

Experiment Number: 00058 - 04
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
Time Report Requested: 11:32:38
First Dose M/F: NA / 04/09/12
Lab: BAT

2-year Core Mice_Final 1

NTP Study Number:	C00058B		
Lock Date:	10/02/2018		
Cage Range:	ALL		
Date Range:	ALL		
Reasons For Removal:	25022 ACCK	25021 TSAC	25020 NATD
	25019 MSAC		
Removal Date Range:	ALL		
Treatment Groups:	Include ALL		
Study Gender:	Female		
TDMSE Version:	3.0.2.3_002		
PWG Approval Date:	NONE		

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

FEMALE MICE

Organ

Adrenal Cortex: Bilateral
Bone
Bone: Joint
Eye: Lens
Heart
Islets, Pancreatic
Kidney
Kidney: Renal Tubule
Liver

Lung
Lymph Node, Mandibular
Lymph Node, Mesenteric
Nose: Olfactory Epithelium
Nose: Respiratory Epithelium
Ovary: Follicle
Ovary: Interstitial Cell
Pancreas: Acinus
Spleen

Thyroid Gland: Follicle
Uterus
Uterus: Endometrium
Vagina
Vagina: Epithelium

Morphology

Vacuolation, Cytoplasmic Focal
Fibro-osseous Lesion
Degeneration
Cataract
Polyarteritis Nodosa
Hyperplasia
Infarct Chronic
Accumulation, Hyaline Droplet
Basophilic Focus
Eosinophilic Focus
Infiltration Cellular Lymphocyte
Mixed Cell Focus
Necrosis
Infiltration Cellular Lymphocyte
Hyperplasia Lymphocyte
Hyperplasia Lymphocyte
Atrophy
Hyperplasia
Cyst
Hyperplasia
Atrophy
Extramedullary Hematopoiesis Increased
Hyperplasia Lymphocyte
Dilation
Inflammation Acute
Hyperplasia Cystic
Inflammation Acute
Hyperplasia

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Adrenal Cortex					
Vacuolation, Cytoplasmic Focal					
LESION RATES					
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/46.01	0/47.58	0/48.51	1/46.27	0/45.06
POLY-3 PERCENT (g)	4.4%	0%	0%	2.2%	0%
TERMINAL (d)	2/40 (5%)	0/40 (0%)	0/44 (0%)	1/39 (3%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	---	---	729 (T)	---
STATISTICAL TESTS					
POLY 3	P=0.390N	P=0.230N	P=0.226N	P=0.498N	P=0.242N
POLY 1.5	P=0.385N	P=0.232N	P=0.230N	P=0.498N	P=0.241N
POLY 6	P=0.395N	P=0.228N	P=0.223N	P=0.502N	P=0.243N
COCH-ARM / FISHERS	P=0.373N	P=0.247N	P=0.247N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.062N	P=0.076N	P=0.076N	P=0.279N	P=0.080N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Adrenal Cortex: Bilateral Vacuolation, Cytoplasmic Focal					
LESION RATES					
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/46.01	0/47.58	0/48.51	0/46.27	0/45.06
POLY-3 PERCENT (g)	4.4%	0%	0%	0%	0%
TERMINAL (d)	2/40 (5%)	0/40 (0%)	0/44 (0%)	0/39 (0%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	---	---	---	---
STATISTICAL TESTS					
POLY 3	P=0.347N	P=0.230N	P=0.226N	P=0.236N	P=0.242N
POLY 1.5	P=0.343N	P=0.232N	P=0.230N	P=0.236N	P=0.241N
POLY 6	P=0.350N	P=0.228N	P=0.223N	P=0.238N	P=0.243N
COCH-ARM / FISHERS	P=0.336N	P=0.247N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.024N*	P=0.076N	P=0.076N	P=0.076N	P=0.080N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Bone Marrow Hypercellularity					
LESION RATES					
OVERALL (a)	1/50 (2%)	2/50 (4%)	5/50 (10%)	5/50 (10%)	3/50 (6%)
POLY-3 RATE (b)	1/46.51	2/47.95	5/49.01	5/47.75	3/45.77
POLY-3 PERCENT (g)	2.2%	4.2%	10.2%	10.5%	6.6%
TERMINAL (d)	0/40 (0%)	1/40 (3%)	3/44 (7%)	2/39 (5%)	0/38 (0%)
FIRST INCIDENCE	579	624	651	455	589
STATISTICAL TESTS					
POLY 3	P=0.437	P=0.511	P=0.114	P=0.108	P=0.300
POLY 1.5	P=0.442	P=0.507	P=0.110	P=0.106	P=0.300
POLY 6	P=0.434	P=0.513	P=0.119	P=0.107	P=0.300
COCH-ARM / FISHERS	P=0.463	P=0.500	P=0.102	P=0.102	P=0.309
MAX-ISO-POLY-3	P=0.169	P=0.293	P=0.057	P=0.051	P=0.151

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Bone					
Fibro-osseous Lesion					
LESION RATES					
OVERALL (a)	8/50 (16%)	3/50 (6%)	2/50 (4%)	2/50 (4%)	7/50 (14%)
POLY-3 RATE (b)	8/46.04	3/47.58	2/48.51	2/46.27	7/45.30
POLY-3 PERCENT (g)	17.4%	6.3%	4.1%	4.3%	15.5%
TERMINAL (d)	7/40 (18%)	3/40 (8%)	2/44 (5%)	2/39 (5%)	6/38 (16%)
FIRST INCIDENCE	723	729 (T)	729 (T)	729 (T)	666
STATISTICAL TESTS					
POLY 3	P=0.198	P=0.089N	P=0.037N*	P=0.044N*	P=0.514N
POLY 1.5	P=0.205	P=0.092N	P=0.040N*	P=0.044N*	P=0.513N
POLY 6	P=0.192	P=0.086N	P=0.035N*	P=0.046N*	P=0.514N
COCH-ARM / FISHERS	P=0.227	P=0.100N	P=0.046N*	P=0.046N*	P=0.500N
MAX-ISO-POLY-3	P=0.094N	P=0.050N*	P=0.019N*	P=0.021N*	P=0.403N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg

Bone: Joint Degeneration

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/46.01	0/47.58	1/48.51	3/46.27	0/45.06
POLY-3 PERCENT (g)	0%	0%	2.1%	6.5%	0%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	1/44 (2%)	3/39 (8%)	0/38 (0%)
FIRST INCIDENCE	---	---	729 (T)	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.631N	(e)	P=0.511	P=0.120	(e)
POLY 1.5	P=0.626N	(e)	P=0.507	P=0.120	(e)
POLY 6	P=0.635N	(e)	P=0.513	P=0.118	(e)
COCH-ARM / FISHERS	P=0.610N	(e)	P=0.500	P=0.121	(e)
MAX-ISO-POLY-3	P=0.206	(e)	P=0.171	P=0.039*	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Brain					
Hydrocephalus					
LESION RATES					
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/46.01	0/47.58	2/48.72	0/46.27	1/45.06
POLY-3 PERCENT (g)	0%	0%	4.1%	0%	2.2%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	1/44 (2%)	0/39 (0%)	1/38 (3%)
FIRST INCIDENCE	---	---	673	---	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.497	(e)	P=0.250	(e)	P=0.496
POLY 1.5	P=0.498	(e)	P=0.246	(e)	P=0.496
POLY 6	P=0.496	(e)	P=0.255	(e)	P=0.495
COCH-ARM / FISHERS	P=0.505	(e)	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.317	(e)	P=0.088	(e)	P=0.158

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Brain					
Infiltration Cellular Lymphocyte					
LESION RATES					
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/46.01	2/47.58	0/48.51	0/46.27	1/45.06
POLY-3 PERCENT (g)	0%	4.2%	0%	0%	2.2%
TERMINAL (d)	0/40 (0%)	2/40 (5%)	0/44 (0%)	0/39 (0%)	1/38 (3%)
FIRST INCIDENCE	---	729 (T)	---	---	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.583	P=0.245	(e)	(e)	P=0.496
POLY 1.5	P=0.585	P=0.242	(e)	(e)	P=0.496
POLY 6	P=0.581	P=0.246	(e)	(e)	P=0.495
COCH-ARM / FISHERS	P=0.591	P=0.247	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.316	P=0.083	(e)	(e)	P=0.158

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Brain					
Polyarteritis Nodosa					
LESION RATES					
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	2/46.01	0/47.58	0/48.51	1/46.27	3/45.06
POLY-3 PERCENT (g)	4.4%	0%	0%	2.2%	6.7%
TERMINAL (d)	2/40 (5%)	0/40 (0%)	0/44 (0%)	1/39 (3%)	3/38 (8%)
FIRST INCIDENCE	729 (T)	---	---	729 (T)	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.076	P=0.230N	P=0.226N	P=0.498N	P=0.490
POLY 1.5	P=0.078	P=0.232N	P=0.230N	P=0.498N	P=0.492
POLY 6	P=0.073	P=0.228N	P=0.223N	P=0.502N	P=0.489
COCH-ARM / FISHERS	P=0.085	P=0.247N	P=0.247N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.106	P=0.076N	P=0.076N	P=0.279N	P=0.317

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Eye					
Phthisis Bulbi					
LESION RATES					
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/46.01	2/47.58	0/48.51	0/46.27	0/45.06
POLY-3 PERCENT (g)	2.2%	4.2%	0%	0%	0%
TERMINAL (d)	1/40 (3%)	2/40 (5%)	0/44 (0%)	0/39 (0%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---	---
STATISTICAL TESTS					
POLY 3	P=0.247N	P=0.512	P=0.489N	P=0.499N	P=0.504N
POLY 1.5	P=0.246N	P=0.508	P=0.493N	P=0.499N	P=0.504N
POLY 6	P=0.249N	P=0.514	P=0.487N	P=0.501N	P=0.505N
COCH-ARM / FISHERS	P=0.242N	P=0.500	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.162N	P=0.294	P=0.158N	P=0.158N	P=0.163N

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Eye: Lens					
Cataract					
LESION RATES					
OVERALL (a)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/46.91	0/47.58	0/48.51	0/46.27	1/45.06
POLY-3 PERCENT (g)	6.4%	0%	0%	0%	2.2%
TERMINAL (d)	1/40 (3%)	0/40 (0%)	0/44 (0%)	0/39 (0%)	1/38 (3%)
FIRST INCIDENCE	462	---	---	---	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.623N	P=0.116N	P=0.113N	P=0.121N	P=0.320N
POLY 1.5	P=0.620N	P=0.117N	P=0.115N	P=0.120N	P=0.316N
POLY 6	P=0.626N	P=0.116N	P=0.112N	P=0.125N	P=0.324N
COCH-ARM / FISHERS	P=0.610N	P=0.121N	P=0.121N	P=0.121N	P=0.309N
MAX-ISO-POLY-3	P=0.029N*	P=0.038N*	P=0.038N*	P=0.040N*	P=0.169N

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TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Harderian Gland Hyperplasia					
LESION RATES					
OVERALL (a)	1/50 (2%)	0/50 (0%)	3/50 (6%)	4/50 (8%)	3/50 (6%)
POLY-3 RATE (b)	1/46.01	0/47.58	3/48.51	4/46.27	3/45.19
POLY-3 PERCENT (g)	2.2%	0%	6.2%	8.6%	6.6%
TERMINAL (d)	1/40 (3%)	0/40 (0%)	3/44 (7%)	4/39 (10%)	2/38 (5%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)	695
STATISTICAL TESTS					
POLY 3	P=0.183	P=0.493N	P=0.325	P=0.180	P=0.299
POLY 1.5	P=0.187	P=0.496N	P=0.318	P=0.181	P=0.299
POLY 6	P=0.179	P=0.492N	P=0.330	P=0.177	P=0.298
COCH-ARM / FISHERS	P=0.203	P=0.500N	P=0.309	P=0.181	P=0.309
MAX-ISO-POLY-3	P=0.128	P=0.158N	P=0.173	P=0.085	P=0.151

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Heart					
Cardiomyopathy					
LESION RATES					
OVERALL (a)	8/50 (16%)	5/50 (10%)	8/50 (16%)	11/50 (22%)	12/50 (24%)
POLY-3 RATE (b)	8/46.01	5/47.77	8/49.35	11/46.27	12/46.17
POLY-3 PERCENT (g)	17.4%	10.5%	16.2%	23.8%	26%
TERMINAL (d)	8/40 (20%)	3/40 (8%)	5/44 (11%)	11/39 (28%)	8/38 (21%)
FIRST INCIDENCE	729 (T)	688	599	729 (T)	589
STATISTICAL TESTS					
POLY 3	P=0.056	P=0.252N	P=0.548N	P=0.308	P=0.227
POLY 1.5	P=0.058	P=0.261N	P=0.570N	P=0.310	P=0.222
POLY 6	P=0.056	P=0.244N	P=0.525N	P=0.298	P=0.236
COCH-ARM / FISHERS	P=0.069	P=0.277N	P=0.607N	P=0.306	P=0.227
MAX-ISO-POLY-3	P=0.098	P=0.171N	P=0.441N	P=0.224	P=0.158

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 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Heart					
Polyarteritis Nodosa					
LESION RATES					
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/46.01	0/47.58	0/48.51	0/46.27	0/45.06
POLY-3 PERCENT (g)	4.4%	0%	0%	0%	0%
TERMINAL (d)	2/40 (5%)	0/40 (0%)	0/44 (0%)	0/39 (0%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	---	---	---	---
STATISTICAL TESTS					
POLY 3	P=0.347N	P=0.230N	P=0.226N	P=0.236N	P=0.242N
POLY 1.5	P=0.343N	P=0.232N	P=0.230N	P=0.236N	P=0.241N
POLY 6	P=0.350N	P=0.228N	P=0.223N	P=0.238N	P=0.243N
COCH-ARM / FISHERS	P=0.336N	P=0.247N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.024N*	P=0.076N	P=0.076N	P=0.076N	P=0.080N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Intestine Small, Jejunum: Epithelium Hyperplasia					
LESION RATES					
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/46.66	0/47.58	2/48.51	0/46.27	0/45.06
POLY-3 PERCENT (g)	2.1%	0%	4.1%	0%	0%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	2/44 (5%)	0/39 (0%)	0/38 (0%)
FIRST INCIDENCE	516	---	729 (T)	---	---
STATISTICAL TESTS					
POLY 3	P=0.321N	P=0.496N	P=0.514	P=0.502N	P=0.507N
POLY 1.5	P=0.320N	P=0.497N	P=0.509	P=0.500N	P=0.505N
POLY 6	P=0.323N	P=0.496N	P=0.517	P=0.505N	P=0.509N
COCH-ARM / FISHERS	P=0.315N	P=0.500N	P=0.500	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.331N	P=0.158N	P=0.296	P=0.160N	P=0.167N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Intestine Small, Jejunum: Peyer's Patch Hyperplasia Lymphocyte					
LESION RATES					
OVERALL (a)	4/50 (8%)	5/50 (10%)	3/50 (6%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	4/46.01	5/47.58	3/48.51	2/46.27	4/45.06
POLY-3 PERCENT (g)	8.7%	10.5%	6.2%	4.3%	8.9%
TERMINAL (d)	4/40 (10%)	5/40 (13%)	3/44 (7%)	2/39 (5%)	4/38 (11%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.587	P=0.521	P=0.471N	P=0.335N	P=0.632
POLY 1.5	P=0.585N	P=0.514	P=0.481N	P=0.334N	P=0.633
POLY 6	P=0.580	P=0.526	P=0.463N	P=0.340N	P=0.630
COCH-ARM / FISHERS	P=0.566N	P=0.500	P=0.500N	P=0.339N	P=0.643N
MAX-ISO-POLY-3	P=0.505N	P=0.385	P=0.326N	P=0.198N	P=0.487

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Islets, Pancreatic Hyperplasia					
LESION RATES					
OVERALL (a)	7/50 (14%)	0/50 (0%)	3/50 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	7/46.33	0/47.58	3/48.80	0/46.27	1/45.06
POLY-3 PERCENT (g)	15.1%	0%	6.2%	0%	2.2%
TERMINAL (d)	5/40 (13%)	0/40 (0%)	2/44 (5%)	0/39 (0%)	1/38 (3%)
FIRST INCIDENCE	649	---	651	---	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.114N	P=0.007N**	P=0.138N	P=0.008N**	P=0.033N*
POLY 1.5	P=0.110N	P=0.007N**	P=0.145N	P=0.007N**	P=0.033N*
POLY 6	P=0.117N	P=0.007N**	P=0.132N	P=0.008N**	P=0.034N*
COCH-ARM / FISHERS	P=0.107N	P=0.006N**	P=0.159N	P=0.006N**	P=0.030N*
MAX-ISO-POLY-3	P<0.001N**	P=0.003N**	P=0.082N	P=0.003N**	P=0.015N*

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Kidney					
Infarct Chronic					
LESION RATES					
OVERALL (a)	3/50 (6%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/46.01	2/47.58	0/48.51	0/46.27	0/45.06
POLY-3 PERCENT (g)	6.5%	4.2%	0%	0%	0%
TERMINAL (d)	3/40 (8%)	2/40 (5%)	0/44 (0%)	0/39 (0%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---	---
STATISTICAL TESTS					
POLY 3	P=0.113N	P=0.485N	P=0.110N	P=0.118N	P=0.122N
POLY 1.5	P=0.111N	P=0.490N	P=0.113N	P=0.118N	P=0.122N
POLY 6	P=0.115N	P=0.481N	P=0.107N	P=0.120N	P=0.123N
COCH-ARM / FISHERS	P=0.108N	P=0.500N	P=0.121N	P=0.121N	P=0.121N
MAX-ISO-POLY-3	P=0.030N*	P=0.313N	P=0.038N*	P=0.038N*	P=0.041N*

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Kidney					
Infiltration Cellular Lymphocyte					
LESION RATES					
OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/46.01	2/47.58	1/48.51	1/46.27	1/45.06
POLY-3 PERCENT (g)	2.2%	4.2%	2.1%	2.2%	2.2%
TERMINAL (d)	1/40 (3%)	2/40 (5%)	1/44 (2%)	1/39 (3%)	1/38 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.555N	P=0.512	P=0.749N	P=0.759N	P=0.756
POLY 1.5	P=0.552N	P=0.508	P=0.753N	P=0.759N	P=0.756
POLY 6	P=0.559N	P=0.514	P=0.745N	P=0.759	P=0.755
COCH-ARM / FISHERS	P=0.542N	P=0.500	P=0.753N	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.638N	P=0.294	P=0.485N	P=0.498N	P=0.494

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Kidney					
Nephropathy Chronic Progressive					
LESION RATES					
OVERALL (a)	13/50 (26%)	14/50 (28%)	10/50 (20%)	20/50 (40%)	17/50 (34%)
POLY-3 RATE (b)	13/46.88	14/47.76	10/48.72	20/47.71	17/46.32
POLY-3 PERCENT (g)	27.7%	29.3%	20.5%	41.9%	36.7%
TERMINAL (d)	10/40 (25%)	12/40 (30%)	9/44 (21%)	15/39 (39%)	13/38 (34%)
FIRST INCIDENCE	491	688	673	603	589
STATISTICAL TESTS					
POLY 3	P=0.109	P=0.523	P=0.280N	P=0.107	P=0.240
POLY 1.5	P=0.113	P=0.516	P=0.293N	P=0.105	P=0.239
POLY 6	P=0.109	P=0.526	P=0.270N	P=0.108	P=0.245
COCH-ARM / FISHERS	P=0.140	P=0.500	P=0.318N	P=0.101	P=0.257
MAX-ISO-POLY-3	P=0.142	P=0.432	P=0.209N	P=0.074	P=0.178

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Kidney: Renal Tubule Accumulation, Hyaline Droplet					
LESION RATES					
OVERALL (a)	0/50 (0%)	3/50 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.01	3/48.21	1/48.51	0/46.27	0/45.06
POLY-3 PERCENT (g)	0%	6.2%	2.1%	0%	0%
TERMINAL (d)	0/40 (0%)	1/40 (3%)	1/44 (2%)	0/39 (0%)	0/38 (0%)
FIRST INCIDENCE	---	540	729 (T)	---	---
STATISTICAL TESTS					
POLY 3	P=0.205N	P=0.127	P=0.511	(e)	(e)
POLY 1.5	P=0.206N	P=0.124	P=0.507	(e)	(e)
POLY 6	P=0.205N	P=0.130	P=0.513	(e)	(e)
COCH-ARM / FISHERS	P=0.207N	P=0.121	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.220N	P=0.046*	P=0.171	(e)	(e)

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Kidney: Renal Tubule Cyst					
LESION RATES					
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/46.01	0/47.58	0/48.51	1/46.27	0/45.06
POLY-3 PERCENT (g)	4.4%	0%	0%	2.2%	0%
TERMINAL (d)	2/40 (5%)	0/40 (0%)	0/44 (0%)	1/39 (3%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	---	---	729 (T)	---
STATISTICAL TESTS					
POLY 3	P=0.390N	P=0.230N	P=0.226N	P=0.498N	P=0.242N
POLY 1.5	P=0.385N	P=0.232N	P=0.230N	P=0.498N	P=0.241N
POLY 6	P=0.395N	P=0.228N	P=0.223N	P=0.502N	P=0.243N
COCH-ARM / FISHERS	P=0.373N	P=0.247N	P=0.247N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.062N	P=0.076N	P=0.076N	P=0.279N	P=0.080N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Liver					
Basophilic Focus					
LESION RATES					
OVERALL (a)	6/50 (12%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	6/46.01	1/47.58	0/48.51	0/46.27	0/45.06
POLY-3 PERCENT (g)	13%	2.1%	0%	0%	0%
TERMINAL (d)	6/40 (15%)	1/40 (3%)	0/44 (0%)	0/39 (0%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---	---
STATISTICAL TESTS					
POLY 3	P=0.048N*	P=0.051N	P=0.013N*	P=0.015N*	P=0.016N*
POLY 1.5	P=0.046N*	P=0.053N	P=0.014N*	P=0.015N*	P=0.016N*
POLY 6	P=0.050N*	P=0.049N*	P=0.012N*	P=0.015N*	P=0.016N*
COCH-ARM / FISHERS	P=0.047N*	P=0.056N	P=0.013N*	P=0.013N*	P=0.013N*
MAX-ISO-POLY-3	P<0.001N**	P=0.022N*	P=0.005N**	P=0.005N**	P=0.006N**

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Liver					
Clear Cell Focus					
LESION RATES					
OVERALL (a)	3/50 (6%)	1/50 (2%)	3/50 (6%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	3/46.01	1/47.58	3/48.51	1/46.27	4/45.06
POLY-3 PERCENT (g)	6.5%	2.1%	6.2%	2.2%	8.9%
TERMINAL (d)	3/40 (8%)	1/40 (3%)	3/44 (7%)	1/39 (3%)	4/38 (11%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.231	P=0.294N	P=0.637N	P=0.303N	P=0.489
POLY 1.5	P=0.236	P=0.298N	P=0.646N	P=0.303N	P=0.490
POLY 6	P=0.226	P=0.291N	P=0.631N	P=0.307N	P=0.486
COCH-ARM / FISHERS	P=0.250	P=0.309N	P=0.661N	P=0.309N	P=0.500
MAX-ISO-POLY-3	P=0.292	P=0.149N	P=0.473N	P=0.153N	P=0.339

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Liver					
Eosinophilic Focus					
LESION RATES					
OVERALL (a)	7/50 (14%)	5/50 (10%)	2/50 (4%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	7/46.01	5/47.58	2/48.51	1/46.27	4/45.53
POLY-3 PERCENT (g)	15.2%	10.5%	4.1%	2.2%	8.8%
TERMINAL (d)	7/40 (18%)	4/40 (10%)	2/44 (5%)	1/39 (3%)	3/38 (8%)
FIRST INCIDENCE	729 (T)	728	729 (T)	729 (T)	589
STATISTICAL TESTS					
POLY 3	P=0.414N	P=0.356N	P=0.067N	P=0.029N*	P=0.267N
POLY 1.5	P=0.408N	P=0.364N	P=0.071N	P=0.029N*	P=0.269N
POLY 6	P=0.419N	P=0.350N	P=0.064N	P=0.030N*	P=0.265N
COCH-ARM / FISHERS	P=0.390N	P=0.380N	P=0.080N	P=0.030N*	P=0.262N
MAX-ISO-POLY-3	P=0.066N	P=0.252N	P=0.035N*	P=0.012N*	P=0.174N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Liver					
Extramedullary Hematopoiesis					
LESION RATES					
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/46.01	0/47.58	1/48.51	1/46.56	2/45.15
POLY-3 PERCENT (g)	0%	0%	2.1%	2.2%	4.4%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	1/44 (2%)	0/39 (0%)	1/38 (3%)
FIRST INCIDENCE	---	---	729 (T)	653	705
STATISTICAL TESTS					
POLY 3	P=0.103	(e)	P=0.511	P=0.502	P=0.233
POLY 1.5	P=0.105	(e)	P=0.507	P=0.502	P=0.233
POLY 6	P=0.102	(e)	P=0.513	P=0.501	P=0.232
COCH-ARM / FISHERS	P=0.110	(e)	P=0.500	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.097	(e)	P=0.171	P=0.161	P=0.076

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Liver					
Fatty Change					
LESION RATES					
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/46.11	0/47.58	1/48.51	0/46.27	1/45.06
POLY-3 PERCENT (g)	4.3%	0%	2.1%	0%	2.2%
TERMINAL (d)	1/40 (3%)	0/40 (0%)	1/44 (2%)	0/39 (0%)	1/38 (3%)
FIRST INCIDENCE	706	---	729 (T)	---	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.672N	P=0.230N	P=0.482N	P=0.236N	P=0.508N
POLY 1.5	P=0.669N	P=0.233N	P=0.488N	P=0.236N	P=0.507N
POLY 6	P=0.675N	P=0.229N	P=0.478N	P=0.239N	P=0.510N
COCH-ARM / FISHERS	P=0.661N	P=0.247N	P=0.500N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.212N	P=0.076N	P=0.270N	P=0.076N	P=0.290N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

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 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Liver					
Infiltration Cellular Lymphocyte					
LESION RATES					
OVERALL (a)	0/50 (0%)	0/50 (0%)	3/50 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.01	0/47.58	3/48.51	0/46.27	0/45.06
POLY-3 PERCENT (g)	0%	0%	6.2%	0%	0%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	3/44 (7%)	0/39 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	729 (T)	---	---
STATISTICAL TESTS					
POLY 3	P=0.372N	(e)	P=0.129	(e)	(e)
POLY 1.5	P=0.372N	(e)	P=0.125	(e)	(e)
POLY 6	P=0.372N	(e)	P=0.131	(e)	(e)
COCH-ARM / FISHERS	P=0.373N	(e)	P=0.121	(e)	(e)
MAX-ISO-POLY-3	P=0.325	(e)	P=0.047*	(e)	(e)

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Liver					
Intrahepatocellular Erythrocytes					
LESION RATES					
OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/46.01	1/47.58	1/48.51	2/46.27	0/45.06
POLY-3 PERCENT (g)	4.4%	2.1%	2.1%	4.3%	0%
TERMINAL (d)	2/40 (5%)	1/40 (3%)	1/44 (2%)	2/39 (5%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)	---
STATISTICAL TESTS					
POLY 3	P=0.258N	P=0.488N	P=0.482N	P=0.692N	P=0.242N
POLY 1.5	P=0.253N	P=0.492N	P=0.488N	P=0.691N	P=0.241N
POLY 6	P=0.262N	P=0.486N	P=0.477N	P=0.692	P=0.243N
COCH-ARM / FISHERS	P=0.240N	P=0.500N	P=0.500N	P=0.691N	P=0.247N
MAX-ISO-POLY-3	P=0.179N	P=0.274N	P=0.270N	P=0.497N	P=0.080N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Liver					
Mixed Cell Focus					
LESION RATES					
OVERALL (a)	0/50 (0%)	0/50 (0%)	3/50 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/46.01	0/47.58	3/48.51	0/46.27	1/45.06
POLY-3 PERCENT (g)	0%	0%	6.2%	0%	2.2%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	3/44 (7%)	0/39 (0%)	1/38 (3%)
FIRST INCIDENCE	---	---	729 (T)	---	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.596	(e)	P=0.129	(e)	P=0.496
POLY 1.5	P=0.598	(e)	P=0.125	(e)	P=0.496
POLY 6	P=0.595	(e)	P=0.131	(e)	P=0.495
COCH-ARM / FISHERS	P=0.604	(e)	P=0.121	(e)	P=0.500
MAX-ISO-POLY-3	P=0.266	(e)	P=0.047*	(e)	P=0.158

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
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 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Liver					
Necrosis					
LESION RATES					
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	8/50 (16%)
POLY-3 RATE (b)	2/47.35	0/47.58	1/48.72	1/46.27	8/45.63
POLY-3 PERCENT (g)	4.2%	0%	2.1%	2.2%	17.5%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	0/44 (0%)	1/39 (3%)	6/38 (16%)
FIRST INCIDENCE	491	---	673	729 (T)	589
STATISTICAL TESTS					
POLY 3	P<0.001**	P=0.236N	P=0.490N	P=0.508N	P=0.039*
POLY 1.5	P<0.001**	P=0.236N	P=0.494N	P=0.504N	P=0.041*
POLY 6	P<0.001**	P=0.237N	P=0.487N	P=0.516N	P=0.038*
COCH-ARM / FISHERS	P<0.001**	P=0.247N	P=0.500N	P=0.500N	P=0.046*
MAX-ISO-POLY-3	P<0.001**	P=0.076N	P=0.275N	P=0.290N	P=0.019*

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
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 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Liver					
Tension Lipidosis					
LESION RATES					
OVERALL (a)	2/50 (4%)	2/50 (4%)	4/50 (8%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/46.01	2/47.58	4/48.51	1/46.27	0/45.06
POLY-3 PERCENT (g)	4.4%	4.2%	8.3%	2.2%	0%
TERMINAL (d)	2/40 (5%)	2/40 (5%)	4/44 (9%)	1/39 (3%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)	---
STATISTICAL TESTS					
POLY 3	P=0.097N	P=0.682N	P=0.362	P=0.498N	P=0.242N
POLY 1.5	P=0.096N	P=0.686N	P=0.353	P=0.498N	P=0.241N
POLY 6	P=0.099N	P=0.679N	P=0.369	P=0.502N	P=0.243N
COCH-ARM / FISHERS	P=0.091N	P=0.691N	P=0.339	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.152N	P=0.486N	P=0.225	P=0.279N	P=0.080N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Lung					
Infiltration Cellular Lymphocyte					
LESION RATES					
OVERALL (a)	0/50 (0%)	3/50 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.01	3/47.58	1/48.51	0/46.27	0/45.06
POLY-3 PERCENT (g)	0%	6.3%	2.1%	0%	0%
TERMINAL (d)	0/40 (0%)	3/40 (8%)	1/44 (2%)	0/39 (0%)	0/38 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---	---
STATISTICAL TESTS					
POLY 3	P=0.207N	P=0.125	P=0.511	(e)	(e)
POLY 1.5	P=0.206N	P=0.123	P=0.507	(e)	(e)
POLY 6	P=0.207N	P=0.126	P=0.513	(e)	(e)
COCH-ARM / FISHERS	P=0.207N	P=0.121	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.217N	P=0.043*	P=0.171	(e)	(e)

Experiment Number: 00058 - 04
 Test Type: CHRONIC
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 Species/Strain: MICE/B6C3F1/N

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 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Lung: Epithelium, Alveolus Hyperplasia					
LESION RATES					
OVERALL (a)	2/50 (4%)	2/50 (4%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/46.01	2/47.58	2/48.51	1/46.27	1/45.06
POLY-3 PERCENT (g)	4.4%	4.2%	4.1%	2.2%	2.2%
TERMINAL (d)	2/40 (5%)	2/40 (5%)	2/44 (5%)	1/39 (3%)	1/38 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.374N	P=0.682N	P=0.675N	P=0.498N	P=0.507N
POLY 1.5	P=0.370N	P=0.686N	P=0.681N	P=0.498N	P=0.506N
POLY 6	P=0.378N	P=0.679N	P=0.669N	P=0.502N	P=0.509N
COCH-ARM / FISHERS	P=0.358N	P=0.691N	P=0.691N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.507N	P=0.486N	P=0.478N	P=0.279N	P=0.289N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Lymph Node, Mandibular Hyperplasia Lymphocyte					
LESION RATES					
OVERALL (a)	0/50 (0%)	4/49 (8%)	5/50 (10%)	0/50 (0%)	7/50 (14%)
POLY-3 RATE (b)	0/46.01	4/46.76	5/48.51	0/46.27	7/45.15
POLY-3 PERCENT (g)	0%	8.6%	10.3%	0%	15.5%
TERMINAL (d)	0/40 (0%)	3/40 (8%)	5/44 (11%)	0/39 (0%)	6/38 (16%)
FIRST INCIDENCE	---	724	729 (T)	---	705
STATISTICAL TESTS					
POLY 3	P=0.026*	P=0.062	P=0.035*	(e)	P=0.007**
POLY 1.5	P=0.027*	P=0.061	P=0.034*	(e)	P=0.007**
POLY 6	P=0.026*	P=0.064	P=0.037*	(e)	P=0.007**
COCH-ARM / FISHERS	P=0.032*	P=0.056	P=0.028*	(e)	P=0.006**
MAX-ISO-POLY-3	P=0.003**	P=0.021*	P=0.013*	(e)	P=0.003**

Experiment Number: 00058 - 04
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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Lymph Node, Mandibular Pigment					
LESION RATES					
OVERALL (a)	0/50 (0%)	2/49 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.01	2/46.74	0/48.51	0/46.27	0/45.06
POLY-3 PERCENT (g)	0%	4.3%	0%	0%	0%
TERMINAL (d)	0/40 (0%)	2/40 (5%)	0/44 (0%)	0/39 (0%)	0/38 (0%)
FIRST INCIDENCE	---	729 (T)	---	---	---
STATISTICAL TESTS					
POLY 3	P=0.376N	P=0.241	(e)	(e)	(e)
POLY 1.5	P=0.376N	P=0.238	(e)	(e)	(e)
POLY 6	P=0.376N	P=0.243	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.377N	P=0.242	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.242N	P=0.080	(e)	(e)	(e)

Experiment Number: 00058 - 04
 Test Type: CHRONIC
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 Species/Strain: MICE/B6C3F1/N

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Lymph Node, Mesenteric Hyperplasia Lymphocyte					
LESION RATES					
OVERALL (a)	11/50 (22%)	10/49 (20%)	11/50 (22%)	4/49 (8%)	7/50 (14%)
POLY-3 RATE (b)	11/46.01	10/46.61	11/48.51	4/45.49	7/45.79
POLY-3 PERCENT (g)	23.9%	21.5%	22.7%	8.8%	15.3%
TERMINAL (d)	11/40 (28%)	10/40 (25%)	11/44 (25%)	3/38 (8%)	6/38 (16%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	671	470
STATISTICAL TESTS					
POLY 3	P=0.156N	P=0.487N	P=0.540N	P=0.045N*	P=0.219N
POLY 1.5	P=0.153N	P=0.498N	P=0.560N	P=0.046N*	P=0.222N
POLY 6	P=0.159N	P=0.479N	P=0.525N	P=0.046N*	P=0.217N
COCH-ARM / FISHERS	P=0.141N	P=0.521N	P=0.595N	P=0.049N*	P=0.218N
MAX-ISO-POLY-3	P=0.129N	P=0.390N	P=0.445N	P=0.024N*	P=0.149N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Lymph Node, Mesenteric Infiltration Cellular Plasma Cell					
LESION RATES					
OVERALL (a)	1/50 (2%)	0/49 (0%)	1/50 (2%)	3/49 (6%)	0/50 (0%)
POLY-3 RATE (b)	1/46.01	0/46.61	1/48.51	3/45.27	0/45.06
POLY-3 PERCENT (g)	2.2%	0%	2.1%	6.6%	0%
TERMINAL (d)	1/40 (3%)	0/40 (0%)	1/44 (2%)	3/38 (8%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)	---
STATISTICAL TESTS					
POLY 3	P=0.483N	P=0.497N	P=0.749N	P=0.299	P=0.504N
POLY 1.5	P=0.477N	P=0.500N	P=0.753N	P=0.300	P=0.504N
POLY 6	P=0.488N	P=0.496N	P=0.745N	P=0.295	P=0.505N
COCH-ARM / FISHERS	P=0.459N	P=0.505N	P=0.753N	P=0.301	P=0.500N
MAX-ISO-POLY-3	P=0.343N	P=0.159N	P=0.485N	P=0.150	P=0.163N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
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 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Mesentery: Fat Necrosis					
LESION RATES					
OVERALL (a)	4/6 (67%)	1/2 (50%)	0/0 (0%)	0/2 (0%)	0/1 (0%)
POLY-3 RATE (b)	4/6.00	1/1.41	0/0.00	0/1.56	0/0.43
POLY-3 PERCENT (g)	66.7%	71.1%	0%	0%	0%
TERMINAL (d)	4/6 (67%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---	---
STATISTICAL TESTS					
POLY 3	(e)	P=0.765	(e)	P=0.288N	P=0.685N
POLY 1.5	(e)	P=0.748N	(e)	P=0.239N	P=0.589N
POLY 6	(e)	P=0.697	(e)	P=0.383N	P=0.777N
COCH-ARM / FISHERS	P=0.218N	P=0.643N	(e)	P=0.214N	P=0.429N
MAX-ISO-POLY-3	(e)	P=0.474	(e)	P=0.134N	P=0.348N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Nose: Olfactory Epithelium Atrophy					
LESION RATES					
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	1/46.04	0/47.58	1/48.72	0/46.27	3/45.53
POLY-3 PERCENT (g)	2.2%	0%	2.1%	0%	6.6%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	0/44 (0%)	0/39 (0%)	2/38 (5%)
FIRST INCIDENCE	723	---	673	---	589
STATISTICAL TESTS					
POLY 3	P=0.050*	P=0.493N	P=0.748N	P=0.499N	P=0.301
POLY 1.5	P=0.051	P=0.496N	P=0.752N	P=0.499N	P=0.301
POLY 6	P=0.050*	P=0.492N	P=0.744N	P=0.501N	P=0.302
COCH-ARM / FISHERS	P=0.054	P=0.500N	P=0.753N	P=0.500N	P=0.309
MAX-ISO-POLY-3	P=0.061	P=0.158N	P=0.484N	P=0.158N	P=0.152

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Nose: Olfactory Epithelium Metaplasia Respiratory					
LESION RATES					
OVERALL (a)	4/50 (8%)	7/50 (14%)	5/50 (10%)	7/50 (14%)	3/50 (6%)
POLY-3 RATE (b)	4/46.01	7/47.60	5/48.51	7/46.47	3/45.47
POLY-3 PERCENT (g)	8.7%	14.7%	10.3%	15.1%	6.6%
TERMINAL (d)	4/40 (10%)	6/40 (15%)	5/44 (11%)	6/39 (15%)	2/38 (5%)
FIRST INCIDENCE	729 (T)	724	729 (T)	677	610
STATISTICAL TESTS					
POLY 3	P=0.263N	P=0.281	P=0.533	P=0.267	P=0.506N
POLY 1.5	P=0.259N	P=0.275	P=0.521	P=0.267	P=0.507N
POLY 6	P=0.266N	P=0.285	P=0.542	P=0.262	P=0.506N
COCH-ARM / FISHERS	P=0.239N	P=0.262	P=0.500	P=0.262	P=0.500N
MAX-ISO-POLY-3	P=0.357N	P=0.187	P=0.398	P=0.173	P=0.354N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Nose: Respiratory Epithelium Accumulation, Hyaline Droplet					
LESION RATES					
OVERALL (a)	13/50 (26%)	14/50 (28%)	15/50 (30%)	13/50 (26%)	10/50 (20%)
POLY-3 RATE (b)	13/47.48	14/48.11	15/48.51	13/47.00	10/45.53
POLY-3 PERCENT (g)	27.4%	29.1%	30.9%	27.7%	22%
TERMINAL (d)	9/40 (23%)	12/40 (30%)	15/44 (34%)	10/39 (26%)	9/38 (24%)
FIRST INCIDENCE	516	570	729 (T)	652	589
STATISTICAL TESTS					
POLY 3	P=0.224N	P=0.516	P=0.438	P=0.579	P=0.358N
POLY 1.5	P=0.211N	P=0.513	P=0.431	P=0.586	P=0.347N
POLY 6	P=0.238N	P=0.512	P=0.435	P=0.562	P=0.373N
COCH-ARM / FISHERS	P=0.174N	P=0.500	P=0.412	P=0.590N	P=0.318N
MAX-ISO-POLY-3	P=0.396N	P=0.427	P=0.352	P=0.488	P=0.277N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Nose: Respiratory Epithelium Hyperplasia					
LESION RATES					
OVERALL (a)	17/50 (34%)	19/50 (38%)	9/50 (18%)	13/50 (26%)	18/50 (36%)
POLY-3 RATE (b)	17/47.60	19/48.39	9/48.98	13/47.04	18/45.35
POLY-3 PERCENT (g)	35.7%	39.3%	18.4%	27.6%	39.7%
TERMINAL (d)	14/40 (35%)	15/40 (38%)	7/44 (16%)	10/39 (26%)	16/38 (42%)
FIRST INCIDENCE	462	570	651	652	666
STATISTICAL TESTS					
POLY 3	P=0.233	P=0.441	P=0.043N*	P=0.266N	P=0.428
POLY 1.5	P=0.256	P=0.433	P=0.047N*	P=0.262N	P=0.447
POLY 6	P=0.212	P=0.449	P=0.040N*	P=0.277N	P=0.411
COCH-ARM / FISHERS	P=0.318	P=0.418	P=0.055N	P=0.257N	P=0.500
MAX-ISO-POLY-3	P=0.300	P=0.360	P=0.027N*	P=0.199N	P=0.349

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Nose: Respiratory Epithelium Inflammation Acute					
LESION RATES					
OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/46.66	1/47.58	1/48.80	0/46.27	1/45.30
POLY-3 PERCENT (g)	4.3%	2.1%	2.1%	0%	2.2%
TERMINAL (d)	1/40 (3%)	1/40 (3%)	0/44 (0%)	0/39 (0%)	0/38 (0%)
FIRST INCIDENCE	516	729 (T)	651	---	666
STATISTICAL TESTS					
POLY 3	P=0.536N	P=0.493N	P=0.484N	P=0.239N	P=0.510N
POLY 1.5	P=0.533N	P=0.495N	P=0.490N	P=0.238N	P=0.508N
POLY 6	P=0.539N	P=0.492N	P=0.480N	P=0.243N	P=0.512N
COCH-ARM / FISHERS	P=0.524N	P=0.500N	P=0.500N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.269N	P=0.276N	P=0.272N	P=0.078N	P=0.292N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Nose: Respiratory Epithelium Inflammation Chronic					
LESION RATES					
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/46.11	0/47.58	1/48.51	2/46.53	0/45.06
POLY-3 PERCENT (g)	2.2%	0%	2.1%	4.3%	0%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	1/44 (2%)	1/39 (3%)	0/38 (0%)
FIRST INCIDENCE	706	---	729 (T)	662	---
STATISTICAL TESTS					
POLY 3	P=0.469N	P=0.494N	P=0.749N	P=0.503	P=0.505N
POLY 1.5	P=0.464N	P=0.496N	P=0.753N	P=0.503	P=0.504N
POLY 6	P=0.473N	P=0.493N	P=0.746N	P=0.500	P=0.506N
COCH-ARM / FISHERS	P=0.449N	P=0.500N	P=0.753N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.386N	P=0.158N	P=0.486N	P=0.284	P=0.163N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Ovary					
Angiectasis					
LESION RATES					
OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/45.04	0/47.58	2/48.51	0/46.27	1/45.06
POLY-3 PERCENT (g)	0%	0%	4.1%	0%	2.2%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	2/44 (5%)	0/39 (0%)	1/38 (3%)
FIRST INCIDENCE	---	---	729 (T)	---	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.499	(e)	P=0.254	(e)	P=0.500
POLY 1.5	P=0.500	(e)	P=0.250	(e)	P=0.501
POLY 6	P=0.497	(e)	P=0.258	(e)	P=0.499
COCH-ARM / FISHERS	P=0.507	(e)	P=0.253	(e)	P=0.505
MAX-ISO-POLY-3	P=0.317	(e)	P=0.091	(e)	P=0.159

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Ovary Atrophy					
LESION RATES					
OVERALL (a)	35/49 (71%)	38/50 (76%)	34/50 (68%)	39/50 (78%)	30/50 (60%)
POLY-3 RATE (b)	35/46.87	38/49.37	34/49.79	39/49.19	30/46.85
POLY-3 PERCENT (g)	74.7%	77%	68.3%	79.3%	64%
TERMINAL (d)	29/40 (73%)	30/40 (75%)	29/44 (66%)	31/39 (80%)	22/38 (58%)
FIRST INCIDENCE	516	570	599	455	589
STATISTICAL TESTS					
POLY 3	P=0.130N	P=0.491	P=0.319N	P=0.383	P=0.183N
POLY 1.5	P=0.115N	P=0.454	P=0.360N	P=0.358	P=0.184N
POLY 6	P=0.138N	P=0.517	P=0.291N	P=0.385	P=0.180N
COCH-ARM / FISHERS	P=0.070N	P=0.387	P=0.440N	P=0.301	P=0.162N
MAX-ISO-POLY-3	P=0.179N	P=0.398	P=0.248N	P=0.298	P=0.129N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Ovary					
Cyst Epithelial					
LESION RATES					
OVERALL (a)	3/49 (6%)	6/50 (12%)	3/50 (6%)	3/50 (6%)	6/50 (12%)
POLY-3 RATE (b)	3/45.04	6/47.74	3/48.51	3/46.27	6/45.21
POLY-3 PERCENT (g)	6.7%	12.6%	6.2%	6.5%	13.3%
TERMINAL (d)	3/40 (8%)	5/40 (13%)	3/44 (7%)	3/39 (8%)	5/38 (13%)
FIRST INCIDENCE	729 (T)	688	729 (T)	729 (T)	691
STATISTICAL TESTS					
POLY 3	P=0.246	P=0.272	P=0.627N	P=0.650N	P=0.244
POLY 1.5	P=0.252	P=0.265	P=0.636N	P=0.649N	P=0.244
POLY 6	P=0.241	P=0.277	P=0.620N	P=0.655N	P=0.243
COCH-ARM / FISHERS	P=0.270	P=0.254	P=0.651N	P=0.651N	P=0.254
MAX-ISO-POLY-3	P=0.250	P=0.174	P=0.463N	P=0.486N	P=0.147

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Ovary					
Infiltration Cellular Lymphocyte					
LESION RATES					
OVERALL (a)	2/49 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/45.04	0/47.58	1/48.72	0/46.27	0/45.06
POLY-3 PERCENT (g)	4.4%	0%	2.1%	0%	0%
TERMINAL (d)	2/40 (5%)	0/40 (0%)	0/44 (0%)	0/39 (0%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	---	673	---	---
STATISTICAL TESTS					
POLY 3	P=0.270N	P=0.225N	P=0.473N	P=0.231N	P=0.237N
POLY 1.5	P=0.267N	P=0.228N	P=0.480N	P=0.231N	P=0.237N
POLY 6	P=0.273N	P=0.223N	P=0.466N	P=0.233N	P=0.238N
COCH-ARM / FISHERS	P=0.260N	P=0.242N	P=0.492N	P=0.242N	P=0.242N
MAX-ISO-POLY-3	P=0.057N	P=0.075N	P=0.264N	P=0.075N	P=0.077N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Ovary: Bursa Cyst					
LESION RATES					
OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/45.04	0/47.58	2/48.51	0/46.27	1/45.06
POLY-3 PERCENT (g)	0%	0%	4.1%	0%	2.2%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	2/44 (5%)	0/39 (0%)	1/38 (3%)
FIRST INCIDENCE	---	---	729 (T)	---	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.499	(e)	P=0.254	(e)	P=0.500
POLY 1.5	P=0.500	(e)	P=0.250	(e)	P=0.501
POLY 6	P=0.497	(e)	P=0.258	(e)	P=0.499
COCH-ARM / FISHERS	P=0.507	(e)	P=0.253	(e)	P=0.505
MAX-ISO-POLY-3	P=0.317	(e)	P=0.091	(e)	P=0.159

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Ovary: Follicle Cyst					
LESION RATES					
OVERALL (a)	10/49 (20%)	4/50 (8%)	5/50 (10%)	5/50 (10%)	9/50 (18%)
POLY-3 RATE (b)	10/45.19	4/47.60	5/48.51	5/46.81	9/45.63
POLY-3 PERCENT (g)	22.1%	8.4%	10.3%	10.7%	19.7%
TERMINAL (d)	9/40 (23%)	2/40 (5%)	5/44 (11%)	3/39 (8%)	6/38 (16%)
FIRST INCIDENCE	691	724	729 (T)	652	666
STATISTICAL TESTS					
POLY 3	P=0.226	P=0.058N	P=0.100N	P=0.113N	P=0.491N
POLY 1.5	P=0.233	P=0.061N	P=0.107N	P=0.116N	P=0.493N
POLY 6	P=0.223	P=0.056N	P=0.095N	P=0.114N	P=0.487N
COCH-ARM / FISHERS	P=0.258	P=0.068N	P=0.122N	P=0.122N	P=0.480N
MAX-ISO-POLY-3	P=0.156N	P=0.034N*	P=0.064N	P=0.070N	P=0.389N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Ovary: Interstitial Cell Hyperplasia					
LESION RATES					
OVERALL (a)	0/49 (0%)	1/50 (2%)	3/50 (6%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/45.04	1/47.58	3/48.51	2/46.27	1/46.05
POLY-3 PERCENT (g)	0%	2.1%	6.2%	4.3%	2.2%
TERMINAL (d)	0/40 (0%)	1/40 (3%)	3/44 (7%)	2/39 (5%)	0/38 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)	171
STATISTICAL TESTS					
POLY 3	P=0.614N	P=0.511	P=0.133	P=0.243	P=0.504
POLY 1.5	P=0.612N	P=0.509	P=0.129	P=0.243	P=0.504
POLY 6	P=0.616N	P=0.513	P=0.136	P=0.241	P=0.504
COCH-ARM / FISHERS	P=0.609N	P=0.505	P=0.125	P=0.253	P=0.505
MAX-ISO-POLY-3	P=0.212	P=0.170	P=0.050*	P=0.080	P=0.162

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Ovary: Rete Ovarii Cyst					
LESION RATES					
OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/45.54	0/47.58	0/48.51	2/46.56	1/45.06
POLY-3 PERCENT (g)	2.2%	0%	0%	4.3%	2.2%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	0/44 (0%)	1/39 (3%)	1/38 (3%)
FIRST INCIDENCE	579	---	---	652	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.420	P=0.491N	P=0.487N	P=0.508	P=0.758
POLY 1.5	P=0.427	P=0.493N	P=0.490N	P=0.509	P=0.760
POLY 6	P=0.414	P=0.491N	P=0.486N	P=0.503	P=0.756
COCH-ARM / FISHERS	P=0.445	P=0.495N	P=0.495N	P=0.508	P=0.747N
MAX-ISO-POLY-3	P=0.317	P=0.157N	P=0.157N	P=0.288	P=0.497

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Pancreas: Acinus Atrophy					
LESION RATES					
OVERALL (a)	3/50 (6%)	1/50 (2%)	1/50 (2%)	1/49 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/46.01	1/47.58	1/48.51	1/45.62	0/45.06
POLY-3 PERCENT (g)	6.5%	2.1%	2.1%	2.2%	0%
TERMINAL (d)	3/40 (8%)	1/40 (3%)	1/44 (2%)	1/39 (3%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)	---
STATISTICAL TESTS					
POLY 3	P=0.162N	P=0.294N	P=0.287N	P=0.308N	P=0.122N
POLY 1.5	P=0.159N	P=0.298N	P=0.293N	P=0.309N	P=0.122N
POLY 6	P=0.165N	P=0.291N	P=0.282N	P=0.311N	P=0.123N
COCH-ARM / FISHERS	P=0.150N	P=0.309N	P=0.309N	P=0.316N	P=0.121N
MAX-ISO-POLY-3	P=0.048N*	P=0.149N	P=0.147N	P=0.156N	P=0.041N*

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Pituitary Gland: Pars Distalis Hyperplasia Focal					
LESION RATES					
OVERALL (a)	8/49 (16%)	8/49 (16%)	10/50 (20%)	7/50 (14%)	8/50 (16%)
POLY-3 RATE (b)	8/45.51	8/46.60	10/48.51	7/46.27	8/45.06
POLY-3 PERCENT (g)	17.6%	17.2%	20.6%	15.1%	17.8%
TERMINAL (d)	8/40 (20%)	7/39 (18%)	10/44 (23%)	7/39 (18%)	8/38 (21%)
FIRST INCIDENCE	729 (T)	724	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.527N	P=0.588N	P=0.456	P=0.486N	P=0.599
POLY 1.5	P=0.514N	P=0.593N	P=0.442	P=0.482N	P=0.605
POLY 6	P=0.541N	P=0.586N	P=0.464	P=0.500N	P=0.592
COCH-ARM / FISHERS	P=0.477N	P=0.607N	P=0.416	P=0.483N	P=0.590N
MAX-ISO-POLY-3	P=0.671N	P=0.479N	P=0.357	P=0.376N	P=0.491

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Pituitary Gland: Pars Distalis Hypertrophy					
LESION RATES					
OVERALL (a)	2/49 (4%)	1/49 (2%)	0/50 (0%)	3/50 (6%)	4/50 (8%)
POLY-3 RATE (b)	2/45.51	1/46.58	0/48.51	3/46.56	4/45.06
POLY-3 PERCENT (g)	4.4%	2.2%	0%	6.4%	8.9%
TERMINAL (d)	2/40 (5%)	1/39 (3%)	0/44 (0%)	2/39 (5%)	4/38 (11%)
FIRST INCIDENCE	729 (T)	729 (T)	---	652	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.060	P=0.492N	P=0.223N	P=0.510	P=0.333
POLY 1.5	P=0.063	P=0.494N	P=0.227N	P=0.511	P=0.336
POLY 6	P=0.058	P=0.491N	P=0.221N	P=0.505	P=0.328
COCH-ARM / FISHERS	P=0.071	P=0.500N	P=0.242N	P=0.510	P=0.349
MAX-ISO-POLY-3	P=0.105	P=0.276N	P=0.075N	P=0.334	P=0.198

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Skin					
Ulcer					
LESION RATES					
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/46.01	0/47.58	2/48.80	0/46.27	2/45.15
POLY-3 PERCENT (g)	0%	0%	4.1%	0%	4.4%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	1/44 (2%)	0/39 (0%)	1/38 (3%)
FIRST INCIDENCE	---	---	651	---	705
STATISTICAL TESTS					
POLY 3	P=0.163	(e)	P=0.251	(e)	P=0.233
POLY 1.5	P=0.164	(e)	P=0.246	(e)	P=0.233
POLY 6	P=0.162	(e)	P=0.255	(e)	P=0.232
COCH-ARM / FISHERS	P=0.169	(e)	P=0.247	(e)	P=0.247
MAX-ISO-POLY-3	P=0.096	(e)	P=0.089	(e)	P=0.076

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Spleen					
Extramedullary Hematopoiesis Increased					
LESION RATES					
OVERALL (a)	17/50 (34%)	21/50 (42%)	22/50 (44%)	14/50 (28%)	11/50 (22%)
POLY-3 RATE (b)	17/48.35	21/48.24	22/49.46	14/47.45	11/47.16
POLY-3 PERCENT (g)	35.2%	43.5%	44.5%	29.5%	23.3%
TERMINAL (d)	12/40 (30%)	16/40 (40%)	19/44 (43%)	11/39 (28%)	7/38 (18%)
FIRST INCIDENCE	462	540	599	572	382
STATISTICAL TESTS					
POLY 3	P=0.021N*	P=0.263	P=0.232	P=0.355N	P=0.147N
POLY 1.5	P=0.020N*	P=0.268	P=0.223	P=0.344N	P=0.144N
POLY 6	P=0.022N*	P=0.251	P=0.237	P=0.378N	P=0.155N
COCH-ARM / FISHERS	P=0.017N*	P=0.268	P=0.206	P=0.333N	P=0.133N
MAX-ISO-POLY-3	P=0.036N*	P=0.199	P=0.176	P=0.280N	P=0.104N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Spleen					
Hyperplasia Lymphocyte					
LESION RATES					
OVERALL (a)	10/50 (20%)	18/50 (36%)	10/50 (20%)	14/50 (28%)	7/50 (14%)
POLY-3 RATE (b)	10/46.01	18/47.58	10/48.51	14/46.27	7/45.47
POLY-3 PERCENT (g)	21.7%	37.8%	20.6%	30.3%	15.4%
TERMINAL (d)	10/40 (25%)	18/40 (45%)	10/44 (23%)	14/39 (36%)	6/38 (16%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)	610
STATISTICAL TESTS					
POLY 3	P=0.077N	P=0.068	P=0.547N	P=0.243	P=0.305N
POLY 1.5	P=0.075N	P=0.065	P=0.565N	P=0.245	P=0.307N
POLY 6	P=0.079N	P=0.070	P=0.533N	P=0.231	P=0.303N
COCH-ARM / FISHERS	P=0.065N	P=0.059	P=0.598N	P=0.241	P=0.298N
MAX-ISO-POLY-3	P=0.097N	P=0.045*	P=0.448N	P=0.175	P=0.219N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Spleen Pigment					
LESION RATES					
OVERALL (a)	2/50 (4%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/46.01	2/47.60	0/48.51	0/46.27	1/45.30
POLY-3 PERCENT (g)	4.4%	4.2%	0%	0%	2.2%
TERMINAL (d)	2/40 (5%)	1/40 (3%)	0/44 (0%)	0/39 (0%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	724	---	---	666
STATISTICAL TESTS					
POLY 3	P=0.502N	P=0.681N	P=0.226N	P=0.236N	P=0.505N
POLY 1.5	P=0.499N	P=0.686N	P=0.230N	P=0.236N	P=0.505N
POLY 6	P=0.505N	P=0.679N	P=0.223N	P=0.238N	P=0.505N
COCH-ARM / FISHERS	P=0.490N	P=0.691N	P=0.247N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.211N	P=0.486N	P=0.076N	P=0.076N	P=0.287N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Spleen: White Pulp Atrophy					
LESION RATES					
OVERALL (a)	2/50 (4%)	4/50 (8%)	3/50 (6%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	2/46.91	4/48.22	3/49.46	5/47.69	2/46.26
POLY-3 PERCENT (g)	4.3%	8.3%	6.1%	10.5%	4.3%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	0/44 (0%)	2/39 (5%)	0/38 (0%)
FIRST INCIDENCE	462	540	599	455	470
STATISTICAL TESTS					
POLY 3	P=0.440N	P=0.350	P=0.524	P=0.223	P=0.689
POLY 1.5	P=0.435N	P=0.346	P=0.515	P=0.222	P=0.688
POLY 6	P=0.445N	P=0.353	P=0.533	P=0.221	P=0.689
COCH-ARM / FISHERS	P=0.416N	P=0.339	P=0.500	P=0.218	P=0.691N
MAX-ISO-POLY-3	P=0.479	P=0.213	P=0.349	P=0.126	P=0.494

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Stomach, Forestomach: Epithelium Hyperplasia Focal					
LESION RATES					
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.01	2/47.58	1/48.66	0/46.27	0/45.06
POLY-3 PERCENT (g)	0%	4.2%	2.1%	0%	0%
TERMINAL (d)	0/40 (0%)	2/40 (5%)	0/44 (0%)	0/39 (0%)	0/38 (0%)
FIRST INCIDENCE	---	729 (T)	690	---	---
STATISTICAL TESTS					
POLY 3	P=0.295N	P=0.245	P=0.511	(e)	(e)
POLY 1.5	P=0.295N	P=0.242	P=0.507	(e)	(e)
POLY 6	P=0.296N	P=0.246	P=0.515	(e)	(e)
COCH-ARM / FISHERS	P=0.293N	P=0.247	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.332N	P=0.083	P=0.172	(e)	(e)

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Thyroid Gland: Follicle Dilation					
LESION RATES					
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/49 (2%)	1/49 (2%)	6/50 (12%)
POLY-3 RATE (b)	0/46.01	1/47.58	1/47.51	1/45.71	6/45.15
POLY-3 PERCENT (g)	0%	2.1%	2.1%	2.2%	13.3%
TERMINAL (d)	0/40 (0%)	1/40 (3%)	1/43 (2%)	0/38 (0%)	5/38 (13%)
FIRST INCIDENCE	---	729 (T)	729 (T)	603	705
STATISTICAL TESTS					
POLY 3	P<0.001**	P=0.507	P=0.506	P=0.499	P=0.014*
POLY 1.5	P<0.001**	P=0.504	P=0.503	P=0.498	P=0.014*
POLY 6	P<0.001**	P=0.508	P=0.509	P=0.497	P=0.014*
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.495	P=0.495	P=0.013*
MAX-ISO-POLY-3	P<0.001**	P=0.166	P=0.167	P=0.157	P=0.005**

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Urinary Bladder Infiltration Cellular Lymphocyte					
LESION RATES					
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	2/46.01	0/47.58	1/48.51	0/46.27	0/44.06
POLY-3 PERCENT (g)	4.4%	0%	2.1%	0%	0%
TERMINAL (d)	2/40 (5%)	0/40 (0%)	1/44 (2%)	0/39 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---	---
STATISTICAL TESTS					
POLY 3	P=0.275N	P=0.230N	P=0.482N	P=0.236N	P=0.247N
POLY 1.5	P=0.272N	P=0.232N	P=0.488N	P=0.236N	P=0.246N
POLY 6	P=0.277N	P=0.228N	P=0.477N	P=0.238N	P=0.248N
COCH-ARM / FISHERS	P=0.265N	P=0.247N	P=0.500N	P=0.247N	P=0.253N
MAX-ISO-POLY-3	P=0.066N	P=0.076N	P=0.270N	P=0.076N	P=0.084N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Uterus					
Angiectasis					
LESION RATES					
OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	2/46.01	2/47.58	1/48.51	0/46.27	3/46.65
POLY-3 PERCENT (g)	4.4%	4.2%	2.1%	0%	6.4%
TERMINAL (d)	2/40 (5%)	2/40 (5%)	1/44 (2%)	0/39 (0%)	1/38 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	---	382
STATISTICAL TESTS					
POLY 3	P=0.301	P=0.682N	P=0.482N	P=0.236N	P=0.506
POLY 1.5	P=0.303	P=0.686N	P=0.488N	P=0.236N	P=0.502
POLY 6	P=0.300	P=0.679N	P=0.477N	P=0.238N	P=0.508
COCH-ARM / FISHERS	P=0.307	P=0.691N	P=0.500N	P=0.247N	P=0.500
MAX-ISO-POLY-3	P=0.287	P=0.486N	P=0.270N	P=0.076N	P=0.331

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Uterus					
Inflammation Acute					
LESION RATES					
OVERALL (a)	5/50 (10%)	1/50 (2%)	2/50 (4%)	5/50 (10%)	0/50 (0%)
POLY-3 RATE (b)	5/46.71	1/47.60	2/48.51	5/46.76	0/45.06
POLY-3 PERCENT (g)	10.7%	2.1%	4.1%	10.7%	0%
TERMINAL (d)	4/40 (10%)	0/40 (0%)	2/44 (5%)	3/39 (8%)	0/38 (0%)
FIRST INCIDENCE	491	724	729 (T)	652	---
STATISTICAL TESTS					
POLY 3	P=0.121N	P=0.097N	P=0.202N	P=0.629N	P=0.034N*
POLY 1.5	P=0.116N	P=0.099N	P=0.207N	P=0.628N	P=0.033N*
POLY 6	P=0.125N	P=0.096N	P=0.198N	P=0.626	P=0.034N*
COCH-ARM / FISHERS	P=0.105N	P=0.102N	P=0.218N	P=0.630N	P=0.028N*
MAX-ISO-POLY-3	P=0.025N*	P=0.044N*	P=0.113N	P=0.499N	P=0.012N*

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
 Time Report Requested: 11:32:38
 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Uterus Thrombus					
LESION RATES					
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/46.01	0/47.58	0/48.51	2/46.49	0/45.06
POLY-3 PERCENT (g)	0%	0%	0%	4.3%	0%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	0/44 (0%)	1/39 (3%)	0/38 (0%)
FIRST INCIDENCE	---	---	---	671	---
STATISTICAL TESTS					
POLY 3	P=0.712	(e)	(e)	P=0.240	(e)
POLY 1.5	P=0.717	(e)	(e)	P=0.239	(e)
POLY 6	P=0.707	(e)	(e)	P=0.238	(e)
COCH-ARM / FISHERS	P=0.731	(e)	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.235	(e)	(e)	P=0.078	(e)

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
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 Black Cohosh
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Uterus: Endometrium Hyperplasia Cystic					
LESION RATES					
OVERALL (a)	41/50 (82%)	31/50 (62%)	45/50 (90%)	41/50 (82%)	45/50 (90%)
POLY-3 RATE (b)	41/48.52	31/47.61	45/49.79	41/47.95	45/47.92
POLY-3 PERCENT (g)	84.5%	65.1%	90.4%	85.5%	93.9%
TERMINAL (d)	34/40 (85%)	28/40 (70%)	40/44 (91%)	34/39 (87%)	38/38 (100%)
FIRST INCIDENCE	462	724	599	652	382
STATISTICAL TESTS					
POLY 3	P=0.009**	P=0.020N*	P=0.279	P=0.560	P=0.109
POLY 1.5	P=0.012*	P=0.019N*	P=0.245	P=0.583	P=0.127
POLY 6	P=0.007**	P=0.026N*	P=0.309	P=0.520	P=0.081
COCH-ARM / FISHERS	P=0.030*	P=0.022N*	P=0.194	P=0.602N	P=0.194
MAX-ISO-POLY-3	P=0.006**	P=0.011N*	P=0.187	P=0.443	P=0.059

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
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 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Uterus: Endometrium Metaplasia					
LESION RATES					
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/46.01	0/47.58	0/48.51	1/46.27	1/45.06
POLY-3 PERCENT (g)	4.4%	0%	0%	2.2%	2.2%
TERMINAL (d)	2/40 (5%)	0/40 (0%)	0/44 (0%)	1/39 (3%)	1/38 (3%)
FIRST INCIDENCE	729 (T)	---	---	729 (T)	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.581	P=0.230N	P=0.226N	P=0.498N	P=0.507N
POLY 1.5	P=0.587	P=0.232N	P=0.230N	P=0.498N	P=0.506N
POLY 6	P=0.575	P=0.228N	P=0.223N	P=0.502N	P=0.509N
COCH-ARM / FISHERS	P=0.604	P=0.247N	P=0.247N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.211N	P=0.076N	P=0.076N	P=0.279N	P=0.289N

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
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 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Vagina					
Inflammation Acute					
LESION RATES					
OVERALL (a)	21/50 (42%)	6/50 (12%)	8/49 (16%)	6/49 (12%)	3/50 (6%)
POLY-3 RATE (b)	21/47.01	6/47.59	8/47.72	6/45.71	3/45.06
POLY-3 PERCENT (g)	44.7%	12.6%	16.8%	13.1%	6.7%
TERMINAL (d)	18/40 (45%)	5/40 (13%)	8/44 (18%)	6/39 (15%)	3/38 (8%)
FIRST INCIDENCE	491	727	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS					
POLY 3	P=0.002N**	P<0.001N**	P=0.002N**	P<0.001N**	P<0.001N**
POLY 1.5	P=0.002N**	P<0.001N**	P=0.003N**	P<0.001N**	P<0.001N**
POLY 6	P=0.002N**	P<0.001N**	P=0.002N**	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P=0.002N**	P<0.001N**	P=0.005N**	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**

Experiment Number: 00058 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1/N

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

Date Report Requested: 12/10/2020
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 First Dose M/F: NA / 04/09/12
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Vagina: Epithelium Hyperplasia					
LESION RATES					
OVERALL (a)	31/50 (62%)	38/50 (76%)	41/49 (84%)	37/49 (76%)	33/50 (66%)
POLY-3 RATE (b)	31/46.78	38/47.59	41/48.16	37/46.93	33/47.37
POLY-3 PERCENT (g)	66.3%	79.9%	85.1%	78.9%	69.7%
TERMINAL (d)	29/40 (73%)	36/40 (90%)	40/44 (91%)	33/39 (85%)	28/38 (74%)
FIRST INCIDENCE	462	727	599	572	171
STATISTICAL TESTS					
POLY 3	P=0.221N	P=0.095	P=0.022*	P=0.119	P=0.446
POLY 1.5	P=0.225N	P=0.097	P=0.018*	P=0.115	P=0.435
POLY 6	P=0.214N	P=0.088	P=0.027*	P=0.120	P=0.455
COCH-ARM / FISHERS	P=0.233N	P=0.097	P=0.014*	P=0.109	P=0.418
MAX-ISO-POLY-3	P=0.136	P=0.062	P=0.013*	P=0.079	P=0.358

Experiment Number: 00058 - 04
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1/N

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LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
(b) Number of tumor-bearing animals/Poly-3 number
(d) Observed incidence at terminal kill.
(e) Value of statistic cannot be computed.
(f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
(g) Poly-3 adjusted lifetime tumor incidence.
(n) No statistics are calculated if all dose groups have fewer than two tumors.
(I) Interim sacrifice
(T) Terminal sacrifice
Tumor rates based on numbers of animals necropsied.
* To the right of any statistical result, indicates significance at ($P \leq 0.05$).
** To the right of any statistical result, indicates significance at ($P \leq 0.01$).
N Indicates a negative trend for all tests
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***