

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
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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HISTORICAL CONTROL STUDIES
From August 2017 report

SAME ROUTE

ALL ROUTES

10260-02 -- 2-Hydroxy-4-methoxybenzophenone (ORAL FEED)

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**FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES EXAMINED.
IN OTHER TISSUES/ORGANS RATES ARE BASED ON THE NUMBER OF ANIMALS NECROPSIED.**

Liver

Lung

Ovary

Pituitary Gland

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

FEMALE MICE

Organ

Liver
Uterus

Morphology

Hepatocellular Carcinoma
Polyp Stromal

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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
Harderian Gland Adenoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	2/50 (4%)	3/50 (6%)	2/50 (4%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	2/46.01	3/47.60	2/48.51	3/46.27	1/45.06
POLY-3 PERCENT (g)	4.4%	6.3%	4.1%	6.5%	2.2%
TERMINAL (d)	2/40 (5%)	2/40 (5%)	2/44 (5%)	3/39 (8%)	1/38 (3%)
FIRST INCIDENCE	729 (T)	724	729 (T)	729 (T)	729 (T)
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	1/50 (2%)				
STATISTICAL TESTS					
POLY 3	P=0.330N	P=0.515	P=0.675N	P=0.503	P=0.507N
POLY 1.5	P=0.325N	P=0.510	P=0.681N	P=0.503	P=0.506N
POLY 6	P=0.336N	P=0.519	P=0.669N	P=0.497	P=0.509N
COCH-ARM / FISHERS	P=0.308N	P=0.500	P=0.691N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.435N	P=0.340	P=0.478N	P=0.326	P=0.289N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	P=0.341	P=0.307	P=1.000	P=0.302	P=1.000
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.516				

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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					
Hepatocellular Adenoma					
TUMOR RATES					
OVERALL (a)	6/50 (12%)	9/50 (18%)	4/50 (8%)	4/50 (8%)	4/50 (8%)
POLY-3 RATE (b)	6/46.16	9/47.59	4/48.51	4/46.27	4/45.19
POLY-3 PERCENT (g)	13%	18.9%	8.3%	8.6%	8.9%
TERMINAL (d)	5/40 (13%)	8/40 (20%)	4/44 (9%)	4/39 (10%)	3/38 (8%)
FIRST INCIDENCE	691	727	729 (T)	729 (T)	695
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	3/50 (6%)				
STATISTICAL TESTS					
POLY 3	P=0.230N	P=0.310	P=0.339N	P=0.368N	P=0.383N
POLY 1.5	P=0.224N	P=0.303	P=0.350N	P=0.367N	P=0.381N
POLY 6	P=0.235N	P=0.313	P=0.332N	P=0.377N	P=0.386N
COCH-ARM / FISHERS	P=0.205N	P=0.288	P=0.370N	P=0.370N	P=0.370N
MAX-ISO-POLY-3	P=0.246N	P=0.221	P=0.232N	P=0.251N	P=0.266N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	P=0.440	P=0.201	P=1.000	P=0.452	P=0.428
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.276				

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 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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					
Hepatocellular Carcinoma					
TUMOR RATES					
OVERALL (a)	3/50 (6%)	3/50 (6%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	3/47.05	3/47.74	0/48.51	2/46.27	1/45.06
POLY-3 PERCENT (g)	6.4%	6.3%	0%	4.3%	2.2%
TERMINAL (d)	1/40 (3%)	2/40 (5%)	0/44 (0%)	2/39 (5%)	1/38 (3%)
FIRST INCIDENCE	462	688	---	729 (T)	729 (T)
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	1/50 (2%)				
STATISTICAL TESTS					
POLY 3	P=0.337N	P=0.655N	P=0.114N	P=0.508N	P=0.321N
POLY 1.5	P=0.330N	P=0.657N	P=0.115N	P=0.503N	P=0.317N
POLY 6	P=0.343N	P=0.655N	P=0.113N	P=0.517N	P=0.326N
COCH-ARM / FISHERS	P=0.313N	P=0.661N	P=0.121N	P=0.500N	P=0.309N
MAX-ISO-POLY-3	P=0.271N	P=0.492N	P=0.038N*	P=0.332N	P=0.170N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	P=0.625	P=0.306	P=1.000	P=0.474	P=1.000
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.285				

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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					
Hepatocellular Carcinoma or Hepatocellular Adenoma					
TUMOR RATES					
OVERALL (a)	8/50 (16%)	12/50 (24%)	4/50 (8%)	6/50 (12%)	5/50 (10%)
POLY-3 RATE (b)	8/47.20	12/47.75	4/48.51	6/46.27	5/45.19
POLY-3 PERCENT (g)	17%	25.1%	8.3%	13%	11.1%
TERMINAL (d)	5/40 (13%)	10/40 (25%)	4/44 (9%)	6/39 (15%)	4/38 (11%)
FIRST INCIDENCE	462	688	729 (T)	729 (T)	695
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	4/50 (8%)				
STATISTICAL TESTS					
POLY 3	P=0.181N	P=0.234	P=0.164N	P=0.402N	P=0.305N
POLY 1.5	P=0.172N	P=0.233	P=0.169N	P=0.394N	P=0.297N
POLY 6	P=0.189N	P=0.232	P=0.163N	P=0.420N	P=0.314N
COCH-ARM / FISHERS	P=0.152N	P=0.227	P=0.178N	P=0.387N	P=0.277N
MAX-ISO-POLY-3	P=0.152N	P=0.166	P=0.102N	P=0.298N	P=0.213N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	P=0.483	P=0.187	P=1.000	P=0.293	P=0.408
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.207				

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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					
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma					
TUMOR RATES					
OVERALL (a)	8/50 (16%)	12/50 (24%)	4/50 (8%)	6/50 (12%)	5/50 (10%)
POLY-3 RATE (b)	8/47.20	12/47.75	4/48.51	6/46.27	5/45.19
POLY-3 PERCENT (g)	17%	25.1%	8.3%	13%	11.1%
TERMINAL (d)	5/40 (13%)	10/40 (25%)	4/44 (9%)	6/39 (15%)	4/38 (11%)
FIRST INCIDENCE	462	688	729 (T)	729 (T)	695
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	4/50 (8%)				
STATISTICAL TESTS					
POLY 3	P=0.181N	P=0.234	P=0.164N	P=0.402N	P=0.305N
POLY 1.5	P=0.172N	P=0.233	P=0.169N	P=0.394N	P=0.297N
POLY 6	P=0.189N	P=0.232	P=0.163N	P=0.420N	P=0.314N
COCH-ARM / FISHERS	P=0.152N	P=0.227	P=0.178N	P=0.387N	P=0.277N
MAX-ISO-POLY-3	P=0.152N	P=0.166	P=0.102N	P=0.298N	P=0.213N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	P=0.483	P=0.187	P=1.000	P=0.293	P=0.408
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.207				

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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					
Alveolar/Bronchiolar Adenoma					
TUMOR RATES					
OVERALL (a)	2/50 (4%)	4/50 (8%)	2/50 (4%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/46.01	4/48.10	2/48.80	2/46.52	1/45.06
POLY-3 PERCENT (g)	4.4%	8.3%	4.1%	4.3%	2.2%
TERMINAL (d)	2/40 (5%)	3/40 (8%)	1/44 (2%)	1/39 (3%)	1/38 (3%)
FIRST INCIDENCE	729 (T)	570	651	665	729 (T)
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	5/50 (10%)				
STATISTICAL TESTS					
POLY 3	P=0.252N	P=0.358	P=0.672N	P=0.690N	P=0.507N
POLY 1.5	P=0.247N	P=0.351	P=0.680N	P=0.690N	P=0.506N
POLY 6	P=0.257N	P=0.364	P=0.665N	P=0.693N	P=0.509N
COCH-ARM / FISHERS	P=0.234N	P=0.339	P=0.691N	P=0.691N	P=0.500N
MAX-ISO-POLY-3	P=0.321N	P=0.221	P=0.476N	P=0.495N	P=0.289N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.263				

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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					
Alveolar/Bronchiolar Carcinoma					
TUMOR RATES					
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/46.01	0/47.58	1/48.51	2/46.27	1/45.06
POLY-3 PERCENT (g)	0%	0%	2.1%	4.3%	2.2%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	1/44 (2%)	2/39 (5%)	1/38 (3%)
FIRST INCIDENCE	---	---	729 (T)	729 (T)	729 (T)
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	0/50 (0%)				
STATISTICAL TESTS					
POLY 3	P=0.371	(e)	P=0.511	P=0.238	P=0.496
POLY 1.5	P=0.375	(e)	P=0.507	P=0.239	P=0.496
POLY 6	P=0.366	(e)	P=0.513	P=0.236	P=0.495
COCH-ARM / FISHERS	P=0.390	(e)	P=0.500	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.210	(e)	P=0.171	P=0.077	P=0.158
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	P=0.192	(e)	P=1.000	P=0.304	P=0.485
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTEs	P=1.000				

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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					
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma					
TUMOR RATES					
OVERALL (a)	2/50 (4%)	4/50 (8%)	3/50 (6%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	2/46.01	4/48.10	3/48.80	4/46.52	2/45.06
POLY-3 PERCENT (g)	4.4%	8.3%	6.2%	8.6%	4.4%
TERMINAL (d)	2/40 (5%)	3/40 (8%)	2/44 (5%)	3/39 (8%)	2/38 (5%)
FIRST INCIDENCE	729 (T)	570	651	665	729 (T)
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	5/50 (10%)				
STATISTICAL TESTS					
POLY 3	P=0.439N	P=0.358	P=0.527	P=0.342	P=0.686
POLY 1.5	P=0.432N	P=0.351	P=0.517	P=0.342	P=0.687
POLY 6	P=0.447N	P=0.364	P=0.535	P=0.339	P=0.685
COCH-ARM / FISHERS	P=0.409N	P=0.339	P=0.500	P=0.339	P=0.691N
MAX-ISO-POLY-3	P=0.543	P=0.221	P=0.352	P=0.204	P=0.491
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.263				

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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					
Cystadenoma					
TUMOR RATES					
OVERALL (a)	2/49 (4%)	3/50 (6%)	4/50 (8%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	2/45.04	3/47.58	4/48.51	4/46.27	2/45.06
POLY-3 PERCENT (g)	4.4%	6.3%	8.3%	8.6%	4.4%
TERMINAL (d)	2/40 (5%)	3/40 (8%)	4/44 (9%)	4/39 (10%)	2/38 (5%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)	729 (T)
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	4/48 (8%)				
STATISTICAL TESTS					
POLY 3	P=0.451N	P=0.525	P=0.372	P=0.350	P=0.694N
POLY 1.5	P=0.445N	P=0.520	P=0.363	P=0.350	P=0.693N
POLY 6	P=0.458N	P=0.529	P=0.379	P=0.344	P=0.693
COCH-ARM / FISHERS	P=0.424N	P=0.510	P=0.349	P=0.349	P=0.684N
MAX-ISO-POLY-3	P=0.528	P=0.349	P=0.234	P=0.211	P=0.499N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	P=1.000	P=1.000	P=1.000	P=1.000	P=1.000
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTEs	P=0.456				

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 or Unspecified Site Adenoma					
TUMOR RATES					
OVERALL (a)	2/49 (4%)	0/49 (0%)	5/50 (10%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	2/45.51	0/46.58	5/48.72	1/46.27	3/45.53
POLY-3 PERCENT (g)	4.4%	0%	10.3%	2.2%	6.6%
TERMINAL (d)	2/40 (5%)	0/39 (0%)	4/44 (9%)	1/39 (3%)	2/38 (5%)
FIRST INCIDENCE	729 (T)	---	673	729 (T)	589
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	0/47 (0%)				
STATISTICAL TESTS					
POLY 3	P=0.391	P=0.232N	P=0.245	P=0.494N	P=0.500
POLY 1.5	P=0.394	P=0.234N	P=0.238	P=0.492N	P=0.501
POLY 6	P=0.389	P=0.232N	P=0.251	P=0.500N	P=0.499
COCH-ARM / FISHERS	P=0.408	P=0.247N	P=0.226	P=0.492N	P=0.510
MAX-ISO-POLY-3	P=0.288	P=0.076N	P=0.145	P=0.276N	P=0.324
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	P=0.276	(e)	P=0.212	P=1.000	P=0.253
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.132				

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 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 PRIMARY TUMORS 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					
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	4/50 (8%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/46.16	1/47.58	4/48.51	1/46.27	1/45.06
POLY-3 PERCENT (g)	2.2%	2.1%	8.3%	2.2%	2.2%
TERMINAL (d)	0/40 (0%)	1/40 (3%)	4/44 (9%)	1/39 (3%)	1/38 (3%)
FIRST INCIDENCE	691	729 (T)	729 (T)	729 (T)	729 (T)
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	0/50 (0%)				
STATISTICAL TESTS					
POLY 3	P=0.434N	P=0.754N	P=0.195	P=0.760N	P=0.755
POLY 1.5	P=0.431N	P=0.756N	P=0.189	P=0.759N	P=0.756
POLY 6	P=0.438N	P=0.753N	P=0.198	P=0.758	P=0.754
COCH-ARM / FISHERS	P=0.420N	P=0.753N	P=0.181	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.505	P=0.491N	P=0.098	P=0.499N	P=0.493
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	P=0.313	P=0.495	P=0.225	P=0.490	P=0.485
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTEs	P=0.147				

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 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 PRIMARY TUMORS 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					
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	4/50 (8%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/46.16	1/47.58	4/48.51	1/46.27	1/45.06
POLY-3 PERCENT (g)	2.2%	2.1%	8.3%	2.2%	2.2%
TERMINAL (d)	0/40 (0%)	1/40 (3%)	4/44 (9%)	1/39 (3%)	1/38 (3%)
FIRST INCIDENCE	691	729 (T)	729 (T)	729 (T)	729 (T)
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	0/50 (0%)				
STATISTICAL TESTS					
POLY 3	P=0.434N	P=0.754N	P=0.195	P=0.760N	P=0.755
POLY 1.5	P=0.431N	P=0.756N	P=0.189	P=0.759N	P=0.756
POLY 6	P=0.438N	P=0.753N	P=0.198	P=0.758	P=0.754
COCH-ARM / FISHERS	P=0.420N	P=0.753N	P=0.181	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.505	P=0.491N	P=0.098	P=0.499N	P=0.493
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	P=0.313	P=0.495	P=0.225	P=0.490	P=0.485
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.147				

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 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 PRIMARY TUMORS 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					
Sarcoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/46.16	0/47.58	2/48.51	1/46.27	0/45.06
POLY-3 PERCENT (g)	2.2%	0%	4.1%	2.2%	0%
TERMINAL (d)	0/40 (0%)	0/40 (0%)	2/44 (5%)	1/39 (3%)	0/38 (0%)
FIRST INCIDENCE	691	---	729 (T)	729 (T)	---
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	0/50 (0%)				
STATISTICAL TESTS					
POLY 3	P=0.358N	P=0.494N	P=0.517	P=0.760N	P=0.505N
POLY 1.5	P=0.355N	P=0.496N	P=0.511	P=0.759N	P=0.504N
POLY 6	P=0.361N	P=0.493N	P=0.521	P=0.758	P=0.506N
COCH-ARM / FISHERS	P=0.345N	P=0.500N	P=0.500	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.386N	P=0.158N	P=0.300	P=0.499N	P=0.164N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	P=0.385	(e)	P=0.308	P=0.490	(e)
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.147				

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 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 PRIMARY TUMORS 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					
Polyp Stromal					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	1/46.01	0/47.58	0/48.51	0/46.27	3/45.91
POLY-3 PERCENT (g)	2.2%	0%	0%	0%	6.5%
TERMINAL (d)	1/40 (3%)	0/40 (0%)	0/44 (0%)	0/39 (0%)	2/38 (5%)
FIRST INCIDENCE	729 (T)	---	---	---	382
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	1/50 (2%)				
STATISTICAL TESTS					
POLY 3	P=0.018*	P=0.493N	P=0.489N	P=0.499N	P=0.305
POLY 1.5	P=0.019*	P=0.496N	P=0.493N	P=0.499N	P=0.304
POLY 6	P=0.018*	P=0.492N	P=0.487N	P=0.501N	P=0.304
COCH-ARM / FISHERS	P=0.021*	P=0.500N	P=0.500N	P=0.500N	P=0.309
MAX-ISO-POLY-3	P=0.023*	P=0.158N	P=0.158N	P=0.158N	P=0.153
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	P=0.120	P=1.000	P=1.000	P=1.000	P=0.301
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTEs	P=0.732				

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 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 PRIMARY TUMORS 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
All Organs					
Hemangiosarcoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	1/50 (2%)	3/50 (6%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/46.01	3/47.86	2/49.14	0/46.27	0/45.06
POLY-3 PERCENT (g)	2.2%	6.3%	4.1%	0%	0%
TERMINAL (d)	1/40 (3%)	0/40 (0%)	0/44 (0%)	0/39 (0%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	658	599	---	---
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	0/50 (0%)				
STATISTICAL TESTS					
POLY 3	P=0.120N	P=0.320	P=0.523	P=0.499N	P=0.504N
POLY 1.5	P=0.119N	P=0.315	P=0.514	P=0.499N	P=0.504N
POLY 6	P=0.121N	P=0.324	P=0.531	P=0.501N	P=0.505N
COCH-ARM / FISHERS	P=0.116N	P=0.309	P=0.500	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.184N	P=0.168	P=0.305	P=0.158N	P=0.163N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	P=0.472	P=0.252	P=0.310	(e)	(e)
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.148				

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 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 PRIMARY TUMORS 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
All Organs					
Hemangiosarcoma or Hemangioma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	2/50 (4%)	3/50 (6%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/46.01	3/47.86	2/49.14	1/46.27	1/45.06
POLY-3 PERCENT (g)	4.4%	6.3%	4.1%	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)	658	599	729 (T)	729 (T)
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	2/50 (4%)				
STATISTICAL TESTS					
POLY 3	P=0.299N	P=0.518	P=0.670N	P=0.498N	P=0.507N
POLY 1.5	P=0.294N	P=0.511	P=0.679N	P=0.498N	P=0.506N
POLY 6	P=0.304N	P=0.523	P=0.661N	P=0.502N	P=0.509N
COCH-ARM / FISHERS	P=0.281N	P=0.500	P=0.691N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.398N	P=0.343	P=0.473N	P=0.279N	P=0.289N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	P=1.000	P=0.492	P=1.000	P=1.000	P=1.000
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.827				

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 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 PRIMARY TUMORS 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
All Organs					
Histiocytic Sarcoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	2/50 (4%)	2/50 (4%)	3/50 (6%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/46.16	2/48.21	3/48.51	1/46.47	0/45.06
POLY-3 PERCENT (g)	4.3%	4.2%	6.2%	2.2%	0%
TERMINAL (d)	1/40 (3%)	0/40 (0%)	3/44 (7%)	0/39 (0%)	0/38 (0%)
FIRST INCIDENCE	691	540	729 (T)	677	---
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	1/50 (2%)				
STATISTICAL TESTS					
POLY 3	P=0.118N	P=0.678N	P=0.523	P=0.498N	P=0.243N
POLY 1.5	P=0.116N	P=0.683N	P=0.515	P=0.498N	P=0.242N
POLY 6	P=0.120N	P=0.674N	P=0.528	P=0.501N	P=0.244N
COCH-ARM / FISHERS	P=0.109N	P=0.691N	P=0.500	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.186N	P=0.482N	P=0.347	P=0.279N	P=0.081N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	P=0.636	P=1.000	P=0.310	P=1.000	P=1.000
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.523				

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 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 PRIMARY TUMORS 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
All Organs					
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	10/50 (20%)	8/50 (16%)	9/50 (18%)	9/50 (18%)	13/50 (26%)
POLY-3 RATE (b)	10/46.75	8/48.55	9/48.85	9/47.39	13/46.49
POLY-3 PERCENT (g)	21.4%	16.5%	18.4%	19%	28%
TERMINAL (d)	7/40 (18%)	5/40 (13%)	7/44 (16%)	5/39 (13%)	8/38 (21%)
FIRST INCIDENCE	579	600	681	634	548
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	5/50 (10%)				
STATISTICAL TESTS					
POLY 3	P=0.123	P=0.364N	P=0.458N	P=0.487N	P=0.310
POLY 1.5	P=0.127	P=0.376N	P=0.472N	P=0.490N	P=0.307
POLY 6	P=0.121	P=0.354N	P=0.448N	P=0.490N	P=0.315
COCH-ARM / FISHERS	P=0.144	P=0.398N	P=0.500N	P=0.500N	P=0.318
MAX-ISO-POLY-3	P=0.217	P=0.275N	P=0.361N	P=0.387N	P=0.231
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	P=0.046*	P=0.255	P=0.229	P=0.225	P=0.186
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.137				

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 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 PRIMARY TUMORS 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
All Organs					
Benign Tumors					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	15/50 (30%)	16/50 (32%)	14/50 (28%)	15/50 (30%)	19/50 (38%)
POLY-3 RATE (b)	15/46.16	16/48.13	14/49.01	15/46.52	19/47.03
POLY-3 PERCENT (g)	32.5%	33.2%	28.6%	32.3%	40.4%
TERMINAL (d)	14/40 (35%)	13/40 (33%)	12/44 (27%)	14/39 (36%)	14/38 (37%)
FIRST INCIDENCE	691	570	651	665	382
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	17/50 (34%)				
STATISTICAL TESTS					
POLY 3	P=0.169	P=0.556	P=0.424N	P=0.578N	P=0.282
POLY 1.5	P=0.171	P=0.537	P=0.452N	P=0.577N	P=0.268
POLY 6	P=0.170	P=0.571	P=0.399N	P=0.586	P=0.296
COCH-ARM / FISHERS	P=0.187	P=0.500	P=0.500N	P=0.586N	P=0.263
MAX-ISO-POLY-3	P=0.300	P=0.469	P=0.343N	P=0.490N	P=0.215
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	P=0.165	P=1.000	P=1.000	P=1.000	P=0.268
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.808				

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 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 PRIMARY TUMORS 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
All Organs					
Malignant Tumors					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	22/50 (44%)	15/50 (30%)	16/50 (32%)	15/50 (30%)	15/50 (30%)
POLY-3 RATE (b)	22/49.36	15/49.48	16/49.29	15/48.31	15/46.49
POLY-3 PERCENT (g)	44.6%	30.3%	32.5%	31.1%	32.3%
TERMINAL (d)	13/40 (33%)	6/40 (15%)	13/44 (30%)	8/39 (21%)	10/38 (26%)
FIRST INCIDENCE	462	540	599	603	548
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	11/50 (22%)				
STATISTICAL TESTS					
POLY 3	P=0.337N	P=0.104N	P=0.152N	P=0.121N	P=0.152N
POLY 1.5	P=0.314N	P=0.105N	P=0.151N	P=0.115N	P=0.138N
POLY 6	P=0.358N	P=0.104N	P=0.157N	P=0.129N	P=0.167N
COCH-ARM / FISHERS	P=0.253N	P=0.107N	P=0.151N	P=0.107N	P=0.107N
MAX-ISO-POLY-3	P=0.171N	P=0.071N	P=0.107N	P=0.086N	P=0.114N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	P=0.098	P=0.229	P=0.213	P=0.224	P=0.216
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.019*				

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 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 PRIMARY TUMORS 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
All Organs					
Malignant and Benign Tumors					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	31/50 (62%)	27/50 (54%)	26/50 (52%)	26/50 (52%)	28/50 (56%)
POLY-3 RATE (b)	31/49.36	27/50.00	26/49.79	26/48.31	28/48.04
POLY-3 PERCENT (g)	62.8%	54%	52.2%	53.8%	58.3%
TERMINAL (d)	22/40 (55%)	17/40 (43%)	21/44 (48%)	19/39 (49%)	19/38 (50%)
FIRST INCIDENCE	462	540	599	603	382
HC TUMORS SAME ROUTE	0/0 (0%)				
HC TUMORS ALL ROUTES	25/50 (50%)				
STATISTICAL TESTS					
POLY 3	P=0.491	P=0.247N	P=0.194N	P=0.243N	P=0.402N
POLY 1.5	P=0.511	P=0.256N	P=0.200N	P=0.229N	P=0.391N
POLY 6	P=0.475	P=0.238N	P=0.191N	P=0.263N	P=0.410N
COCH-ARM / FISHERS	P=0.513N	P=0.272N	P=0.210N	P=0.210N	P=0.342N
MAX-ISO-POLY-3	P=0.372N	P=0.188N	P=0.143N	P=0.185N	P=0.326N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	P=0.053	P=0.316	P=0.485	P=0.329	P=0.229
CURR VS HC SAME RTE	(e)				
CURR VS HC ALL RTES	P=0.203				

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
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

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.
- (h) Historical Controls statistic is not calculated when the HC Poly-3 rate is higher than the Poly-3 rates for all dose groups.
- (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 ***