY 1.5	P=0.129N	P=0.057N	P=0.214N	P=0.061N
POLY 6	P=0.154N	P=0.075N	P=0.164N	P=0.090N
RAO-SCOTT	P=0.152N	P=0.071N	P=0.198N	P=0.078N
LITTER C-A/FISHERS	P=0.103N	P=0.036N*	P=0.388N	P=0.036N*

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Tooth: Dentine Degeneration				
LESION RATES				
OVERALL (a)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/1 (0%)
LITTERS (b)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/1 (0%)
POLY-3 RATE (c)	0/0.00	0/0.00	0/1.00	0/0.89
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
RAO-SCOTT	(n)	(n)	(n)	(n)
LITTER C-A/FISHERS	(n)	(n)	(n)	(n)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Urinary Bladder Inflammation Chronic				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	0/25 (0%)	2/25 (8%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (c)	0/41.83	2/39.70	0/42.83	0/35.85
POLY-3 PERCENT (g)	0%	5%	0%	0%
TERMINAL (d)	0/28 (0%)	1/24 (4%)	0/29 (0%)	0/20 (0%)
FIRST INCIDENCE	---	570	---	---
STATISTICAL TESTS				
POLY 3	P=0.394N	P=0.225	(e)	(e)
POLY 1.5	P=0.386N	P=0.228	(e)	(e)
POLY 6	P=0.401N	P=0.223	(e)	(e)
RAO-SCOTT	P=0.461N	P=0.359	(e)	(e)
LITTER C-A/FISHERS	P=0.368N	P=0.245	(e)	(e)

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<hr/>				
Uterus				
Adenomyosis				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	1/49 (2%)
LITTERS (b)	0/25 (0%)	2/25 (8%)	2/25 (8%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	2/39.32	2/43.25	1/34.89
POLY-3 PERCENT (g)	0%	5.1%	4.6%	2.9%
TERMINAL (d)	0/28 (0%)	1/24 (4%)	1/29 (3%)	1/20 (5%)
FIRST INCIDENCE	---	691	608	729 (T)
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.535	P=0.223	P=0.244	P=0.464
POLY 1.5	P=0.565	P=0.227	P=0.241	P=0.476
POLY 6	P=0.492	P=0.220	P=0.249	P=0.447
RAO-SCOTT	P=0.545	P=0.256	P=0.287	P=0.457
LITTER C-A/FISHERS	P=0.619	P=0.245	P=0.245	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Uterus Dilation				
LESION RATES				
OVERALL (a)	2/50 (4%)	3/50 (6%)	9/50 (18%)	22/49 (45%)
LITTERS (b)	2/25 (8%)	3/25 (12%)	8/25 (32%)	16/25 (64%)
POLY-3 RATE (c)	2/42.25	3/39.65	9/43.56	22/43.23
POLY-3 PERCENT (g)	4.7%	7.6%	20.7%	50.9%
TERMINAL (d)	0/28 (0%)	2/24 (8%)	7/29 (24%)	6/20 (30%)
FIRST INCIDENCE	670	588	608	430
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.471	P=0.027*	P<0.001**
POLY 1.5	P<0.001**	P=0.480	P=0.026*	P<0.001**
POLY 6	P<0.001**	P=0.463	P=0.028*	P<0.001**
RAO-SCOTT	P<0.001**	P=0.468	P=0.042*	P<0.001**
LITTER C-A/FISHERS	P<0.001**	P=0.500	P=0.037*	P<0.001**

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<hr/>				
Uterus Hemorrhage				
<hr/>				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	8/49 (16%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	0/25 (0%)	8/25 (32%)
POLY-3 RATE (c)	1/42.03	0/39.18	0/42.83	8/38.65
POLY-3 PERCENT (g)	2.4%	0%	0%	20.7%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	0/29 (0%)	1/20 (5%)
FIRST INCIDENCE	677	---	---	478
<hr/>				
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.514N	P=0.496N	P=0.010**
POLY 1.5	P<0.001**	P=0.510N	P=0.498N	P=0.011*
POLY 6	P<0.001**	P=0.518N	P=0.495N	P=0.009**
RAO-SCOTT	P<0.001**	P=0.552N	P=0.555N	P=0.030*
LITTER C-A/FISHERS	P<0.001**	P=0.500N	P=0.500N	P=0.012*

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Uterus				
Hyperplasia Atypical				
<hr/>				
LESION RATES				
OVERALL (a)	3/50 (6%)	4/50 (8%)	5/50 (10%)	5/49 (10%)
LITTERS (b)	3/25 (12%)	4/25 (16%)	5/25 (20%)	5/25 (20%)
POLY-3 RATE (c)	3/42.39	4/39.24	5/42.83	5/34.89
POLY-3 PERCENT (g)	7.1%	10.2%	11.7%	14.3%
TERMINAL (d)	2/28 (7%)	3/24 (13%)	5/29 (17%)	5/20 (25%)
FIRST INCIDENCE	556	712	729 (T)	729 (T)
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.230	P=0.458	P=0.361	P=0.254
POLY 1.5	P=0.267	P=0.471	P=0.359	P=0.289
POLY 6	P=0.185	P=0.445	P=0.363	P=0.210
RAO-SCOTT	P=0.217	P=0.433	P=0.346	P=0.232
LITTER C-A/FISHERS	P=0.331	P=0.500	P=0.351	P=0.351

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Uterus				
Inflammation Acute				
<hr/>				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	2/50 (4%)	4/49 (8%)
LITTERS (b)	2/25 (8%)	0/25 (0%)	2/25 (8%)	4/25 (16%)
POLY-3 RATE (c)	2/41.83	0/39.18	2/43.43	4/36.91
POLY-3 PERCENT (g)	4.8%	0%	4.6%	10.8%
TERMINAL (d)	2/28 (7%)	0/24 (0%)	1/29 (3%)	0/20 (0%)
FIRST INCIDENCE	729 (T)	---	538	478
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.070	P=0.252N	P=0.681N	P=0.280
POLY 1.5	P=0.075	P=0.247N	P=0.687N	P=0.296
POLY 6	P=0.065	P=0.255N	P=0.674N	P=0.259
RAO-SCOTT	P=0.081	P=0.271N	P=0.673N	P=0.295
LITTER C-A/FISHERS	P=0.083	P=0.245N	P=0.695	P=0.334

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Uterus				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	4/50 (8%)	6/50 (12%)	7/50 (14%)	7/49 (14%)
LITTERS (b)	4/25 (16%)	6/25 (24%)	6/25 (24%)	7/25 (28%)
POLY-3 RATE (c)	4/42.07	6/39.65	7/43.35	7/38.45
POLY-3 PERCENT (g)	9.5%	15.1%	16.2%	18.2%
TERMINAL (d)	2/28 (7%)	5/24 (21%)	5/29 (17%)	1/20 (5%)
FIRST INCIDENCE	677	588	608	430
STATISTICAL TESTS				
POLY 3	P=0.232	P=0.331	P=0.277	P=0.208
POLY 1.5	P=0.246	P=0.342	P=0.270	P=0.222
POLY 6	P=0.209	P=0.321	P=0.285	P=0.189
RAO-SCOTT	P=0.236	P=0.325	P=0.278	P=0.208
LITTER C-A/FISHERS	P=0.266	P=0.363	P=0.363	P=0.248

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<hr/>				
Uterus				
Polyarteritis Nodosa				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/49 (2%)
LITTERS (b)	0/25 (0%)	0/25 (0%)	2/25 (8%)	1/25 (4%)
POLY-3 RATE (c)	0/41.83	0/39.18	2/43.03	1/35.18
POLY-3 PERCENT (g)	0%	0%	4.7%	2.8%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	1/29 (3%)	0/20 (0%)
FIRST INCIDENCE	---	---	676	650
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.288	(e)	P=0.243	P=0.466
POLY 1.5	P=0.310	(e)	P=0.240	P=0.477
POLY 6	P=0.257	(e)	P=0.247	P=0.450
RAO-SCOTT	P=0.349	(e)	P=0.339	P=0.519
LITTER C-A/FISHERS	P=0.349	(e)	P=0.245	P=0.500

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Uterus				
Squamous Metaplasia				
LESION RATES				
OVERALL (a)	21/50 (42%)	25/50 (50%)	30/50 (60%)	38/49 (78%)
LITTERS (b)	19/25 (76%)	20/25 (80%)	20/25 (80%)	23/25 (92%)
POLY-3 RATE (c)	21/43.35	25/43.48	30/45.43	38/45.34
POLY-3 PERCENT (g)	48.4%	57.5%	66%	83.8%
TERMINAL (d)	16/28 (57%)	16/24 (67%)	21/29 (72%)	17/20 (85%)
FIRST INCIDENCE	556	386	538	430
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.257	P=0.063	P<0.001**
POLY 1.5	P<0.001**	P=0.252	P=0.056	P<0.001**
POLY 6	P<0.001**	P=0.275	P=0.077	P<0.001**
RAO-SCOTT	P<0.001**	P=0.259	P=0.072	P<0.001**
LITTER C-A/FISHERS	P=0.096	P=0.500	P=0.500	P=0.123

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
<hr/>				
Uterus				
Thrombus				
<hr/>				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	5/50 (10%)	5/49 (10%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	5/25 (20%)	5/25 (20%)
POLY-3 RATE (c)	1/41.83	0/39.18	5/43.51	5/36.79
POLY-3 PERCENT (g)	2.4%	0%	11.5%	13.6%
TERMINAL (d)	1/28 (4%)	0/24 (0%)	3/29 (10%)	1/20 (5%)
FIRST INCIDENCE	729 (T)	---	608	478
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.017*	P=0.513N	P=0.110	P=0.073
POLY 1.5	P=0.020*	P=0.509N	P=0.106	P=0.081
POLY 6	P=0.014*	P=0.516N	P=0.115	P=0.064
RAO-SCOTT	P=0.030*	P=0.523N	P=0.147	P=0.101
LITTER C-A/FISHERS	P=0.025*	P=0.500N	P=0.095	P=0.095

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

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First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Uterus				
Ulcer				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	3/50 (6%)	9/49 (18%)
LITTERS (b)	0/25 (0%)	1/25 (4%)	2/25 (8%)	8/25 (32%)
POLY-3 RATE (c)	0/41.83	1/39.18	3/43.16	9/38.37
POLY-3 PERCENT (g)	0%	2.6%	7%	23.5%
TERMINAL (d)	0/28 (0%)	1/24 (4%)	2/29 (7%)	2/20 (10%)
FIRST INCIDENCE	---	729 (T)	638	475
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.487	P=0.124	P<0.001**
POLY 1.5	P<0.001**	P=0.491	P=0.122	P<0.001**
POLY 6	P<0.001**	P=0.484	P=0.127	P<0.001**
RAO-SCOTT	P<0.001**	P=0.556	P=0.208	P=0.009**
LITTER C-A/FISHERS	P<0.001**	P=0.500	P=0.245	P=0.002**

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/09/2020
Time Report Requested: 09:53:31
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Uterus: Cervix Hyperplasia				
LESION RATES				
OVERALL (a)	3/50 (6%)	1/50 (2%)	1/50 (2%)	3/49 (6%)
LITTERS (b)	3/25 (12%)	1/25 (4%)	1/25 (4%)	3/25 (12%)
POLY-3 RATE (c)	3/41.89	1/39.18	1/42.83	3/34.89
POLY-3 PERCENT (g)	7.2%	2.6%	2.3%	8.6%
TERMINAL (d)	2/28 (7%)	1/24 (4%)	1/29 (3%)	3/20 (15%)
FIRST INCIDENCE	715	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.362	P=0.329N	P=0.297N	P=0.576
POLY 1.5	P=0.379	P=0.322N	P=0.301N	P=0.606
POLY 6	P=0.339	P=0.335N	P=0.292N	P=0.532
RAO-SCOTT	P=0.342	P=0.345N	P=0.323N	P=0.561
LITTER C-A/FISHERS	P=0.413	P=0.305N	P=0.305N	P=0.666

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

CAS Number: 84776-26-1

Date Report Requested: 10/09/2020

Time Report Requested: 09:53:31

First Dose M/F: 07/03/12 / 07/02/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Uterus: Endometrium Hyperplasia Cystic				
LESION RATES				
OVERALL (a)	19/50 (38%)	26/50 (52%)	23/50 (46%)	13/49 (27%)
LITTERS (b)	14/25 (56%)	18/25 (72%)	18/25 (72%)	10/25 (40%)
POLY-3 RATE (c)	19/42.91	26/42.49	23/44.74	13/35.98
POLY-3 PERCENT (g)	44.3%	61.2%	51.4%	36.1%
TERMINAL (d)	14/28 (50%)	19/24 (79%)	17/29 (59%)	9/20 (45%)
FIRST INCIDENCE	606	386	538	586
STATISTICAL TESTS				
POLY 3	P=0.089N	P=0.079	P=0.321	P=0.303N
POLY 1.5	P=0.057N	P=0.087	P=0.297	P=0.238N
POLY 6	P=0.158N	P=0.069	P=0.348	P=0.411N
RAO-SCOTT	P=0.094N	P=0.100	P=0.332	P=0.308N
LITTER C-A/FISHERS	P=0.039N*	P=0.189	P=0.189	P=0.198N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Vagina				
Inflammation Acute				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	4/50 (8%)	0/50 (0%)
LITTERS (b)	1/25 (4%)	0/25 (0%)	4/25 (16%)	0/25 (0%)
POLY-3 RATE (c)	1/42.46	0/39.18	4/43.40	0/35.85
POLY-3 PERCENT (g)	2.4%	0%	9.2%	0%
TERMINAL (d)	0/28 (0%)	0/24 (0%)	1/29 (3%)	0/20 (0%)
FIRST INCIDENCE	524	---	644	---
STATISTICAL TESTS				
POLY 3	P=0.514N	P=0.516N	P=0.185	P=0.534N
POLY 1.5	P=0.484N	P=0.511N	P=0.182	P=0.521N
POLY 6	P=0.560N	P=0.521N	P=0.189	P=0.551N
RAO-SCOTT	P=0.491N	P=0.557N	P=0.246	P=0.553N
LITTER C-A/FISHERS	P=0.441N	P=0.500N	P=0.174	P=0.500N

Experiment Number: 00058 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Black Cohosh

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LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
- (b) Number of litters with tumor-bearing animals/number of litters examined at site
- (c) 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 Rao-Scott statistic performs the Poly-3 test with an adjustment for within-litter correlation.
The Litter C-A/Fishers statistic compares directly the litter incidence rates.

*** END OF REPORT ***